Environmental Sciences Europe
a SpringerOpen Journal

DISCUSSION Open Access

REACH and occupational health and safety

Thea Hammerschmidt*† and Romy Marx*†

Abstract

Introduction: The EU legislation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) aims to improve the level of human health and environmental protection which has also implications for occupational health and safety. The authors describe their own subjective definition of 'the ideal REACH world' from an occupational point of view as a desirable but unobtainable goal. The practicability of proposed REACH instruments is discussed in relation to specific constraints imposed by the legal framework itself and by contravention against and misinterpretation of the law. This is based on their experiences from within a competent authority.

Results: The first years of REACH were characterised by learning-by-doing for all those involved in developing and implementing this legislation. All of the elements of the REACH process have been started and for occupational safety experts, the question arises whether these procedures improve the health and safety at the workplace. Although REACH delivers new benchmarks (e.g. derived no-effect levels (DNELs)) to substantiate risk assessment at the workplace many instruments still need improvement. The warranty of validity, usability and accessibility of the collected data as well as the thorough description of safe uses (in eSDS) in the whole supply chain will be great challenges in the next years. Additionally, although the candidate list is one of the most promising tools by driving the process of substitution, the prioritisation is not efficient to improve occupational health and safety.

Discussion: The legislation cannot deliver on all of the expectations met in 'the ideal REACH world' from an occupational point of view since it is necessary to also consider issues such as the principle of proportionality, the complexity of the legislation, competing objectives, and scientific limitations. It is early days for the REACH process; consequently, work practices, guidelines and legal decisions need to be further improved to achieve the required compliance. These changes will help to reduce problems associated with implementation and clarify interpretation of the legal text. Overall, the required outcomes from the REACH process can be achieved for the workplace with the will and support of those involved in implementing the relevant health and safety legislation.

Keywords: REACH; Occupational health and safety; Derived no-effect level; Chemical safety report; Exposure scenario; Safety data sheet; Worker legislation; Worker; Registration; SVHC; Candidate list

Background

On 1 June 2007, the legislation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) came into force. REACH shall ensure the safe manufacturing, placing on the market and use of chemicals in the European Union. Registration aims to deliver data on hazards as well as descriptions of appropriate risk management measures (RMM). Evaluation comprises dossier and substance evaluation to ensure high quality of the registrations, and to remove data gaps and identify risks which need further regulation. Where risks are not being properly controlled, REACH provides two risk management measures: authorisation and restriction. To date (status May 2013), approximately 28,000 registration dossiers for substances were submitted and processed. The dossier evaluation is ongoing and 427 dossiers have been checked for compliance by the end of 2012 [1]. The substance evaluation has only started in 2012 and the first draft decisions on information requirements have been submitted to the registrants. Subsequent conclusions on the necessity of further risk management measures are still pending for most substances. The inclusion of substances in the candidate list

* Correspondence: hammerschmidt.thea@baua.bund.de; marx.romy@baua.bund.de
†Equal contributors
Federal Institute for Occupational Safety and Health (BAuA), Friedrich-Henkel-Weg 1-25, 44149 Dortmund, Germany

for authorisation by identification as a substance of very high concern (SVHC) has made good progress. Twenty-two substances are included into Annex XIV, and for 11 substances (status December 2013), the latest application date has already expired. The first restrictions proposed by Member States have been adopted and Annex XVII has been amended [2-4]. Deeper insight into the aforementioned instruments of REACH and their legal background can be found elsewhere [5] and will therefore not be discussed herein.

REACH objectives with regard to occupational health and safety

The prerequisite to apprehend the authors' approach in reflecting REACH is to understand their definition of an ideal workplace achieved by the instruments given with REACH. In the discussion, the term 'the ideal REACH world' is a benchmark with which the current and future implementation and its influence on the health and safety of workers are compared. As the use of the term 'ideal' indicates the authors are of the opinion that the henceforth described 'world' can and will not exist:

'The ideal REACH world' required that all harmful substances existing at the workplace would be fully registered. Each of these substances would have a corresponding technical dossier complemented by a chemical safety report (CSR) in which adequate and conclusive exposure scenarios (ES) describing the safe use of substances in their whole life cycle would be included. This would be underpinned by a full, valid and unambiguous physicochemical and toxicological assessment of the hazardous properties of a substance including limit values for these harmful effects. Relevant SVHCs would be replaced by less hazardous, alternative substances or processes. All information would be communicated clearly and concisely, meeting the needs and knowledge of all user groups along the whole supply chain. The recommended measures would be applied by the downstream users. If these ideals were met and all of those managing processes complied accordingly, chemical hazards would be adequately controlled in the workplace.

In the following, the authors want to reflect whether 'the ideal REACH world' can be met and whether REACH will lead to improvements in occupational health and safety.

Introduction

The REACH regulation aims to ensure a high level of protection for the environment and human health as well as improving the function of the European trading and manufacturing markets [6]. The burden of proof that has been transferred to industry is to ensure that manufacturing, importing, distribution and use of substances does not cause adverse effects. This requirement applies to manufacturers, importers, distributors and downstream users within the supply chain. However, there is an overlap between the objectives of this legislation and those which already apply to protect workers from the risks of exposure to hazardous substances. REACH legislation applies without prejudice to workplace health and safety legislation (e.g. 98/24/EC, 2004/37/EC [7,8]).

The European Commission states that 'the arrival of REACH does not mean that employers' obligations are duplicated'. Employers have little more to do than review their risk management in the light of new information received and implement changes where necessary [9]. Thereby, REACH supports duties of employers under workplace legislation by improving for example the employers' risk assessment with additional information. Simultaneously, registrants' compliance with REACH in terms of appropriate and correct chemical safety assessment depends on input from knowledge about the properties of substances during their specific uses at workplaces. This information is already required by health and safety legislation and is part of the mandatory risk assessment for activities involving hazardous substances or processes.

One of the main aims for REACH implementation is to fill data gaps about possible hazards of chemicals manufactured, imported and used at community level. Information is compiled by the registrants and conveyed to the European Chemicals Agency (ECHA) where this information is collated. The obligation to register substances on their own or in mixtures manufactured and imported in the EU in quantities of one tonne or more per year will be completed on the first of June 2018 (for reference see Table 1). Then ECHA will have gathered the most extensive structured data collection on chemicals compared to anywhere else worldwide.

Results

In the following chapter, the authors describe the potential of the REACH instruments to improve occupational health and safety from their point of view by comparing it to the outlined REACH 'ideals'. The impact of the

Table 1 Registration duties for different tonnage bands and corresponding deadlines within the framework of REACH

Tonnage band	Time since enforcement	Registration deadline
≥1,000 t/a	3.5 years	Dec. 1, 2010
CMR substances ≥1 t/a	3.5 years	Dec. 1, 2010
Environmental hazards ≥100 t/a	3.5 years	Dec. 1, 2010
≥100 t/a	6 years	Jun. 1, 2013
≥1 t/a	11 years	Jun. 1, 2018

t/a, tonnes per annum.

registration process, the chemical safety reports, proposed new exposure limits, the extended safety data sheets, and the substitution of SVHC on workers' health and safety are discussed in separate paragraphs.

General obligation to register and information requirements

In 'the ideal REACH world', all substances alone, or in mixtures, would be registered with a complete submission of valid and conclusive data (for reference see first column of Additional file 1).

However, the registration processes under REACH do not require that each chemical substance in the workplace is covered and fully examined. The regulation generally exempts certain substances (e.g. non-isolated intermediates or waste) and sectors extensively regulated by other legislation (e.g. use as a biocide). Annexes IV and V of REACH list other substances excluded from registration either because this is deemed inappropriate or because sufficient information is available already.

A minimum tonnage of the manufactured or imported substance is necessary to trigger registration (1 t/a). The extent of mandatory information is reduced for on-site isolated (OSII) and transported isolated intermediates (TII). The toxicological information requirements increase with increasing tonnage bands only. From an occupational point of view, the profile of use of a substance and information about high exposures and wide dispersive professional uses would serve as more effective triggers. Read-across approaches and waiving of studies can also be justified. The registration requirements of REACH exclude chemical agents not intentionally produced or those present in the workplace for reasons not directly associated with occupation [7].

In addition to the exemptions described above, the complexity of the regulation may make compliance a challenge. Some interpretations of the legal text are still subject to interpretation by the member states, ECHA, the Commission and the relevant bodies (RAC, SEAC) established under REACH. A summary of the more prominent drawbacks in the legislation relevant to the registration requirements is given in the second column of Additional file 1.

Based on the recent experience, reasons for non-compliance can be various. One example of non-compliance with legal provisions is that the exemptions from the registration requirements are not correctly understood. A very common problem is that the identity of the substance under consideration is often not clear or even incorrect [10]. Furthermore, the definition of intermediates and the term 'strictly controlled conditions' (SCC) is interpreted differently between the authorities and some companies [11]. To avoid unjustified toxicological tests, read-across approaches are made or certain toxicological tests are waived for unjustified reasons. Furthermore, the compilation of registration dossiers is performed very differently by each SIEF and different registrants may comply differently in a way not readily understandable for competent authorities or the downstream users. Non-compliance with the legal framework will occur when these assumptions, and estimations are not disclosed and/or not justified and when the technical dossier and the CSR are inconsistent. A non-exhaustive summary of these discrepancies is summarised in column 3 of Additional file 1.

Overall, the data requirements of REACH represent a meaningful step towards collecting structured information on all substances present in the European market. It will be the great challenge in the future to ensure the validity, usability and accessibility of these data.

Chemical safety report

In 'the ideal REACH world', the CSR for all hazardous substances would include adequate and conclusive exposure scenarios describing safe uses of the substance sufficient for workplace risk assessments (see column 1 of Additional file 2).

A CSR is obligatory for all registered substances used above 10 tonnes per annum and if the substance fulfils the criteria for hazards listed in Regulation (EC) No 1272/2008 (or PBT or vPvB), then exposure scenarios also need to be developed. These exposure scenarios describe the processes, operational conditions and RMM for the safe use throughout the whole life cycle for a substance. This is the centrepiece of REACH by which standards of health and safety at work can be raised, but the requirements of the CSR are challenging.

The registrant is obliged to describe the manufacture and use of the substance for all workplaces along the supply chain, even for processes the manufacturer does not control. Frequently, the supply chain is long and complex and a direct exchange with those end users who understand relevant workplace circumstances affecting exposure level is not possible. Various combinations of operational conditions and RMM can be chosen to achieve a safe use. The challenge is to choose and implement realistic parameters in accordance with workplace legislation. This demands sufficient input and experience from the downstream users to create a high level of abstraction; this was not required from manufacturers and importers before REACH.

Therefore, registrants commonly describe exposure scenarios on the basis of newly developed models which are based on more generic-tiered and conservative approaches. Mechanisms for upstream communication about new or deviating information on hazards and classification, impracticable parameters and the appropriateness of certain RMM are required under REACH, but

are not as yet well established. A 'non-exhaustive' list of factors that limit the attainment of 'the ideal REACH world' at the workplace is summarised in column 2 of Additional file 2.

A list of factors that lead to non-compliance within the legal framework is given in column 3 of Additional file 2. One reason for non-compliance with the legal framework is that the whole life cycle of use for a substance is not covered. Maintenance work, cleaning of the facilities, and waste/recycling of the substance are uses frequently neglected from consideration. The evaluation processes show that in some cases, exposure scenarios are missing for common uses or that invalid exposure scenarios are provided. Hazardous transformation and/or degradation products from which a risk arises are not assessed in the scenarios describing the use of their precursor substances. The reasons for these deviations are usually based on missing or inefficient consultation or missing or unsuitable feedback from downstream users during the boundary conditions that applied for the first registration deadline in 2010. Further non-compliance can be attributed to registrants' failure to realise that the REACH regulation applies without prejudice to the workplace health and safety legislation. For example, the hierarchy of measures defined under STOP principle (substitution, technical measures, organisational measures, and personal protective equipment) has to be implemented [7]. Whilst an assessment of substitutes is not required of the REACH registrant, they are expected to follow the TOP principle whereby the use of personal protective equipment to reduce exposure to a hazard is further down the control hierarchy and other measures of control have to be considered first. The permanent use of personal protective equipment is not an adequate means to minimise the risk of exposure in the long term, and is not considered acceptable in most cases; especially in cases technical measures could be applied instead.

Another aspect of this process is that registrants need to assess substances alone and not in the context of other substances in a mixture. An assessment for a substance in all existing mixture combinations would be impossible for the registrants. Whilst other potentially hazardous substances cannot be considered in undertaking the REACH registration of a specific substance these do need to be included when duty holders conduct a risk assessment of the workplace under existing health and safety legislation. In the context of workplace legislation, the definition of hazardous substances is wider than the scope of REACH and comprises substances classified according to the Classification, Labelling and Packaging (CLP) legislation and those that do not meet the CLP classification criteria but may be a hazard under workplace circumstances [7].

REACH requires manufacturers and importers to describe safe uses of their substances in the supply chain for the first time. This task is challenging. Whether the REACH process can deliver its benefits for occupational health and safety mainly depends on the efforts of industry and the value of the feedback from downstream users.

DNELs - new exposure limits?

In 'the ideal REACH world', limit values would apply to all hazardous substances to inform control actions (for reference, see column 1 of Additional file 3).

At the EU level, two concepts for deriving occupational exposure limit values exist. The first being binding occupational exposure limit values (BOELVs) for which member states are obliged to derive national limit values equal to or lower than the BOELV [7,8,12]. For their derivation, toxicological information, socio-economic information and technical feasibility factors need to be taken into account [13]. The second set are the indicative occupational exposure limit values (IOELVs) [14-16] for which member states are obliged to derive national limit values that can either be higher or lower than these IOELVs. These limit values were based on consideration of evidence for an impact of the substance on health [13]; currently 5 BOELVs and 112 IOELVs have been set. For both sets of limits, the focus is on airborne exposure rather than dermal contact. The progress with the EU standards can be compared to historical national exposure limits. For example, in Germany, occupational exposure limit values for inhalation have been derived for 386 substances [17].

Annex I of the REACH regulation introduces new health-based reference values above which humans should not be exposed. This level of exposure is the derived no-effect level (DNEL). As there are different types of exposure and target groups (worker, consumer), different types of DNELs are defined. For the workplace, eight types of DNELs are relevant (see Table 2).

As a rule for risk management, the lowest inhalation DNEL and the lowest dermal DNEL are considered the

Table 2 Types of relevant DNELs for workers

Duration	Target location	Exposure route
Acute	Local	Dermal
		Inhalation
	Systemic	Dermal
		Inhalation
Chronic	Local	Dermal
		Inhalation
	Systemic	Dermal
		Inhalation

most relevant. DNELs can only be derived when quantitative dose–response relationships for the adverse effects under discussion exist. For most carcinogenic and mutagenic effects mechanistic considerations reveal a lack of a threshold, and therefore, the derived minimal-effect level (DMEL) shall be derived. However, this parameter is not defined in the legal text, but only in the guidance documents [13]. In Germany, a newly developed risk-based concept for carcinogens is currently under evaluation [18]. Three risk bands and respective tiered risk management measures were agreed on by employees' and employers' representatives and authorities. But across the EU community, actors subject to REACH are left to make the decision which risk reference values to apply to carcinogens and mutagens for which a threshold effect level cannot be determined. Therefore, there is a strong need to implement a politically agreed risk value for these substances of high concern.

In an attempt to gain an overview of existing DNELs and DMELs and to assess their impact on occupational health and safety, the data from ECHA's publicly accessible database [19] were analysed.

After the first registration deadline on December 2010, approximately 5,000 individual substances were registered including intermediates (OSII, TII) and low tonnage substances (1 to 10 t/a) for which no DNELs and DMELs were derived. The analysis revealed 1,728 substances with unambiguous identity for which 4,765 DNELs and DMELs for workers were derived. Number and type of DNELs and DMELs depend on the identified uses and exposure scenarios submitted with the registration of a substance. In ECHA's public database, the DNELs and DMELs are presented deep within the structure. An easily accessible and searchable source which specifically provides DNELs and DMELs for registered substances was made available by the German social accidence insurance [20]. It is not possible to conclude whether all DNELs and DMELs required by REACH have been derived because the number of DNELs and DMELs depend on the hazard, the existing exposure and the approach chosen.

Furthermore, when comparing publicly available data with the chemical safety report which is not publicly accessible, DNELs and DMELs can sometimes be found in the latter document only. Irrespective of these issues, the number of existing DNELs and DMELs is significantly higher than the number of BOELVs and IOELVs that had been introduced at community level before REACH came into force and higher than the number of national, e.g. German, OELs [17]. DNELs are not workplace limits that are legally binding and have not been through a rigorous process of setting. They can only act as guidance to assess whether the protection measures taken are adequate.

The Guidance Document R.8 describes the derivation of DNELs [13]. In principle, DNEL derivation and OEL derivation (at least in Germany) follow the same guidelines in extrapolation from experimental results onto the workplace exposures limits. Figure 1 shows that approximately 60% of all DNELs were derived for chronic systemic exposure routes. Since chronic DNELs are in principle lower than the corresponding acute DNELs, it is rather uncritical to refer to chronic DNELs for acute exposure, too. Hence, the derivation of chronic DNELs will - in terms of management strategies for occupational health and safety - also be preventive to acute effects.

The focus of DNELs seems to be primarily on systemic effects. Hence, an underestimation of local effects (corrosion, irritation and sensitisation) cannot be excluded at this point, and therefore, these effects seem to be insufficiently considered in the chemical safety assessments.

The analysis of DNELs also revealed that only for a few substances, different registrants derived different DNELs. Figure 2 shows that the difference between registrant's DNELs ranges in the majority of cases between factors of 1 and 5, but in a few cases, the deviations are more pronounced.

Table 3 displays the example of a single substance for which three registrants derived three different values. The DNEL of Registrants A and B diverge by a factor of 16.6 and registrants C submitted a DMEL instead of a DNEL. The exemplary substance is not classified as a carcinogen or mutagen and therefore there is no necessity to derive a DMEL. Deriving a DMEL for such a substance is simply wrong. It also shows that confidence in DNELs derived by registrants might be questioned. However, the authors do not know whether a more systematic examination of the data would reveal a greater prevalence of presumably incorrect DNELs and DMELs.

Although this discrepancy between DNELs in registrations is obviously present, it does not negate the legal framework but limits the anticipated REACH 'ideal' for effective control of workplace exposures. Downstream users of these registrants are confronted with different reference values which might then lead to different RMM being implemented. Stricter RMM might lead to competitive disadvantages. Further reasons for non-compliance in this area can be found in column 2 of Additional file 3.

In the context of REACH, DNELs and DMELs are the reference values that have to be compared with the values derived for exposure. Uses of a substance that result in a risk characterisation ratio (RCR - quotient of exposure level and effect level) below 1 are considered to be safe, while $RCR > 1$ will require additional measures to be prescribed in the exposure scenario in order to define an acceptable risk.

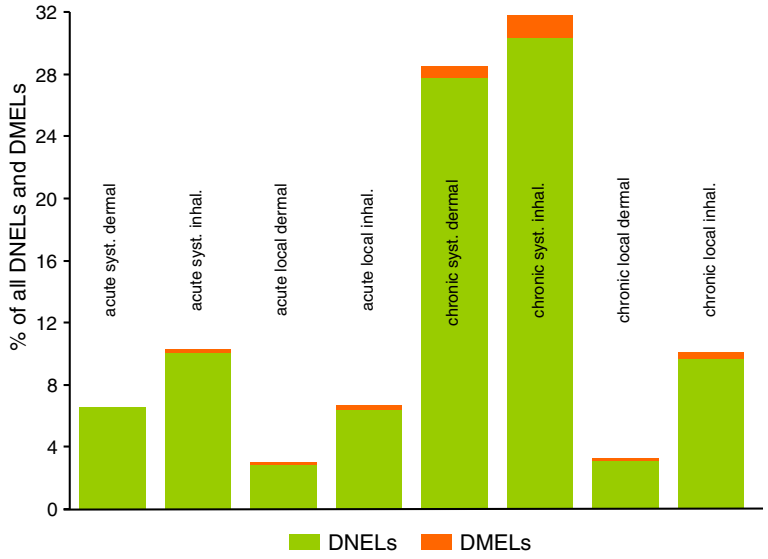

Figure 1 Distribution of DNELs and DMELs over different routes of exposure. A number of registered substances (1,728) showed clear identity and had at least one DNEL or DMEL for workers. In sum, of 4,765 values, app. 60% were derived for chronic systemic exposure via skin and inhalation. The DMELs are part of the displayed columns (orange) and contributed only to a small degree to all values.

Overall, the implementation of the REACH regulation resulted in an increased number of benchmarks to define harmful exposure levels. In addition, working practices that are obviously unsafe (e.g., showing RCR much larger than 1) may not be reported as an 'identified use' but as a 'use advised against'. By this means some critical uses of hazardous substances might decrease. Obviously, these values are only helpful, if properly derived on the basis of the most robust and latest data. The authors want to point out that although DNELs and DMELs do not directly entail legal consequences, with respect to workplaces, they will be and are regarded as an additional reference value for risk assessment [21].

Communicating information via (extended) safety data sheets

In 'the ideal REACH world' the (extended) safety data sheet would provide information that is clear and relevant to workplace situations and would represent a transfer from the registrant to the recipient and vice versa (for reference see column 1 of Additional file 4).

The safety data sheet (SDS) shall enable the recipient to take the necessary measures to protect the health of workers and the environment. Under current health and safety legislation the SDS is the main information source for employers undertaking risk assessment involving hazardous substances. The legal obligations of article 37

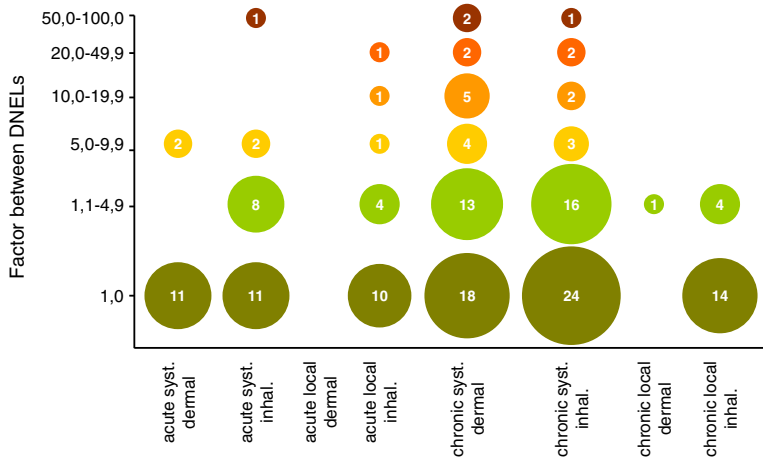

Figure 2 Difference between DNELs of different registrations. The graph shows the relative ranges of DNELs from different registrations for the same substance. The factors were calculated relative to the lowest DNELs for each substance, and the bubble areas are proportional to the number of factors in the indicated range.

Table 3 Example of a substance with three registrations and the differing derived DNELs and DMEL

2,6-Di-tert-butyl-p-cresol	Acute syst. inhal.	Long-term syst. dermal
Registrant A	-	DNEL 0.5 mg/m^3
Registrant B	-	DNEL 8.3 mg/m^3
Registrant C	DMEL 2.0 mg/m^3	-

(7) of REACH require those who prepare a CSR to place the relevant exposure scenario in an annex to the SDS. This SDS is called extended safety data sheet (eSDS). The (e)SDS links legislations of placing chemicals on the market and worker protection. A CSR has to be provided for specific registered substances only; however, in workplaces, mixtures of substances are commonly used [22]. Therefore, most employers will be confronted with exposure scenarios that apply only for a minority of their workplace chemicals. It is the formulator as the first downstream user who mainly has to deal with the problem of utilising the exposure scenarios provided in the eSDS, and to consolidate them along with relevant information into SDSs for their products. Exposure scenarios, especially those for the workplace, are likely to be numerous and specific to bespoke processes and business practices. For a widely used solvent with for example 10 identified uses often as many as 80 different contributing exposure scenarios are compiled. Many of these exposure scenarios may be quite similar and differ only in minor details. It is difficult to consolidate all of this information into a handful of relevant specifications for safe handling as required in Sections 7 and 8 of the SDS. This is an important issue as the SDS is intended to be a clear and concise document, which takes into account the specific needs and knowledge of the user group.

The new requirements concerning communication in the supply chain and downstream user compliance are sources of non-compliance with REACH (see a non-exhaustive summary in column 3 of Additional file 4). As a rule, the attached exposure scenarios are neither available in a harmonised and structured format nor aggregated into predictive descriptions that are representative for the majority of workplaces at the moment. These problems clearly show the need to create a common format for the exposure scenarios and to clearly define and structure the relevant information that has to be transferred from the CSR to the exposure scenario annexed to the SDS. In addition, even though it is legally acceptable to attach all exposure scenarios (see column 2 of Additional file 4), recipients would benefit more if suppliers provided only those exposure scenarios relevant to the recipient.

On the other hand, the recipient, be it the formulator or the end user, has to check whether he complies with the conditions set out in the exposure scenario received with the substance. This is especially important in cases downstream users receive a generic exposure scenario and need to decide whether this is sufficient for a specific workplace. With respect to REACH, they are obliged to apply, as a minimum, the conditions of the exposure scenario communicated to them. With respect to worker legislation, downstream users have to identify further workplace-specific conditions and hazards in their risk assessment. It is essential that inadequate exposure scenarios are amended to enhance their value to users of that information. In order to achieve this, recipients need to give feedback to their supplier(s) on the appropriateness of RMM, occupational conditions and process parameters as well as the readability of the eSDS. The quality of the CSR, especially the exposure scenarios, will improve when the knowledge of end users is fully integrated to ensure relevance of this information. For example, do exposure scenarios point to practical and relevant control measures, or do they point to measures that are potentially in conflict with other elements of health and safety legislation? REACH provides two mechanisms to address the appropriateness of exposure scenarios: the option to make details of a downstream use known to the registrant to enable him to prepare appropriate exposure scenarios (articles 37(2) and (3)) or the option of upstream communication of inappropriate RMM in received exposure scenarios (Article 34).

The first two REACH registration phases delivered data that should have increased the quality of SDS [23]. At the moment, this envisaged improvement is hindered by lack of experience, the use of instruments still under development, especially for exposure assessment (Eteam project [24]), lack of structured templates and lack of easily exchangeable formats for information exchange (under development: ESComXML) [25]. The rush to be 'REACH-compliant' to fulfil the minimum requirements of registration of dossiers on schedule and to prepare (e) SDS [23,26] might have led to the submission of incomplete and incorrect registration dossiers and the recommendation of inappropriate RMM. The focus of industry may shift to improving the quality of the registration dossiers and SDS when these more time-consuming processes are completed. Whilst the eSDS is still at an early stage of implementation, the authors of this paper conclude that cooperation and improved awareness within the supply chain can improve the foundation for the safe handling of chemicals at workplaces.

Substitution of substances of very high concern

In 'the ideal REACH world', all substances of which the use comprises a risk would be identified and substituted (see column one of Additional file 5).

In focussing solely on occupational health and safety, the authors do not agree with the identification of SVHC substances based only on their hazard classification without risk characterisation of the substance as applied at the moment. However, the legal text of REACH is not so specific. SVHC by definition of the REACH regulation are those substances that are included in the candidate list for authorisation on the basis of their classification as CMR, their PBT or vPvB properties or of their equivalent level of concern (ELC) [27]. In 2010, the EU commissionaires Tajani and Potočnik asked the Member State Competent Authorities and ECHA to intensify their work to accomplish the inclusion of 136 substances into the candidate list. This goal was hardly achieved and therefore the European Commission initiated a roadmap of SVHC stating that until 2020, the candidate list should contain all relevant substances [28].

The purpose of the candidate list can be interpreted quite differently. The hazardous properties of a substance alone are sufficient for the SVHC identification, and at first sight, filling the candidate list is straightforward. This approach can prevent the use of an equally hazardous substance as an alternative. However, experience from workplace risk assessments demonstrates that considering the hazard status alone without considering the risk likelihood of exposure can be meaningless. Consequently, when the risk is foreseeably low and can be controlled by suitable RMM, the authors are of the opinion that resources would be better allocated to activities tackling substances associated with high risks.

The process of identifying SVHC is well under way and constitutes a clear incentive for the continuous elimination of CMR substances. However, CMR substances have always been in the focus of regulation [8] and are a significant, but not the most frequent problem in workplaces. Currently, the SVHC process is very focused on CMR substances and PBT/vPvB substances. So far (status December 2013), only seven substances (respiratory sensitisation, endocrine disruption) out of 144 were identified as SVHC due to article 57f where identification was of 'equivalent level of concern' to the related SVHC. From an occupational safety point of view, it could be argued that substances with less pronounced hazard properties, but high risks for exposure and harm (e.g. substances that are skin sensitising or STOT RE) might also be subjected to SVHC identification and authorisation. In particular, substances causing dermal allergies might be candidates for such considerations because of the increasing frequency and gravity of skin diseases as observed at a community level [29,30]. Nevertheless, this definitely needs a case by case investigation and discussion of every single substance.

Substances listed in the candidate list may be prioritised by ECHA and the member state committee (MSC) for inclusion into Annex XIV of the REACH regulation. The prioritisation approach developed by ECHA [31] considers the inherent properties, the volume and the wide-dispersive use of a substance. Each criterion is divided into categories of different scores (initially published values, see Tables 4, 5 and 6). These were developed in a way that the criteria are weighed with 18%, 41% and 41%, respectively. The recommendation criteria do not give priority to substances relevant for worker exposure. The maximum score for inherent properties can only be achieved in case of substances that are PBT and vPvB or PBT with T being non-threshold C or M. Giving the highest score to environmental hazards was an attempt to promote the prioritisation of this specific concern since most of the substances with PBT and/or vPvB properties have low volumes and have proven to be hardly prioritised. According to the guidance given by ECHA [32], the 'wide disperse use of a substance is characterised by the assumption that the substance is used by consumers or by many users in the public domain, including small, non-industrial companies'. Consequently, the high scoring values for wide-dispersive use generally gives priority to substances largely found in consumer products. From our point of view, promotion of substances that are relevant for worker exposure (e.g. widespread use: 'Uses taking place at many places, which however do not result in significant releases of a substance, may be considered only as 'widespread' but not as 'wide-dispersive' [33]) is missing. The following fictional example using revised but not yet published scores shall elucidate that there are scenarios that will clearly prevent a fast and necessary promotion from the candidate list to Annex XIV of a substance for which a risk has been identified: Assuming to have a substance toxic to reproduction, that is produced in volumes of 10 to 100 t/a and used community-wide in a non-diffuse manner in 100 sites would gain a score of 6. Assuming further that more than 1,000 workers are exposed and limit values are exceeded, further legislation is deemed appropriate from occupational safety and health point of view. Since the criteria do not take the risk into account, the substances would not be prioritised for a long time due to a low score. From our current experience, we would at least question effectiveness as well as efficiency of the current

Table 4 Inherent properties and their corresponding scores

Inherent properties	Score
C, M with threshold or R	0
C or M without threshold	1
PBT or vPvB	3
PBT and vPvB or PBT with T non-threshold Cor M	4

Table 5 Volumes of substance and their corresponding scores

Volume	Score
<1 t/a	0
<10 t/a	1
10 to 100 t/a	3
100 to 10^3 t/a	5
10^3 to 10^4 t/a	7
>10^4 t/a	9

scoring system in relation to occupational health and safety.

Eventually, the commission will decide on the inclusion in Annex XIV which prohibits all uses of the substance unless authorisation for a specific use is granted. An application date and the latest date of use ('sunset date') will be announced and industry can decide whether to apply for authorisation or switch to suitable alternatives. Taking account of ECHA's capacities and the undefined period of time for comitology to take place, only a limited number of SVHC can be included into Annex XIV at a time. The REACH legal text does not specify if and when prioritisation from the candidate list into Annex XIV will take place which causes great planning uncertainties for industry. Authorisation shall be granted if the risk to human health or the environment is demonstrated to be adequately controlled (article 60(2)). If adequate control cannot be demonstrated, authorisation may only be granted if it is shown that socio-economic benefits outweigh the risks (article 60(4)).

Substitution is always the preferred option, although it is not always technically feasible - either by exchange of the substance or by alternative technical processes, or by a combination of these options. Considerations on suitable alternatives include an assessment whether the substitution will result in reduced overall risk and whether the alternatives are technically and economically feasible for the applicant. When there are no suitable alternatives, authorisation may be granted if the socio-economic benefit outweighs the residual risks from using the substance. The authors want to note that only the future will show whether applicants with either few or many resources will be treated equally upon authorisation applications. It will be interesting to see if and how the committee for the socio-economic assessment will tackle this topic.

Table 6 Number of sites of substance and their corresponding scores

Wide dispersive use	Score
Number of Sites	
0	0
0 to 10	1
10 to 99	2
≥ 100	3
Potential for release	
Insignificant	0
Non-diffuse/controlled	1
Diffuse, significant, uncontrolled	3

In response to REACH implementation, industry reacted proactively in some cases and even tried to phase out substances that fulfil the criteria for inclusion into the candidate list for Annex XIV (personal communication with industry). From this perspective, the authors consider the impending authorisation process based on the hazard status an effective instrument to drive a focus on substitution. Whether such substitution will result in the desired reduction of overall risks needs to be examined. Sometimes, little is known about the hazards and risks associated with alternative chemicals. Even less is known about products imported into the European Union that contain the same substances.

In conclusion, based on the authors' knowledge and experience, the authorisation process is one of the most promising tools under REACH by which improvement of environmental and human safety and health can be made driving the process of substitution. However, this prioritisation is not in the authors' view being efficient to improve occupational health and safety.

Discussion

In the authors' experience, the first years of REACH were characterised by learning-by-doing for the industry, the competent authorities, ECHA and non-governmental organisations. Since all of the relevant processes have started, a first résumé can be drawn. In this paper, the authors have assessed progress with implementing the REACH instruments, highlighting promising developments, as well as challenges and limitations particularly for occupational health and safety:

Have the REACH instruments improved the health and safety of workers in companies?

REACH aims to deliver structured and accessible information on chemicals, e.g. toxicological and physicochemical information to achieve adequate classification and labeling, or DNELs. Relevant data are publicly available in the ECHA database. Classification, information on the uses, operational conditions and relevant risk management measures are communicated via SDS. The understanding of manufacturers and importers on the life cycle of their substances has also increased. Bidirectional communication and collection of knowledge about hazardous substances in use have been achieved in some cases ensuring more reliable data within the supply chain. These achievements are clearly a large step

forward. With DNELs, a new type of reference values for safe use has been introduced and made available for many substances that had no OEL before. Whilst the quality of some of the DNELs/DMELs might need improvement, the derivation of these values is a gain for occupational health and safety. The instrument of authorisation for SVHC has also intensified industries' efforts in substitution of the most hazardous chemicals. From the authors' point of view, the transfer of the burden of proof to the manufacturers and suppliers of chemicals has increased their efforts to tackle unknown and neglected risks from hazardous substances.

However, a gap in the application of these processes to improve standards of occupational health and safety remains. There are a number of caveats that have to be applied and which have been summarised in Additional files 1, 2, 3, 4 and 5 (columns 2, respectively). These current limitations should provide a focus to further develop practical means for duty holders to apply REACH in the context of occupational health and safety.

Anyway, 'the ideal REACH world' in which only adequately controlled uses exist in relation to occupational health and safety (reflected in Additional files 1, 2, 3 and 4 (columns 1, respectively)) can and will not exist. The described picture is an unobtainable goal and serves as an orientation for further efforts.

Which obstacles persist?

In article 1 of the REACH regulation, the goals are set out to ensure a high level of protection of human health and the environment based on the precautionary principle, whilst improving free trade and circulation of substances on the internal market enhancing both competitiveness and innovation [27]. The combination of these objectives in REACH is challenging: Global competitiveness and adequately controlled risks can be conflicting interests. Obviously, the substitution of a SVHC comprising high risks is desirable, but not always immediately technically feasible. Furthermore, protection of the environment, the consumer and the worker can be competing objectives in relation to obligations stipulated in the law and its interpretation. Meeting at least one of these other obligations may present obstacles to improve occupational health and safety standards. One example is the definition of criteria for the prioritisation of SVHC for inclusion in Annex XIV which may place substances of high risk for the workplace on a holding position on the candidate list.

These challenging objectives and the broad goals of the REACH regulation are not the only sources of problems for implementing this legislation in the workplace. The shifting of the burden of proof for the protection of human health and the environment from the regulator to the industry was challenging and time-consuming because industry had to adapt to these concepts and introduce suitable processes. It is important that REACH processes leave room for individual solutions as duty holders and the companies they represent differ greatly in their size, resource base and access to expert knowledge that will be required to address some aspects of the legislation. But this simultaneously leads to drawbacks. For example, the process for preparing exposure scenarios is not prescribed in the legislation and so various approaches have been developed. This is a challenge for the recipients of the SDS coping with different formats.

These principles and concepts will persist in the future and will hinder the implementation of 'the ideal REACH world' in relation to occupational health and safety. In addition to the complexity of the legislation, scientific limitations regarding occupational exposure to some substance will also persist.

How can implementation problems be overcome?

Despite persisting problems, the authors are optimistic that not all obstacles will remain. The interpretation of the legal text will become more consistent. To increase compliance with legal obligations and provide further clarification support is offered at national and community level in the form of guidance and immediate helpdesk support by authorities and industrial organisations. This support is constantly adapted to the increasing knowledge on the interpretation of the legal text and to the common working practice. The industrial organisations seem to increase their efforts of support and thereby gain more importance for duty holders. A good overview on these industry sponsored activities can be found on the Cefic website [34] or for a special focus on exposure scenarios, in the exchange network on exposure scenarios (ENES) [35].

Guidance is also being improved based on knowledge from the workplace assessment of exposure and this is being triggered by on-going evaluation processes performed by ECHA and the member states. Evaluation is one instrument that will reveal and reduce data gaps and should reduce legal non-compliance of the type outlined in Additional files 1, 2, 3 and 4 (columns 3, respectively). When a registration dossier is submitted to ECHA, it generally passes only an IT-supported accordance check which might not reveal incorrect information. A closer look at the registration dossiers is then carried out by ECHA on 5% of the registrations via a formal dossier evaluation. The focus so far has been on the evaluation of toxicological assessment and environmental questions. ECHA's current approach shifts to a targeted approach, namely selecting specific points of concern. Considering occupational health and safety, it is desirable to enhance the emphasis on exposure and risk

management in the future. However, the evaluation of exposure scenarios is difficult at the moment and in most cases has to be done manually. Exposure scenarios are submitted in the CSR in PDF format and are not part of the registration dossier that is submitted in a structured and IT-searchable format (IUCLID) [36]. ECHA provides an IT-application named CHESAR [37] that is linked with IUCLID and able to generate the CSR and exposure scenarios for communication in the eSDS in a structured, harmonised and efficient way.

The first results of the evaluation processes show that some exposure scenarios and risk management measures from the first registrations may be very schematic, incomplete, inadequate, and/or overprotective and may not respect the hierarchy of risk management measures. ECHA's current approach in dossier evaluation shifts to a targeted approach, namely selecting specific points of concern. Considering occupational health and safety, it is desirable to enhance the emphasis on exposure and risk management in the future.

Which REACH instruments need to deliver their full potential?

While the registration, dossier evaluation and improvement of communication along the supply chain are progressing, other REACH processes have just started.

The substance evaluation (SEv) process involves an in depth analysis of a carefully selected set of substances (e.g. missing information about substance properties reflecting risks or exposure-related information) and highlight where there is a need for further risk management or regulation. These data gaps can be addressed by ECHA's decision on additional requirements on the registrant. In those cases where the SEv process identifies a need for further regulation, authorisation requirements or restrictions might be initiated. Only a few substances have been taken through the SEv process to date, and so the value of this new instrument will only become clear in future. The first results of the evaluation processes show that some exposure scenarios and RMM from the first registrations may be very schematic, incomplete, inadequate, and/or overprotective and may not respect the hierarchy of RMM. The SEv is a promising instrument to identify work-related risks and to decide if further regulation is needed.

The process of authorisation for SVHCs will achieve its full potential in promoting substitution of hazards when companies proactively change formulations and downstream users demand that suppliers avoid using SVHCs in their products. The process of identifying SVHC and their prioritisation within Annex XIV leaves room for improvement in assessing risks of exposure to these substances in the occupational setting. Granted authorisations cannot be evaluated so far as no decision on an application has been made.

Conclusions

In this article, the authors have evaluated the development, challenges, and limitations to implementation of REACH in the occupational setting in order to examine to what extent the REACH 'ideals' can be achieved. In some respects, this has proven challenging because of the current 'state of the art' with REACH as well as knowledge and experience of those implementing the legislation. There is clearly ambiguity in the minds of some regarding the application of REACH in their business aspects, and concerns that the legislation is placing a disproportionate burden on industry. The regulation is still at an early stage of implementation after 6 years and not all of the tools have fully been used or exploited to their full potential. Quality control processes like dossier evaluation, substance evaluation and regulatory processes like SVHC identification, authorisation and restriction have just started. Some inherent legal aspects of the process may hinder to reach the objectives in relation to health and safety at work, especially competing objectives and those provisions that narrow the scope of REACH. By the establishment of raised awareness, good work practices, improved communication, further guidelines, and decisions of the national enforcement authorities as well as the European Court of Justice compliance problems will be reduced. Therefore, the authors are confident that with more routine experience of the REACH processes and with support from all parties involved, improvements in workplace health and safety standards can be achieved although the outlined 'ideal REACH world' cannot be achieved.

Additional files

Additional file 1: Data generated due to REACH registration duties and reasons which oppose 'the ideal REACH world'. Non-exhaustive summary.

Additional file 2: Data generated through the CSR.

Additional file 3: Limit values generated through REACH.

Additional file 4: Communication of exposure scenario information via (extended) safety data sheets.

Additional file 5: SVHC identification and substitution.

Abbreviations

A: annum; AGS: Ausschuss für Gefahrstoffe (German Committee on Hazardous Substances); BOELV: binding occupational exposure limit value; C: carcinogenic; CHESAR: Chemical Safety Assessment and Reporting tool; CSR: chemical safety report; DGUV: Deutsche Gesetzliche Unfallversicherung (German social accident insurance); DMEL: derived minimal-effect level; DNEL: derived no-effect level; ECHA: European Chemicals Agency; ELC: equivalent level of concern; ENES: exchange network for exposure scenarios; ES: exposure scenario; ESCom: Exposure Scenario for Communication; Eteam: 'The Evaluation of Tier 1 Exposure Assessment Models under REACH'; IOELV: indicative occupational exposure limit value; IUCLID: International Uniform Chemical Information Database; M: mutagenic; MDA: 4,4′-diaminodiphenylmethane; MSC: Member State Committee; PBT: persistent, bioaccumulative and toxic; R: toxic to reproduction; RAC: Risk Assessment Committee; RCR: risk characterisation ratio; REACH: Registration

Evaluation Authorisation and Restriction of Chemicals; RMM: risk management measures; eSDS: extended safety data sheet; SEAC: Socio-economic Assessment Committee; SEv: substance evaluation; SIEF: Substance Information Exchange Forum; SME: small and medium enterprises; STOT RE: specific target organ toxicity repeated exposure; SVHC: substance of very high concern; t: tonnes; T: toxic; vPvB: very persistent and very bioaccumulative.

Competing interests
The authors declare that they have no competing interests.

Authors' contributions
TH and RM contributed equally to this discussion and have read and approved the final manuscript.

Authors' information
TH and RM work in the assessment unit for occupational safety and health.

Acknowledgements
The authors thank Eva Lechtenberg-Auffarth and Ulrich Föst for critical revision of the manuscript and for discussion of the content.

Received: 17 May 2013 Accepted: 14 February 2014
Published: 5 March 2014

References

1. ECHA: **Evaluation under REACH - progress report 2012.** 2013
2. EC: **Commission Regulation (EU) No 848/2012 of 19 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards phenylmercury compounds.** 2012. L 253/5.
3. EC: **Commission Regulation (EU) No 412/2012 of 15 May 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).** 2012. L 128/1.
4. EC: **Commission Regulation (EU) No 836/2012 of 18 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards lead.** 2012. L 254/4.
5. Schulte C, Tietjen L, Bambauer A, Fleischer A: **Five years REACH - lessons learned and first experiences. I. An authorities' view.** *Environ Sci Eur* 2012, **24**(1):31.
6. EC: **The treaty on the functioning of the European Union.** 2008. C115/47.
7. EC: **Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual directive within the meaning of article 16(1) of directive 89/391/EEC).** 1998:11. OJ L131.
8. EC: **Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (sixth individual directive within the meaning of article 16(1) of council directive 89/391/EEC).** 2004. L 229/23.
9. EC: **Guidance for employers on controlling risks from chemicals.** 2010.
10. EC: **Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee aof the Regions in accordance with Article 117(4) of REACH and Article 46(2) of CLP, and a review of certain elements of REACH in line with Articles 75(2), 138(2), 138(3) and 138(6) of REACH.** 2013. 049 final.
11. ECHA: **Screening of registration dossiers for intermediates.** 2012.
12. EC: **Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work.** 2009. L330/28.
13. ECHA: **Guidance on information requirements and chemical safety assessment - chapter R.8: characterisation of dose [concentration]-response for human health.** 2012.
14. EC: **Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.** 2000. L 142/47.
15. EC: **Directive 2006/15/EC of 7 February 2006 establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC.** 2006. L 38/32.
16. EC: **Directive 2009/161/EU of 17 December 2009 establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC.** 2009. L338/87.
17. AGS: **TRGS 900 - Arbeitsplatzgrenzwerte.** 2006.
18. AGS: **The risk-based concept for carcinogenic substances developed by the committee for hazardous substances - from limit-value orientation to an action-oriented approach.** 2013.
19. ECHA: **Dissamination site - registered substances.** 2013. http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances.
20. DGUV: **GESTIS DNEL database.** 2013. http://dnel-en.itrust.de/nxt/gateway.dll/dnel_en/000000.xml?f=templates$fn=default.htm$vid=dneleng:ddbeng$3.0.
21. AGS: **Announcement 409 - Using REACH-information for health and safety at work.** 2013.
22. Council of the European Union: **Interinstitutional file: 2003/0256 (COD), 2003/0257 (COD).** 2004.
23. EC: **Commission staff working document - general report on REACH.** 2013. SEC(2006)924.
24. BAuA: **BAuA developmental project 2303: validation of models for the initial estimation of occupational exposure (tier 1) in the chemical safety assessment under REACh.** To be finished by the end of July 2013; 2012.
25. Cefic: **ES for communication XML standard - description.** 2010.
26. EC: **Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).** 2010. L 133/1.
27. EC: **Regulation (EC) No 1907/2006 of the European Parliament 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 7/68/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EEC and 2000/21/EC.** 2006. L 396.
28. EC: **Roadmap on substances of very high concern.** 2013.
29. Eurostat: **Health and safety at work in Europe (1999–2007).** 2010.
30. De Craecker W, Roskams N: **Op de Beeck R: Occupational skin diseases and dermal exposure in the European Union.** 2008. ISBN 978-92-9191-161-5.
31. ECHA: **General approach for prioritisation of substances of very high concern (SVHCs) for inclusion in the list of substances subject to authorisation.** 2010.
32. ECHA: **Guidance on information requirements and chemical safety assessment - chapter R.16: environmental exposure estimation.** 2012.
33. ECHA: **Background document to the decision of the executive director of ECHA, ED/32/2011 - selection criteria to prioritise substances for substance evaluation (2011 CoRAP selection criteria).** 2011.
34. Cefic: **Guidance and tools.** 2013. http://www.cefic.org/Industry-support/Implementing-reach/Libraries/.
35. ECHA: *Exchange network on exposure scenarios (ENES).* 2013. http://echa.europa.eu/web/guest/about-us/exchange-network-on-exposure-scenarios.
36. EC: **International uniform chemical information database (IUCLID).** 2007(5).
37. ECHA: **Chemical safety assessment and reporting tool.** 2013.

doi:10.1186/2190-4715-26-6
Cite this article as: Hammerschmidt and Marx: **REACH and occupational health and safety.** *Environmental Sciences Europe* 2014 **26**:6.