



REACH and OSH

The extended Safety Data Sheet under REACH and Risk Assessment in Occupational Health and Safety – Evaluation of a VCI Expert Workshop

1. Background

The interaction of REACH and the occupational health and safety (OSH) legislation is increasingly coming into focus of public authorities. However, up until now the REACH and OSH actors do not have a sufficient common understanding of the data in exposure scenarios and their use in risk assessments at the workplace in operational practice.

In a VCI workshop in March 2019¹, these interfaces were analyzed by REACH and OSH experts from VCI member companies, based on concrete examples of tasks and substances – in order to merge knowledge and experience from both fields.²

Next, an interdisciplinary expert group further developed these findings.

The following report on this is structured as follows:

1. Background
2. Overview of the risk assessment approach in OSH
3. The extended Safety Data Sheet (eSDS) as a source of information for risk assessment in OSH - basic considerations
4. Exposure scenarios under REACH and risk assessment in OSH – existing experiences
5. Conclusion and options for action

Annexes

¹ Concept of the VCI Expert Workshop “The extended Safety Data Sheet under REACH and the Risk Assessment in Occupational Health and Safety”: See Annex IV

² The complete workshop documentation is available for VCI members.

2. Overview of the risk assessment approach in OSH

Employers are under the obligation to prepare and update risk assessments for workplaces/tasks of their staff prior to starting the work. The following chart shows the steps of the risk assessment process (nos. 1 to 8) as a continuous improvement process. In addition to the respective step as such, it is noted which pieces of information are primarily required or used in this step. Further relevant details are given in Annex I.

This description does not address which of these information pieces are provided under REACH but initially focuses on the information needs under OSH requirements. Chapter 3 then explains which information the eSDS under REACH can contribute to the risk assessment process.

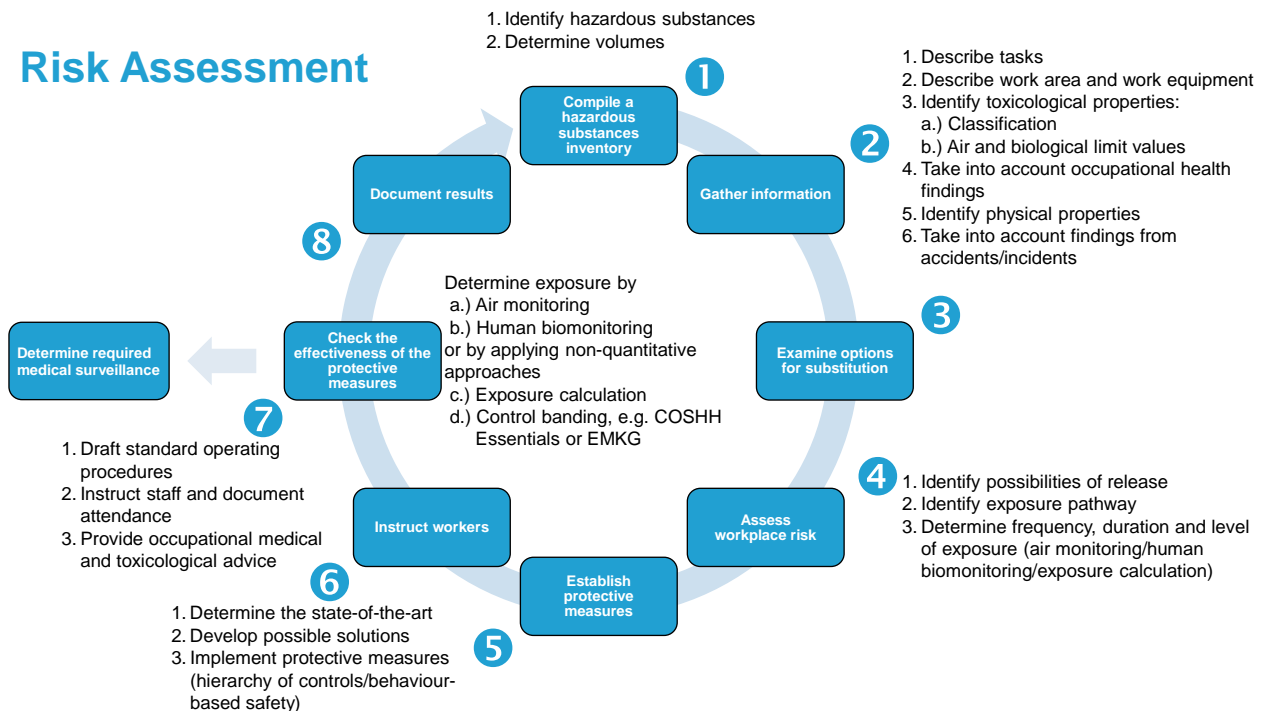


Fig. 1: Risk assessment in OSH

3. The extended Safety Data Sheet (eSDS) as a source of information for the risk assessment in OSH - basic considerations

The eSDS under REACH is divided into 16 sections (mandatory format) and possibly an annex with exposure scenarios (requirements for the content but no mandatory format defined under REACH).

An analysis of the SDS sections and the annex shows that the safety data sheet basically contains much of the information that is needed for the assessment of substance related health risks within the risk assessment process in OSH. This includes the classification and labeling of the substance/product or relevant components, DNELs and other limit values as well as the conditions of use and risk management measures. The analysis also shows which information is not included for preparing a workplace and task-based risk assessment. The SDS does not contain any information on other potential hazards and risks at the workplace, such as physical hazards (noise, vibration, radiation, slipping, tripping, falling, falling from heights, etc), risks due to biological agents or ergonomic or psychosocial hazards, as these are not subject to the REACH regulation but are part of European and national OSH legislations.

The following chart gives an overview which of these information important for the risk assessment in OSH can be taken from which section of the eSDS or its annex. Particularly relevant sections are named separately while others are summarized. Further details are provided in the table in Annex II.

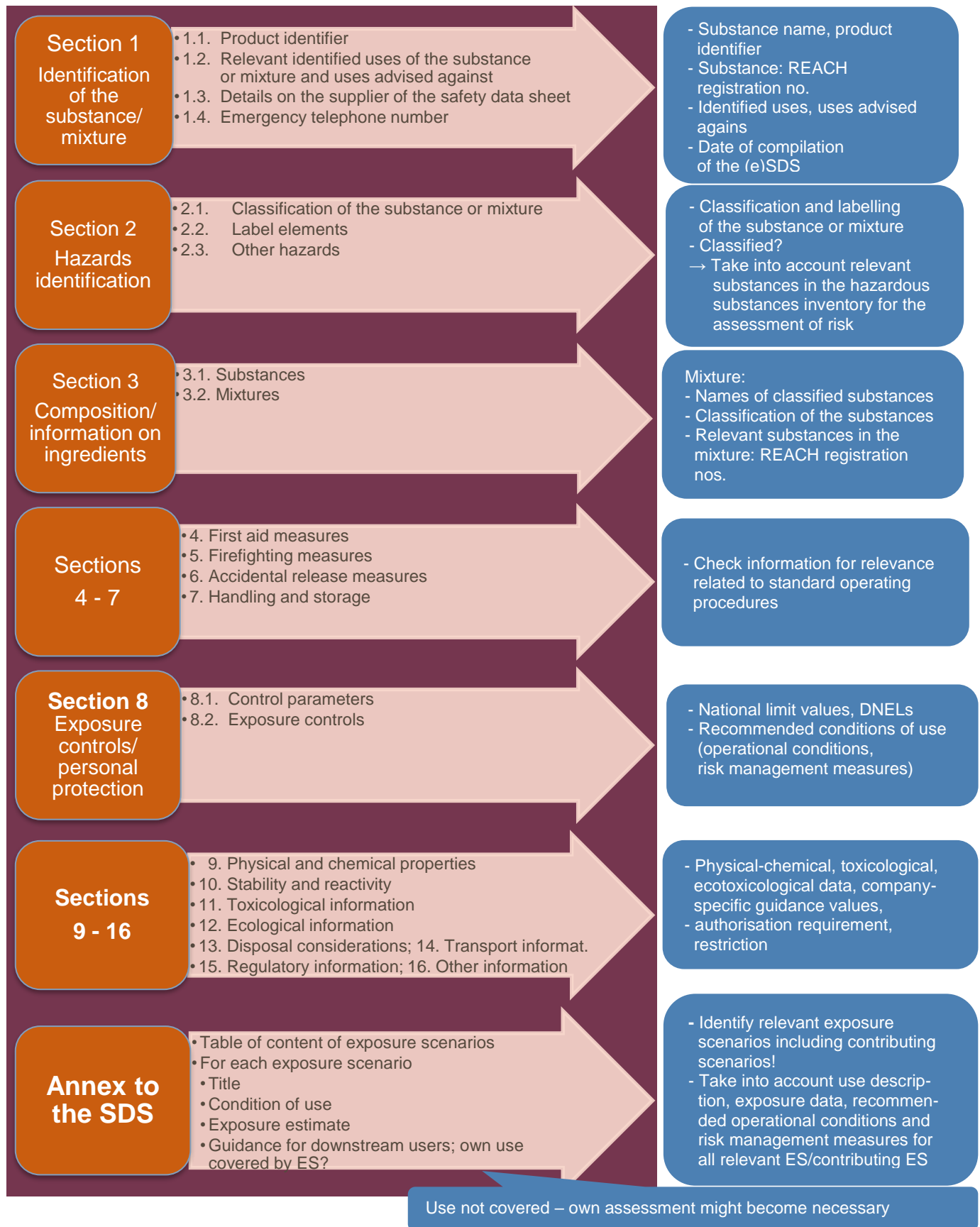


Fig. 2: The extended safety data sheet as a source for risk assessment in OSH

4. Exposure scenarios under REACH and risk assessment in OSH – experiences

4.1 Experiences from the VCI workshop

During the joint development of risk assessments based on extended safety data sheets of substances, REACH and OSH experts from VCI member companies deepened their knowledge of these tasks and gained positive experiences in collaboration. They urgently recommend intensifying the cooperation between these disciplines inside companies.

Extended safety data sheets cover relevant or identified uses. These can be industrial, professional or consumer uses, and the effects on both human health and the environment must be taken into account. By contrast, risk assessment at the workplace must usually cover several tasks carried out by the same worker during a working day and must grant safety and health at the workplace.

The following considerations make the starting points in this setting:

- In principle, the sections in the main part of safety data sheets contain essential information for the preparation of risk assessments at the workplace. They are supplemented by exposure scenarios.
- The intention of the REACH Regulation is that the data which are compiled, made available or generated by the registrants in accordance with the REACH information requirements reflect the overall data situation for a substance in principle. Especially where exposure scenarios were developed, the eSDS communicates not only physical-chemical and (eco)toxicological data but also the conditions of use and risk management measures along the supply chain.

Therefore, exposure scenarios must cover a large number of workplaces along the value chain, in some cases even across industries, and generally can thus not provide a specific risk assessment at an individual workplace. According to OSH legislation, this must be done workplace and task specific. Consequently, it is not covered by the SDS from a supplier.

- When carrying out risk assessments for working with hazardous substances in companies, REACH information and the communicated risk management measures must be taken into account.³ However, starting points for the assessment are the specific tasks, workflows, procedures as well as working, operating and environmental conditions in day-to-day operations of the company, which need to be determined and assessed. In addition, the company could already have internal

³ According to the German Hazardous Substances Ordinance (GefStoffV), the employer is accountable for preparing the risk assessment for tasks involving hazardous substances. However, this obligation is supported by OSH and/or Industrial Hygiene professionals and Occupational Physicians on basis of the German OSH act (ArbSchG).

exposure data for the respective tasks to be performed and other experiences, e.g. findings from medical surveillance. Furthermore, the risk assessment must take into account not only the possible risks posed by the substance used but also other risks that might exist at the workplace at the same time – in order to lay down meaningful and targeted protective measures for operational practice.

Working together in the workshop and based on subsequent analysis, the participants identified the following options for improvement:

- Communication between REACH and OSH experts is a prerequisite for developing close-to-reality exposure scenarios.
 In this way, the greatest possible benefit can be achieved for operational practice. In particular, this applies to knowledge of relevant tasks. Therefore, communication should be intensified with experts from both disciplines, e.g. through in-house workshops (for example, using the VCI concept or adapted company concepts).
- Especially the knowledge of relevant tasks is essential for those preparing exposure scenarios and OSH and Industrial Hygiene officers.
 Alongside workshops, also walk-throughs, contact persons with specific knowledge of the tasks and/or workplaces or exposure scenarios and the joint preparation of use descriptions can help to expand knowledge of the relevant tasks. Suitable contact persons are, inter alia, plant management (e.g. plant manager, plant foreman, safety foreman or shift supervisor), OSH and Industrial Hygiene experts as well as Occupational Physicians.
- The development of close-to-practice exposure scenarios along the supply chain additionally requires an exchange with key customers or sector organizations, where appropriate.
 If knowledge about relevant tasks or workplaces is not available within the company, an exchange with key customers or sector organizations can be useful or necessary to map exposure scenarios in the supply chain that closely reflect real practice. "Use maps" (use descriptions generated by a sector group)⁴ are an example of such an exchange, which contributes to more practical input data for the preparation of exposure scenarios.
- Work environment, workflows and work equipment are relevant and must be taken into account when preparing exposure scenarios.
 Not only the conditions at the respective workplace (e.g. ambient temperature, existing protective measures such as local exhaust ventilation) but also the workflows are relevant (e.g. different or repetitive tasks typically performed by the same worker). Photographs of typical workplaces and detailed descriptions of tasks can provide valuable input to those preparing the exposure scenario. Plant visits provide further detailed information to persons carrying out the risk assessments or generating use maps.

⁴ ECHA website on Use Maps: <https://echa.europa.eu/de/csr-es-roadmap/use-maps/concept>

- Avoid redundancies and inconsistencies in safety data sheets.
 Repetitions and inconsistencies between the SDS sections in the main part and the exposure scenarios lead in practice to avoidable questions and misunderstandings. As a result, essential pieces of information for carrying out the risk assessment cannot be identified beyond doubt or only with difficulty. Some points for possible improvements can be found in the following chapter 4.2 of this report.

Workshop Results – First Interim Conclusions:

Communication between REACH and OSH experts is a prerequisite for the development of close-to-reality exposure scenarios and to achieve the greatest possible benefit for operational practice. In particular, this concerns knowledge about relevant tasks. For this reason, communication should urgently be intensified, e.g. by in-house workshops with experts from both disciplines (e.g. using the VCI concept or adapted company concepts). If such expertise is not already available in a bundled form (e.g. as a "use map"), an exchange with key customers or sector organizations is helpful.

Redundancies and inconsistencies in safety data sheets must be avoided so that essential information for carrying out the risk assessment can be better identified. Potentials for such improvements are addressed in the following chapter 4.2 of this report.

4.2 Further experiences from the preparation and follow-up of the VCI workshop

Already in the preparation of the workshop, a VCI team examined in more detail the following questions, based on the SDSs of three substances:

- Which information from the eSDS are generally used for the risk assessment at the workplace?
- Which information on a specific task (e.g. Proc 8b - transfer of substance or mixture (charging and discharging) at dedicated facilities – in facilities specifically intended for only one product) are found in the main part and which in the exposure scenario?

The result of this examination was the following:

- The inhalation and dermal exposure pathways are relevant for OSH.
 Ingestion is usually less important, if good hygiene practices are complied with or is only relevant for consumer protection.
 - The DNELs given in the safety data sheet are used, but not the PNECs.
 - Also, not all use descriptors are equally useful; the process categories (PROCs) but not the environmental release categories (ERCs) are used by persons performing risk assessment at the workplace.

- The risk assessment focuses on health hazards as well as fire and explosion hazards. Environmental hazards are also determined for information purposes and included in standard operating procedures.
- Exposure scenarios can and must specify certain information compared to the SDS sections.
 - Precise technical conditions: The exposure scenario or the selected PROC provide requirements which technical conditions must be available at the workplace.
 - Usually, e.g. section 8 of the SDS only points to a possible need for local exhaust ventilation (LEV). In the main part of the SDS, this has only the character of a recommendation. By contrast, in the exposure scenario the need for LEV is specified in a binding manner, as it constitutes a necessary component of the risk management measures – in order to achieve safe use in the calculation models.
 - The effectiveness of the LEV is often assumed to be 90% in calculation models, which corresponds to an exposure reduction by a factor of 10. In reality, the effectiveness of the LEV can deviate from this (in both directions: better or worse). If a limit value is allegedly exceeded, it must therefore be checked which of the protective measures (generally a combination of different protective measures in the hierarchy of controls) is not (no longer) sufficiently effective. In this context, the functionality of the LEV must always be checked in practice and its effectiveness must be verified as far as feasible.
 - For risk characterization, limit values (DNELs) are used in calculation when preparing the exposure scenario, so that one does not need to fall back solely to the classification and labelling of a substance. For substances without health-based limit values (e.g. most CM substances with risk-based limit values), the classifications (or national and/or EU-wide limit values, if available) initially provide information on the possible health risk.
 - Basically, available options for eye and hand protection are limited, so that information on this in the SDS section 8 should usually be sufficient.
 - Eye/face protection options: Safety glass, safety goggles (different designs), face shield; danger and likelihood of contact are relevant. In particular, the person responsible for OSH must assess the likelihood of exposure for the individual workplace and, if necessary, must determine e.g. the individual protective measures mentioned above.
 - Hand protection options: Hazards posed by the substance, likelihood of contact, type and layer thickness of the material, breakthrough time must be taken into account.
 - Measures against inhalation exposure can be more diverse. Here, the exposure scenario can contain additional information.

■ Eliminate contradictions between REACH measures and the OSH hierarchy of controls.

Up to now, the OSH hierarchy of controls has not been taken into account in calculation models, so that personal protective equipment and also respiratory protection are recommended as permanent measures. In particular, the use of burdensome Personal Protective Equipment (PPE) as a permanent measure contradicts the requirements of the [German] Hazardous Substances Ordinance. This could be remedied by excluding such cases already in the calculation models or, at the latest, when preparing the SDS (e.g. by an appropriate IT rule set).

■ Resolve redundancies and contradictions between the main part and the annex of the SDS by way of "best practice" rules.

So far, the main part of the SDS (sections 7 and 8) provides general information on conditions of use and risk management measures, which is partly not consistent with information given in specific exposure scenarios. There is room for improvement and, at least, it should be clearly visible in the future whether the information in the main part should be used side-by-side or whether it should be replaced by more specific information from the exposure scenario. The information must be complete; duplication and inconsistencies can be avoided by sufficiently concrete references between the main part and the annex.

The following options are thinkable:

- Only generic information in the main part, specific information (only) in the exposure scenario: e.g. indicate that a glove, eye protection, exhaustion etc. may be required depending on the task (or, if possible, provide generic statement on when certain measures are necessary) and reference to the exposure scenarios for detailed information.
 - Include measures that apply for all scenarios in the main part and refer to exposure scenarios for further supplementing measures that might be applicable.
 - As above – but with case distinctions according to duration, frequency, indoor or outdoor use, etc.
 - No information; reference to the exposure scenarios.
- It is necessary to translate certain data on the effectiveness of protective measures into information suitable for OSH.
- Data on the effectiveness for protective measures in the SDS are based on the factors which were used in the exposure estimation model within the preparation of the exposure scenario, i.e. they state the minimum reduction effect that must be achieved as compared with a scenario without this measure, in order to make the respective scenario applicable.
 - With regard to gloves, this information is therefore required for the REACH assessment, but it should be translated into a manufacturer-independent material specification and a breakthrough time (protection factor according to

DIN EN ISO 374-1, breakthrough time according to DIN EN 16523) for communication with OSH actors. The effectiveness of ventilation and exhaust air systems depends on the construction and equipment on site (as well as the respective hazardous substances).

■ Risk assessment and its operational documentation also meet REACH requirements for checking and assessing use conditions of substances at the workplace.

A risk assessment, as described in tables 1 and 2, should be recognized as sufficient implementation of the check whether a use is covered and safe, also regarding the compliance with downstream user obligations under REACH. The operational documentation, which includes inter alia standard operating procedures, documents the result of the check or the safe use conditions.⁵

If the use of a substance is not covered by a REACH exposure scenario, the risk assessment identifies safe use conditions. A refinement of the determination of hazardous effects, as compared with the information in the SDSs received, during a risk assessment is only necessary in a few cases and would then need to be documented too.

Therefore, the risk assessment and its documentation (including standard operating procedures) should be deemed equivalent to an exposure scenario of a downstream user.

Consequences for REACH requirements in the preparation of "Downstream User Chemical Safety Reports" were not discussed in the VCI workshop. There are strong doubts whether the additional summary of substance-related use conditions in a further document, an exposure scenario or a chemical safety report (according to Article 37(4) in conjunction with Annex XII) has added value. Irrespective of this, there can be notification obligations vis-à-vis ECHA under REACH Article 38 in conjunction with Article 37(4).

⁵ Position of the BAuA (German Federal Institute for Occupational Safety and Health) on the implementation of exposure scenarios of September 2020: "The BAuA takes the view that every employer should be able to use other risk management measures if it can be proven that the same level of protection is achieved. This possibility is implemented analogously in the technical regulations (Technisches Regelwerk). Consequently, the precise naming of specific risk management measures in the exposure scenarios of REACH registrations is not always decisive for OSH. Rather, it is about a starting point for demonstrably equivalent protective measures." (Translation by VCI for the purposes of this report)
https://www.baua.de/DE/Themen/Arbeitsgestaltung-im-Betrieb/Gefahrstoffe/REACH-Bewertungsstelle-Arbeitsschutz/pdf/Gefahrungsbeurteilung-Expositionsszenarium.pdf?__blob=publicationFile&v=3

Findings from the preparation and follow-up of the workshop – second interim conclusions:

Those responsible for performing risk assessments need clear explanations of which data in the SDS can or should be used and how. In this report, tabular overviews are given for illustration purposes – firstly, starting from the risk assessment approach and, secondly, from the safety data sheet (tables 1 and 2).

Chapter 4.2 provides further information on how to find in a targeted manner and how to correctly interpret the information in the SDSs received in operational practice as well as observations on the need for improvement.

For this purpose, public authorities and parties preparing eSDSs should jointly agree on "best practices" for improving the following aspects:

- Avoid contradictions between REACH measures and the hierarchy of controls, which is well-established and acknowledged.
- Translate information on the effectiveness of risk management measures (e.g. gloves or LEV) into assessment criteria suitable for OSH (e.g. regarding material, layer thickness and breakthrough time for a glove instead of a percentage of effectiveness).
- Better matching of use conditions/risk management measures with tasks.
- Resolve redundancies and contradictions between the main part and the annex of the SDS by "best practice" rules.

This report includes first relevant suggestions.

A risk assessment at the workplace, as described in tables 1 and 2, should be recognized as a sufficient check of whether a use is covered and safe, also regarding the compliance with downstream user obligations under REACH. This is because the operational documentation, which includes inter alia the standard operating procedures, comprises the result of the check or the safe use conditions.

5. Conclusions and options for action

In a VCI workshop in March 2019, the interface of the extended safety data sheet and the risk assessment at the workplace was jointly analyzed by experienced REACH and OSH experts from VCI member companies on the basis of concrete examples of tasks and substances, in order to merge knowledge and experience from both fields.

It was found that communication between REACH and OSH experts is a prerequisite for the development of close-to-reality exposure scenarios, so that the greatest possible benefit is achieved for operational practice. In particular, this concerns (detailed) knowledge about relevant tasks. Therefore, communication should be urgently intensified, e.g. by in-house workshops with experts from both disciplines.

So far, there is a lack of explanations that would make the similarities and differences between the contents and intentions of extended safety data sheets and risk assessments transparent. Moreover, the person in charge of conducting risk assessments needs clear, well-arranged explanations as to which pieces of information from the eSDS can or should be used and how. In the follow-up to the workshop, the overviews in this report (tables 1 and 2 and pertinent explanations) were elaborated; they are intended to contribute to the above.

The report also provides background information on the practice of preparing extended safety data sheets, which on the one hand should contribute to a better understanding of the data obtained and on the other hand have potential for improvements.

The discussions in VCI showed that there are not yet sufficiently clear rules and/or practices for the eSDS as to which information on risk management should be provided in the main part and which in the annex, respectively.

Therefore, public authorities and persons preparing SDSs should agree on “best practices” to improve the following aspects:

- Avoid contradictions between REACH measures and the hierarchy of controls as required by good OSH practices and regulation.
- Translate information on the effectiveness of risk management measures into evaluation criteria suitable for OSH.
- Better matching of conditions of use/risk management measures with tasks.
- Resolve redundancies and contradictions between the main part and the annex of the SDS by “best practice” rules.

The report includes relevant suggestions that could be discussed more widely in a stakeholder dialogue (e.g., as part of the development plan for REACH Review Action 3).

The analysis also showed that the conditions of use of the substances used in the workplace are automatically checked and assessed when the risk assessment at the workplace and subsequent operational documentation (including the elaboration of standard operating procedures) are carried out.

Also in the case of a substance use not being covered by the safety data sheet received, the documentation of the risk assessment/standard operating procedures contain(s) the necessary OSH measures. This documentation should be deemed equivalent to the risk management information in an exposure scenario or the chemical safety report of a downstream user and should be recognized as such. Duplication of work through the additional preparation of a chemical safety report (DU CSR) should be avoided.

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- Identification no. in the EU Transparency Register: 15423437054-40
- The VCI is registered in the “public list on the registration of associations and their representatives” of German Parliament (Deutscher Bundestag).

The VCI represents the politico-economic interests of over 1,700 German chemical companies and German subsidiaries of foreign businesses. For this purpose, the VCI is in contact with politicians, public authorities, other industries, science and media. In 2019 the German chemical industry realised sales of over 198 billion euros and employed around 464,000 staff.

Annex I

Carrying out a task-based risk assessment – What information from the SDS can be taken for the individual steps of the risk assessment at the workplace?

Table 1 gives an overview of the information that are generally available for risk assessment from a competently prepared extended safety data sheet. The following information can be taken from the various columns:

- Column 1: Work steps and tasks in risk assessment process in OSH
- Column 2: Statement whether and where in the eSDS information can be found for the respective step of the risk assessment named in column 1
- Column 3: Identification of the information from sections 1 to 16 of the SDS which, from the authors' viewpoint, can be used for the risk assessment
- Column 4: Identification of the information from the annex of the SDS (or exposure scenarios) which, from the authors' viewpoint, can be used for the risk assessment
- Column 5: Explanation of how the information identified/specified in column 3 and/or column 4 can be used for the risk assessment
- Column 6: Details of the steps of a risk assessment (column 1) in operational practice

Together, columns 5 and 6 show how a task-based risk assessment can be conducted in operational practice using information from the eSDS.⁶

⁶ The intention of this project report is to give an overview of the basic procedure for carrying out risk assessments in OSH. In the concrete individual case, further details might have to be considered to ensure the completeness of a risk assessment. The analysis performed is based on eSDSs for substances. While the structure of the main part of the eSDS is the same for substances and mixtures, exposure scenarios in the annex are only mandatory for substances. For mixtures, information on safe use can be communicated in the main part or in an annex.

Table 1: Purposes of the risk assessment and potential relevant contributions from the eSDS

Risk assessment: Task	In section	SDS infor- mation for hazardous substances management	ES information for hazardous substances management	Use of SDS/ES information in the risk assessment	Further points for carrying out of the risk assessment
1. Compile a hazardous substances inventory a) Identify hazardous substances b) Determine volumes	Independent from SDS	ad a): see 2c)		e.g. identify relevant hazardous substances based on communicated classifications (H phrases)	- Identify hazardous substances for affected workplaces - Identify volumes handled
2. Gather information					
a) Describe tasks	Annex to SDS (ES)		- Short title - Use description	- Take into account ES: check existence of described OC and RMM	- Describe activities/tasks regarding possibilities of release/exposure (e.g. aerosol applications) - Estimate possible volume released
b) Describe work area and work equipment	No information relevant to the work area is given, but might contain relevant OC and RMM in the annex				- Estimate surface/volume of the work area, clarify ventilation situation and, if possible, air exchange rate - Check use of ventilated (hand-held) tools (if applicable) - Clarify existence of permanent or provisional containment

Risk assessment: Task	In section	SDS information for hazardous substances management	ES information for hazardous substances management	Use of SDS/ES information in the risk assessment	Further points for carrying out of the risk assessment
c) Identify toxicological properties - classification	Sections 2 and 11: 2.1 Classification 2.2. Label elements 11 Toxicological information Section 3: 3.1 Substances 3.2 Mixtures	<ul style="list-style-type: none"> - Classification, H phrases - Hazard pictograms - Signal words - For mixtures: Composition and concentration ranges of constituents present 		Information a) on acute and chronic health hazards (hazard class) b) on the possible „level” of health hazard (hazard category) c) for mixtures: relevant for the definition of exposure measuring/ assessment (see 4.)	<ul style="list-style-type: none"> - Understand/clarify classification (hazard class); if there are questions, carry out research in public sources and, if necessary, obtain additional toxicological expertise - Identify acute and chronic health hazards and assess them in a task specific approach (take into account hazard category); if necessary and possible, obtain additional human-toxicological expertise - Identify H phrases for standard operating procedures
d) Air and biological limit values	Section 8: 8.1 Control parameters	IOELV/BOELV, national air and biological limit values, DNEL	Levels of exposure of contributing scenarios	Information on a) Time-weighted average and peak limitation factor b) Skin absorption c) Monitoring procedures d) Level of the magnitude of exposure to be met	<ul style="list-style-type: none"> - Search on national (if necessary, international) limit values - Determine limit values to be monitored (time-weighted average and short-term exposure value) - Check skin absorption and assess effects (additionally to exposure to liquids, also

Risk assessment: Task	In section	SDS information for hazardous substances management	ES information for hazardous substances management	Use of SDS/ES information in the risk assessment	Further points for carrying out of the risk assessment
					take into account gas/vapour phase exposure) - Identify suitable/ conditionally suitable measuring methods (cp. IFA work folder)
e) Occupational health findings	No information provided				- Clarify and take into account conspicuous findings from occupational medical checks/surveillance - Find out whether there are complaints from staff (e.g. odour nuisance)
f) Identify physical properties	Section 9: 9.1. Physical and chemical properties	e.g. aggregate state, odour/odour threshold, pH value, boiling point, vapour pressure, particle size distribution, dusting behaviour		Items of information that influence air concentration give indications of the magnitude of task specific exposure	- Search physical-chemical data which influence the release behaviour (e.g. vapour pressure or dustiness behaviour)
g) Findings from accidents and incidental release	No information provided				Information from operational practice: Check whether incidental releases or accidents occurred in the past. Check root cause

Risk assessment: Task	In section	SDS information for hazardous substances management	ES information for hazardous substances management	Use of SDS/ES information in the risk assessment	Further points for carrying out of the risk assessment
					analysis and take results into account
3. Examine options for substitution	Section 1: 1.2 Relevant identified uses		Unidentified uses and uses advised against, possibly in section 1.2 of the SDS	Unidentified / registered uses and uses advised against	- Discuss possibilities for substitution with the operator
4. Assess risk					
a) Identify possibilities of release			Exposure estimation	Provides information on the magnitude of the task specific exposure to be expected	- Visit workplaces (walk-trough), identify work steps with release potential, e.g. filling or decanting
b) Identify exposure pathway			Exposure estimation		- Identify exposure pathway, inter alia inhalation and/or dermal exposure
c) Determine frequency, duration and level of exposure (air monitoring/ human biomonitoring/ exposure calculation)	Annex to the SDS (ES)		- Use conditions - Exposure estimation	Provides information on maximally tolerable frequency and duration	- Optimise work organisation - Limit frequency and duration of the task per shift, per week, per year in practice - Limit the number of affected workers - Assess existing data from air monitoring and human biomonitoring; if necessary or based on QM criteria (TRGS 400, TRGS 402, TRGS 903, DIN EN 689 and

Risk assessment: Task	In section	SDS information for hazardous substances management	ES information for hazardous substances management	Use of SDS/ES information in the risk assessment	Further points for carrying out of the risk assessment
					DIN EN 482) collect and assess new exposure data (air monitoring)
5. Determine protective measures					
a) Determine the state-of-the-art b) Develop possible solutions c) Implement protective measures (hierarchy of controls/behaviour-based safety)	ad a): no information provided ad b) and c): Section 2.2: Label elements Sections 7 and 8.2: Protective measures and exposure limitation in the SDS annex (ES)	P phrases Recommendations for measures	Measures (OC/RMM) Note: Hierarchy of measures not included in exposure assessment tools	Check whether RMMs are in place and assess existing, deviating protective measures in comparison	<ul style="list-style-type: none"> - Assess machines/ apparatuses/workplace situations against the state-of-the-art (from experience) - Assess workplace hygiene (tidiness, cleanliness, behaviour-based safety) - Identify improvement potentials (take into account P phrases) and develop options for action (consider time and investment requirements)
6. Instruct workers					
a) Draft standard operating procedures	Sections 2 and 3 (see 2.c.) Section 4: First aid measures	e.g. measures after skin contact e.g. suitable extinguishing agents	OC/RMM of the ES, if applicable	Check use and level of detail of the information	Draft standard operating procedures based on the task based risk assessment

Risk assessment: Task	In section	SDS information for hazardous substances management	ES information for hazardous substances management	Use of SDS/ES information in the risk assessment	Further points for carrying out of the risk assessment
	Section 5: Firefighting measures Section 6: Accidental release measures Section 7: (see 5a./b.) Section 13: Disposal considerations	e.g. protective equipment e.g. suitable containers for disposal			
b) Instruct workers and document attendance	No information provided				Instruct workers before they start performing the task
c) Provide occupational medical and toxicological advice	No information provided				
7. Check the effectiveness of the protective measures Determine by exposure measurements a.) Air Monitoring	No information provided No information provided		Minimum effectiveness according to recommended RMM of the ES	Check the effectiveness of the recommended RMM as compared with existing protective measures (as far as possible)	<ul style="list-style-type: none"> - Check the functioning of the protective measures/facilities - Verify effectiveness with the help of measured exposure data

Risk assessment: Task	In section	SDS information for hazardous substances management	ES information for hazardous substances management	Use of SDS/ES information in the risk assessment	Further points for carrying out of the risk assessment
b.) Human biomonitoring or by applying non-quantitative approaches c.) Exposure calculation d.) Control banding, e.g. COSHH Essentials or EMKG	Section 8 (see 2.d.)				
8. Document results	Independent from SDS				

Annex II

Extended Safety Data Sheet – What is useful for the risk assessment in OSH?

Based on the sections of the eSDS and the elements of its annex, Table 2 gives an overview of which information can and should be included in steps of the risk assessment. It is complementary to Table 1.

- ▶ Column 1: Mandatory sections and content of the SDS (according to mandatory format) and typical content of exposure scenarios in the annex to the SDS (no binding format requirements).
- ▶ Column 2: Identification of information from the eSDS which, from the authors' viewpoint, can be used for risk assessment (cp. columns 3 and 4 of Table 1).
- ▶ Column 3: Explanation of how information identified/specified in column 2 can or should be used for risk assessment (cp. column 5 of Table 1).
- ▶ Column 4: Comments

With regard to the exposure scenario, it should be noted by way of example using an ECHA example which content might be relevant. Naming and structure can vary, depending on the author of the SDS.

Table 2: The sections of the extended SDS and their use for risk assessment in OSH

Section SDS (mandatory)/ Section ES (not binding)	Concrete data suitable for use in risk assessment	Benefit for risk assessment
SECTION 1: Identification of the substance/mixture and of the company/undertaking 1.1. Product identifier 1.2. Relevant identified uses of the substance or mixture and uses advised against 1.3. Details of the supplier of the safety data sheet 1.4. Emergency telephone number	1.2 Use	Section 1.2 can provide initial indications as to whether basically an assessment of the activity/task was carried out within a chemical safety assessment and eSDS preparation under REACH. The own use might be verified as an identified use. Whether the company's activity was covered in the above can then be checked with the help of the annex (ES).
SECTION 2: Hazards identification 2.1. Classification of the substance or mixture 2.2. Label elements 2.3. Other hazards	2.1 Classification of the substance/mixture	1. Hazardous substances inventory: - Include the substance - Include the classification of the substance (H phrases) - Include labelling in the section „Hazards to human health and the environment“ in the standard operating procedure
SECTION 3: Composition/information on ingredients 3.1. Substances 3.2. Mixtures	3.2 Information on classified components of a mixture: name, concentration	1. Hazardous substances inventory: - Include mixture - Include classification of the mixture (H phrases)
SECTION 4: First aid measures 4.1. Description of first aid measures 4.2. Most important symptoms and effects, both acute and delayed 4.3. Indication of immediate medical attention and special treatment needed	4.1 Description of first aid measures 4.3 Indication of immediate medical attention and special treatment needed	Check use (depending on workplace and task based risk assessment) in the standard operating procedure Include suitable measures in section “First aid” of the standard operating procedure

Section SDS (mandatory)/ Section ES (not binding)	Concrete data suitable for use in risk assessment	Benefit for risk assessment
SECTION 5: Firefighting measures 5.1. Extinguishing media 5.2. Special hazards arising from the substance or mixture 5.3. Advice for firefighters	5.1. Extinguishing media 5.2. Special hazards arising from the substance or mixture	Check use (depending on workplace and task based risk assessment) in the standard operating procedures Include suitable measures in the section „Conduct in the event of danger“ of the standard operating procedures
SECTION 6: Accidental release measures 6.1. Personal precautions, protective equipment and emergency procedures 6.2. Environmental precautions 6.3. Methods and material for containment and cleaning up 6.4. Reference to other sections	6.1.1 For non-emergency personnel 6.3 Methods and materials for containment and cleaning up	Check use (depending on workplace and task based risk assessment) in the standard operating procedures Include suitable measures (P phrases) in the section "Protective measures and rules of conduct in the event of danger“ of the standard operating procedures
SECTION 7: Handling and storage 7.1. Precautions for safe handling 7.2. Conditions for safe storage, including any incompatibilities 7.3. Specific end use(s)	7.1 Precautions for safe handling	Check use (depending on workplace and task based risk assessment) in the standard operating procedures Include suitable measures (P phrases) in the section "Protective measures and rules of conduct“ of the standard operating procedures
SECTION 8: Exposure controls/personal protection 8.1. Control parameters 8.2. Exposure controls	8.2 Use conditions = operational conditions and risk management measures 8.1.4 DNEL	Determining suitable protective measures. It might be possible to take over RMM from the eSDS
SECTION 9: Physical and chemical properties 9.1. Information on basic physical and chemical properties 9.2. Other information	Physical-chemical data	Determine information on fire and explosion hazards
SECTION 10: Stability and reactivity 10.1. Reactivity	10.6 Hazardous decomposition products	To be taken into account in the risk assessment

Section SDS (mandatory)/ Section ES (not binding)	Concrete data suitable for use in risk assessment	Benefit for risk assessment
10.2. Chemical stability 10.3. Possibility of hazardous reactions 10.4. Conditions to avoid 10.5. Incompatible materials 10.6. Hazardous decomposition products		
SECTION 11: Toxicological information 11.1. Information on hazard classes as defined by CLP Regulation 11.2 Information on other hazards		
SECTION 12: Ecological information 12.1. Toxicity 12.2. Persistence and degradability 12.3. Bioaccumulative potential 12.4. Mobility in soil 12.5. Results of PBT and vPvB assessment 12.6. Endocrine disrupting properties 12.7 Other adverse effects	Not relevant for the risk assessment of workers	
SECTION 13: Disposal considerations 13.1. Waste treatment methods		Check use (depending on workplace and task-based risk assessment) in the standard operating procedures Include suitable measures (P phrases) in the section "Proper disposal" of the standard operating procedures
SECTION 14: Transport Information 14.1. UN number or ID number 14.2. UN proper shipping name 14.3. Transport hazard class(es) 14.4. Packing group 14.5. Environmental hazards 14.6. Special precautions for user		

Section SDS (mandatory)/ Section ES (not binding)	Concrete data suitable for use in risk assessment	Benefit for risk assessment
14.7. Transport in bulk according to IMO instruments		
SECTION 15: Regulatory information 15.1. Safety, health and environmental regulations/ legislation specific for the substance or mixture 15.2. Chemical safety assessment	Possibly reference to national provisions Possibly authorisations, restrictions	Take into account the legal provisions Observe use bans
SECTION 16: Other information		
EXPOSURE SCENARIO	No mandatory format	
Table of content of exposure scenarios – after SDS and before scenarios	Not mandatory, but recommended as ENES deliverable to quickly find the relevant ES	First identify the relevant exposure scenarios in the table of content
Title section	Short title: describes „scope“ of the ES Title: ES name	See above
Conditions of use affecting exposure		
Exposure estimation and references to its source	Decision by person preparing the ES in what format/what order to document the use conditions and exposure estimations for all “Contributing ES” to one given ES. Content: - Operational conditions – OC e.g. concentration, physical properties, process temperature, duration and frequency of use, internal/external application - Risk management measures (RMM), e.g. technical, organisational, PSA	Enables an orienting risk assessment for the workplace Supports the determination of permitted applications and, if necessary, appropriate protective measures

Section SDS (mandatory)/ Section ES (not binding)	Concrete data suitable for use in risk assessment	Benefit for risk assessment
	<p>differentiated by scenarios contributing to specific activities</p> <p>Exposure estimation (taking into account recommended OC/RMM) comprises:</p> <ul style="list-style-type: none"> - Method - Exposure level - Risk characterisation ratio RCR - If applicable, maximum volume that can be handled safely <p>for all relevant protection goals/exposure pathways/contributing scenarios</p>	
<p>Guidance to DU to evaluate whether he works inside the boundaries set by the ES</p>	<p>Optional; where applicable, adaptation of recommended use conditions / RMM is permitted</p>	<p>Extends the number of possible options, might be helpful in determining safe working conditions that can be implemented on site</p>

Annex III

Exposure models and their parameters with influence on exposure assessment

When developing exposure scenarios and demonstrating safe use in the context of REACH registration, mathematical models for exposure assessment are often used – as in most cases no data on existing workplace exposures are available. In order to cover a multitude of uses of a substance and large numbers of different workplaces and resulting exposure profiles, a tiered approach for the estimation is often applied.

The example taken here is ECETOC TRA (ECETOC, 2004), which is a simple estimation model and is, therefore, often used for initial exposure estimation as part of the exposure assessment under REACH.

Depending on the process categories (PROC) used, this mathematical model assumes a basic exposure which is modified by various parameters, e.g. exposure duration or ventilation and their associated factors.

The following parameters are used in ECETOC TRA to estimate workplace exposure:

Parameter	Option	Factor	Remarks
Process categories (PROC)	1 - 25c		
Lifecycle stage	Use at an industrial site		For use at an industrial site, the TRA presupposes that there is better equipment, monitoring and training as compared with the professional environment, e.g. constant monitoring of exposure as part of regular inspection and maintenance: incorporation of safe working practices in instructions and EHS management systems.
	Application by professional users		This is the basic case in TRA and corresponds to use in conditions where basic education and training for employees should be ensured according to EU H&S provisions (in particular 89/391/EC and 98/24/EC)
Duration of activity	> 4 h (standard)	1	
	1 - 4 h	0.6	
	15 min to 1 h	0.2	
	< 15 min	0.1	
Use of ventilation?	outside a building	0.7	An effectiveness between 75% and 97% is assumed for an extraction system, depending

Parameter	Option	Factor	Remarks
	inside a building	1	on the respective PROC. The values follow general guidance in this field (e.g. HSE 2008). These values were discussed with UK HSE and are intended to reflect a typical workplace situation and not a "best practice" situation.
	inside a building with local exhaust ventilation (LEV)	0.05 - 1 dep. on PROC	
	inside a building with good general ventilation	0.7	
	inside a building with stronger general ventilation	0.3	
	inside a building with LEV and general ventilation	0.7 * 0.05 - 1 dep. on PROC	
	inside a building with LEV and stronger general ventilation	0.3 * 0.05 - 1 dep. on PROC	
Use of respiratory protection and, if so, what minimum effectiveness?	no	1	
	0.9	0.1	
	0.95	0.05	
Substance as constituent of a mixture?	no	1	
	> 25 %	1	
	5 – 25 %	0.6	
	1 – 5 %	0.2	
	< 1 %	0.1	
Dermal protection/ gloves	no	1	Any type of protective or gauntlet glove without permeation data and without employee training
	protective gloves,	0.2	Protective gloves with existing permeation data showing that the material provides

Parameter	Option	Factor	Remarks
	protection factor 5		sufficient permeation time against the substance.
	protective gloves, protection factor 10	0.1	Chemical protective gloves with basic employee training
	protective gloves, protection factor 20	0.05	Chemical protective gloves (personal protective equipment, category 3 according to the PPE Regulation (EC) 2016/425 with mandatory special instruction (according to DGUV 100-001) including exercises, e.g. in the use of PPE

With this exposure model and its parameters, the interface problems between OSH and REACH in the preparation and communication of the results in the extended SDS are intended to be demonstrated.

Example: Ventilation

Ventilation or extraction of contaminated air is a central element of exposure control at the workplace.

ECETOC TRA offers six different options for the type of ventilation/extraction when using a substance inside a building.

The designations in the model are generic and do not provide further indications on type or design.

The technical reports appertaining to ECETOC TRA give detailed information on the applicability of the different options and their background, also by resorting to examples. However, such knowledge cannot be assumed for a practitioner on site.

Due to the generic information in the model used, this is also communicated in most cases in the description of the exposure scenario in the annex to the SDS with such phrases:

Local extraction	Effectiveness: 80%
Provide a good standard of general ventilation (not less than 3 to 5 times the air exchange rate per hour)	Effectiveness: 30%

It is not clear from this information what type or design of local extraction is required. Only a specification for the effectiveness of the technical ventilation is provided.

Example: Dermal protection/protective glove

Wearing adequate gloves when using hazardous substances protects against dermal contact with the hazardous substance and thus against possible damage to the health of workers.

The effectiveness of the protection is determined by the glove material and its thickness, which in turn depend on the hazardous substance used and the activity.

The protective effect also results from the correct use of the glove, i.e. the correct donning and, above all, the careful taking off of used protective gloves, i.e. without contaminating the skin or other surfaces.

- ECETOC TRA offers four different options for protective gloves and a corresponding effectiveness.
- However, this effectiveness is not based on the glove material and its thickness, but a correct selection is generically assumed.
- Also, a distinction is made between basic employee training and specific activity training, and their correct implementation by workers is used as a reasoning for the different effectiveness of the protective effects.

Therefore, this information is helpful in demonstrating general safe use when preparing the chemical safety report under REACH, but it does not add any value in the verification of safe use at a specific workplace. This is because concrete details on the glove material and required layer thickness are lacking. Moreover, a precise definition of the terms "basic employee training" and "specific activity training" is missing.

Conclusions (Annex III):

As these examples show, in practice a certain description in the exposure scenario (e.g. local extraction device) can correspond to the protective measures at the workplace, but their effectiveness can differ significantly from the effectiveness assumed in an exposure model such as ECETOC TRA, so that the factors used do not apply to the specific application.

When preparing the risk assessment and the standard operating procedures, it is thus necessary to use the information that reflect the real situation.

Therefore, conditions and protective measures described in the communicated exposure scenarios must always be critically reviewed.

Annex IV

Concept of the VCI Expert Workshop “The extended Safety Data Sheet under REACH and the Risk Assessment in Occupational Health and Safety”

Motivation and Goal

Within the VCI workshop, the interface between the extended safety data sheet under REACH and the risk assessment in occupational health and safety (OSH) was analysed by REACH and OSH experts from VCI member companies, based on concrete examples of tasks/activities and substances – in order to merge the expertise and experiences from both fields of work.

The workshop focused on the following:

- Use of relevant eSDS information (e.g. in sections 1, 2, 8, annex) for the risk assessment
- Substances (mixtures were not included)
- Risks through hazardous substances

Further aspects at the interface of REACH and OSH, such as limit values (national limit values/OEL versus DNEL), were not addressed.

A total of 34 persons (including the moderators) participated in the workshop.

Structure of the workshop

Introduction – Presentations

First of all, there was an introduction to the workshop by short presentations:

- Motivation and expectations of the participants (overview of feedback received by the VCI in the run-up to the workshop via the registration form)
- Motivation for and objective of the workshop
- Brief introduction to the extended safety data sheet and exposure scenarios under REACH
- For orientation: overview of the OSH tasks, focusing on risks from substances and risk assessment

After that, the group work on case studies was explained:

- Methodology of the subsequent group work phases (work with flip chart, metaplan and post-its)
- Setting of tasks/guiding questions in the group work (mixed groups were formed in advance, on the basis of feedback on REACH and OSH expertise)

Sequence of the group work (two phases)

Instructed by group moderators, 3 groups (10 participants each) worked self-organised on one of the following examples:

- Dipping of metals in nitric acid (production scale)
- Tank truck filling of isophorone diamine
- Drum filling (200 l drums) with NMP

For the above, the following materials were provided to the participants as hand-outs in each case:

- Guiding questions for the group work (6 questions)
- Photos and short verbal description of the task/activity to be assessed
- Safety data sheet of the relevant substance
- Template for the OSH risk assessment
- PROC list (descriptors for process categories - excerpt from ECHA guidance)
- BG RCI (German social accident insurance institution for the raw materials and chemical industry) – support material A 17 "Risk assessment – hazards catalogue" (Handreichung A 17 "Gefährdungsbeurteilung – Gefahrenkatalog")

The guiding questions and related, more detailed work instructions for the group work included the following points:

- Perusal of work materials and identification of individual tasks/activities or aspects of tasks/activities, including workplace and working conditions
- Identification and assessment of potential hazards
- Identification of the process categories (PROCs) of individual tasks/activities
- Necessary/relevant information for the risk assessment when working with hazardous substances
- Where to find these pieces of information in the extended safety data sheet

- Carrying out the risk assessment (focus on health hazards possibly caused by substances)
- Assessment of the pieces of information from the extended safety data sheet (sufficient, helpful, lacking, misleading, information gaps?)
- Assessment which tasks/work steps were easy and which were difficult or not solvable

After dealing with the first three questions, an interim report was given by each group to the plenary. After a break, the remaining questions were covered by the groups and then the results of this work were also reported in the plenary.

Summary

After that, the workshop moderators summed up the most important results, in particular what went well and what caused problems. They put up the results for discussion.

A detailed documentation of the results, including all materials, in German language is available at VCI-Online (in the members' section).