

TNO report

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Optimizing the benefit of REACH worker exposure assessments: ensuring meaningful health risk communication – LRI-B23

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Summary

Presently, there is a lack of knowledge on the effectiveness of the information exchange on safe use conditions up and down the supply chain.

The aim of the present research project CEFIC LRI B23 was to provide a substantial contribution to the knowledge needed to optimize information exchange on safe use conditions, specifically under REACH. More specifically, the project focused on improving the understanding of the present information exchange to arrive at safe use conditions and what is needed in this respect from suppliers and downstream users. Which sociological factors influence how information on safe use conditions is comprehended and communicated up- and down the supply chain? Finally, how the present methods and tools can be modified to improve safe use conditions. In order to answer these questions, several research activities were carried out.

First of all, a literature study was carried out examining previous developments, existing processes and tools on communication of safe use conditions up and down supply chains. The literature study included 21 tools, of which 16 were analysed in more detail. These incorporated EU legal tools (i.e., REACH, CSR, ES, SDS), ECHA guidance documents and others such as Use Maps, SWEDS, or SUMIs. Also 44 documents on research or opinions about how the information (should) function were found, of which 21 were examined more closely. These studies were published between 2012 and 2020, consisting of scientific studies, posters / presentations of stakeholder meetings, news articles, summary reports or meeting summaries. Results were summarized in a data extraction table including relevant elements such as source, method used, results and conclusions (See appendix 2).

Secondly, an empirical study was carried out to assess the present communication practices up- and downstream as well as the needs of stakeholders. This research activity comprised online interviews with a total of six use cases representing different Dutch downstream companies, two sector organizations and two registrants. The use cases varied in number of employees (ranging from <10 to >1000), different levels of technological sophistication, comprised various sectors, and types of chemical products, to name a few. In total, interviews were held with 21 stakeholders, concerning a total of 37 REACH documents relating to a specific substance. Interview questions were based on McGuire's Persuasion-Communication Matrix, which was used as a background model to collect and interpret the up- and downstream health risk communication in this empirical field study.

Lastly, three workshops with relevant national and international stakeholders were held in order to gather and discuss potential recommendations for improvement of processes, methods and tools. The workshops aimed at validating the results from the literature and empirical field study in an European context, identifying potential improvements of exposure tools, and general improvement of health risk communication. In total, 25 participants from 10 European countries, and five members of the monitoring team participated in the workshops consisting of breakout rooms and plenary sessions.

The following 13 conclusions are drawn in Chapter 5 from the research.

 There are several activities (finalized or ongoing) to improve communication on safe use of chemicals in the scope of REACH and some tools have been developed to improve the communication.

- Actual end user representatives appear not to be extensively involved in the activities and developments related to communication of safe use information in the scope of REACH.
- 3. End users of chemicals do not differentiate in practice between different regulations such as REACH, OSH and CLP
- 4. ESs are rather unknown by end users, partly because they tend to use mixtures, for which ESs are not required.
- 5. ESs are generally considered too long and too complex.
- 6. Updates of SDSs and ESs are not consistently forwarded down the supply chain and also not always within larger companies.
- 7. Feedback on safe use information and how it is communicated does not regularly occur and is not structurally organized.
- 8. Stakeholders in the supply chain seem to blame others for not fulfilling their REACH obligations which lowers their sense of responsibility.
- 9. The awareness and understanding of REACH and associated information decreases down the supply chain and also with decreasing size and decreasing technological advancement of the companies.
- 10. Improvement of collaboration between REACH and OSH (domain and expertise) is considered relevant in companies, sector organizations and at European and national authority level.
- 11. There is limited involvement of various sector organizations in the up- and downstream communication.
- 12. The issues identified, partly via the case studies in this study in the Netherlands, are recognized by international workshop participants.
- 13. REACH is an international (EU-wide) legislation, but the surrounding area (legislation, organisations and culture) is more national, which influences how REACH is perceived and implemented in practice.

The following recommendations are provided in Chapter 6.

- Clarify the intended target group for the REACH documents, specifically the ES and ensure that the REACH documents are accompanied with understandable information adapted to the intended target group.
- To limit the length and complexity of REACH documents, specifically the ES, they should be simplified in format and content and, as far as possible, tailored to specific target groups.
 - a. Experts in large companies can work with complex technical documents
 - b. Responsible persons (usually the employer) in smaller and less technologically advanced companies should receive, in addition to the SDS, more tailored, pragmatic information in terminology understandable to them (e.g., use icons, less jargon and abbreviations, more tailored to the workplace, less pages, no conflicting information from different documents). However, these responsible persons should be able to understand and apply RMM to the workplace, or realise that something needs to be done and hire an expert
 - c. Therefore, responsible persons in end user companies could be educated (guidance and training) in the interpretation and use of (extended)Safety Data Sheets.
- 3. Digitization of the documentation and the transfer (e.g., XML files), specifically of SDSs and ESs, can facilitate tailoring of information to target groups and updating documents in an automated way.
- 4. The several potentially useful tools that already exist could be better implemented and aligned with the target audience. A more detailed study of why specific tools are not better implemented could be useful for this purpose.
- 5. Arrangements should be made to ensure more and better feedback from receivers of safe use information (downstream) to the suppliers (upstream), that is:

- The relevance of providing feedback should be made clear to downstream users:
- b. Suppliers should actively ask for feedback;
- c. Proper digitization may help in the provision of feedback;
- d. Develop a standardized manner to implement the legal feedback structure up- and downstream which is already part of the REACH legislation.
- 6. End users or their representatives should be more involved in the (further) development of safe use information in REACH and of the tools to communicate that information.
- 7. It is recommended that not yet (very) active sector organizations play a larger role in the communication processes, specifically to support the smaller companies in their sector:
 - a. A legal role for sector organizations in the process might be useful;
 - b. Financial support for sector organizations e.g. from subsidies or innovation funds could be helpful;
 - ECHA could provide more guidance for sector organizations on how to improve the supply chain communication. An ENES like platform should be realized.
- A better harmonization should be arranged between the REACH and OSH regulations and documentations, both in the information as well as in the expertise.
 - a. OSH expertise should be involved in interpreting REACH information for end users, either via sector groups or external experts. Also vice versa would be beneficial.
 - b. OSH legal requirements (such as the mandatory hierarchy of control) should be respected under REACH information (Exposure Scenarios) provided to Downstream users. REACH and OSH language and measures need to be harmonized. Upstream communication of relevant data needs to be improved.
 - c. Bring REACH and OSH experts into contact with each other like in trainings and workshops.
 - d. Collaboration between REACH and OSH should be established at the national and European authority level.
- Promote using the insights from the social sciences in the REACH and OSH domain.

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1 Introduction

REACH is the basic chemicals legislation in the EU. The European Chemicals Agency (ECHA) describes on their website the legislation regarding REACH and provides tools and practical guidance to companies which have responsibilities under REACH. The website description includes the processes, products and stakeholders. For instance, a supplier should create an extended Safety Data Sheet (eSDS, which includes descriptions of conditions of use and risk management measures in Exposure Scenarios (ES)) and provide this eSDS to the downstream user. Ideally, there is a two-way interaction between supplier and downstream user. While communication of safe use conditions downstream is a business-to-business activity, the provision of information on use conditions upstream can be done by representatives like sector organizations. The downstream user can provide information on use conditions directly to their supplier. Standardised information on typical, and generally considered safe, use conditions are provided by some downstream user sectors via Use maps and Sector-Specific Worker Exposure Determinants (SWEDs). The derivation of information to be communicated upstream or downstream is generally done by experts on chemical exposure and risk assessment. Concerns are raised whether the present processes and tools are appropriately implemented in real-life and thus actually lead to functioning safe use conditions at the workplace, thereby adequately contributing to the safety of the workers.

The provision of ES with SDS is obligatory with the supply of substances. When mixtures are supplied the relevant information from the ES must be provided with the products, but not necessarily in the form of an ES. This further amplifies abovementioned concerns. Initiatives have been taken, by downstream users and suppliers (manufacturers, importers and all intermediate actors supplying products to further downstream users) and/or their sector organisations, to translate the information from ES to information that is intended to be more user-friendly and understandable. Specifically for mixtures, there have been initiatives, started by the cleaning products sector, to develop mixture-related information tools, such as "Safe Use Information for Mixtures" (SUMI). The European Network on Exposure Scenarios (ENES), a network of authorities and industry, in its implementation plan 2018 mentions 24 actions for improvement. This includes "Adaptations in the ES for communication (to fit the needs of the recipient)." and "Define methods and tools to process the contents received at end use level." A BAuA-project that contributes to the ENES objectives is to "Analyse current communication practice on risk and risk management through the supply chain (Research project REACh2SDS)." This project is running with mainly lead registrants for substances between 100 and 1,000 tonnes per annum. It does have an element of testing suitability of eSDS for employers to use information for the German workplace control scheme for hazardous substances and the intention to ensure outcomes of relevance for all stakeholders.

Currently there is a lack of knowledge on how effective the information on safe use conditions up and down the supply chain is, and there are gaps in the running development programs in this field. The question is what really happens between a specific supplier and Downstream User (DU) in practice and how this communication can be further improved. Research is needed that describes how a supplier communicates safe use conditions in a proper manner to a DU and how the DU implements this information and responds to it if necessary.

1.1 Objectives

The present CEFIC LRI B23 project therefore aims to study how the information from REACH, specifically in the Exposure Scenarios, is understood and acted on by downstream users within their workplaces and how this communication can be further improved.

The main objective of the project is to provide a substantial contribution to optimisation of information on safe use conditions, specifically in REACH.

To achieve this main objective, a number of sub-objectives have been defined:

- Create a better understanding of how safe use conditions are presently derived and how they are communicated up and down the supply chain;
- Create a better understanding of the needs of suppliers and downstream users related to information to enable them to a) derive and describe and b) implement and sustain safe use conditions;
- Assess the sociological and other factors that influence how information on safe use conditions (and the need for these) is comprehended by actors in the supply chain and assess the influence of these factors on how that information is communicated and used;
- 4. Assess how the present methods and tools for communication of information on safe use conditions up and down the supply chain can be modified to improve the understanding and use of the information both in creating Exposure Scenarios and in applying them to the workplace of downstream users.

Another objective is to share understanding gained and suggestions for improvement of the process of creating and communicating information on safe use of chemicals with the key stakeholders.

1.2 Project structure

To reach the objectives of the project it has been organized in four work packages, see Figure 1.1.

WP1: <u>Analysis of existing information</u>: Analysis of existing information related to present up- and downstream communication of information on safe use conditions of chemicals.

WP2: <u>Gathering and analysing in-depth knowledge</u>: Gathering and analysis of in-depth information on up- and downstream communication on use conditions. This included the perception of the ideal situation, the knowledge, understanding and use of the tools and methods and of the present situation. This also included analysis of the needs of stakeholders (in the supply chain, but also e.g. authorities) for optimisation of derivation and implementation of safe use conditions to reach the ideal situation. It also included analysis of factors influencing the effectiveness of communicated information and the implementation and sustained use of safe use conditions.

WP3: <u>Suggestions for improvement</u>: Develop suggestions for improvement of tools and methods for deriving and communicating safe use conditions up and down the supply chain, to ultimately improve implementation and sustained use at the workplace. In other words: suggestions to enable a move from the present to the ideal situation, (partly) by modifying the tools and methods.

WP4: <u>Reporting and dissemination</u>: Report the project in a report and scientific manuscript for publication as well as via presentation or poster at a relevant conference or workshop.

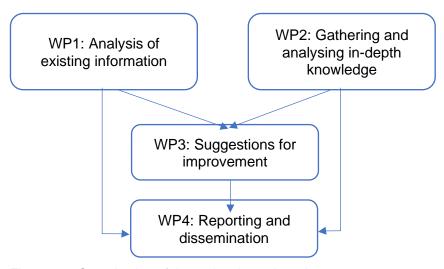


Figure 1.1. Organization of the project in work packages.

1.3 Project consortium

One of the great advantages of this project was that experts from various disciplines have worked together:

- TNO expertise in toxicology, chemical risk assessment, occupational exposure, performing measurements in both experimental and work settings and in building and analysing data(bases).
- TNO experts from other research groups that have expertise on risk perception, health (risk) communication, psychological decision making, determinants of behaviour change, intervention mapping, and implementation of innovations.
- Triskelion B.V. with experience in the regulatory hazard, exposure and risk assessment of chemicals for human health. Triskelion B.V. has a vast experience in practical work for industry as well as research for authorities in the scope of REACH.

A Monitoring Team was established and coordinated by CEFIC LRI with the support of ECETOC, the European Centre for Ecotoxicology and Toxicology of Chemicals. This Monitoring Team is an advisory board that acts on behalf of CEFIC LRI as a monitor, evaluator and discussion partner for the duration of the project. The members of the MT were:

- Océane Albert (CEFIC) till June 2020
- Yuri Bruinen de Bruin (CEFIC) since October 2021 till December 2021
- Bruno Hubesch (CEFIC)
- Dook Noij (retired from Dow Benelux B.V.) (chair)
- Wouter ter Burg (RIVM, the Netherlands)
- Evelyn Tjoe Nij (Dow Benelux B.V.)
- Chris Money (Cynara Consulting Ltd, United Kingdom)
- Urs Schlüter (BAUA, Germany)
- Paul van de Sandt (Belgian Shell NV) till July 2021
- Celia Tanarro (ECHA)
- Jan Urbanus (Belgian Shell NV) since July 2021

In total there have been 9 meetings: a kick-off, 7 progress meetings and a closing meeting. Members of the MT also participated in the workshops of work package 3.

1.4 Structure of the report

The present report describes the results of the research done in each of the work packages. Chapter 2 presents the results of the literature study analysing the existing information (WP 1). Chapter 3 describes the empirical field study in which in-depth knowledge was gathered and analysed (WP 2). Chapter 4 provides the results of the suggestions for improvements collected in the workshops (WP 3). Chapters 2, 3 and 4 all end with a conclusion and discussion section regarding the results of that specific work package. Readers can also only focus on Chapter 5 presenting the overall conclusions and Chapter 6 the recommendations for improvement of the health risk communication in the supply chain based on all the information gathered in each of the work packages from the project. Appendix 1 presents a glossary in which abbreviations and some terms are described.

2 Analysis of existing information

2.1 Introduction and objectives

2.1.1 Introduction

Safe use of chemicals is a fundamental aspect in ensuring the health and well-being of workers. With the introduction of the REACH regulation (EC 1907/2006) (European Commission, 2006), more information became available on the intrinsic properties and use of chemical substances. This wider data set may enable a better assessment of the risks and control measures when using chemical substances and mixtures. In accordance with REACH, the conditions for manufacturing, safe handling and disposal of substances should be well-described in a registration dossier. This registration also mentions how an end user can control the exposure to humans and the environment in so-called exposure scenarios (ES). Typically, ESs provide information on the assessment of approved uses, including the systematic descriptions of tasks in contributing scenarios, whereby each contributing scenario is defined by a so-called Process Categories (PROCs), for example: PROC10: roller application or brushing, operating conditions (OC), for example: limit duration to 1 hour, and risk management measures (RMM), for example: local exhaust ventilation. This information is determined by the manufacturer or importer of a substance and described in a Chemical Safety Report (CSR) of which the ESs are an element. In addition to this downward flow of information to end users ("top-down", see Figure 2.1), the upstream or "bottom up" communication on actual use conditions is also important as it should trigger assessment of all the uses and use conditions.

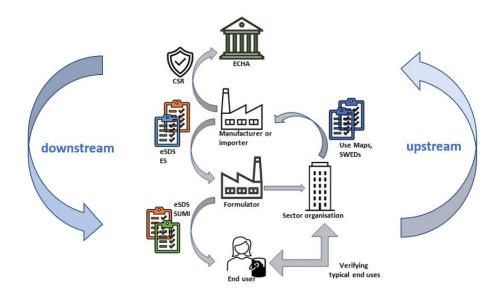


Figure 2.1: Communication flows in the REACH process (the direct communication from end user to manufacturer or importer is missing from this picture).

Within the supply chain, the manufacturer/importer could distribute substance information via ES annexes appended to a safety data sheet (SDS). Companies that use these substances for producing mixtures, i.e. formulators, may consolidate the recommendations for safe use into the body of their SDS, create one mixture ES as an appendix to their SDS or append all relevant ES information in annexes to the SDS in a so called extended SDS (eSDS). The communication on safe uses is ideally bi-directional as end users can also provide, directly or via their sector organisations or the organisations of formulators, information on typical use conditions by e.g. Use

maps and Sector-Specific Worker Exposure Determinants (SWEDs) (see Figure 2.1). These Use maps and SWEDs then contain the relevant uses and activities, described in PROCs, with the OCs and RMMs that are typically used (and considered safe by the DU).

In the present project, the term 'tools' is used to indicate a wide arrange of items that are intended to contribute to the realisation of safe use of chemicals via communication of information through the supply chain. In this broad definition, a legal instrument can be a tool, because it requires certain communication to be made. A guidance document on how to communicate information is also a tool in this definition. And finally, there are, of course, IT tools, such as software formats for information exchange.

The term 'studies' is also used in a very broad way. A study, in this project, is any documented item that provides either research or practical experience or stakeholder opinion on how communication of information on safe use conditions is or should be functioning. Therefore, scientific studies fit within this definition, but also descriptions of what the members of sector organisations experience as well as opinions of stakeholders on what can or should be improved in the scope of communication of safe use conditions.

In itself, some aspects of the REACH regulation can be seen as a tool in the communication of aspects of safe use of chemicals, because it contains the rules for ESs, that are to be appended to SDS of substances. ESs are specifically intended to communicate how a substance can (or should) be used safely, but the SDS themselves also are (partly) designed to communicate how a substance should be used safely.

The legal tools in REACH are depicted in Figure 2.2.

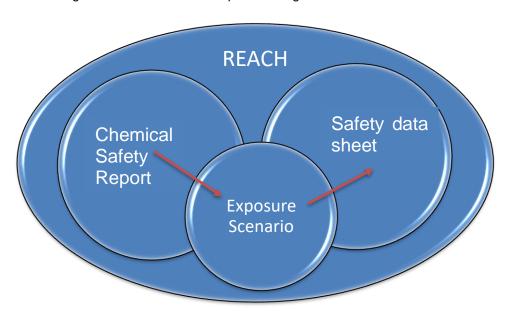


Figure 2.2. The legal tools for communication of safe use information in REACH; while the Chemical Safety Report is not per se a tool for safe use information, it is the source of much of the information and therefore it is depicted here too.

The REACH Regulation requires the creation of the CSR, which reports the hazards and uses of the substance and, if the tonnage is above 10 tonnes per year, the

exposure that may occur and the OCs and RMMs that result in safe use. Within the CSR, these OCs and RMMs resulting in safe use are described in the form of ESs. The relevant ES needs to be appended to the SDS, for communication of characteristics of the substance and safe use conditions in the supply chain. Substances that have been found in toxicological testing or due to human experience or epidemiological research to lead to one or more effects on human health or the environment or to physico-chemical effects, such as explosion, are considered hazardous substances. There is a large set of specific endpoints for hazards, each with their specific criteria. For substances that are not considered hazardous, no ES has to be created and no SDS has to be supplied in the supply chain. For mixtures of substances that are hazardous, the supply of an SDS to companies receiving the mixture is required. However, the addition of one or more ESs of hazardous components to the SDS for mixtures is one of the options to inform on safe use conditions, but is not obligatory. The information may also be communicated in the body of the SDS or in a mixture-ES created by the formulator.

Basically, the REACH regulation requires both communication from the end of the supply chain to the beginning (bottom-up or upstream) and the other way around (top-down or downstream). The top-down communication is largely laid down in the law via the legal requirements on SDSs and ESs. Title IV of REACH is "Information in the supply chain". Art. 31 lays down requirements for SDSs, that are further specified in Annex II of the regulation. The top-down communication is obligatory as indicated by the wording: "The supplier of a substance or a mixture shall provide...." And, in the same article: "Any downstream user shall include....", as well as: "Any distributor shall pass on...."

Bottom-up information requirements are, however, not strictly obligatory. Article 37 on Downstream users starts with: "A downstream user or distributor may provide information to assist in the preparation of a registration." This is followed by: "Any downstream user shall have the right to make a use, as a minimum the brief general description of use, known in writing (on paper or electronically) to the manufacturer, importer, downstream user or distributor who supplies him.....". A downstream user can also make their own chemical safety assessment for uses they do not want to be known by the upstream registrants or for uses not supported by those registrants.

Although there is a legal difference between top-down and bottom-up communication of information on safe use of chemicals in REACH, both are necessary to allow appropriate assessments of risks. Without knowledge of uses and use conditions downstream, the registrants (upstream stakeholders, including manufacturers and importers) cannot create appropriate ESs for hazardous chemicals and cannot provide proper advice on safe use conditions. We therefore consider bottom-up information on uses and (common) use conditions to be part of the communication of safe use information under REACH.

Evidently, REACH requires a large amount of information to be communicated within the supply chain. In 2013, the European Chemicals Agency, ECHA, initiated the CSR/ES Roadmap (ECHA, 2013) to further enhance the communication within the supply chain of chemicals. In addition to that, the Exchange Network on Exposure Scenarios (ENES), a collaboration of authorities and the industry, has also been working on further improvement of the communication on safe use. This includes activities named "Adaptations in the ES for communication (to fit the needs of the recipient)." and "Define methods and tools to process the contents received at end use level." A running project with ENES is to "Analyse current communication practice on risk and risk management through the supply chain (Research project REACh2SDS)." ongoing This BAuA-project (https://www.baua.de/EN/Tasks/Research/Research-projects/f2415.html) is running predominantly with lead registrants for substances in the range of 100 and 1,000 tonnes per annum. It will shed a light on the suitability of eSDSs for employers to use

information for the German workplace control scheme for hazardous substances and the intention to make sure the result is relevant to all stakeholders.

2.1.2 Objectives WP1

The existence of the mentioned Roadmap and the activities performed under ENES show that to date the information on safe use conditions up and down the supply chain is still considered not to match the needs and expectations. Concerns have been raised in meetings and discussions (as indicated later in this chapter), that the present processes and tools for communicating safe use information do not sufficiently contribute to the safety of workers. The objective of WP1 was to analyse existing information related to present up and downstream communication of information on safe)use conditions of chemicals. For this, we compiled already available documentation on how information is currently exchanged between up and downstream users to ensure that end users can handle chemicals safely. Hence, the current chapter is an assessment on what has been reported before on communication on safe use of chemicals.

The focus in the analysis of existing information is on methods and tools for communicating OC and RMM as well as on studies and other documentation describing how this communication is perceived and whether this is considered to result in actual improvements of safe use practices. The knowledge on the existing information related to present up and downstream communication of information on safe use conditions of chemicals provides input and background for WP2, where stakeholders of companies are interviewed on their experience with the communication and safe use of chemicals.

2.2 Methods

In order to get a thorough insight in existing documentation on communication of safe use of chemicals we collected data with respect to the following:

- the legal requirement on communicating use conditions and risk management measures both up- and downstream, leading to safe use of chemicals;
- guidance on the communication of the safe use of chemicals;
- methods and tools developed to facilitate the communication on the safe use of chemicals;
- studies in which it is examined how this communication actually works;
- running initiatives, programs or projects related to this communication.

The search for relevant documentation started with the prior known information of the researchers and was expanded by information and sources provided by the members of the monitoring team of the project. As a good starting point for finding relevant tools and supporting material, we used the ECHA website as it serves as a powerful storage location of several tools and directs to a broad collection of guidance documents on how to use chemicals safely, Use maps, specific formats and templates, extensive fact sheets and standard phrases to be used for the communication within the supply chain. Additional searches were performed online and in the literature databases PubMed and Google Scholar. Websites of some institutes that are pro-actively involved in the development or study of tools and/or communication on safe use of chemicals were also taken into account, e.g. that of the Health and Safety Executive (HSE) in the UK. Where relevant, the "snowball method" was used to gather information referred to in already retrieved documents. For online searches, the following list of key words was selected for finding relevant information (see Table 2.1)

Keywords related to Tools	Keywords related to actors or projects	Keywords related to processes, or related aspects
Chemical Safety Assessment / CSA	REF-5 project	Communication
Chemical Safety Report / CSR	REACh2SDS	Implementation
Exposure scenarios	ENES / Exchange Network on Exposure Scenarios	Understanding
SUMI	REACH Supply chain	Incentives
GEIS	REACH and Occupational Safety	Exchange
Safety data sheet	DUCC (Downstream Users of Chemicals Co-ordination group)	Risk management
Extended safety data sheets		Hazard
EGRET (ESIG Generic Exposure Scenario (GES) Risk and Exposure Tool)		
Chesar		
Sector-specific Worker Exposure Descriptions (SWEDs)		

Table 2.1. Keywords used in the search for information

These keywords were then used by combining keywords related to tools, projects or actors with keywords related to processes and related aspects. For example, a combination of 'SUMI [AND] Implementation' was used or 'DUCC [AND] Communication. This pairing of keywords using [AND] was done to prevent a very large number of references to factual descriptions on the tools as well as to avoid references to processes such as 'communication' in general, without any connection to safe use of chemicals.

In the search for tools, a substantial number of potentially relevant items were found. There are specifically very many guidance documents by ECHA (in various levels of detail, running from factsheets to extensive guidance document, of which already 27 documents under 'Guidance on information requirements and chemical safety assessment'), other authorities and also some by sector groups, that touch upon the communication upstream and downstream of information on safe use conditions. Many of these tools, which are mainly in the form of guidance documents, focus on the description of the REACH processes and requirements in general and not specifically on communication of safe use information, though this is sometimes a part of the guidance. An example is the guideline by the automotive sector: Automotive Industry Guideline on REACH (version 4.0) (ACEA 2018). This guideline is available in multiple languages. Other examples are the Exposure Scenarios Guidance for DU-mmies by Eurometaux (2011) and the guidance by IFRA (2012). However, these guidances do not provide any other guidance on communication than already in the ECHA REACH guidance.

There are also websites from authorities in EU member states that provide information or guidelines in their own language on REACH. Often, this is relatively brief information with links to the Guidance documents at ECHA (some of which exist in multiple languages). These websites from authorities are often linked to the national REACH helpdesk, as e.g. is the case in Germany, where the REACH-CLP-biocides helpdesk has various pages, including one on Safety data sheets (BAuA). In Germany, several specific guidance documents have been published, some also in English. Examples are:

- Announcement 409 Using REACH-information for health and safety at work: https://www.baua.de/EN/Service/Legislative-texts-and-technicalrules/Rules/TRGS/Announcement-409.html
- REACH and Occupational Safety: https://www.baua.de/EN/Topics/Workdesign/Hazardous-substances/REACH-assessment-unit/REACH-and-OSH.html

 "Comparison of workplace risk assessment in OSH and exposure scenarios in REACH" (Vergleich Gefährdungsbeurteilung im Arbeitsschutz und Expositionsszenarium nach REACH):

https://www.baua.de/DE/Themen/Arbeitsgestaltung-im-

Betrieb/Gefahrstoffe/REACH-Bewertungsstelle-

Arbeitsschutz/pdf/Gefaehrdungsbeurteilung-Expositionsszenarium.pdf

These websites and documents are not specifically discussed in our report, because they focus mainly on describing the REACH processes and requirements, which are already described in various forms and levels of detail by the ECHA Guidance documents.

Furthermore, there is a multitude of (text) formats, spreadsheets and an xml-format for facilitating exposure assessment or for information exchange between software tools. Exposure estimation tools are mainly for estimating exposure levels, often based on already communicated or estimated input on conditions of use or existing risk management measures, and to determine the necessary conditions and risk management measures for safe use. They may provide output in a specific format for communication, but these outputs are not directly communicated in the supply chain as safe use information. Therefore these tools are not evaluated in this project. To further increase harmonisation, work has been done to harmonise the conditions of use of different models as far as possible. The xml-format is mainly a technical implementation of structured formats, which is considered independent from the formats from which they are created. These tools may be created to assist in fulfilling legal obligations, in communication between (software of) stakeholders and/or they may be created to assist in achieving the ideal situation of save use. While the general idea of using xml-format may be relevant, an evaluation of the specifics of this format is considered outside the scope of this project.

A complete search of websites of the numerous downstream users sectors in 28 member states (UK was still a member state) was not performed, since searching would take a lot of time and the possibility to find important new information was considered very low.

Twenty-one originally selected items in the area of what we considered 'tools' were analysed more in detail and the relevant aspects were entered into the data extraction table (Appendix 2: Data extraction table). The selection was based mainly on the title of the document and on a quick look into the document or file if the title did not provide sufficient indication. Because many guidance documents by various publishers mainly describe the general requirements of REACH, without adding specific guidance to the exact method of communicating safe use information, the more general guidance documents from various publishers have not been selected. Based on the analysis of these items, a more limited selection of 16 'tools was further selected to be described in Appendix 3: Tools.

In the search for studies, a large number of items was found, of which, specifically in the literature study, very many appeared to provide a hit mainly on one aspect, but not on both tool AND actor/projects or relevant aspects. These were not selected. A selection was made by title and abstract first. Items appearing to probably contain relevant information, based on the title, for this project were further analysed and reported in the data extraction table (Appendix 2: Data extraction Table). This resulted in 44 items in the data extraction table. Based on this further analysis, a further selection was made. Some items, suggested by the monitoring team, appeared to be more an indication of potential (sector) groups having been active in developing tools or discussing their functioning in workshops. These items were not further followed-up, unless we could find actual documents on their websites. Other items that were deselected were considered too far removed from communication on

safe use of chemicals, e.g. a study on the effectiveness of Mental Health First Aid training in the workplace.

The description of tools (and studies) is done accounting for differentiations related to the structure of the communication flow as described in Figure 2.1:

- Upstream versus downstream communication (or 'top-down' versus 'bottom-up');
- Stakeholders involved (e.g., sector associations);
- Steps in the supply chain; and
- Substances or mixtures.

2.3 Results

We summarised the retrieved information in a Data Extraction Table in which the documents were described on various characteristics. Different elements were captured including the source, method used, the results and the conclusions, see Appendix 2. A description of the tools and the relevant highlights of the studies are given in Appendices 3 and 4, respectively.

2.3.1 Tools

This Work Package has gathered existing information on the communication on safe use of chemicals, related to the REACH regulation. To enable or ensure safe use of chemicals, which is a major goal of the REACH regulation, various 'tools' have been developed.

An overview of the tools described in this report is provided in Table 2.2.

Table 2.2. Overview of described tools (see our definition of the term 'tools' in 2.1.1)

No.	Tool (reference to more information)	Туре	Publisher ^{a)}	Main purpose	Relevant for	Direction of communication	Step
1	REACH (European Commission, 2006)	Legal text	EU Parliament and Council	To ensure a high level of protection of human health and the environment	Substances mainly; some parts for mixtures	Mainly top-down, but some bottom- up facilitated	Full supply chain
2	Chemical Safety Report (ECHA 2018a)	Assessment report (requirements)	EU Parliament and Council	To assess risks of chemicals and define safe use conditions	Substances	Top-down	Full supply chain
3	Exposure Scenario (ECHA, 2018b)	Safe use descriptions	EU Parliament and Council	To describe safe use conditions in a structured way	Substances	Top-down	Each scenario one step in the supply chain; full set of scenarios full supply chain
4	Safety data sheet and labels ^{b)} (ECHA, 2020b, ECHA, 2021)	Description of hazards and safe use conditions	EU Parliament and Council	To communicate information on hazards and safe use down the supply chain	Substances and mixtures	Top-down	Full supply chain
5	ECHA Guidance in general (ECHA website)	Guidance documents, factsheets, interactive website	ECHA	Provide guidance on all aspects of REACH including communication up and down the supply chain	Substances mainly, partly for mixtures	Mainly top-down, but partly bottom- up as well	Full supply chain, but focus on top of the supply chain
6	ECHA Guide on Safety data sheets and Exposure scenarios (ECHA, 2018b)	Guidance document	ECHA	Provide information on what Safety data sheets and Exposure Scenarios should include and where to find the information	Substances and mixtures	Top-down	Full supply chain
7	eSDS ECHA Factsheet (ECHA, 2016)	Factsheet	ECHA	Introduction on Safety data sheets and Exposure Scenarios	Substances and mixtures	Top-down	From registrants to formulators (mainly)
8	ESCom phrase catalogue (Cefic, 2018) And xml-standard	Standard phrases And IT communication standard	Cefic, BDI	To ensure use of harmonised terminology in Safety data sheets And harmonised transfer of data between information systems	Substances mainly, partly for mixtures	Top-down	Full supply chain
9	Generic Exposure Scenarios (ECHA 2018c, Money et al., 2011; Tietz & Margary, 2019)	Generic description of exposure situations in downstream sectors using REACH terminology and parameters used in exposure assessment tools	Sector groups (mainly formulators)	To communicate common use conditions and risk management measures for a downstream use sector to the registrants	Substances (mainly)	Bottom-up	From end users via formulators to registrants

No.	Tool (reference to more information)	Туре	Publisher ^{a)}	Main purpose	Relevant for	Direction of communication	Step
10	Use maps (AISE website; ECHA, 2020a; ECHA website 'Use map templates and submission')	Structured spreadsheets (usually)	Formulator sector groups	To ensure that realistic and practical use conditions are used in development of Exposure Scenarios	Substances (though based on uses of mixtures usually)	Bottom-up	From Formulator to registrant)
11	SWEDs (ECHA, 2020a)	Structured spreadsheets and xml formats	Formulator sector groups	To facilitate information on realistic and practical use conditions to be used in Chesar ^d)	Substances (though based on use of mixtures usually)	Bottom-up	From formulator to registrant)
12	SUMI (AISE safe use; NVZ, 2018)	Short simple descriptions of safe use conditions of mixtures	Formulator sector groups	To communicate safe use conditions in understandable format to downstream users	Mixtures	Top-down	From formulator to end user
13	Supply Chain Communication Guidance (Cefic, 2009)	Guidance documents on various aspects of supply chain communication, xml formats for communication and functional requirements for IT tool	Cefic (and DUCC and FECC)	To inform on and improve supply chain communication methods (such as Use maps, xml formats)	Substances	Mainly top-down	Mainly from registrant to formulator; partly further downstream and partly upstream
14	Blueprint coherent system (Cefic & VCI, 2019)	Concept ^{e)}	ECHA	Describe coherent system of tools for communicating safe use information in REACH	Substances and mixtures	Both bottom-up and top-down	Full supply chain, but mainly between registrants and formulators
15	Workplace instruction cards (DGUV, 2012, 2019)	Short simple descriptions of safe use conditions for activities or substances products	Various, often suppliers of SDS software (via their software)	To inform workers at the workplace how to perform activities (with chemical products or other hazards) safely	Substances and mixtures	Top-down	From management or SDS supplier to workers at end users
16	Lead Component Identification Methodology (LCID) (Cefic & VCI, 2018, 2019)	Guidance documents with examples	Cefic and VCI	To identify the components of a mixture that determine the safe use conditions	Mixtures	Top-down	From formulators to end users

a) Here the publishers of the basic set-up of the tools are presented, not the final creators of filled-in formats, tools or documents.

b) Safety data sheets here include also the extended Safety data sheets to which Exposure Scenarios are appended; SDS and labels are regulated in different Regulations (REACH and CLP), but they are considered highly connected and therefore entered in one item here

c) The tools describe the end uses, but these are described by the formulators and communicated upstream to the registrants.

d) Chesar is a software tool, developed by ECHA, that can be used to assess risks of substances and uses and create the Chemical Safety Report.

e) While this is not a separate tool as such, it is mentioned here to indicate the direction of development of tools foreseen by main stakeholders.

As can be seen in Table 2.2, the majority of the described tools is fully or mainly on single substances. They are also mainly for top-down communication. The tools that are mainly related to bottom-up communication are all created by formulator sector groups and their purpose is to communicate structured information from the end users to the registrants at the top of the supply chain. The subject of these tools (Use maps and SWEDs) is not the use at the formulator (though this may be included), but the use and use conditions at the end users. So, information on the end users is compiled by their suppliers (formulators) and submitted to the registrants. The formulator sector groups involved in this process are generally involved stakeholders in the REACH process that are well aware of the legal requirements and the legal tools and also of the language and terminology used by the registrants. In their position in the middle of the supply chain, they are familiar with a large part of the uses, made of their products and of the operational conditions by end users. However, direct involvement of actual end user organisations in the developments of these tools is not clear from the documentation (see for example AISE website; Cefic, 2009; DUCC, 2015; ECHA, 2013; ECHA, 2018d; ENES, 2020; IFRA, 2012; NVZ, 2018). The Generic Exposure Scenarios (Money et al., 2011), have been created in cooperation with end user organisations. Presumably, information from or cooperation with end user organisations has also been used to create Use maps and SWEDs. There is no information of the actual processes used for involving these end user organisations in the pages at ECHA or the DUCC that describe these tools.

To enable setting safe use conditions for mixtures, Cefic and VCI developed a method called Lead Component Identification method (LCID) (Cefic & VCI, 2018, 2019). The main goal of that method is to decide which of the components of a mixture determine what the safe use conditions are. While their guidance also refers to different options for communication and the potential to integrate the method in IT tools, this is not further developed yet. It is therefore not considered to be a tool for actual communication of safe use.

One specific tool is developed for communication from formulators to end users and it is specifically intended for <u>mixtures</u>. This tool, SUMI, is, just like the Use maps and SWEDs, developed by formulator sector groups. In the document published by DUCC on the concept of SUMI, the SUMI are considered part of the 'bottom-up' approach by DUCC, as indicated by the header of paragraph 1.1: "The DUCC 'bottom-up' approaches for the safe use of mixtures, including the SWEDs (ECHA, 2020) and the SUMIs" (DUCC, 2015). However, we consider the SWEDs to be a bottom-up tool and the SUMI to be a <u>top-down</u> tool, because it intends to send information from the formulators to the end users.

Another type of tool is specifically for translating information from SDS (including exposure scenarios when relevant) to workers at the workplace. This is the Workplace Instruction Card. A German version is called 'Betriebsanweisung' (DGUV, 2012, 2019). The Workplace Instruction Card, that is not per se limited to safe use of chemicals, but may also be about other hazards, intends to translate the information on safe use from SDS (and other sources) into simple and understandable messages for workers. They often contain pictograms to facilitate quick understanding, also for those that may not have a high level of literacy or may not adequately speak the local language. Various producers of software for SDS have a module to create Workplace Instruction Cards. In the Dutch cleaning industry, a bipartite organisation has developed a tool to translate the predecessor of SUMI (called GEIS) into Workplace Instruction Cards, called in Dutch "WIKmaker" (RAS website).

The tools that we found that were created by actual end user organisations all consisted of general guidelines that describe REACH processes and requirements and they did not focus on communication of safe use information. This may be due

to the methodology of our search, that relied upon two main elements: literature search in databases and via a search engine and existing knowledge at the researchers and the monitoring team. It is possible, that some (national) end user organisations have created specific tools for communicating information on safe use conditions upstream or for communicating information from REACH tools in a more understandable format to their members. However, such tools, if they exist, have apparently not gained widespread attention, because they are not found in the literature or on the ECHA website.

2.3.2 Studies

A substantial number of 'studies' have been discovered and described, covering the publication period 2012-2020. Approximately one-third of the studies covered in this report can be considered 'scientific studies' and another one-third consists of posters and presentations, presented at meetings by stakeholders. The other documents include news articles, summary reports and meeting summaries. Most of the studies we have described are related to REACH, but a few are more related to CLP. One study, that was on communication (via labels) to the general public, was included, because we consider the issues in communication to the general public to be very common to the issues in communication to SMEs and therefore the findings of that study can have relevance for this project (ECHA, 2012).

One thing that was found in several studies, is that the implementation of the communication processes as foreseen in REACH is work in progress. According to the report by Federchimica (2017), it will take time for all the mechanisms to be fully understood and implemented. And ECHA in a recent communication considered that the REACH communication processes consist of several building blocks that are not all in place yet (ECHA, 2019). In early stages of REACH (2012-2013), it was considered that information exchange is challenging, but will be essential to ensure safe use (Schenk & Antonsson, 2015), that the communication flow needs to be improved (Apatsidou et al., 2018), but also that at that time the (e)SDS that were supplied with substances were not sufficient in relation to usability by end users (Marquart & Dieperink-Hertsenberg, 2016). The 'work in progress' may also be the reason why a very large percentage of respondents from the Finnish industry was not familiar with the concept of ESs and many had never seen any (nor in Italy, in the same study; ECHA, 2019; Tranfo et al, 2020). However, this is explained in the study report by the fact that ESs are not obligatory for mixtures and the majority of end users mostly use mixtures. Furthermore, it is noted that there appear to be gaps in the flow of the eSDS along the supply chain; they do not always reach the lower part of the supply chain (Tjoe Nij, 2019).

Regarding the potential of REACH tools, including ESs, to have an effect on safe use in actual downstream workplaces, there are generally positive feelings. In a study among and related to Swedish downstream users, most informants considered that ESs hold potential as information source for safe use practices. And the research on the potential use of ESs and SUMI as a source for 'Safe practice' descriptions, which are a possibility to describe specific use situations in a way that allows users not to perform their own workplace safety assessment, also concluded that the ESs have a potential to be used for such purposes. Of course, they should be valid and sufficiently conservative (due to the requirements for 'Safe practices'), but also specific enough (Marquart et al., 2014) The same researchers, while finding that no (e)SDS had sufficient quality and usability at the time of study, also reported that when ESs were added to the Safety data sheet, in about two-thirds of the cases they provided added value over the body of the SDS, due to more specific description of risk management measures (Marquart & Dieperink-Hertsenberg, 2016). Labour inspectors in a study also considered that Exposure Scenarios could have added value, but mostly if the downstream user companies have dedicated employees for safety issues. The added value of ESs for SMEs might be limited (ECHA, 2019). The issue of validity and specificity of ESs is also mentioned in a study by national inspectorates, that found that the deficits in CSRs, including not-specified risk management measures, were copied into the ESs, diminishing their usefulness downstream (ECHA Forum, 2019). The fact that CSRs are not all compliant with the requirements, e.g. by having a discrepancy between the process and the reported risk management measures, was still reported in the short poster of the ongoing REACh2SDS project (Kämpfer et al., 2018).

Complaints about ESs are voiced in several documents. Often mentioned complaints are, that they are too long and it is difficult to find relevant information. Also, the formulators and distributors indicate that Exposure Scenarios from different suppliers may provide different information, which then have to be consolidated, see (Apatsidou et al., 2018; Federchimica, 2017 Garmendia Aguirre, 2017; Marquart et al., 2014; Schenk & Antonsson, 2015; Wijnhoven, 2018).

Several sources point towards issues with the language (terminology) used in communication, that is not always understandable or appropriate for end users responsible for implementing safe use methods. Expertise is needed to understand and use tools such as Safety data sheets and Exposure Scenarios and such expertise is not always available, specifically at SMEs (Apatsidou et al., 2018; Chemical Watch, 2013; ECHA, 2019; Federchimica, 2017; Marquart et al., 2014; Wijnhoven, 2018).

Variability in end users is considered an issue that makes it more difficult to reach optimum communication. As mentioned before, according to labour inspectors, information that is useful for larger companies with experts may not be useful for SMEs (Schenk & Antonsson, 2015). In several sources, the needs and concerns of SMEs, that may have limited awareness or understanding of REACH and of safe use information in general, is considered an issue in need of more attention (Apatsidou et al., 2018; ECHA, 2019; Jezso, 2020; Schenk & Antonsson, 2015; Wijnhoven, 2018). Also other sources mention variability in knowledge and experience as relevant (Chemical Watch, 2013; ENES, 2019; Schenk & Antonsson, 2015). In a study on CLP and GHS pictograms, Apatsidou and co-workers (2018) found that age, work experience and profession significantly correlated with the level of familiarization with CLP. Reading the label is also related to educational level of responders.

Perhaps due to the aspect of 'work in progress' it was found in 2015, that REACH has not yet had a major impact on the occupational risk management of downstream users. For industries with substantial expertise on chemical risks, i.e. those in the chemical industry or other large industries (e.g. automotive), it was found that the REACH tools did not have an important effect on the workplace safety, because the safety standards are already higher than those in the ESs (Tioe Nii, 2019). This is probably an effect of the in-house expertise used in performing workplace safety assessments that can be specific to the workplace. The second REACH review (published in 2018), however, observed that REACH does deliver results related to the improvement of risk management measures at the workplace, as well as improvement of the communication and transparency in the supply chain (Jezso, 2020). But e.g. a representative from the chemical industry, in a role as downstream user, reflects that the similarity between REACH and the occupational safety and health legislation is a drawback and that this last legislation is much more targeted at workplace risk assessment (Tjoe Nij, 2019). Nevertheless, the stakeholders in the REACH community appear to consider that the suppliers' risk management advice may significantly contribute to the workplace risk assessment (Schenk & Antonsson, 2015). The results from a study in Italy suggest, that this is mainly due to modified classification of substances, because this was the most reported reason for updating

the workplace risk assessment after receiving a (new or updated) Safety data sheet (ECHA, 2019).

Unfortunately, no study was found that analysed the actual implementation and effectiveness of SUMI, the only tool, described in this report, that is specifically aimed at providing practical information on safe use to end users. An important relevant aspect of this tool is that it is focusing on mixtures, which is important because most products used by end users are mixtures.

While there are certainly critical points raised by various studies on the proper functioning of REACH and the safe use communication therein, there are clearly also positive messages. A substantial number of stakeholders, including authorities and major industrial sectors are doing work to improve the flow of information upstream, via Use maps and SWEDs, and they consider that this works well (DUCC, 2015; ENES, 2020; Portugal, 2019). Furthermore, the potential of the REACH tools is recognized, as described earlier. A benefit of REACH, that is mentioned in several sources, is the increased and improved information on the hazards and risks of chemicals, e.g. via the ECHA website. Also, the quality of SDS was considered to be improved (Chemical Watch, 2013; ENES, 2019; Jezso, 2019; Schenk & Antonsson, 2015; Tjoe Nij, 2019).

The Forum REF-5 project positively concluded that: "Many of the duty holders comply with the provisions of the regulation which concerns compilation, distribution and use of safety information in the form of the chemical safety report and exposure scenarios/extended SDSs for substances. Systems are in place to allow the transfer and communication of safe use information within the supply chain" (ECHA Forum, 2019). And the preliminary results of the REACh2SDS project show that the majority of the CSRs studied can be considered as compliant (Kämpfer et al., 2018). Of course, this does not per se imply that these CSRs and the ESs therein lead to improvements in workplaces after communicating downstream. Compliance of a CSR with the legislation does in itself not lead to understandable messages for end users being sent in a practically useful form. Regarding the SDSs, many responders in a study in Finland found the required information easy to find in the SDS. The sections they tend to look for are the ones on hazards and on personal protection (ECHA, 2019), which are actually in the body of the SDSs and not in the ESs.

As mentioned earlier, it is taken from the second REACH review that REACH delivers results related to the improvement of the risk management measures at the workplace and also on the communication and transparency in the supply chain (Jezso, 2019).

Independent of whether or not the present tools and methods deliver positive results already, there are various recommendations for improvements mentioned in the different documents, some of which are specifically designed to provide recommendations. Next to recommendations aimed at specific elements, there are a couple of more general and repeated recommendations.

A substantial part of the work of stakeholders, at the top-end and middle of the supply chain, as well as of ECHA, is focused on increased harmonisation of formats, tools, phrases and approaches. While this may lead to efficiency for those same stakeholders, they also consider that it will improve the quality of the information being transferred, at least by preventing discrepancies between actors' communication. Also, an idea appears to be that harmonising communication will facilitate understanding at the receiver, since the receiver will become familiar with the type of communication. While Use maps and SWEDs are already important tools for harmonisation, further harmonisation and also digitalisation is recommended by these involved stakeholders (ECHA, 2019; ENES, 2019; ENES, 2020; Garmendia Aguirre, 2017; Jezso, 2019; Pollard, 2019; Portugal, 2019). However, not all

stakeholders are fully convinced of the benefits of further harmonisation. Some member states and the SME group SMEUnited consider that harmonisation will not solve problems, due to the fact that end users are variable and therefore need targeted, specific advice. There is also the fear that standardisation leads to less specific, more general information (Buxton, 2020). In the studies on the REACH tools, lack of specificity of safe use advice is often reported to be a reason for lack of added benefit (ECHA Forum, 2019; Marquart & Dieperink-Hertsenberg, 2016; Marquart et al., 2014; Schenk & Antonsson, 2015).

Another type of recommendation is the need to increase awareness among stakeholders, specifically, of course, those not very involved yet. It has been reported, that end users need to be more involved and also that the occupational safety and health community should be involved, because they can target information better to the end users (Apatsidou et al., 2018; Chemical Watch, 2013; Jezso, 2020; Schenk & Antonsson, 2014). Awareness of REACH requirements and tools was found to be rather low at end users in several studies. The awareness and familiarity with ECHA guidance documents was also found to be low at end users, but they were very aware of guidelines by national occupational health and safety institutes (ECHA, 2019). This is a similar finding as made regarding awareness of the CLP Regulation and GHS pictograms in a study in Greece (Apatsidou et al., 2018). This and other studies recommend awareness raising campaigns at end users of chemicals.

In a study on communication of safety information to the general public, some key points are mentioned in relation to awareness-raising activities, that can probably be extrapolated to awareness-raising activities at end user companies (ECHA, 2012):

- There is a need to address national hazard perception patterns
- Both the general group as well as specific audiences need to be targeted
- A variety of didactic means should be used, including web pages, leaflets, audiovisual material, etc.
- Awareness-raising activities need to play on emotional drivers of risk-related behaviour
- Safety behaviour is influenced by an experience-related, rather than informationbased hazard perception.

2.4 Discussion

This report describes tools prescribed and partly used to ensure proper communication of safe use information. These tools have largely been developed by authorities (e.g. legal tools, large numbers of guidance documents and formats) and by formulator sector groups. There is limited indication of actual involvement of further downstream actors in the development of the tools. For example, Use maps and SWEDs have been created by formulator sector groups. Experts on occupational safety and health from these groups and from manufacturers are known to have been involved in these activities. It may well be, that actual end users (downstream users further down the supply chain than formulators) have participated in the development of these Use maps and SWEDs, but that is not clear from the documentation of the tools.

The purpose of tools created for upstream communication of use (conditions) is to allow registrants to create ESs that fit to the actual uses, as far as known to the creators of the tools. This, logically, impacts the terminology used, because it must be directly translatable to terms used in e.g. exposure assessment models. As such, the tools could therefore be used to translate terminology from end users into terminology for registrants. However, the present ESs keep the terminology that is used for exposure assessment and there is no translation back to the terminology of end users. The ESCom phrases aim at ensuring consistency and quality in wording, which can be helpful. But consistent wording usually implies generic wording and this may not always be fit for the end user receiving the information. Workplace Instruction

Cards, specifically developed for, and in cooperation with, the target group, may be a method to provide understandable and useful information to those that need it. The SUMI are specifically developed for translation of (multiple) Exposure Scenarios to a form and language that is intended to be understandable for end users. They have to be implemented for specific end users groups by the formulators creating products for these end user groups. Whether or not end users are specifically involved in the implementation of specific SUMI-implements is not clear from the documentation received. In The Netherlands, a bipartite organisation of employers and employees in one end user sector group has been specifically involved in the creation of SUMI for that end user group. Personal communication with a representative of that organisation indicates that this process is not yet finalized and that the use of these SUMI is (therefore) not yet widespread. A tool to create Workplace Instruction Cards from the predecessor of SUMI (GEIS) was a result from this activity

The number of actual (scientific) studies on the functioning of the upstream and downstream communication on safe use conditions in the scope of REACH is limited. There are a few studies, that have used interviews or surveys (Apatsidou et al., 2018; ECHA, 2019; Federchimica, 2017; Reihlen et al., 2019; Schenk & Antonsson, 2015; Tranfo et al., 2020) under end users, formulators, (labour) inspectors and other stakeholders or under the general public. These studies are most relevant to get information on what actually is done with the communicated safe use information, either at registrants, formulators, end users or the general public and on how the communication is perceived by these groups. These studies mainly focus on awareness, use and views related to legal tools (Apatsidou et al., 2018; ECHA, 2012; Federchimica, 2017; Schenk & Antonsson, 2016).

There are also a few studies in which experts base their findings on an analysis of legal tools, such as CSRs, ESs or SDSs (ENES, 2020; Kämpfer et al., 2018; Marquart & Dieperink-Hertsenberg, 2016; Marquart et al., 2014) and a study by inspectors in several parts of the supply chain, focusing on compliance with legal obligations and the use of the legal tools (ECHA Forum, 2019). These studies are useful to obtain information on how experts, not from the supply chain, view the quality and use of the communication tools studied. However, they do not provide direct information on the actual implementation of improvements or on the perception of actual end users. They focus mainly on the validity of exposure estimates and the adherence to (legal) requirements. Another aspect in these studies is the expert opinion on the potential usefulness of these tools for communicating safe use information (ECHA Forum, 2019; Marquart & Dieperink-Hertsenberg, 2016; Marquart et al., 2014; Kämpfer et al., 2018).

The remainder of what was described under 'studies' consists largely of stakeholder presentations of their experiences and opinions. These are considered to be based on the actual experiences of members of sector groups or other stakeholder groups and can give important information on how the collective of stakeholders considers the tools for communication on safe use conditions to work. Due to a lack of studies (scientific or expert) on other tools than legal tools, the conclusions on such tools can therefore only be based on the opinions presented by stakeholders or experts and not on real studies. More details on the specific findings of these studies in relation to the mentioned elements are provided in Appendix 4.

True scientific studies with proper scientific methods (e.g., representative sampling, non-leading questions, proper statistics) on the actual effect (increased safe use of substances) of the available tools were not found. There were no studies comparing how safe use was before or after use of the tools or for (randomly chosen) comparable situations with or without the use of the tools. Such studies should lead to scientifically valid results. Analysis by experts of tools and communication (not involved in the creation of the studied tools and communication) may somehow be

biased by their interests, e.g. if they do create other tools. Of course, stakeholders presenting information on tools they themselves have (co-)created can be expected to be relatively positive about their tools. And stakeholders that consider legislation largely as a burden probably are more negative about legal tools, while inspectors would be expected to be positive about legal tools, but critical about the compliance. Nevertheless, the opinions by stakeholders should be considered highly relevant. It is the stakeholders that have to work with the tools to result in safe use of chemicals. While stakeholder (and expert) views cannot prove that certain tools are really effective, they can provide relevant indications as well as suggestions for improvement that can be further developed.

2.5 Conclusions

The key points that have been derived from this Work Package have been summarized below.

1. There is substantial activity by authorities (including ECHA), registrants (as represented by Cefic and sector groups) and formulators (represented by their sector group) to improve communication on safe use of chemicals in the scope of REACH up and down the supply chain. This resulted in a number of specific tools to complement the legal tools (see Appendices 3 and 4).

These tools are mainly for upstream communication of use conditions that are presently common and assumed to be safe. How often and how well these non-legal tools are actually used has not yet been studied. There have also been no independent studies of whether the use of these tools improves the quality of the Exposure Scenarios and the communication downstream. The formulators and registrants involved in the development and discussions around these tools consider them very useful.

 Actual end users (except registrants and formulators that are also end users themselves) and their representatives do not appear to be involved in the activities and developments related to communication on safe use of chemicals in the scope of REACH (see AISE website; Cefic, 2009; DUCC, 2015; ECHA, 2013; ECHA, 2018d ENES, 2020; IFRA, 2012; NVZ, 2018).

Whether the apparent lack of involvement of actual end users also reflects a real lack of involvement is not completely clear. In The Netherlands, representatives of end users in one sector have been involved in developing specific SUMI, but, as far as we are aware, this process is not finalised. This issue of lack of involvement of actual end users is discussed with actual end users in Work Packages 2 and 3.

3. At end user level, the awareness and understanding of legal tools of REACH, specifically the Exposure Scenario, is not very high (see Apatsidou et al., 2018; ECHA, 2019; Jezso, 2020; Schenk & Antonsson, 2015; Wijnhoven, 2018).

This can partly be explained by the fact that end users tend to use many mixtures for which the supply of Exposure Scenarios is not obligatory. It may also be caused by the fact that REACH has been evolving over time and that some of these studies are from an earlier phase of REACH. And the lack of understanding of the terminology and (legal) language of REACH and guidance documents may be a factor too.

 Many end users consider the Exposure Scenarios (if they know them) as too long, too complicated and too technical in terminology. They find it difficult to obtain information from these documents. (see Apatsidou et al., 2018; Chemical Watch, 2013; ECHA, 2019; Federchimica, 2017; Garmendia Aguirre, 2017; Marquart et al., 2014; Schenk & Antonsson, 2015; Wijnhoven, 2018)

This is a rather often presented issue. This view on Exposure Scenarios may result from the practice, observed by the authors of this study, that several registrants simply attach all Exposure Scenarios to their SDS. If formulators then simply push this through to end users, these end users can end up with many Exposure Scenarios not relevant to their use. Some bulk substances have more than 20 Exposure Scenarios, which explains the length of complete sets of Exposure Scenarios. No tools have yet been developed to present Exposure Scenarios for substances in a much more understandable and shorter format with less (exposure assessment focused) technical terminology.

 Actual end users tend to mostly use mixtures, while most tools in the scope of REACH focus on single substances (see Chemical Watch, 2013; ECHA, 2019; Federchimica, 2017; Jezso, 2019; Schenk & Antonsson, 2015; Wijnhoven, 2018;)

This has been described as a possible cause for lack of awareness of Exposure Scenarios at end users at key point 3. The SUMI are the only tool accounting for that issue, but there were no studies in which use, proper functioning and perception of this tool was actually studied.

 There is substantial variation in awareness of REACH requirements and the relevant tools, that is related to factors such as expertise, experience, sector, educational level (see Apatsidou et al., 2018; Chemical Watch, 2013; ECHA, 2019; Jezso, 2020; Schenk & Antonsson, 2015; Wijnhoven, 2018).

This implies that such aspects should ideally be taken into account when communicating information on safe use conditions. Communication that may be successful for one group might not be successful for another group.

 The tools developed by stakeholders almost all focus on upstream communication (see AISE website; ECHA 2018c; ECHA, 2020; ECHA website; Money et al., 2011; Tietz & Margary, 2019).

A possible explanation is in the fact that a lot of work needed to be done by registrants to create all the REACH dossiers and that they therefore communicated with their direct clients (mainly formulators) on the uses and conditions to be covered in the registrations. However, due to the lack of downstream communication tools (outside of SUMI), the actual downstream communication almost fully relies on the legal tools of REACH and mainly on the Safety datasheets and Exposure Scenarios. This may be caused by the focus of stakeholders on complying with legal requirements. However, that does not imply that other, more effective, communication methods cannot be developed and used.

8. The tools for upstream communication function well and more specific implementations of these tools by sector groups not yet active in this field are recommended (see ENES, 2020; Jezso, 2019; Portugal, 2019;).

This conclusion is not based on independent studies, but on the impressions by involved stakeholders.

 There is a substantial focus on harmonization, standardization and digitalization in the activities of the active stakeholders (see ECHA, 2019; ENES, 2019; ENES, 2020; Garmendia Aguirre, 2017; Jezso, 2019; Pollard, 2019; Portugal, 2019)

Main goals of harmonization and digitalization appear to be consistency in results and efficiency in the performance of the activities. Lack of consistency has been mentioned as a problem with Exposure Scenarios and therefore harmonization can be part of the solution. Digitalization is a general tendency in businesses and can fit with their need to use resources efficiently. Whether harmonization, standardization and digitalization is going to solve existing problems in the communication is questioned by some stakeholders, who consider that the actual problems are not related to these solutions (see Buxton, 2020) or leading to a too generic approach.

- There is one tool, SUMI, specifically developed by formulator sector groups for downstream communication to end users. This tool, SUMI, has been developed. Studies on its implementation in practice or its effectiveness were not found (see AISE website; ECHA, 2018d; ECHA, 2019; ENES, 2020; NVZ, 2018).
- 11. The implementation of REACH has resulted in improved and increased availability of information on hazards of substances (see Chemical Watch, 2013; ENES, 2019; Jezso, 2019; Schenk & Antonsson, 2015; Tjoe Nij, 2019)

There was substantial agreement on this between stakeholders, as far as visible in the studies. This is not surprising since there are very strict and clear requirements for hazard data to be gathered and presented in REACH dossiers. The creation of a REACH dossier therefore often resulted in filling of existing data gaps.

 The (improved) hazard information and information on personal protection are the main information gathered by end users, mainly from the body of the Safety data sheet (see Apatsidou et al., 2018; ECHA, 2019; Schenk & Antonsson, 2015).

The data mainly used by end users comes from the body of the Safety data sheet and has been in these documents long before REACH was started.

 Improved hazard information is also a major driver for end users to modify their workplace safety assessment and risk management (see Apatsidou et al., 2018; ECHA, 2019; Schenk & Antonsson, 2015).

This point is logically related to the previous point. If end users look for hazard information mainly, they will also use that as a basis for changes in the workplace. And if they do not get or cannot find relevant information in Exposure Scenarios (key points 3 and 4), they can, of course, also not use the information from the Exposure Scenarios.

14. Exposure Scenarios have not yet had a major impact on workplace risk management (see Chemical Watch, 2013; ECHA, 2019; Federchimica, 2017; Schenk & Antonsson, 2015; Tjoe Nij, 2019; Tranfo et al., 2020).

This is a logical consequence of earlier mentioned key points, including key points 3, 4 and 12. If this situation persists, a major tool from REACH will not have fulfilled its potential.

 However, there is potential for a relevant role of Exposure Scenarios in the improvement of working conditions, provided the information is valid. specific and understandable (see Chemical Watch, 2013; Marquart et al., 2014; Schenk & Antonsson, 2015).

This potential is mentioned by experts from upstream stakeholders (registrants, formulators) and inspectors as well as from consultants and academia.

16. There is a need for awareness-raising at end user level on the relevance and potential of Exposure Scenarios and tools such as SUMI, that translate Exposure Scenarios into practical communication on safe use of mixtures (see Apatsidou et al., 2018; ECHA, 2019; Jezso, 2020; Schenk & Antonsson, 2015; Wijnhoven, 2018).

Awareness-raising activities should be targeted and should account for differences in target populations and use available knowledge on effective communication of (complex) information (see Apatsidou et al., 2018; Buxton, 2020; Chemical Watch, 2013; ENES, 2019; Jezso, 2020; Pollard, 2019; Schenk & Antonsson, 2015).

Awareness-raising is, of course, only a first step in the process to change ESs and other tools from unknown and underused to successful tools in the communication of safe use information.

17. It is considered that the occupational safety and health community should be more involved in the communication of safe use information coming from REACH (see Apatsidou et al., 2018; Chemical Watch, 2013; Jezso, 2020; Schenk & Antonsson, 2015; Tjoe Nij, 2019).

The occupational safety and health experts are trained to assess situations in actual workplaces and to recommend improved OC and RMM, taking account of legal rules, such as the STOP principle (using, in order of preference: Substitution, Technical measures, Organizational measures and Personal protection to reduce risks). These experts should be able to translate the (technical and generically described) safe use conditions from Exposure Scenarios to practical OC and RMM in real workplaces. They may also be helpful to modify or translate the terminology in exposure model, to make them more understandable to end users.

3 Gathering and analysing in-depth knowledge

This chapter describes an in-depth empirical field study of the up- and downstream communication on safe use conditions of harmful chemicals in The Netherlands. Both streams, its related stakeholders and instruments are studied from the perspective of the downstream user (work package 2A) and the registrants and sector organizations (work package 2B). In this way we gain insight in the actual benefits and possible issues with the implementation of the REACH-legislation in practice.

3.1 McGuire's Persuasion-Communication Matrix

McGuire's Persuasion-Communication Matrix (1984, 1985, 2001) serves as a background framework to answer the objectives for this work package. It describes a general model for the communication process that is relevant for this project and is depicted in Table 3.1.

Table 2.4 As	01/05/101/10	f MaCuira'a	Darausaian (Communication	Matrix
Table 5. L. An	overview o	i wccuire s	Persuasion-u	Johnmunication	ivialitix.

	Message Source	Message Design	Delivery Channel	Receiver	Context
Orientation to the message	564.66	Doorgii	- Cildillioi	110001101	Contoxt
Exposure					
Attention					
Interest/Liking					
Comprehension					
Acceptance and Use					
Acquisition					
Agreeing					
Memorising					
Retrieving					
Deciding					
Acting					
Sustained use					
Reinforcement					
Consolidation					

McGuire's Persuasion-Communication Matrix describes a general model of a communication process. The matrix consists of five communication components (the columns):

- 1. Message source (e.g., credibility of the sender)
- 2. Message design (e.g., content, lay-out)
- 3. Delivery channel (e.g., type of media)
- 4. Receiver (e.g., beliefs, prior knowledge of the person receiving the message)
- 5. Context (e.g., environmental factors influencing the message)

The matrix also describes twelve steps that comprise three phases an individual passes through in the communication process (the rows). For instance, a downstream user provided with an eSDS first has to orient him-/herself to this data sheet (i.e., pay attention, be interested and comprehend). Secondly, 'acceptance and use' implies checking if operational conditions and risk management measures in the ES correspond to the DU's situation. DUs may actively divert from the eSDS and will have to take action for themselves. DUs decide what action is needed (confirm, adapt or decline). If the ES applies (after adjustments) the DU has to ensure that the operational conditions and risk management measures are implemented and regularly checked whether these are still the same.

The matrix in itself will not differentiate those communication elements that are critical for effective risk management. The matrix guides how the communication process upstream or downstream for a DU can be described so that finally the DU works according to established safe use conditions.

3.2 The study method

Online interviews were held with different Dutch stakeholders in the supply chain of REACH substances. Not only end users, but also formulators, registrants and sector organizations were included in this study.

The independent TNO ethical committee reviewed and approved the study design for both work packages (number 2020-068) on August 7, 2020.

To emphasize the importance of having both a down- and upstream focus, this study was divided into two work packages 2A (downstream) and 2B (upstream).

3.2.1 Work package 2A: Downstream communication

The first work package focused on getting an in-depth view of REACH from the perspective of a variety of Dutch downstream users. In collaboration with the CEFIC LRI monitoring team, a selection of six different types of downstream users was construed, taking into account various relevant characteristics of the downstream user. The following characteristics have been taken into account:

- number of employees like SME's and larger companies
- level of technological sophistication
- participation in organized or less-organized sectors
- the quality of the supply chain regarding length and coordination
- more or less knowledgeable on occupational and environmental health
- national versus international organizations
- different sectors
- type of chemicals like single substances as well as mixtures of chemicals

We assume that these characteristics affect the down- and upstream health risk communication of these downstream users. These characteristics are also not independent but are related, like a large company usually is more knowledgeable on occupational and environmental health and also more knowledgeable on chemical regulations and their obligations for industry. Studying these various downstream users in the present study shows if these characteristics of downstream users do affect REACH communication. Table 3.2 gives an overview of these cases that the project team and monitoring team construed in the meeting of May 20, 2020.

Table 3.2. An overview of the six use cases construed for an in-depth study.

	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6
Number of employees	Ca. 100	> 1000	< 10	10-50	> 1000	Ca. 400
(Inter)national	international	international	national	national and international	national or international	national or international
Technological sophistication	High	High	Low	Low to medium	Low to high	Medium
Sector	Machine building & Packaging	Electrical & electronic equipment	Specific construction company	Formulation of chemical products	Road and tunnel building	Formulation of cosmetics and cleaning agents
Organisation of sector	Machine Building: well organised, Packaging: Unknown	Well organised	self- employed with contacts in sector organisation	Well organised	Well organised	Well organised
Knowledge of org. and env. Health	Present	Present	Limited to none	Limited	Present	Present
Types of chemical products	Specific products	Various products	Various products	Various products	Various products	Various products

To ensure the privacy of the participating companies, non-disclosure agreements (NDA) were signed between TNO and each participating company. In this NDA the anonymity of the companies and its employees is guaranteed. The NDA also states that the interview recording and the analysis of the individual interviews are to be deleted upon completion of the report. This ensured the possibility for the participants to share internal or confidential information during the interviews. Furthermore, the employees that participated in the interviews signed an informed consent ensuring that they are well informed on their individual privacy upon the interview.

The research team set out to find companies that met the criteria of the six use cases as presented in Table 3.2 and willing to participate in the study. We used the network of our project team (TNO and Triskelion) and the network of the CEFIC LRI Monitoring team to find matching companies. The general procedure was that after finding a contact person in a company we sent an information letter explaining the purpose and design of the study and the requirements for the company. Extra explanation was provided by telephone if requested. When the company agreed to participate the NDA had to be setup and signed. Next, it had to be decided whom to interview in the company and about which specific chemical substance. Table 3.3 provides an overview of the inclusion of the six companies.

Table 3.3. An overview of the inclusion and interviews with the six companies to build use cases.

use cases.	04	00	0	0 1	0	00
	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6
Date first contact	17-06-2020	05-06-2020	15-07- 2020	16-10-2020	20-08-2020	21-08-2020
Contact person	Company	Company	Sector organizatio n	Sector organisation	Company	Company
Date NDA	31-08-2020	11-08-2020	NA ¹	NA	25-08-2020	24-09-2020
Date first interview	21-01-2021	10-11-2020	18-01- 2021	02-02-2021	10-12-2020	15-12-2020
Date last interview	22-01-2021	26-11-2020	NA	NA	12-01-2021	28-01-2021
Number of interviews & Interviewees	A. technical sales manager B. HSE specialist C. sales director Benelux	A. team leader B. senior operator C. two HSE managers D. contact person Health and Safety + HSE coordinator E. SHE database administrat or F. senior operator	self- employed handyman	Group interview with 4 persons: representati ves of 2 sector organisation s, 1 formulator paint, 1 formulator glue and sealant	A. purchasing director B. manager safety C. QSHE advisor/sa fety expert D. employee QSHE departme nt + manager purchasin g dept. E. building contractor	A. manager R&D, Legal affairs B. employee dept. regulatory affairs
Interviewers ²	JW	JW, PS, HB	JW	JW, WO, JS (moderator)	PS, JW	JW
Number of documents	18	6	1	NA	5	7

¹ NA = Not Applicable

Table 3.3 shows that it usually took several months between the first contact with the company and the last interview. Also two companies we contacted did eventually decline to participate, but these were replaced by alternative companies as described below. Also we could not always follow the general inclusion procedure. For case 3 we searched for a small (< 10 employees) construction company. A sector organization in Building & Infrastructure supported us by sending the information leaflet to their members, resulting in a self-employed handyman willing to be interviewed. In this case only an informed consent was signed and not an NDA. For case 4 the contacted company declined to participate in August 2020. We contacted the sector organization for 'producers of paint and printing ink' if they could distribute the information leaflet of the study among their members. The sector organization did not want to burden their members with this request, but offered to have a group interview with two of their members and a representative of this sector organization and a representative of the sector organization 'producers of glue and sealant'. The refusal of the first company contacted for case 6 in June 2020 was explained by "Your request is appreciated, but unfortunately our conclusion is that we cannot participate due to other priorities." Fortunately, the second company we contacted agreed to participate. That the inclusion took quite some time and flexibility could be partly due to the corona crisis that started in March 2020. Companies were probably busy with mitigating the corona situation, and had less time and energy to participate in a study.

In order to elicit during the interview how the up- and downstream communication regarding REACH documents in a company is realized, we decided to focus on a specific substance for each company. The company provided the research team with

² Initials of the interviewers (JW = Joeri Willemsen, PS = Paul Schuurman, WO = Wilma Otten, HB = Henry Boumann, JS = Jody Schinkel)

all documents related to safe working with that substance in the context of REACH (e.g., SDSs, ESs), and sometimes with additional OSHE documents for working with that substance (e.g., Work Instruction Cards). The interview protocol followed the steps in McGuire's Persuasion-Communication Matrix by first asking questions about the 'Orientation to the message', like how they received the document, from whom, and whether the document was interesting and understandable. The step 'Acceptance and Use' included questions considering whether they agreed with the content of the document and if the content fits their company. The last step '(Sustained) use' focused on how they handled the document in their company and if they changed how they worked with the substance based on the document. In each of these steps there was attention for the source, message design, delivery channel and receiver of the documents.

Table 3.3 also describes the number and job title of employees in a company we interviewed and the number of internal REACH related safety documents provided by the company. Case 2 and case 5 are large companies, thus we interviewed more employees. Case 3 'self-employed handyman' was of course just one person to interview, but also only one "document", being the information on the bottle of a cleaning agent, which is not a REACH document. The interviews lasted 60 to 90 minutes and took place via videocalls due to the restrictions and limitations brought by the corona crisis. The first interviews were held for case 2. For that case usually two interviewers were involved, that is, one with chemical risk/exposure expertise and one with psychological communication/behavior change expertise. After these interviews we decided to deviate from the interview protocol, as we thought that it was not necessary to have an expert on chemical risk/exposure present during each interview. Therefore, in the remaining interviews usually one expert on communication regarding safe use of chemicals was the interviewer. For case 4 we also asked a business developer familiar with this sector to moderate the group interview. With permission of the interviewees, the interviews have been recorded to enable a more extensive thematic analysis. For each company the results of the analyses of the interviews were described in separate reports for each company in which the interviewees and their responses were described anonymously. These reports were officially approved by the contact person of each individual company prior to inclusion of the anonymized results in this report. In total 18 interviews were conducted with in total 24 persons and 37 internal safety and REACH documents were analyzed for work package 2A.

3.2.2 Work package 2B: Upstream communication

By interviewing registrants and branch organizations also the perspective of upstream users was added to the perspective of downstream users. As with the downstream users, the participating organizations have been anonymized. All interviewees provided informed consent prior to the interview. An NDA was not necessary because in the interviews we did not focus on internal REACH documents regarding a specific substance. Thus, during these interviews a different interview protocol was used that focused more on the role of the stakeholders in the supply chain.

The interview protocol started with inquiring if the REACH legislation was familiar, how they came into contact with it and how they evaluated it. Next, the REACH documents (SDS, ES, SUMI) were mentioned and the roles and responsibilities of the organization regarding these documents, their evaluation of these documents (e.g., comprehensible, useful) and updating these documents. In general the role and responsibilities of organizations within the REACH legislation and how it can result in working safely with hazardous chemicals was discussed. Finally, we asked for suggestions to improve the up- and downstream communication.

Including two sector organizations was relatively easy, because we already contacted the sector organizations for support in finding use case companies in work package 2A. The group interview for Use Case 4 including a representative of the sector organization of 'producers of paint and printing ink' and a representative of the sector organization 'producers of glue and sealant' was also used as information for the upstream communication of sector organizations. The second sector organization was the sector organization in Building & Infrastructure that supported us in Case 3. On March 23, 2021 a representative of the organization was interviewed.

It proved much more difficult to include registrants. Although the project team and monitoring team put much effort in the inclusion, we have interviewed two registrants instead of the planned three registrants. The first registrant was interviewed on March 23, 2021, and the second interview was in English on April 21, 2021. Another third registrant that we already contacted in November 2020, declined to participate in May 2021. With support from the monitoring team a possible third registrant was identified. However, after a first unsuccessful attempt, due to time constraints we decided not to further follow up the third registrant and to have two registrants in total. These last three interviews (one sector organization, two registrants) were conducted by one interviewer (JW) and lasted between 30 and 60 minutes. They were also recorded and analyzed thematically.

3.2.3 Analyses and Report

For each use case company we provided a company specific report describing the results of the interviews anonymously. For each report we qualitatively analyzed which topics were discussed in each separate interview. Thus each interview was summarized by the main interviewer in topics illustrated by quotes of the interviewee. These summaries were reviewed by the other interviewers and the work package leader. Next, these summaries were combined into a company specific report. In this way we could describe the view of different interviewees on one topic, for instance on updating the REACH documents or which departments or employees were involved in dealing with REACH documents in their company. This report was sent to the company contact person for approval. All use cases approved their company specific report. The companies also appreciated the feedback and possible improvements suggested by the researchers of how they dealt with REACH documents. Examples of this feedback are suggestions for process improvements, errors in information feedback loops and missing documents or safety features. These results are generically and not specifically discussed in section 3.2.5. due to the sensitive nature of these results and privacy of the participating companies as agreed upon in an NDA with TNO.

The interviews with the sector organization and registrants were analyzed in the same way as the use cases. We fed back the main conclusions from each interview to the interviewees. These were also approved by the individual interviewees.

In this chapter we report the generic conclusions from the six use cases and the interviews with the sector organizations and registrants. To reach these generic conclusions we interpreted these data by sorting, comparing and coding various topics from the specific use case reports and interviews with registrants and sector organizations. A drawback of this approach is that these generic conclusions are less specific, but we cannot provide the specific details given the NDAs. The advantage of this approach is that more shared and important topics are revealed. These topics are issues that were mentioned by multiple companies or we as researchers identified these topics because of differences between companies, like the effect of the size of the company. We illustrate these conclusions with quotes from the interviews identified as Use Case company 1-6, and interviewee A to maximum F (e.g., UC 2A), two sector organizations (i.e., SO 1 or SO 2) and two registrants (i.e., R 1 or R2).

3.3 Results

The health risk communication regarding working safely with hazardous substances from a REACH perspective is enormously varied as the interviews showed. It involves various stakeholders in the supply chain (registrants, formulators, downstream users) that are organized differently depending on sector, size of the company and the specific hazardous substance or mixture. The Persuasion-Communication matrix of McGuire (1984, 1985, 2001) is a framework developed to describe the one-on-one communication of one message source, one message design, one receiver and one delivery channel in one context going through the phases and steps resulting in sustained behavior change intended by the communication. However, within one supply chain several cycles of this matrix are repeated, like registrants sending SDSs to formulators or downstream users. Within a downstream user sending SDSs to another downstream user or work instruction cards to employees in the workplace. In the interviews we collected information on factors in the Persuasion-Communication matrix, however this information necessarily only tells the story in broad strokes given the relative small sample of uses cases and other stakeholders in the present field study.

We present the results following the columns of the matrix (message source, message design, receiver and delivery channel) but have to combine some columns given the complexity of the up- and downstream communication in the supply chain. The fifth column 'context' refers to environmental factors, like noise, clutter etc influencing the message and was hardly mentioned in the interviews, and therefore no separate results are presented regarding this column. In section 3.2.5 we describe how the use cases managed the REACH documents and additional solutions for improving the communication in the supply chain by registrants and sector organizations. In section 3.2.6 we present a behavioral change perspective on how to support working safely with hazardous chemicals by an individual employee. However, we start with an observation that interviewees sometimes did not distinguish between regulations related to REACH, OSH, and CLP.

3.3.1 REACH, OSH and CLP

In the interviews we realized that it was not always clear who is the intended target group of REACH information. For instance, are employees at the workplace working with hazardous substances a target group of REACH information or do they fall under the responsibility of OSH regulations. Or maybe only the HSE/OSH specialists in a downstream user company are the target group of REACH information. Interviewees usually perceived REACH and OSH as one stream of safety information and regulations that finally had to increase working safely at the workplace.

One interviewee explicitly mentioned that safety at the workplace could be enhanced by improving the interplay between the REACH legislation and Occupational Safety and Health domain.

"For instance the REACH-OSH initiative that allows companies to use a proper workplace assessment as alternative for exposure scenario's is an initiative that is giving hope to end users. A downside to new initiatives and solutions is that they cause confusion for the end users. This is because these solutions are not aligned but work parallel to each other, making it more difficult to know exactly what needs to be done and how." (R 1)

"The information on extended safety data sheets is important to know for the company that uses these substances. In general it is the occupational hygienist or safety coordinator of the factory site that has to translate these documents into practical work instructions for the operators. Initiatives as SUMI are mentioned as a

possible way to make this translation obsolete in time, although the simplification always implies information is getting lost." (R 1)

Also two interviewees provided examples of CLP regulations as part of REACH documents, illustrating that they mix up both regulations.

"What makes it difficult is that the labels and abbreviations are not always clear. 'H225', that really doesn't tell me anything from the outside. Another example is the 'Category 2' label. It is not clear to me what exactly that would mean. I have to look up what a category 2 exactly means." (UC 2A)

The above quote regarding H225 also illustrates that this interviewee does not realize that it is not in line with the CLP regulation to only present the codes. Codes can be provided but the text has to be provided.

"The increasing complexity makes it increasingly difficult to see the forest for the trees. Some of the rules that have now been created are unnecessary and result in a lot of extra work without increasing safety: A good example of this is the new and complex way of notifying dangerous mixtures at the poison centers in Europe. For better communication with the poison control center in the event of an emergency, the label/packaging must be provided with a 16-character UFI code. In case of a minor change in the composition, not relevant for the poison center and not relevant for the classification and labeling of the product, the UFI code changes. As a result, the label has to be revised again, which again entails a lot of work and costs." (UC 6B)

3.3.2 Message design

The message design (e.g., content, lay-out, format) of the present SDSs and ESs emerged as an important topic of discussion during the interviews. We address this in three different topics.

3.3.2.1 Safety data sheets and Exposure scenarios

In all six use cases the SDSs and especially the ESs received the same criticism. SDSs and ESs are considered important documents to implement the REACH legislation:

"Yes, the information from suppliers is improved, especially due to REACH and the registration obligation and due to the requirements imposed on the documents. In addition, the enforcement of this: strict checks are carried out on the quality of that information, not only among users but also among manufacturers." (UC 2E)

However, especially for downstream users, it has two major issues. The first drawback of SDSs is that the majority of interviewees consider the documents to be too complex and too long, especially when ESs are added. Many downstream users did not understand large parts of the SDS itself or did not read them at all due to their complexity.

"The abbreviations and codes used in this document are too complex for end users. Nobody reads this. However, it is still information that needs to be communicated." (UC 5D)

"The safety data sheet is not very easy to read. A professional user receives training for this and must therefore be able to understand it. The Safe Use of Mixtures Information has already greatly simplified this. However, it is not easy to simplify this further because it simply remains complex matter." (UC 6A)

"Customers often do not understand the safety data sheet and then start googling for answers, which leads to wrong insights. Now this is mainly taken care of by workshops." (UC 1B)

The formulators, registrants and sector organizations also emphasized that they often have to address questions and concerns that indicate a lack of understanding of the SDS.

"The extended safety data sheet is often very long and unnecessarily complex. The reality has been translated into REACH language, but only few people understand this REACH language, so the document has largely fallen on deaf ears. An initiative where there is one safety data sheet per substance, instead of each supplier making its own, is a good initiative." (R 2)

For instance, certain sections of the SDS (e.g., Section 11 on toxicology) are not relevant for most downstream users. Adding such sections increases the complexity of the SDS without adding value. Furthermore, due to the complexity some end users overestimate the dangers of a substance, because they do not know how to correctly interpret the hazard information regarding a substance. As a solution, end users often mention simplifying or a 'light' version of the document, more like the work instruction cards, with only personal protective equipment and other essential information for practical use. Where in the supply chain this practical version of an SDS and ESs should be developed is open for discussion. The last formulator or the end user are often suggested, but that becomes more troublesome with smaller companies. However, only a practical version may not provide the information necessary for an expert or certain conclusions may be less accepted due to missing argumentation. In one use case all SDSs were converted in more practical work instruction cards which were physically present on all workplaces. Even then these work instruction cards may not be used as illustrated in this quote.

"When I train new employees, I use a practical approach: I first demonstrate the actions and in this way I teach the new employee the correct actions for working safely. The documentation does not play a major role in this." (UC 2F)

Related to the REACH-OSH interplay and intended target group for REACH information one could question if SDSs (REACH) are meant to be directly used by employees in the workplace or that work instruction cards (OSH) should be used. It is clear that SDSs can be one important source of information.

Secondly, the standardized format of an SDS is seen as both a benefit and as a drawback. By using a standard format, an SDS is easier to comprehend. If one is familiar with the structure, it makes these complex documents easy to scan and enables finding specific information quickly. A possible drawback of this format is that it limits providing context and nuance, which could support the end user to interpret the information as it makes it more personally relevant. For example, one use case wanted to add a free text block under the hazard statement codes to explain that a specific code only applies to the substance in respirable aerosol form, while the company uses the substance in liquid form. Also another use case indicated to appreciate more free text possibilities. However, these use cases did not realize that there are already free text fields in an SDS.

"It would be nice to have a little more space to be able to add certain information to a safety data sheet at our own discretion. Sometimes certain information is lost because it has to be cast in a certain format. This could be solved by using more free text blocks." (UC 6A)

3.3.2.2 Updates in Safety data sheets

SDSs have to be updated on a regular basis, due to new scientific insights, changing regulation or classification, updated information from a supplier or just because of a periodic review of the document. If an update is available it is important that all the users of the substance receive or have access to this update. In four use cases and also by one sector organization the topic of malfunctioning of updates was mentioned. Often companies have an ongoing contract with a supplier to deliver a substance on a regular basis. In that case the SDS is appended by the supplier in the first delivery of the substance and processed by the company. However, in all the following deliveries no (updates of) the SDS is appended or a notification that the SDS is updated. It is also common that the sales department receives the update or notification, but does not send it to the proper stakeholder in their company. In that case, end users use SDSs outdated years ago, sometimes containing wrong classifications or missing essential risk management measures.

"It can also sometimes be the case that the supplier changes the composition of a product and does not inform us of this. Then a factory site or an operator may find out that our classification of that substance is different from that of the supplier. If that happens, we have to adjust our classification." (UC 2E)

"As a supplier you have a duty to inform the downstream user in the event of major changes. Our company assumes that this indeed happens, because otherwise it is not possible to actively check for updates for all safety data sheets. In our experience our suppliers are quite fast and reliable in passing on updates in the safety data sheets. ... There are certainly also suppliers who have their affairs a lot less organized." (UC 1B)

"In case of updates, we will receive the new safety data sheet from the contract supplier. However, this doesn't happen often. It also happens that suppliers are negligent in forwarding an updated safety data sheet and that the contract supplier has to actively follow up." (UC 6A)

3.3.2.3 Complexity may hinder working safely

The interviewees perceived the REACH legislation and its related documents as a quite complex subject. Not only the legislation itself, but also the topic (safe handling of hazardous substances) requires higher education and advanced understanding. Even experts that work on REACH related topics on a daily base often admit that it is an inherently complicated topic to assess the exposure to mixtures of different hazardous substances that have various exposure levels and limits.

"A normal person doesn't understand it and even people who are in it have to look really closely. In fact you have to be a toxicologist to understand Section 11." (UC 1B)

Not only the assessment of exposure risk is seen as inherently complex, also the REACH legislation regarding these assessments is perceived as (too) complex.

"I absolutely understand the added value of REACH and that the legislation certainly contributes to working safely with hazardous substances. However, I also think that the legislation is extremely complex and the rules are often 'overshot'." (UC 4/SO 1)

Although the inherent complex nature of the safe handling of hazardous substances is acknowledged, many interviewees expressed concerns that the complexity of the REACH legislation and documents (e.g., safety data sheet) may result in a less safe working environment, because resources can only be spent once. Interviewees spend much time and energy to understand the documents in order to meet the

regulations instead of spending this time to create a safe workplace for their employees. It seems that the REACH regulation has increased the knowledge and awareness regarding working safely with hazardous substances at a certain level of the companies, like the Occupational Health, Safety and Environment specialists in large companies. However, the transformation of this knowledge in easily implemented work instruction cards or risk management measures seems a bottleneck in working safely for employees at the workplace.

"Exposure scenarios only make working with hazardous substances more complicated, so that safety data sheets are only read and used less because users can no longer see the forest for the trees. The average user simply wants to know what to do (mask on or not) and does not need dozens of pages of calculations and toxicological information. It is becoming increasingly complex and the goal of safer working is being surpassed." (UC 4/SO 1)

Two use cases and one registrant thought the REACH legislation was complex, because not only experts on safe handling of hazardous substances influence the legislation, but also lawyers, politicians and lobbyists. These latter stakeholders lack the necessary knowledge to oversee the impact of their proposed changes in the legislation. For instance, several times the changes in REACH legislation were attributed to political interest (both national as European) and not so much to the interest of the chemical industry or the workers using hazardous chemicals.

"It is a legal requirement to train personnel who work with isocyanates. For our company this is an issue because the application of isocyanate as we do is not discussed in the training sessions. Thus, our customers are required to undergo a training that does not contribute to safer working with that substance." (UC 1B)

"Another example is the way polymers are handled. We've spent months explaining exactly what polymers are and how they work, but it's just not understood and (possibly) wrong choices are being made. They [non-experts like lawyers, policy officers or politicians] want to do it right, but they don't understand reality and that causes a disconnect. These kinds of choices should actually be made by substantive experts who can understand the consequences of their choices for industry and safety." (R 2)

One registrant pointed at the role of ECHA as a controlling institute in this context.

"It happens regularly that things change at ECHA that have a major impact on the industry. A small adjustment can already mean that a registrant has to do certain (or even several) technical assessments again or differently. That is something that is often not given enough thought when making these changes." (R2)

3.3.3 Message source and receiver in the supply chain

In the supply chain a receiver (e.g., a formulator) may become a source to a downstream user. Therefore we describe aspects of both sources and receivers in this section.

3.3.3.1 Small and large companies

The size of a company relates to their compliance with REACH legislation: a larger company complies more with the legislation. Within the REACH legislation small companies are in a difficult position. First, smaller companies are quite often not familiar with REACH. Moreover, it seems they underestimate the risk of health problems when working with hazardous substances.

"The problem is not that those companies are not reached, but that they are really not involved. The need to work safely is there, but the knowledge to realize that these substances are really dangerous in the long run is lacking." (SO 2)

"Many workers do not see PU foam or road paint or an adhesive very differently from a brick or a metal pipe: only as a building material. As a result, they do not have the idea that they are working with a hazardous substance and they will not actively check a work instruction card as quickly." (UC 5B)

"I did not know that pur foam and construction glue have harmful effects. I know that turpentine and similar substances that evaporate are harmful, but I do not know what effects these substances may have on my health." (UC 3)

It also seems that the time invested in (and hence knowledge about) REACH and safe use of hazardous substances seems to increase with company size. A further complication is that smaller companies tend to use more mixtures or 'mixtures of mixtures' while having less resources to acquire supporting tools or systems. So while the knowledge and resources decrease in small companies, the complexity of the situation in which to apply REACH information increases.

"This missing expertise becomes more severe as the company in question gets smaller. Smaller companies are less likely to employ experts who have the knowledge to properly understand a safety data sheet. To make up for this missing expertise of the customers, it is common for our company to give a workshop when selling our products. In this workshop matters related to product safety are discussed and information from the safety data sheet is placed in context. An extensive manual has also been written for the same purpose. During the workshop, advice is also given on the personal protective equipment to be used for that specific set-up." (UC 1B)

"Not supporting smaller companies properly is a problem in which everyone, from government to semi-government to supplier, all have a part to play. ... At the moment, too little energy is being invested by certain parties. Sector organizations should be more actively involved in developing such an approach, but also in developing REACH legislation. In general, you see a small group of people who are always present, but that group is too limited so that problems are approached from a too one-sided view. That group should become wider and more mixed." (SO 2)

Furthermore, small companies have different needs as large and technologically advanced companies. Whereas bigger and more advanced companies prefer detailed information, smaller companies prefer practical and simple guidance about working with the product. Many interviewees addressed that the current REACH legislation is tailored to bigger companies and does not take into account the needs of the smaller companies.

"I and similar small companies usually purchase materials through a business wholesaler for building materials. Here, a small construction company can basically buy everything it needs. However, documentation on safety (for example a safety data sheet) is not always included. If they are included, however, I mostly don't read them. It has not been taught to us either, not even in the past at the contractor where I worked. I have been working with these substances for a long time and therefore know what the risks are." (UC 3)

The problems small companies have with REACH increases when they do not invest time and energy in it while the complexity of REACH grows by implementing more

rules, tools and changes. This complexity exceeds the skills and knowledge of the small companies, so that they 'give up' on the REACH legislation.

Large companies handle REACH differently, but may end up having the same problems at the workplace as small companies. One use case was a large international company in which the process of dealing with REACH documentation was a complex system involving different divisions and people. For instance, when buying a new hazardous substance the supplier provides the safety data sheet with the substance to the Health, Safety and Environment (HSE) coordinator, who has to ask permission from the HSE management for using this substance. If permitted the safety data sheet goes to the company division that creates company versions of the safety data sheet and sends this version to the HSE coordinator. Then the HSE coordinator sends the safety data sheet to the health and safety contact person, who finally sends it to the operators who use the hazardous substance. In this complex process not all parties involved know who is responsible for which part within this process. Given this large communication chain resulting in a safety data sheet reaching the end user (i.e., the operator), miscommunication, noise and errors might occur in each step down the chain. However, we did not encounter examples of these possible 'noise and errors' in the interviews. We observed that time and energy was invested to work safely in the workplace by ensuring the correct precautions, instruments and instructions are available and discussing what is going well or what needs to be done differently.

Concluding, it seems that small companies profit less from the REACH legislation than large companies. Smaller companies are less familiar with REACH, underestimate the long-term risks of working with hazardous substances, and often lack the knowledge, time and resources to apply guidance documents (e.g., safety data sheets) in their workplace.

3.3.3.2 Organization of a sector

Not only the size of a company relates to their compliance with REACH legislation, also the organization of the sector in which the company operates has an effect. For instance for the use case in the 'Road and tunnel building' sector the chain of safety communication starts with that the company has the building contract, but they hire various contractors, who also hire various subcontractors, and finally "you see a dented van with five Poles arriving at your construction site to do the job." (UC 5B) All (sub)contractors are obliged to provide a safety plan to the company, in which the hazardous substances used by the (sub)contractor and their SDSs are included. However, because of the long chain of (sub)contractors this safety plan does not guarantee that the final subcontractor is aware of the SDS of the chemicals used by the five Poles in a dented van. Also the company inspects whether the safety rules are followed on the construction sites. However, "on paper it seems all arranged, but in practice it can be difficult to realize everything according to these paper rules" (UC 5D). This fragmentation in the 'Road and tunnel building' sector was mentioned by the interviewees as an obstacle for working safely with hazardous substances. Other mentioned sectors that need to improve in dealing with the REACH legislation are startups and e-commerce companies. Sector organizations see a role for themselves in improving sector specific improvements.

"In principle, the REACH legislation is seen as useful and valuable. What is missing is the last step. The piece that makes the legislation practical and concrete for the end users. The difficult thing about this is that the government always takes a broad view of the Netherlands and this is actually something that needs to be tackled per sector. So there is also a role for other parties." (SO 2)

3.3.3.3 Responsibility, feedback and international parties in the supply chain
Many parties have misconceptions about which stakeholder in the supply chain is
responsible for complying with the REACH legislation. End users and formulators
state that they receive insufficient input (e.g., SDSs) from upstream stakeholders, so
that they cannot meet all rules in REACH.

"Producers who supply directly to the market are under a magnifying glass by controlling authorities. While the basics were not quite right at the time. At the supplier of the raw materials, things are often not in order and we have to take care of that, because we are checked." (UC 6B)

"The sometimes wide margins of how dangerous substances are in the safety data sheets are a problem, because that is almost unworkable for us. If you mix it up and recalculate it again, you'll never get it right. If a raw material supplier sits high in its margin, you will also end up higher. Then you get an overrating. It actually starts with that. That is a direct result of the legislation that is becoming stricter." (UC 4/SO 1)

The registrants acknowledge this sentiment and agree that there are indeed 'cowboys' who do not supply the correct information. However, the interviewed registrants are convinced that they do not deliver incorrect or insufficient information. Their opinion is that the end users lack the knowledge, skills and resources to correctly interpret and use the information that registrants provide.

This points at a diffusion of responsibility. End users and formulators point upstream, while registrants point downstream. However, we have only interviewed a limited number of companies, which could bias this result.

The interviews clearly showed that the quality of the information supplied from upstream stakeholders is very important for the formulating companies and end users. It seems that this quality is not always (and not for every supplier) guaranteed.

"There is a lot of information missing at the beginning of the chain, which means that we, as formulators, have to puzzle a lot to meet the obligations. It is important to arrange it well up front so that the parties later in the chain can pick it up right away." (UC 4/SO 1)

For effective communication in the supply chain a feedback loop is essential. The source needs to know if the message is received and understood by the receiver. In the interviews two questions addressed this feedback loop: (1) Do you understand this document (receiver)? And (2) Did you check if the receiver understood the document (source)? The responses were mostly negative. It did not matter if an SDS was sent to a coworker from a different division or a client. Hardly ever, the receiver of a document could provide feedback to the source or simply ask questions.

"We have established a number of working groups with a number of factory sites to assist with tools we are developing. But in practice, I think we have too little contact with the operators on the workplace to really have a picture of what is going on there." (UC 2E)

The result of this top-down communication flow is that the document developers are not in contact (either direct or indirect) with the users, resulting in a mismatch in information and poor understanding. The registrants are aware of this problem as illustrated by the following quote.

"At the moment there is no motivation for the downstream user to send information upstream. That would often require spending time and effort in measuring and

reporting on (possibly sensitive) processes in the organization without them getting anything in return, creating an impregnable membrane. However, this upstream communication is necessary for the registrants, formulators and other stakeholders to get a good understanding of the way a chemical is used.

As a registrant it is very difficult to make exposure scenario's for substances or mixtures when it is unknown how and under what circumstances the product will be used. There is a balance between trying to be halfway accurate while not spending countless hours to create thousands of exposure scenario's to make sure every possible combination, concentration and condition is covered. When we start to talk about mixtures this whole situation becomes even more complex." (R 1)

If the supply chain involves parties from abroad the complexity further increases. The following factors complicate working in line with REACH in an international context (both in the EU as outside) according to three use cases and one registrant.

Firstly, outside the EU different legislation applies, so that companies have to use various formats increasing the workload. SDSs are not accepted in every country in the world and even if they are accepted, the required content might differ. For formulators that use substances from outside the EU it is often quite difficult to get SDSs or other essential information for those substances.

"We work with suppliers or customers who are not based within the EU and are therefore not covered by REACH. This creates difficult situations. Both the lack of comparable legislation and even contrasting legislation ensure that the information required under REACH is not available, limited or difficult. Many countries outside the EU have a situation like us 20 years ago." (UC 4/SO 1) [authors: However, if you import into the EU, REACH regulation does apply to the importer]

"Rules and classification systems are not or not properly aligned, making it very complex to work together outside the EU." (R 2)

Secondly, also within the EU one sector organization perceived there are differences in the interpretation of REACH. Local authorities might ask companies to change REACH related documents as their interpretation of REACH is different than the interpretation of their neighboring country, resulting in double work for the companies. However, legally, a company has to comply with REACH and with national legislation. The following quote illustrates the perception of differences between national and EU legislation.

"All EU Member States also have national legislation that not only differ from each other, but are also not always in harmony with REACH, so that companies are given the choice of which legislation or interpretation should be followed and when. This makes certain processes almost impossibly complex, so that a safety data sheet or label that according to Dutch standards perfectly meets the obligations in other countries is still rejected." (UC 4/SO 1)

Additionally, three use cases addressed the quality differences between the EU countries. Some EU countries hardly or minimally comply with the REACH legislation.

3.3.4 Message channel

The REACH documents (SDSs and ESs) were usably attached as a PDF in an email. In the interviews the message channel in itself was not really elaborated on. The topic of digital tools in helping to comply with REACH did come to the surface.

Most companies strongly rely on digital tools to help them to comply with the REACH legislation. Several software solutions were mentioned that create or store SDSs or

comply with other safety requirements. Online platforms for storing SDSs or work instruction cards and even mobile apps that grant access to these documents for all employees. Not all applications seem to be tested with the end users on usability. Also software platforms exist that automatically generate SDSs of mixtures with the input of the exact mixture formula and current SDSs of the ingredient substances. Digital tools are also available to generate risk- and exposure assessments for mixtures and even action plans how to deal with those risks. The need for these software solutions grows as the complexities in regulation increases. Although this might be a solution for companies, it became apparent that these software solutions have downsides as well.

Firstly, when end users hire an external company to support with meeting REACH regulation, the end users often think that this company will help them to fulfill all REACH requirements. However, these external companies may have a more limited scope. For instance, when a tool stores and categorizes all SDSs, this might lead to the false sense that these SDSs are also checked for compliance with REACH, which is often not the case.

Secondly, by outsourcing these processes companies themselves become unfamiliar with these processes and as such depend on those companies without being able to check the quality. Quality control on digital tools can help such companies with limited knowledge.

"Some of the safety data sheets we get are really bad. This is sometimes due to pushbutton IT systems producing sheets that just don't make sense. Making a safety data sheet is so specialized that there are only a few people who can still do it. Of course, it should not be the case that legislation is so complex that only few people understand it." (UC 4/SO 1)

Thirdly, the quality of the software solutions varies strongly. Software that generates SDSs for mixtures may follow one of the recommended REACH assessment methods (e.g., ECETOC TRA, Stoffenmanager, ART, EMKG, MEASE) and have a link to the relevant REACH databases. To calculate risk and exposure assessments, the use, exposure times per substance per workplace will also have to be determined and can be either measured or entered in these types of software systems. "Loading" this software with this information may not always be done correctly. There are also SDSs made by hand in close collaboration with the supplier and manufacturer, which are then made available via online platforms. Companies that do not comprehend the full requirements of REACH, also can hardly assess the quality of the SDSs made available via online platforms, whether the SDS is made by hand or by using software tools. Moreover, the following citation warns for too much optimism regarding digital tools.

"However, a software platform will never be able to interpret a safety data sheet or make it understandable. Context and data to be on the safety data sheet are defined by REACH. Data published on the safety data sheet is based on EU standardized/defined test protocols." (UC 1.3)

Lastly, not all end users are comfortable with these software solutions. We came across a company that invested heavily in a custom build smart phone application for every employee containing a database with all the relevant safety documentation and the SDSs/work instruction cards for all substances used by the company. All managers and office workers believed they had a beautiful solution, but some operators believed that the system was incomplete and spent time searching the SDS via Google to print it and store it in a binder. One additional reason was that colleagues not having access to the application could still use the documents.

3.3.5 Additional solutions and improvements

In the previous sections already various solutions to the noted problems were indicated. In this section we describe how the various use cases deal with the REACH documents and the eventual improvements of this process suggested by the researchers. One large company has an elaborated procedure to handle the REACH documents. In section 3.2.3.1, we described the involvement of the Health, Safety and Environment (HSE) coordinator, who asks the HSE management permission to use a substance. This HSE management checks whether that substance may be used, whether the correct precautions (can) be taken and whether it is not possible to use another substance that is less dangerous or harmful. Next, the HSE coordinator sends the eSDS of this substance to the company wide safety division specialized in these documents. This division creates company versions of the eSDS and work instruction cards, which are sent back to the HSE coordinator who distributes it to the health and safety contact person, who finally sends it to the operators who use the hazardous substance. The researchers mentioned the following possible improvements. (a) Parties in this process knew their own role, but were not always aware of the responsibilities of other parties involved. (b) The way updates of an eSDS were managed was unclear, for instance the purchasing department probably did not sent updates to the specialized safety division. Also this safety division could digitally notify HSE coordinators of updates, but the coordinators could have switched-off these notifications. (c) This safety division indicated a lack of feedback from the operators in the workplace whether their documents were useful. Another company provides the REACH documents with its product, but also decided to provide a work instruction card with icons how to use the product. The researchers pointed out to the company that depending on the region these work instructions cards were not always provided to the consumer company. The company also gives a training to explain and demonstrate the safe use of its product tailored to the specific work context of the consumer company. They also use a software platform that automatically generates SDSs of mixtures with the input of the exact mixture formula and current SDSs of the ingredient substances. That software platform also stores and updates the SDSs of substances and mixtures at least every three years or earlier if an SDS changed significantly.

A small company provided the following suggestions to improve working safely with chemicals: (a) More pictures/symbols that show what certain substances do to your body (cf. cigarette packs), (b) Special safety training (e.g., Safety, Health and Environment (SHE) Checklist Contractors) costs too much time, money and effort, (c) Instead providing information about working safely at trade fairs, with very practical solutions for small businesses, (d) Certain tool suppliers organize demonstration evenings/workshops. This is free and includes food and is therefore very popular with small business owners.

A larger company has outsourced the storage of SDSs and the translation of an SDS into work instruction cards. These documents are also accessible through an app on the mobile phone of regular employees. A drawback is that most persons working for this company are hired through (sub)contractors and as such not have access to this app. A plus of the app is that all documents are up to date, but users are not notified if a document is updated. Other possible improvements the researchers noted were: (a) providing work instructions cards in other languages than Dutch, (b) be complete with work instruction cards (e.g., from various manufacturers of the same substance or substances that subcontractors use), (c) develop an implementation plan for the app so that it is really used, and (d) suggestions for other functionalities in the app to support working safely (e.g., how to provide feedback about a work instruction card). Besides the app also other measures are taken to support working safely like regular checks of workplaces whether (sub) contractors and workers comply with the safety rules.

Another company sells a mixture that is formulated by a contract supplier based on the instructions of the selling company. The contract supplier buys the ingredient substances from manufacturers and receives the SDS for the substances from them. The selling company receives the mixture and the SDSs of the ingredient substances and produces their own SDS for their mixture. The selling company also produces a product information sheet containing a brief explanation of the product and the instructions for use in the form of icons (i.e., on dosage and use). This product information sheet is available on their website.

Quite some solutions were suggested by sector organizations or registrants to improve the effectiveness of REACH in the supply chain. The following suggestions were made that slightly overlap with suggestions in previous sections:

- No different implementations of REACH in the EU member states, that is, variation in level and manner of enforcement of REACH requirements.
- Making a transformation from SDSs to a user of a mixture is best done via the SUMI. Then it is important that the SWED information is better shared by the registrants.
- By grouping certain substances you can simplify things, like not determining the PPE for each separate substance but for a group of substances.
- Harmonize classification levels for certain substances. A mixture may have different classifications depending on variation in just one ingredient, although the mixture itself is known by one name. Another situation is that companies have to classify the mixture themselves if the classification is missing in the SDS and use the wrong classification.
- Using icons for end users, but be aware how they are interpreted. For instance, the icon that indicates harm in the long term covers many consequences (e.g., allergies, cancer) and one carcinogen has negative consequences in just a small amount, whereas other carcinogens need a very large amount to cause cancer.
- Try to translate the specialist language into laymen language. For instance, avoid using jargon and abbreviations.
- Adapt communication to different target groups. So not only for large companies, but also a text for small companies and even the employees.
- Automating the flow of information (e.g., using an XML file) and sharing it through the supply chain using a fixed format, facilitates downstream users to use it (e.g., from manufacturer to the downstream user to the users of risk inventory & evaluation and work instruction cards). For example, a small company could have this automatically read in via a RI&E (Risk Inventory & Evaluation) instrument instead of having to retype that information from an SDS.
- There needs to be more consultation between government (regulatory and controlling side) and industry.
- A more active role of the registrant in stimulating upstream communication is (almost) impossible given all the different end users. A possible solution is combining the voices of the end users via sector organizations and consortia.
- Develop one large general database containing all the data regarding hazardous substances that can be accessed by every company that works with hazardous substances. That could be managed, for example, by a semi-governmental organization that focuses specifically on security, similar to what already exists in the United States.

The problem with most of these solutions is that implementation needs resources (time and money) and actions from various stakeholders in the supply chain. Often these solutions may improve the overall safety of the supply chain, but do not result in a direct return on investment for a stakeholder, according to some interviewees. For these reasons these solutions may not be realized, because stakeholders are not willing or able to invest in these ideas.

Moreover, these improvements require cooperation among a lot of companies and institutes. Initiating this is a difficult job for a single company wanting to improve the

safety in the supply chain. This can be achieved by more influential stakeholders, like government agencies (e.g., setting the framework, inform through workshops).

3.3.6 End users working safely at the workplace

During the interviews we heard several statements regarding barriers or drivers for employees to work safely with hazardous substances. Although this is more an OSH related than a REACH topic, in the end all risk information regarding hazardous chemicals is intended to promote safe use in the workplace. In this section we focus on a model that describes determinants of people's behavior, namely the 'Integrative Model of Behavioral Prediction' (Fishbein, 2008; Fishbein & Ajzen, 2010). Figure 3.1 depicts this model showing that some factors influence the intention (i.e., motivation) to behave a certain way, and other factors influence how motivation is translated in actual behavior. We use this model to describe some of our results from the interviews.

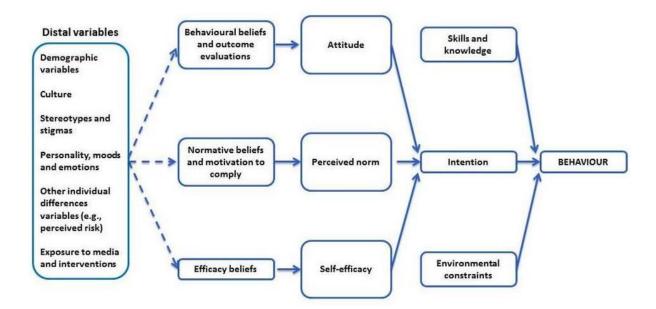


Figure 3.1. The Integrative Model of Behavioral Prediction".

The first step in working safely with a hazardous substance is that end users need to be aware of the hazard and that risk management measures exist to deal with that hazard. However, frequently interviewees mentioned that end users in the workplace were unaware and not knowledgeable, especially in small companies. They do not know these risks and also do not know the REACH documents explaining these risks. If they know (where to find) a safety data sheet, these are usually too complex and too abstract.

"What exactly does that mean for me as a painter?" (UC 5E)

The attitude regarding working safely relates to the expected positive and negative consequences of working safely or not. The attitude influences the motivation to work safely. Quite often end users don't expect negative consequences of working unsafely with a hazardous substance. One reason being that they have been working with the same hazardous substances for a long time without negative consequences.

"Many employees do not look at the documents because they have been working with the material for a long time and therefore think they 'know'." (UC 5E)

That is the drawback of many of these hazardous substances that the real harm caused by them is a long term consequence, whereas the short term negative consequence is not substantial.

"I regularly notice the ethanol vapour, sometimes it almost gets me high, then I'll leave the door ajar, but I don't put on a mask" (UC 3)

The attitude towards taking risk management measures is sometimes ambiguous, balancing positive and negative consequences.

"I see some added value in attention for working with hazardous substances. On the one hand my health is important, on the other hand taking protective measures is often at the expense of pragmatism or efficiency." (UC 3)

The social norm is also a factor affecting motivation. The following quote illustrates that taking risk management measures is not always valued or executed by coworkers, decreasing the motivation.

"Wearing personal protective equipment is often seen among his colleagues (other (sub)contractors and freelancers) as exaggerated and sometimes even a bit ridiculed: "Here he comes with his glasses again"." (UC 3)

"Also in my environment, I do not often see that gloves are used when working with polyurethane foam." (UC 3)

Self-efficacy refers to the believes an end user has that he/she is able to perform the behaviour. We did not explicitly encounter this in the interviews, probably because the risk management measures are usually easy to carry out. So self-efficacy and skills may not be important determinants for working safely.

Even if an end user is motivated to work safely there are several environmental constraints that hinder this behavior being really executed.

"There are so many rules on the construction site that the employees can no longer see the forest for the trees. There is also not always the peace and time to go through all the documents." (UC 5E)

"Work gloves are included with the purchase of polyurethane foam. However, I usually do not wear them. If I wear them, it is usually to avoid getting my hands [authors: visually] dirty, not necessarily for safety reasons. I usually do not wear the gloves because it is not practical. It hinders me in carrying out my work because it is less easy to grasp small things (screws, etc.)." (UC 3)

Finally, it is mentioned that it is difficult to change habits. Habits are not part of the Integrative model because that model focuses on conscious behavior change. Habits are more automated, unconscious behaviors.

"It is sometimes difficult to deal with changing regulations. If someone has been working in a certain way in the workplace for years, it is difficult to get those employees to follow appropriate safety procedures." (UC 2D)

Another environmental factor is that the risk management measures can differ for specific substances and working conditions. Thus if you usually work without glasses, you may forget using glasses if you work with a different substance.

"Glasses are sometimes forgotten as a protective measure with ethanol. Because employees work with ethanol about 15 times a day and they have to wear the glasses, but sometimes not for other actions, therefore colleagues sometimes need a reminder." (UC 2A)

3.4 Conclusion and discussion

From the interviews we conclude that the implementation of REACH has resulted in improved and increased availability of information on hazardous substances. In various companies we spoke with dedicated OSH specialists who were motivated to comply with REACH and to improve working safely at their company. We also got the impression that an important element of the compliance with REACH was that this compliance is monitored. However, at the same time the interviews show that the REACH legislation is considered complex as are the SDSs, ESs, and guidance documents. Stakeholders have to spend much time to fulfil the REACH obligations, and although this increases knowledge regarding hazardous chemicals, the sentiment seems that the time effort does not always match the knowledge profit. Another observation is that REACH seems not well known by the employees at the workplace, especially at small companies. This relates to the observation that the interplay between REACH and OSH should be more clearly demarcated and concretized. It is probably more important that employees understand the workplace risk assessment and implementation of the necessary risk management measures. For a variety of reasons those employees do not always use these risk management measures whether resulting from REACH or OSH, where a main factor seems to be that they underestimate the long-term health risks of repeated exposure to (small doses) of hazardous substances compared to the relative inconvenience of personal protective measures.

We found that interviewees did not differentiate between information coming from REACH or information coming from other legislative requirements, such as the CLP Regulation. The interviewees do not naturally separate the information based on the legal background. They apparently see the full set of information as coming from 'chemical legislation'. This is a relevant finding, because REACH functions in the full complexity of the communication and information occurring in companies. Therefore, improvements should not focus on REACH as a legislation in itself, but on the contribution that improvements in REACH (or REACH communication processes) can have on the final goal, which is safe use of chemicals.

We used the Persuasion-Communication matrix of McGuire (1984, 1985, 2001) as a framework to describe the topics in the interviews. The message design (e.g., content, lay-out, format) was the first topic. Downstream users, especially SMEs, think SDSs and ESs are too long, too abstract, too complex and hard to implement, especially the ESs. This is surprising because the ESs should summarize the key information from the chemical safety assessment prepared for REACH registration of a substance. ESs describe how the registrant recommends that the user of chemical products should control the exposure of workers, consumers and the environment, in order to ensure the safe use of the substance. Exposure scenarios describe operating conditions and risk management measures at the workplace. The benefit of ESs is not always realized because sometimes too many ESs are attached to one safety data sheet. For a downstream user it is difficult to select the relevant operating conditions and risk management measures for his situation. It could also be that the ESs do not apply to the situation of that company and the working conditions of its employees. Another reason could be that the ESs are too difficult to understand due to expert language in the scenarios. Thus, also for OSH people at companies implementing the ESs at their workplace can be a challenge.

All in all, it seems that companies and workers still first focus on the personal protective measures described in the SDS. However, safety experts and OSH legislation emphasize the STOP principle in which first attention has to be paid to the appropriate substitution of substances, engineering controls and organizational measures for working safely with hazardous substances as more extensively described in ESs.

The SUMI was intended to be more concrete and implementable in the workplace. However the interviewees hardly mentioned the SUMI. If mentioned they valued the more practical description of this document compared to the eSDSs. This results from the fact that the SUMI are hardly implemented and used, thus being quite unknown. One of the reasons being that SUMI is quite recent and not a legal requirement in REACH.

Another factor from the Persuasion-Communication matrix of McGuire relates to the characteristics of the message source and receiver. For instance if the source is a trusted registrant or seen as a "cowboy", or that the REACH legislation is perceived as overstepping its rules or being influenced by politicians and bureaucrats. The message source is sometimes confusing because for one specific substance there are multiple companies supplying this substance each providing their own SDS and there is not always consensus between these sources. Characteristics of the receiver, like expertise, experience, and educational level also influence the effect of the message design like the perceived complexity. We noted that especially SMEs have more constraints to fulfill REACH obligations, like expert knowledge and resources. Sector organizations could play an important role to promote communication on chemical risks and to develop other tools/documents and/or processes to support SMEs. One reason being that they can represent the interest of several SMEs in a certain sector.

Another observation is that in the supply chain the end users being the employees, are not really involved in upstream communication, but the end users being the employers, are involved. The SDS and ESs are cascaded downstream, eventually adapted (analyzed and translated) to work instruction cards, and "dropped" at the employees. Some companies provided a training how to work safely or more experienced operators demonstrated to new employees how to work safely. However, it seems that the employees are not consulted about their opinion and experiences of working with REACH related documents or work instruction cards. However, how in a company working safely with chemicals is implemented relates to OSH regulation and not so much to REACH regulation. Thus, the upstream communication from the end users (employers) through the sector organizations to the registrants and formulators can be improved. This no-feedback communication also takes place at companies from OSH personnel to employees working with the substances.

We noted that stakeholders seem to blame others in the supply chain for not fulfilling their REACH obligations. Downstream users point upward to registrants and formulators for not providing correct and understandable information, whereas upstream users point downward that downstream users do not understand their information due to a lack of expertise. This diffusion of responsibility and blaming each other seems to increase on an international level, especially if suppliers from outside the EU are involved. It comes across as if the responsibility for preventing harm due to working with hazardous substances is not an intrinsic value for some commercial companies or supply chains. It seems that it has to be enforced by law as REACH and OSH legislation do. However, we did interview one company who explicitly told us that they trusted their suppliers in providing the correct safety information.

The results and insights presented are based on the information provided by the interviewees. As such they present the opinions, experiences and perceptions of the interviewees. For instance, several times the changes in EU chemical legislation were attributed to political interest (both national as European) and not so much to the interest of the chemical industry or the workers using hazardous chemicals. These interviewees could have an accurate or inaccurate impression of how legislation is changed, but it negatively impacts the image of (and thereby the willingness to comply with) EU chemical legislation either way.

Our conclusions are based on a small number of selected interviews from the wide variety of stakeholders in the up- and downstream of REACH health risk communication. We did include a diversity of companies and observed more awareness of REACH requirements to be related to factors such as expertise, experience, sector, educational level, and the size of the company. Especially small companies seem to invest less in knowledge, skills and resources to deal with the REACH legislation. In this way, a broad representation of companies and organizations involved was reached. The results, at least on issues where the cases have a large degree of agreement, can therefore be considered reasonably representative for the present situation in the Netherlands.

The downside of using the case study methodology is the fact that it is very labor intensive and not many cases can be studied. The analysis of the information from the cases is therefore qualitative, focusing on the substantive topics in the interviews. The methodology prohibits a full statistical interpretation of the results.

Despite substantial efforts by the research team and the monitoring team of the project, two interviews did not occur as planned. (a) We did not study a case of a company with a size of 10-50 employees in the formulation of chemical products. Instead a group interview was held with representatives from two formulator sectors and representatives from companies in these formulator sectors. (b) We interviewed two instead of three Dutch registrants. While these deviations of our plan may have influenced the results, we think this had only a small impact given the data saturation we already reached.

The research team decided after the six interviews for case 2, that it was not necessary to have an expert on chemical risk/exposure present during each interview. We noted that the interviews were more focused on the communication exchange of eSDSs up- and downstream and in the company than on the chemical content of the REACH documents. If the content of the documents was discussed it was more on a general level (e.g., too difficult) and not regarding the specific chemical input.

A drawback of the present limited and variety of parties in the supply chain is that the conclusions are relatively wide-ranging, because they originate from this divers and small group of participants. The suggestion for a potential future project is to select a more homogeneous group, like SMEs in a specific sector, and to use interviews and questionnaires to get a more specific picture of the REACH communication in the supply chain for SMEs in that specific sector. The picture of this particular supply chain can be broadened by including SMEs from other sectors or other stakeholders from the same sector.

In order to conclude whether information on safe use conditions, specifically in REACH, can be optimized so that ultimately employees work safely with hazardous substances in the workplace, different research and comparisons should also be done. We should compare the situation before and after REACH and check for instance whether occupational diseases due to working with hazardous chemicals occur less after REACH (i.e., prospectively study companies that start applying REACH for a (new) product). However, (a) the registration of these occupational diseases is usually insufficient or absent, (b) the health effects of working with hazardous chemicals is usually long term, (c) the base-rate of these health effects is low thus difficult to demonstrate, and (d) there is no control group thus also other

factors could affect a difference before and after REACH. We also suggest to study the effect of individual REACH requirements on safety to get better insights in which parts of REACH do or do not contribute to a safer work environment. This would provide insights in further improvements in the regulation (or its implementation) to increase the effectiveness of REACH. The present interviews provide a good impression how various stakeholders in the supply chain presently perceive and deal with REACH and the related documents.

In the following two sections we make a comparison with the results of work package 1 and focus on the use of a behavior perspective in this study.

3.4.1 Behavioral perspectives

We introduced the 'Integrative Model of Behavioral Prediction' (Fishbein, 2008; Fishbein & Ajzen, 2010) (see Figure 3.1) to frame our interview results regarding employees working safely with hazardous substances. However, this framework also applies to using REACH documents. First we present conclusions and insights on working safely with hazardous substances:

- The employees lack an awareness and understanding that substances can be hazardous for their health in the long run.
- They formed habits to work with these substances and these work well in their opinion. Attitudes to working safely are ambiguous in that health is valued, but bring with them practical limitations.
- Also social norms of coworkers are not always positive regarding working safely.
- Various barriers were mentioned like too many safety rules, time pressure, and that taking protective measures hinders the execution of the work.

Each of the factors in the integrative model can be influenced by behavior change techniques (Kok et al. 2016; Michie et al. 2013), like providing a role model demonstrating the behavior to influence a sense of self-efficacy or providing information on positive and negative consequences to influence the attitude.

Risk perception is not one of the explicit factors in the integrative model, although risk perception features in other behavioral models. We would like to add some insights from the risk perception literature, because the interviewed employees seem to downplay the negative consequences of working unsafely with hazardous substances. As mentioned before one reason is that the negative health consequences usually will establish in the long run and (therefore) also cannot unequivocally be linked to specific unsafe work practices with specific products, while the positive consequences of working unsafely are in the short term. As such these risks are similar to the risks involved in an unhealthy life style, like unhealthy eating, insufficient exercise, drinking alcohol, smoking, not sleeping well, and stress. The positive consequences are immediate (immediate stress relief after smoking a cigarette), but the negative consequences are long term (lung cancer). If people think they can control a risk or whether it is a voluntary risk they think the activity is less risky than when it is an uncontrollable or involuntary risk. It is also quite common for people to be unrealisticly optimistic regarding controllable risks, namely that they think the negative health impact won't happen to me (Weinstein, 1980). People also underestimate the increase in probability that an event will happen to them after repeated exposures. These biases may explain why employees downplay the risks involved. Scaring people by emphasizing the negative consequences of risks is not a reasonable intervention, because people may deny these risks if they are not also told how to manage those risks. In that sense eSDSs are doing a good job by providing information on the risks and also describing risk reducing measures.

The 'Integrative Model of Behavioral Prediction' also discerns intention (i.e., motivation) from behavior. Thus, attitude, self-efficacy and social norms influence the intention, whereas environmental constraints and skills determine if intention

translates into actual behavior (change). Thus for working safely, if using a mask is the protective measure there should be masks easily available (i.e., no environmental constraint) and employees should be able to correctly use the masks (i.e., skills and training plus supervision).

The risk communication in the supply chain seems strongly focused on informing people about the risks of chemicals by providing information in (e)SDSs. Making people aware and knowledgeable is a preliminary step in changing behavior. It seems that more attention should be paid to the factors that motivate people to work safely and actually behave safely.

The same behavioral factors influence whether people use REACH documents, whether they are registrants, formulators or OSH persons in downstream companies. First they need to be motivated to use the documents, thus a positive attitude (i.e., expecting more positive than negative consequences of using REACH documents), self-efficacy (i.e., belief that one can use the documents), and positive social norms (i.e., you see other persons or companies using the documents and you expect that those persons/companies/other relevant stakeholders think you indeed should use those documents). To actually use the REACH documents a person needs skills and knowledge and the absence of environmental constraints.

In this respect it is important to describe the various behaviors of the stakeholders in the up- an downstream supply chain and how each behavior may be differently affected by factors described by the 'Integrative Model of Behavioral Prediction'. For instance, providing feedback from a company end user on ESs of a product to the formulator is a different behavior than a manufacturer providing an ES to a formulator.

There are many more behavior change techniques (Kok et al. 2016; Michie et al. 2013) than those influencing the factors in the 'Integrative Model of Behavioral Prediction'. A final example refers to rewards and punishments. Within REACH not following the legislation can result in financial fines. This does affect behavior. But rewards usually work better. For instance recognition or an award for the company that uses REACH documents in a sector organization meeting or "newspaper".

4 Workshop reports

4.1 Introduction

In order to share our gained understanding in WP 1 and WP 2 and discuss about improvements with international key stakeholders in the up- and downstream process of creating and communicating on safe use of chemicals, three workshops were organized on the 20th and 21st of October 2021.

The three workshops concerned:

- A. The validation of the downstream user results in the European context.
- B. Improvement of exposure tools.
- C. Improvement of health risk communication.

The setup and results emerging from the workshops are described in the following.

4.2 Participants

In total, 68 potential participants were invited for the three workshops. The project or monitoring team designated them as experts in either risk communication, Occupational Health, Safety & Environment (OHSE), authorities in the field of working with hazardous substances (e.g., the Dutch National Institute for Public Health and the Environment), industry or academia. Furthermore, authors of relevant articles and researchers of relevant studies were approached and experts were asked to appoint further experts to participate. In order to enable international validation of the results from Work Package 2 (see chapter 3) and to gather information from different countries, participants from 14 different European countries (i.e., Germany, Denmark, Poland, Great Britain, Sweden, Norway, Belgium, Italy, Finland, Austria, France, Greece, Slovakia and the Netherlands) were approached.

In total, 30 participants took part in the workshops (16 in workshop A, 17 in workshop B and 23 in workshop C, including 4 or 5 members of the monitoring team). An overview of participants per workshop can be found in Appendix 5.

4.3 Workshop set up

Given the corona pandemic it was decided to have online workshops using MS Teams. In order to gather in-depth information as well as stimulate group discussion, all workshops followed a similar structure. Workshop A and B took place on Wednesday October 20, and Workshop C on Thursday October 21, 2021. The workshops were prepared by the project team and a dedicated TNO facilitator. A more detailed description of the three workshops can be found in Appendices 6, 7, and 8.

4.3.1 1st Plenary session

After being welcomed and a short introduction of participants (using either MentimeterÒ or the chat), the Cefic LRI B23 project was shortly described. It was pointed out that the goal of the project was to optimize the benefit of REACH worker exposure assessments by improving meaningful health risk communication up- and down the supply chain. Also the goal of each workshop was mentioned. After a short recap of the methods used for both the literature study (Work Package 1) and empirical study (Work Package 2), relevant insights on the results of these work packages were shared in the plenary session. In the first two workshops, relevant results were polled (using MentimeterÒ) among the participants in order to assess recognition and/or gather opinions concerning the findings.

In workshop A, six results were discussed concerning the message, receiver or sender of health risk communication, such as "REACH information is just one of the

factors promoting working safely by end users in the workplace." Participants were asked to indicate (using MentimeterÒ) how strongly they recognize this finding in their country using a 5-point Likert scale ranging from 1='not at all' to 5='very strongly'. In workshop B, four statements were formulated to be polled (using MentimeterÒ) by the participants, such as "End user representatives should be more involved in development of exposure tools", again using a 5-point Likert scale ranging from 1='fully disagree' to 5='fully agree'.

Workshop C discussed five concerns and possible improvements arising from the discussions in workshop A and B. For instance, concerns relating to 'exposure scenarios and (e)SDS being too complex', 'existing exposure tools insufficiently leading to useful results for end users' and 'cooperation between REACH and OSH'.

4.3.2 Breakout rooms

Following a short break, participants were split in groups to discuss one or more topics more thoroughly in separate breakout rooms, led by a facilitator belonging to the project team. The groups were split according to country in workshop A and according to expertise in workshop B. Workshop C consisted mostly of participants who took part in either workshop A or B or both. While in workshop A and B, groups were shuffled after 20 to 25 minutes, in workshop C groups remained the same for the course of in-depth breakout room discussion. The discussions were noted by either the facilitator or note taker in order to enable reporting back during the 2nd plenary discussion.

In workshop A, participants had 45 minutes to discuss two different main results. Discussions revolved around recognition of the findings in participants' own countries, how their countries deal with the issue at hand as well as other best practices or ideas to solve this problem. After 20 minutes, participants were reshuffled to three different breakout rooms. Ideas on how to tackle the issues were noted and presented back to the group during the 2nd plenary discussion.

During workshop B, participants were split in four breakout rooms to discuss each two of the findings. Participants in the breakout rooms therefore talked about the polled statements and discussed various in-depth follow-up questions relating to the statement. Participants were reshuffled after 20 minutes to a different breakout room. Conclusions were noted in order to be shared in the 2nd plenary session.

In workshop C, participants were split into five breakout rooms to discuss (1) the preconditions, (2) barriers and promoters, (3) key stakeholders, and (4) next steps in order to realize the best ideas as elaborated on during workshops A and B. Participants with various backgrounds discussed these aspects. Insights were noted by the facilitators in order to report findings during the 2nd plenary session.

4.3.3 2nd Plenary session: Discussion and conclusion

Following a short break, all three workshops ended with plenary sessions in which participants presented and discussed the main points from the breakout room sessions. During this plenary session, participants who did not discuss a certain result or concern in a breakout room of workshops A, B or C were invited to discuss this result or concern.

At the end of each workshop, participants were thanked for their participation and asked permission for their names to be stated in the present report. There were no objections.

4.4 Results

During the three workshops, several themes recurred during the discussions. These themes were (1) complexity of documents (incl. tools), (2) SMEs, (3) feedback and responsibilities in the supply chain, (4) cooperation between REACH and OSH and

5) internationalization. These theme's and resulting insights are discussed in further detail below.

4.4.1 (1) Complexity of documents

In the context of complex documents participants raised the question if REACH documents are just a piece of paper without proper communication, implying that implementation is more than providing the paper information. Participants stated that users should not only be provided with documents and/or tools, but should also be educated and/or trained in using them in the intended way. However, the impression arose during the workshops that the output of documents and tools is often not easily understood by the downstream users. If so, the goal of the document and/or tool is not reached.

4.4.1.1 Why do downstream users perceive/experience the documents to be too complex? Various reasons were discussed during the workshops why downstream users may experience REACH documents and/or tools as too complex. A relevant question in this regard is who is the specific downstream user and who is the intended user of this documentation? Is this the worker in the workplace, the employer of an SME, or an OSH specialist like an occupational hygienist? During the workshops it became clear that especially for workers and employers of small SMEs, the documents and tools are too complex. Reasons are (a) they are too generic, thus not tailored to their specific work situation, (b) certain input parameters in the tools are not understandable (e.g. "ventilation with 80% efficiency") which hinders proper risk assessment, (c) the output of tools is also not always understood, and (d) specific terminology in tools and/or documents (e.g., exhaust ventilation). Thus a certain amount of knowledge and expertise is needed to manage and interpret REACH documents, implying that the issue of complexity especially will apply to SMEs. In order to overcome the complexity and therefore difficulty to understand documents and tools under REACH, certain improvements were suggested. Two broad categories were discerned: (1) simplification of documents and (2) education of the end user.

4.4.1.2 Possible solutions

(1) Simplification of documents/tools

The simplification of documents can be realized via various pathways that are complementary rather than conflicting. Ways to simplify documents and tools include (a) using simple terminology which is comprehensible for the user, (b) transforming and thereby tailoring information to the target audience, thereby including relevant users in the development thereof (c) limiting information, and (d) providing guidance. Most of these simplifications are applied in Work Instruction Cards (WIC) that translate an eSDS and ES to instructions in a specific sector, and even individual workplaces.

(a) Terminology

First of all, the terminology should be simplified. The present terminology is based on industrial applications instead of the practical wording used by workers. Additionally, while harmonizing the language was appreciated, terminology needed also to be tailored to a specific sector. While work instruction cards should be in simple language and user based formats (i.e., "local language on the work floor/sector"), experts such as occupational hygienists may require a different language. This brings us to the next potential area of improvement; tailoring information to the target audience.

(b) Tailor information to the target audience

Another way to simplify the information is tailoring, also called "fit for use" of the REACH documents and tools, that is, transforming the documents and tools directly to the specific sector. Identification of real work situations rather than theoretical simplified scenarios in (e)SDSs are especially valuable since participants indicated that those scenarios are too generic. Tools were also judged to be too general which makes application to a specific work situation difficult, necessitating to understand the limitations of each tool for different applications. Conflicting information from different documents or tools was also mentioned as potential source for misunderstanding. Workplace specific information such as work instruction cards were much appreciated. Participants further suggested to provide the most relevant information (from SDS/ES) in an electronic transferable format (e.g., XML) so that formulators can more easily choose and select the relevant parts to inform the downstream user. It was strongly recommended to involve the actual downstream user in creating the relevant information in order to verify comprehensibility and completeness.

Facilitating the tailoring of information enables not only filtering the information but also limiting the amount of information. Furthermore, information may not only be tailored to a specific sector but also to the particularities of a country.

Participants pointed out that an eSDS providing tailored information for a variety of sectors may result in an even more complex eSDS. Then, the sector can extract and use the information it needs from this eSDS. This eSDS thus needs to have information about the model behind it, calculations and how to scale your exposure calculation, etc.

(c) Limit information/simplify format

Besides tailoring information, participants suggested simplifying information by limiting the information in a simpler format. Three to four pages for all uses were said to be "digestible". To get there, the most important information, which has to be provided through the supply chain, should be selected / included. To further simplify use of the documents, a format such as a transferable XML was proposed by several participants.

(d) Provide guidance

Tools should provide users with more guidance on how to (practically) implement Risk Management Measures (RMM) or the use of control strategies from control banding tools. Some participants indicated that tool developers have the duty to help their users by providing them with the necessary information and guidance on how to use their tools. This was perceived as part of the business model to inform users on how to improve and maintain the model within a relevant time frame. However, many tools have been created in (EU or national) research projects and there is no 'business' for those tools. The tools are free to use and do not create any research funds for the developers to work on further improving the tool or providing additional user training and/or guidance. Some tools were not based on a scientific background or at least it was not transparent if they were, according to some participants. Besides transparent documentation, another part of the business model should be to provide trainings, support platforms such as a helpdesk, or explanatory (YouTube) videos. But as stated above, this can only be cost-effective if the user pays for the use of the tool or for these additional training and support. Additionally, REACH guidance should be improved based on lessons learned. Transforming the tool to an action plan, as suggested by one of the participants, offers another option to provide quidance.

(2) Education of downstream users

Another way to overcome the complexity of documents is to educate downstream users. A downstream user legally is a company. However, a company does not act,

but responsible persons in a company act and these vary. Depending on the size and kind of company the responsible person could be the employer, an OHS professional, an occupational health contact person, a team leader, a foreman or an individual employee. As competencies may vary, downstream users may be educated on basic REACH information such as how to read SDS and ES and use tools appropriately. This could be realized by workshops, tools like work instruction cards or the provision of videos. This may also require train the trainer programs. Improved expertise of the downstream users may result in a better implementation of REACH information. Education may be especially valuable for SMEs since they often lack the expertise, knowledge and thus capability to adequately implement REACH. Sector organization were said to potentially assist in this process. A reported hindrance for sector organizations is that sector organisations have no legal role in REACH and that they need to be paid for their efforts. Therefore their activity largely depends on whether their members see sufficient benefits for the sector organisation to play a role.

4.4.1.3 Steps to take

In workshop C participants mentioned the following steps to simplify documents / tools. (a) To improve REACH guidance based on lessons learned from people who use(d) this guidance. (b) Make sure that the downstream (eSDS) information is correct and digitally transferable (e.g., XML). (c) EU authorities (e.g., ECHA) in collaboration with sector organizations could stimulate the official translation of terminology to ensure a harmonized wording across European countries, and enforce rules to ensure involvement of experts at the workplace (which is lacking in SMEs). The following steps were mentioned to improve the knowledge / expertise. (a) Sector organizations could transfer this knowledge to the workplace, (b) videos and to-the-point guidance could be created, and (c) use the train-the-trainer principle to train persons from various companies in one sector.

4.4.2 (2) SMEs in REACH

During the workshops, SMEs and their ability to fulfill REACH obligations emerged as recurring theme.

4.4.2.1 Which problems do SMEs face regarding REACH obligations?

Larger companies were mentioned to have better trained personnel in handling the REACH documentation (e.g., occupational health specialist) compared to SMEs, which was experienced to be a precondition according to participants to follow REACH obligations "Many SMEs still struggle with having the SDS available at the workplace. This has to be solved before we can start using the hazard information. [...] Then when the companies are large enough to have employed a HSE professional we can start focusing on enhancing the risk assessment including exposure assessment. etc.", (participant workshop A). Obviously, this necessary expertise can be hired by SMEs from consultancy companies, but SMEs were said to lack the necessary resources like time, knowledge, capability and finances to adequately fulfill REACH obligations themselves or to hire this expertise. Especially when staff has been working with the same hazardous substances for a long time (without any visible/experienced negative short-term consequences), risk of working with these substances may be (highly) underestimated due to the low risk perception and consequent low necessity to mitigate these risks.

Furthermore, REACH was said to be less visible in SMEs. According to the participants, this might be due to less motivation and a more negative attitude as well as the (great) amount of information to deal with. This general finding corresponds with findings of WP 2 where a handyman referred to the lack of motivation and resources since in his opinion, investing in REACH meant losing time, which could otherwise be spent on "real work" with clients and therefore making money.

Awareness of the benefits and necessity of implementing REACH was mentioned as a key aspect. Yet, the behavior change literature describes that only awareness is not sufficient to realize behavior change. Awareness (including risk perception) has to translate into beliefs about the pros and cons of the behavior and its consequences which form the attitude. The attitude is one of the determinants of the intention. Intention in itself is one of the determinants of behavior, as well as skills and environmental constraints (see Integrative Model of Behavioral Prediction, Fishbein, 2008; Fishbein & Ajzen, 2010). Thus, awareness is just the start of behavior change and many more determinants have to be addressed.

Other factors contributing to how different large companies and SMEs are able to meet REACH obligations were discussed during the workshop. Participants mentioned the trade association of the company (i.e., association that acts to promote the interests of, and to set standards within a sector or industry) as well as the role within the supply chain (e.g. registrant, formulator, etc.).

4.4.2.2 Possible solutions

Solutions entail *internal improvements*, which can be realized by increasing or expanding internal expertise by means of education like training or workshops. Also, more *external methods* were suggested such as guidance by either documents, support platforms or the availability of external expertise. Quite often sector organizations were suggested as an external method to assist SMEs in interpreting eSDS. Moreover, incentives such as financial benefits to comply with the implementation of REACH were proposed. Another solution was the simplification of REACH documents to be more accessible, readable and attractive – especially for SMEs lacking expertise (see also 'complexity of documents' as recurring theme). Furthermore, information regarding hazards, exposure and control measures tailored to the needs and characteristics of SMEs were suggested to provide opportunities for positive change. Tailoring the information entails amongst others, sector-specific information and the provision of the information necessary for the end user in question (as discussed earlier in complexity of documents).

4.4.2.3 Steps to take

In order to promote the realization of aforementioned suggestions, authorities may play an important role. As a regulator they have the power and means to increase awareness concerning the need to and may promote (financial) incentivization to fulfill REACH obligations.

Eventually, it are authorities who can encourage using external REACH and OSH expertise. This may be done by means of promotion campaigns. Furthermore, they can stimulate/implement the translation of supporting information to a common language/terminology which is easily understood by SMEs.

4.4.3 (3) Feedback and responsibilities in the supply chain

Within REACH three general parties are described in the supply chain:

- manufacturers or importers of chemical substances that have to register these substance (i.e., registrants);
- formulators that use the substances to formulate a product; and
- end users that use these products.

REACH regulation requires among other things that registrants communicate the health and environmental risks of hazardous chemical substances through SDS and ES to the formulators who at their turn are obliged to inform their customers, the end users. End users and formulators can voluntarily inform suppliers upstream about uses of substances that are not yet registered or that conditions of use in their workplace are not covered in the SDS or ES. Figure 2.1 describes this feedback loop in the supply chain.

4.4.3.1 Problems in the feedback loop of the supply chain

Each party in the supply chain has different legal REACH obligations and different roles and resources to ensure that at the end of the chain workers manage hazardous chemicals safely. As discussed in topics 'complexity of documents' and 'SMEs' the SDS and ES are not really suited to inform end users, especially in SMEs. Given the three different parties the participants indicated that it is more about how to transfer the information from one level to the next level. Parties also talk different languages and it seems more about interfacing between parties than direct communication between parties. Also the need for a distinction was mentioned between downstream communication of SDS and ES, which is a legal requirement and for which many things have been arranged, compared to communication upstream where less has been arranged.

The supply chain is often (very) long, thus communication and feedback is a slow process according to the participants. Registrants upstream have sometimes no clue who buys their products and also the other way around. This is one of the reasons that registrants argue that they lack sufficient feedback from downstream users. Besides the length of the supply chain, there is also quite a large variety within parties. For instance in a formulator company we may discern workers at the workplace, HSE professionals, purchase, and legal requirements. All have different needs and hence should be involved differently in the communication and feedback regarding hazardous chemicals. Questions were raised about the involvement of end users in the upstream level, because the gap between the two levels is too big. The problem seems to be the complexity and length of the supply chain, especially if it goes across borders.

Given the responsibility to inform each other about hazardous chemicals it seems that people sometimes point towards each other without knowing who this other is. This is not surprising given the long supply chain. It was noted that in case of a special product the knowledge regarding hazards and safe use was good at the side of downstream users, whereas for more general products (e.g., paint) this was less the case. The question was raised whether it concerned communication about hazards or about safe use. Regarding responsibility it was also mentioned that registrants and formulators are more concerned about putting a product on the market than about safe work. This is of course logical, because their business model is to sell products and not to ensure safe use. Nevertheless, ensuring safe use shall be part of their business model, but there seems currently no clear solution on how to accomplish this. In the context of simplifying SDS and ES information (see topic "complexity of documents") the question was raised who is responsible in the supply chain that this simplified information is still complete and correct.

4.4.3.2 Proposed solutions

Several solutions were mentioned in the workshops. We describe three solutions more extensively: (a) the role of sector organizations, (b) digitization of information, (c) improving the existing legal feedback structure and we further describe (d) other solutions mentioned.

(a) Role of sector organizations

Sector organizations are the interface or intermediates between end users and parties upstream in the supply chain. Sector organizations do not have an official role in REACH legislation, so they also don't have a legal responsibility. Very frequently participants said that sector organizations should be strengthened. For instance, at the moment most activities regarding REACH in the sector organizations are voluntary and that makes it vulnerable. There should be more financial support, like in the Netherlands authorities subsidized sector organizations for specific actions related to safe use of chemicals in the past. Not all sectors have sector organizations and there is also quite some variety in sector organizations themselves. Some sector organizations have few members and some many members, and usually large

companies are a member of sector organizations. It was also mentioned that membership of some sector organizations is diffuse and not clear for single companies. In those cases companies do not request help from sector organizations. In this context the question was raised why these organizations do not take their role to work 'for' their members, the companies in the sector. Also national sector organizations should be supported by European sector organizations. CEFIC and DUCC represent various sector organizations on a European level and make research funds available to conduct research into safe use.

Sector organizations could play a role in developing a harmonized approach to communicate to end users according to the participants. Especially in translating generic ES in more specific safe use conditions and risk reducing measures for a specific sector. Also to develop and provide courses to train and educate end users. Participants thought that making funds available to outsource training to relevant parties would be very valuable. Sector organizations could also play a role in digitization of REACH documents. Regarding the upstream communication sector organizations with (internal or external) OSH expertise could work on sector specific input for registrants, preferably by cooperation between formulator sector and end user sector.

It was mentioned that ECHA could provide more guidance for sector organizations. Also because REACH is not always high on the agenda of sector organizations. Specifically the ECHA ENES program was brought forward in this context. One reason is that large companies usually have a bigger say in the sector organizations, but the small companies have a stronger need for support. Given that the needs of large companies probably differ from small companies, sector organization should be aware of those different needs and influence. The discussion among the participants concluded that if small companies were sufficiently involved in ENES, that ENES could support sector organizations in this context.

(b) Digitization of information

During various discussions participants pointed out the benefits of having REACH documentation and other information available in a digitized format like XML. It would speed up the communication, make it more accessible and easier to select relevant information. Participants said that there was already a lot going on regarding data exchange although it is work in progress. The question was brought forward who is responsible for this digitization process. The registrants and formulators that send out the SDS and ES were mentioned, but also IT companies.

Participants discussed the legal acceptability of digital formats like XML. Some thought it was required to send something in a printed paper format (e.g., a PDF) and that XML and digital links were prohibited. Participants proposed to have this sorted out by a legal expert and clearly communicated which digital forms are accepted. In this context also the different ways the laws are enforced in European countries was mentioned.

(c) Improving the existing legal feedback structure

In workshop C it was mentioned that a legal feedback structure up- and downstream is already part of the REACH legislation, but support should be developed to implement this legal feedback structure. A standardized letter was suggested that parties could use to ask for and provide feedback to other parties. Especially a format is needed for upstream communication to support downstream users to have their uses implemented as identified uses of substances in the CSR. Given the slow process, participants also insisted that the feedback would be provided in a timely manner. Preconditions stated were that this letter should be accepted by the parties in the chain, resources should be provided to develop and implement this letter (e.g., to ECHA) and registrants should be rewarded to update their CSR with the feedback also after the registration deadline. Having such a letter in XML-format would accelerate the feedback process and make it more accessible.

The participants pointed out that new solutions like such a letter need time to really work. Also that one should focus on making existing solutions more accessible and not to develop new add-ons too fast. For implementation one should focus on the experienced benefit of a solution: "What's in it for me when I take the effort to provide feedback". Besides the parties in the supply chain also sector organizations and the European Commission were seen as stakeholders. A next step to develop and implement such a letter would be that CEFIC or DUCC (Downstream Users of Chemicals Coordination Group) asks for a meeting of ENES (Exchange Network on Exposure Scenarios) to discuss this idea further.

(d) Other solutions mentioned

The parties in the supply chain should recognize and be aware of the need for feedback to improve the communication in the supply chain. To promote feedback from downstream users upstream they could be incentivized and convinced about the benefits. Another suggestion was to oblige employers to provide feedback upstream. Also the role of authorities was mentioned to approach downstream users directly about the use and processes of substances. There could be a role for authorities in quality control of the feedback loop in the supply chain. Direct contact between parties was seen as a solution, especially upward to suppliers. However, suppliers might be hesitant to include new uses of a chemical by downstream users in the SDS and ES. This is not a solution if downstream users and registrants are competitors. In that case a downstream user may make its own dossier about hazards and safe use.

Another way to improve the communication and feedback in the supply chain is to clarify and strengthen the cooperation between REACH and OSH. This topic will be discussed next.

4.4.4 (4) Cooperation between REACH and OSH

REACH and OSH are two different legislations both concerned with working safely with hazardous chemicals. REACH is *de* facto focused at the industrial companies that produce or work with hazardous chemicals. This is caused by the fact that the legislation is about communication of hazards and safe use for single chemical substances that may be used by many different formulators to formulate mixtures (products) and by end user companies for a variety of purposes, mostly in the form of mixtures. REACH is organized on a more European level. OSH is focused at the safety of workers at the workplace of single companies regarding uses of all chemical substances/mixtures at the various workplaces in that single company. OSH is organized on a more national level, although the underlying legislation is also European.

4.4.4.1 Problems in REACH and OSH coordination

Participants of the workshops strongly favored more collaboration between REACH and OSH because this is lacking in their opinion. They indicated that given the shared goal of REACH and OSH (i.e., working safely with hazardous chemicals) there should be no competition between REACH and OSH. It appeared that countries differ in the way they handle REACH and OSH. For instance, a workshop participant mentioned that in one country not many resources are spent on REACH, because the focus is on OSH regulations. The question is how to combine the more generic REACH tools and documentation with the company specific OSH tools and documents.

OSH legislation is older than the REACH legislation. Companies that (in their view) already have shown that processes are safe under the OSH regulations, now feel that they need to check again if they fulfill REACH obligations. This may feel like extra and unnecessary, so motivation for this extra effort is lacking. This is the case in Germany for instance for which workshop participants mentioned that people working

under OSH think everything under REACH is an additional workload. Most workshop participants realize that OSH and REACH should work together, but only a few people are connected to both domains. Also within larger companies there is still a gap in knowledge, expertise and language between REACH experts and OSH experts. Also when REACH and OSH experts meet in workshops or conferences they need a lot of time to find a common language, because they use words differently. In this context the added value of REACH in relation to OSH was questioned. However, the participants agreed that REACH resulted in more information on chemical hazards and how to deal with it.

Another point that participants raised was that REACH concerns single chemical substances, whereas most companies use many different chemicals and many chemical products consist of mixtures of substances. OSH is focused on safe working conditions at the workplace of all chemicals, products and mixtures. In this respect participants often referred to the SUMI a tool which offers companies a standardized way to communicate Operational Conditions and Risk Management Measures. It was first developed for the industrial and professional cleaning sector. It was recommended that sector organizations develop SUMIs for other sectors as well. Another suggestion was to develop generic SUMIs that end users can further translate into practical information. A workshop participant suggested substituting dangerous substances, that is, to remove dangerous substances as much as possible from mixtures, which is according to the STOP strategy.

Also the cooperation on authority level could be improved as well on the legislation as execution side. In a number of European countries, OSH and REACH competences are in different authorities, and may have different priorities. Even at EU level there is a differentiation between DG Employment (OSH) and ECHA (REACH). Participants indicated that different authority groups also tend to 'compete' regarding competences and power.

4.4.4.2 Possible solutions

The participants recognized the supplemental value of REACH and OSH to promote working safely with hazardous chemicals. OSH experts know the real situation and understand the technical wording in the company. As such they can fill in the more generic SDS and ES documents with the specifics of the company.

Overall the most mentioned solution was to bring REACH and OSH experts into contact with each other, because this is lacking. There should be a mutual understanding and respect that both aim to improve the workers' health and protect the environment. Training and workshops where both experts attend is a first step. Also in publications the reciprocal value of REACH and OSH in working safely could be better described.

Frequently the easy reuse of REACH data for OSH purposes and vice versa was mentioned by the participants. They advised to have an agreed concept on when and how to reuse REACH and OSH data. This would require a harmonization of the REACH and OSH terminology. The easy reuse of data would be promoted by digitization of the documents (see topic 'feedback and responsibilities in the supply chain').

Sector organizations could play an important role in bringing REACH and OSH experts into contact within specific sectors. For instance by asking feedback from OSH experts on REACH dossiers. ECHA could provide more guidance on this matter. It was however noted that sector organizations do not have the formal responsibility and often lack the resources to work on this.

Participants promoted bringing OSH and REACH together also on the authority level. For instance, checking whether the REACH and OSH regulations are really aligned and complementary. The target audience of REACH could also be more clearly delineated. The proposition was that OSH experts in formulator or end user companies would be the target audience of REACH documents.

4.4.5 (5) Internationalization

The goal of workshop A was to validate whether the results and conclusions from both the literature study in WP 1 and empirical study in WP 2 were recognized in an international context. In this section, the overall conclusion regarding this question is discussed.

In general, recognition of the results by the participants from various countries in Europe were mixed regarding the six statements that were asked in the Mentimeter® poll. In depth information and discussions regarding each of these statements can be found in Appendix 6.

- 1. The first statement, being "Many downstream users consider the ES and eSDS to be too complex" was strongly recognized in all participating countries. In total, participants scored an average 4.3 out of 5, with scores ranging from 3 to 5. As pointed out by the participants, there are no country specific solutions yet. However, as can be read in "complexity of documents", there were many promising potential improvements discussed.
- 2. The **second** statement was "Resources spent to REACH can better be spent to really improve safe working conditions". This average score was 2.7, with scores ranging from 2 to 4, implying mixed recognition. In some countries, it was argued that not many resources are spent on REACH as the focus lies on OSH regulations. A reason could be that REACH information is experienced as "too general and therefore not directly applicable at the workplace" (summary workshop A). Other participants indicated that REACH documents provided more information on chemical hazards and how to deal with it. Therefore money spent on REACH was money spent to promote safe working conditions. Some participants thought this statement was unclear and did not know how to react to it.
- 3. The third statement that "The one-size-fits-all approach of REACH hinders effective communication for specific companies, like SMEs" was rated with a mean score of 3.1, with scores ranging from 1 to 5. This score indicates some recognition, but also diversity in opinions. This diversity probably reflects multiple interpretations of the statement. Some participants did not agree with the one-size-fits-all element. Other participants did not think it hindered effective communication with specific companies. However, as described in topic 'SMEs' participants did recognize that large companies differed from SMEs in how to deal with REACH and this was recognized in most European countries.
- 4. The **fourth** statement, "Feedback is lacking, especially from end users to upstream users" was rated with a 3.5, with scores ranging from 1 to 5, but mostly skewed to the recognized side of the distribution. Points discussed were that registrants seem to lack sufficient feedback from downstream users and that end users are not motivated to provide feedback upstream. Suggestions for possible improvements are discussed in 'Feedback and responsibilities in the supply chain'.
- 5. The **fifth** statement "There is a diffusion of responsibility in the supply chain" was rated with an overall score of 3.4, with scores ranging from 2 to 5. This implies that there is some recognition in the international context. For some participants, it was not clear what was meant by diffusion. Other participants mentioned how people may point towards each other without knowing who the respective "other" is. More about the diffusion of responsibility can be found in 'Feedback and responsibilities in the supply chain'.
- 6. The sixth statement "REACH information is just one of the factors promoting working safely by end users in the workplace" was highly recognized internationally, with an average score of 4.6. Scores ranged from 2 to 5 with most of the participants strongly agreeing with the finding. During workshop A, aspects concerning both the feedback mechanism, cooperation between REACH and OSH and complexity of documents were touched upon. These included for example the employer's responsibility to ensure a culture in which enough time

is spent on protective measures, as well as removing the discrepancies between REACH and other legislations (like OSH).

4.5 Conclusions

The workshops, based on findings of the literature and empirical study elaborated on in chapters 2 and 3 yielded many good suggestions for further improvements to increase working conditions under REACH. These include improvements concerning e.g. simplification of documents or formats which allow for easier transfer of documents, or enhancing assistance for SMEs. Authorities and groups such as sector organizations were said to have a relevant role in implementing many of the suggestions, among which enforcing legal feedback structures or bringing together REACH and OSH representatives. Most of the solutions discussed related to various concerns and propose to actively involve the end user, by e.g. training them to improve their knowledge and capability to understand and act on REACH regulations, as well as involvement in the development of tools and documents. Lastly, great improvements can be realized when ensuring that REACH and OSH go along rather than working in (apparent) contradictive or duplicative ways. However, responsibility and first steps to take remain unclear at times.

We first present the conclusions regarding the four recurring themes in the discussions of the workshops.

4.5.1 Complexity of documents

Concerning the documents and tools provided under REACH, various suggestions were made including tailoring information to the target audience, hereby involving relevant stakeholders in the development to ensure use of appropriate terminology, simplification of the format and the provision of guidance. Furthermore, educating end users was proposed as a pathway to more effective health risk communication. In order to get there, first steps to take are the digitization of documents to allow for splitting up relevant information for each target group, the provision of an official translation of terminology and arrangements to ensure the involvement of experts at the workplace (e.g., input of sector organizations through legal changes in REACH or financial input from national of EU authorities, or companies know that there are national helpdesks to support them with REACH).

4.5.2 SMEs

In order to improve health risk communication among SMEs, various approaches were suggested. These include internal improvements such as education of workers and therefore increasing the knowledge and capability to implement REACH, as well as external improvements such as the provision of support to SMEs in implementing REACH. In order to reach these improvements, SMEs need to realize that implementing REACH is important and beneficial, and that they can get support in this. Authorities could therefore print flyers pointing out above mentioned points, encourage using external REACH and OSH expertise and propose incentives while enabling the translation of supporting information.

4.5.3 Feedback and responsibilities in the supply chain

Main problems for feedback in the supply chain are the following:

- The legal opportunity to provide upward feedback is part of REACH, but there is no obligation to either provide or ask for feedback.
- Long and complex supply chain thus communication and feedback is a slow process.
- Stakeholders in the supply chain point at each other that they have to take responsibility or that they forego this responsibility (i.e., downstream users point upward, and upstream users point downward).

 Commercial companies have also other predominant interests than safe use of chemicals, like financial interests.

Various general solutions were proposed to improve the upstream communication, like:

- Motivating downstream users to provide information to upward parties. This could be done by (in)direct contact in providing information/ education or at the other extreme enforced by authorities by checking companies if they comply with the ES received and taken action accordingly. Sector organizations were frequently mentioned to have an important role in up- and downward communication and feedback given their intermediate position between end users and upstream users.
- Sector organizations could be financially strengthened by national authorities and supported by European sector organizations. However, sector organizations could then lose their independency of authorities. Financial support could also be via in kind contributions and support from member companies. It was also said that sector organizations vary in how well they are organized. Also the influence of large companies in sector organizations was discussed, while smaller companies need more support form sector organizations.
- There was unclarity which digitized forms of an SDS are legally acceptable. However everybody agreed that digitization would be a step forward in communication and feedback in the supply chain.
- A standardized letter was suggested to support parties to ask for and provide, especially end users to provide feedback to upstream suppliers, so that the legal feedback structure in REACH can be better implemented.

4.5.4 Coordination REACH and OSH

The participants of the workshop mentioned various discrepancies in the coordination between REACH and OSH. Also several solutions were offered, albeit with very generic character. Also the position paper of CEFIC on "How to get the interface between the REACH & OSH in motion?" (October 2021) very adequately describes ways how to coordinate REACH and OSH processes, but concrete next steps are missing and also who should take them. The responsibility for promoting REACH and OSH alignment lays with industry. Regulators have a responsibility to coordinate it on a legal level and basis. Actually, at a European level this is already an ongoing activity (e.g., Chemical watch 2020).

4.5.5 Internationalization

Regarding validation of the results as uncovered during the literature and Dutch empirical study, recognition by the workshop participants from various European countries was mixed and depending on the statement discussed. While the low recognition concerning resources being spent on REACH may be due to the fact that some participants may have experienced this statement to be somewhat ambiguous, participants were on average rather neutral regarding the one-size-fits-all approach. diffusion of responsibility and lack of feedback. This might be due to the fact that stakeholders from different countries either experienced good practice examples (such as actively reaching out for feedback) or encountered different parties pointing fingers towards each other. Yet, both the documents being perceived as being too complex for downstream users and the fact that REACH information is just one of the factors promoting working safely by end users in the workplace were internationally recognized. This leads to the overall conclusion that, while European countries may differ in which kinds of hurdles they encounter in the implementation of REACH, there seems to be an international need to go a step further than improving solely provision of information, or comprehensibility of SDS and ES.

4.5.6 Risk communication and behavior change

In the discussion of REACH documents a strong focus during the workshop was on awareness and information. However, information alone is never the key to behavior change. Besides the simplification of documents and education of downstream users, it is important that other aspects are also taken into consideration as described in section 3.3.1, like factors that affect motivation (e.g., attitude, social norm and self-efficacy) and actual behavior change (e.g., skills, environmental barriers). Thus, while documents and tools should provide the necessary information in a comprehensible and suitable format, the next steps are to make sure that this information leads to behavior change. This may entail factors related to the Integrative Model of Behavioral Prediction' (Fishbein, 2008; Fishbein & Ajzen, 2010) (see Figure 3.1), but also factors related to other psychological mechanisms like (biases in) risk perception and unconscious processes (e.g., nudging).

It is important to specify which behavior one wants to change. As described in section 3.3.1, it can be a specific behavior to work safely with hazardous substances like wearing gloves or putting on the ventilation, sending an eSDS to the formulator, using an SDS, providing feedback to a sector organization, producing a work instruction card or educating workers on working safely. Each behavior has different actors and may have different determinants for change.

The Persuasion-Communication matrix of McGuire provides good insight in the oneon-one communication between a source that sends a message through a channel to a receiver. Within a supply chain several cycles of this matrix are repeated. So, the matrix can be used to describe each separate cycle, but the transition from one cycle to the other is not really covered in the matrix, therefore not identifying possible noise resulting from the transitions. For instance, ES frequently are transferred throughout the chain by simply attaching it to SDS. Then there is still originally one source of the ES, but this eSDS will be evaluated differently by different sender-receiver dyads down the supply chain. Upstream dyads may understand and approve this practice, whereas dyads more downstream may be confused and evaluate this practice negatively. One of the key transitions involves going from a REACH to OSH perspective when cascading down to the end user and vice versa up to the formulators/manufacturers. For instance, registrants mainly want to describe how a chemical can be used in a safe way, based on the STOP principle, but the use maps for example are built on how the products are currently used. And there was no review process by hygienists, or even registrants. As described in sections 4.4.4. and 4.5.4. the interaction between the REACH and OSH community should be improved at national and European levels.

When deciding which persons to invite for participation in the workshops we also noticed that there are various communities involved in working safely with hazardous chemicals, but these are primarily focused on the occupational health expertise rather than on the social science perspectives. We wanted to include participants that were familiar with REACH and a social science perspective (e.g., behavior, communication), but found it hard to locate persons who had both expertise. In order to use insights from social science the various domains have to come to "speaking terms", like expertise on REACH and OSH, and social science and chemical exposure, because each of these expertise has their own terminology and professional domains, which hardly overlap. It will take effort and time to get these various domains in closer collaboration.

4.5.7 General workshop conclusions

The workshops confirmed that many of our general conclusions were already part of the shared knowledge in the REACH community across the EU. However, this knowledge had not in all cases been explicated and validated through literature research (WP 1), empirical research (WP 2) and expert knowledge (WP 3) till now. By explicating these general concerns, possible solutions were addressed in the

workshops, especially in workshop C and subsequently reported in a thematic / structured way in this report. Although various solutions were mentioned during the workshops, concrete steps to implement these solutions are usually lacking (see also Appendix 8). This may be partly due to too limited time to dig into those specific steps during workshop C, which would require specific workshops per solution.

One of the problems for implementation of the solutions is that the stakeholders are described in very general terms like ECHA, registrants, formulators, end users, European Commission, authorities, industry or sector organizations. No specific stakeholder is appointed that takes the responsibility (and has the means) to start implementing the solutions. For instance, a concrete step for developing support to meet the existing legal feedback structure in REACH was that CEFIC or DUCC (Downstream Users of Chemicals Coordination Group) ask for a meeting of the Exchange Network on Exposure Scenarios (ENES) to discuss this matter further. However, nobody has been given this task in CEFIC or DUCC yet. Another example is the suggestion that sector organizations should cooperate more on the authority level or that these organisations should be subsidized nationally or supported by European counterparts.

5 Discussion and conclusions

The main objective of the project was to provide a substantial contribution to optimisation of information on safe use conditions, specifically in REACH. The cumulative results of the three work packages (WP 1 'analysis of existing information', WP 2 'empirical case studies', and WP 3 'workshops') highlighted various observations regarding this information and provided solutions for optimisation of the communication. Although the methods to collect the data differed between the work packages, the general results from all three work packages largely elucidated similar themes in the observations and each of the work packages used the results from the previous work package as a starting point. The workshops confirmed that many of our generic conclusions were already part of the shared knowledge in the REACH community, but that it is very valuable that this knowledge has been explicated, validated and reported in a structured way in the present project.

The project was focused at a very generic level, targeting on (a) the international literature evaluating REACH communication, (b) case study interviews in a diverse but limited set of Dutch companies and stakeholders, and (c) extrapolating to the European level in the workshops. The main discussions and conclusions from this project are listed below:

 There are several activities (finalized or ongoing) to improve communication on safe use of chemicals in the scope of REACH and some tools have been developed to improve the communication.

Activities to improve the communication of safe use information that have been performed have led to the following tools for upstream communication: generic exposure scenarios, use maps and SWEDs. These available tools, that are used in practice, improve the consistency of information used by registrants to assess the risks and necessary safe use conditions. A standard phrase catalogue for exposure scenario terminology (ESCom) is developed and in use. That system increases consistency in wording in downstream communication. For improvement of assessment and communication of safe use information of mixtures, the Lead Component Indicator approach and SUMI have been developed. The use of these approaches/tools was not yet found to be widely implemented. These tools can at least help increase consistency in information for users of mixtures. It is known that at least in one end-user sector, the SUMI are further translated into workplace instruction cards to assist implementation of safe use conditions at the actual workplace.

The current CEFIC LRI B23 project is a further initiative to improve the safe use communication. The possibility of using digital communication (e.g., XML files) for SDSs was suggested as an option to improve for instance the updating of SDS, but also to tailor information to specific target groups. The use of digital tools to develop and manage information on substances and mixtures was pointed out in the case studies. There is insufficient knowledge on the actual implementation of such tools and options as well as on their effectiveness in improving the communication. For instance, while it is clear, that a tool like SUMI has not yet been widely implemented in many sectors and companies. It is not clear from the analysis of existing information nor from case studies and workshops whether this is only because SUMI is too recently developed, or whether there are other reasons why it is not widely used.

2. Actual end user representatives appear not to be extensively involved in the activities and developments related to communication of safe use information in the scope of REACH.

A general finding is that actual end users of chemical products (i.e., companies downstream from formulator companies) or their representatives are not extensively involved in the developments around communication of safe use information in the scope of REACH. This may be partly compensated by the input of formulators who know the uses of their products well and who also involve their end users in the development of their tools. However, active participation of such end users cannot be shown from the data in our project. For example, the downstream user organisations involved in discussions in the European Network on Exposure Scenarios (ENES) are all formulator organisations and no organisations of nonformulator users of substances or mixtures (which we consider 'end users'). Since many REACH estimates are for use of substances and mixtures at end user companies, this is considered to be an important finding of this study. Proper communication requires sufficient knowledge of the needs and possibilities on both sides (sender and receiver). Lack of knowledge (on requirements and on risks and risk assessment) at end user level, which was considered relevant for many end users groups, hinders effective communication. Furthermore a lack of involvement in the development of tools and information will decrease the confidence of the receivers in both the sender and the message and therefore hamper the implementation.

3. End users of chemicals do not differentiate in practice between different regulations such as REACH, OSH and CLP

In the case studies, it was observed that interviewees did not differentiate between information coming from REACH or information coming from other legislative requirements, such as the CLP Regulation or other chemicals legislation, including the chemical parts of OSH. Several interviewees referred to classification and labelling issues to illustrate the complexity of the documents. However complexity of classification and labelling is not related to REACH, but to the CLP Regulation. It is clear that interviewees working with safe use information on substances do not naturally separate the information based on the legal background. They apparently see the full set of information as coming from 'chemical legislation'. For this study, it implies that it is difficult to evaluate the actual aspects of safe use communication specifically related to REACH itself. However, it also indicates that efforts to improve communication of safe use information should not only be focused on REACH, but should account for the full chemical legislation, including the relevant parts of OSH.

4. ESs are rather unknown by end users, partly because they tend to use mixtures, for which ESs are not required.

As far as studies have been performed, the awareness and understanding of the requirements and processes of REACH as well as of the existing tools is much lower in end users than in registrants and formulators. This was also a clear finding in the case studies, which was recognized by the workshop participants. Many end users, according to studies, have not received any ESs. And in end user companies, the safe use information that is mostly used is the hazard information and the information on personal protective equipment in the SDS. Such information already existed in the same form before REACH and therefore cannot be considered a contribution to improved communication of REACH. The fact that end users predominantly use mixtures, for which the provision of ESs is not required by REACH, may be an important reason for this situation, as suggested in all work packages. However, there are no studies that either support or contradict this thesis. Whether provision of ESs (preferably dedicated to specific uses) for mixtures would make a difference cannot be evaluated based on present knowledge. Some specific tools have been developed to communicate the safe use information for mixtures, for example Lead Component Identification Methodology and SUMI, but there is no information allowing an evaluation of their effectiveness.

5. ESs are generally considered too long and too complex.

The length and complexity of REACH documentation (specifically ESs) is often reported, by those who have received them or have an opinion on them, e.g. from hearsay, to hinder better communication of safe use information through the supply chain. The perception of complexity may partly be caused by unclarity on the target reader of the REACH documents at the receiver side of the downstream user. It is not very clear to people interviewed or filling in questionnaires, whether REACH information is targeted only at experts (e.g., HSE professionals, occupational health contact person), that should use the information to assist end user companies in managing the risks, or whether end user companies themselves (employers and employees), including SMEs should be considered the target. During the expert workshops in this project, there was general agreement that the documents are not targeted at workers themselves and shall first be transformed into workable information. Long documents are often seen as complex and responsible persons at (mainly SME) end users are not accustomed to the language used in these documents. Single ESs (i.e., descriptions of safe use information for one specific use scenario) can be rather short (one or two pages). However, if all ESs are appended to the SDS of a widely used substance, the total page count can easily reach hundreds of pages. At least a certain amount of knowledge and expertise is required to manage and interpret REACH documents.

Part of the observed complexity of REACH documents is caused by the fact that each supplier of a substance has to deliver their own version of the same type of document. While it is allowed to harmonize the safe use information between suppliers (if possible), this does not per se happen as it is not required by legislation. This leads to differences between safe use information of the same substance or for very similar products, depending on the supplier as remarked in the case studies and recognized during the workshops.

6. Updates of SDSs and ESs are not consistently forwarded down the supply chain and also not always within larger companies.

One finding regarding SDSs is that updates either are not consistently sent to the end user company or that they appear not to reach the people who actually have to work with substances or products or those directly responsible for how the work is safely performed. If suppliers do send updates, they sometimes appear to be stuck in files and not reviewed for potential changes to be made in working conditions. In this way, potentially relevant changes in safe use information may be missed, while proper communication might have led to improvements in working conditions.

7. Feedback on safe use information and how it is communicated does not regularly occur and is not structurally organized.

The lack of updates is probably related to another finding, which is that the communication of safe use information, once REACH registrations have been made, is generally one-way (top down). SDSs, sometimes with ESs attached are sent down the supply chain. However, no feedback is provided or asked for (bottom up). So, while there are general complaints about these documents users of chemical substances and products, specific complaints about specific documents are not generally submitted to the suppliers. This, of course, does not help to improve the documents, because suppliers may think that 'no news is good news'. To ensure proper communication, feedback is critical. The sender should check whether the information is what the receiver needs and whether it is understood, helpful and can be used for further actions. The receiver should ensure that their interpretation of information in documents is indeed what was intended by the sender. Certainly if documents are considered too long and too complex, there is a role for the sender to provide clarity in what is sent and for the receivers to explain what they think they can handle and what elements are not understood. However, the fact that the receiving

companies can be highly variable in size and expertise level will make providing proper clarity when sending the documents difficult.

The supply chain is often (very) long and may involve many (international) parties, thus communication and feedback (if any) is a slow process according to participants of the workshops. Also, due to the many intermediate steps that may occur, including distributors and whole-sale organizations, the knowledge on which actors actually use certain substances is limited at the top of the supply chain, while the actors at the bottom of the supply chain do not know who the original manufacturers are of substances that are in the products they use. This complexity is one of the reasons that the feedback loop up- and downstream is malfunctioning. Additionally, there is no legal requirement to provide feedback communication up the supply chain, which can be better arranged.

8. Stakeholders in the supply chain seem to blame others for not fulfilling their REACH obligations which lowers their sense of responsibility.

From the case studies it seems that stakeholders blame others in the supply chain for not fulfilling their REACH obligations. Downstream users point upward to registrants and formulators for not providing correct and understandable information (or any information at all), whereas upstream users point downward that downstream users do not understand their information due to a lack of expertise and not providing any feedback. This diffusion of responsibility and blaming each other seems to increase on an international level, especially if suppliers from outside the EU are involved.

The length and complexity of the supply chain may also hamper the implementation of various solutions because these solutions do not result in a direct return of investment for a stakeholder. Moreover, these improvements require cooperation among different stakeholders in the supply chain. Initiating improvements in REACH communication for the entire supply chain is a difficult job for a single company. This can be achieved by more influential stakeholders, like government agencies (e.g., setting the framework, inform through workshops). Nevertheless, this does not refrain individual companies from implementing safe use in their own company, nor from attempting to improve the communication on safe use of chemicals they are themselves responsible for.

The awareness and understanding of REACH and associated information decreases down the supply chain and also with decreasing size and decreasing technological advancement of the companies.

A clear result is that size and technological advancement of the company matters. Larger companies with expertise in chemical handling and knowledge of chemical risks tend to have (or hire) experts to help them in managing those risks. Such experts are also able to interpret REACH documents and therefore can help to ensure that information in those documents is actually used to improve safe use by workers in the workplace. This is one of the reasons why tailoring of information to target groups may be a way forward. Safe use information for large and technologically advanced companies with internal experts can be technical and complex, while for SMEs and companies that do not consider themselves as users of chemicals' information should preferably be in another form, less technical and more focused on what needs to be done.

In the case studies also the organization level of a sector affected the risk communication in the supply chain, e.g. whether hiring (sub)contractors was inherently part of the sector.

 Improvement of collaboration between REACH and OSH (domain and expertise) is considered relevant in companies, sector organizations and at European and national authority level. A strongly supported finding is that there should be a better alignment between REACH and OSH (at the level of authorities, experts and information). It is acknowledged that REACH provides valuable information on hazards and risks, and that people and experts responsible for OSH should use that information to improve safe use conditions. On the other hand, OSH information is relevant to be used in developing ESs, OCs and RMMs in REACH assessments. Several interviewees and workshop participants thought that if a proper chemical risk assessment already exists in a company, that the REACH information, except when new hazards are identified, will not significantly change that assessment and the related risk management. In case of new identified hazards, high quality REACH information should be very valuable (if this information is appropriately communicated to the user). On the other hand, it is known that not in all workplaces a proper chemical risk assessment is performed, in which case REACH information probably will also not have an important impact.

OSH and REACH regulations should be better aligned, but only relatively few people are connected to both domains. Also within larger companies there is often still a gap in knowledge, expertise and language between REACH experts and OSH experts. An advantage of proper collaboration with OSH-representatives is that they tend to know the specific situation in their workplaces. Also, they are known at the workplace and therefore probably generally more trusted as source of information than the suppliers of REACH documents. OSH experts can also assist in raising awareness and in interpreting information coming from REACH. Where necessary, they can also indicate in their companies a need for external support.

Fortunately, at a European level there are already activities to promote the cooperation between REACH and OSH. For instance, the position paper of CEFIC (2021) and the executive director of ECHA Hansen urges better alignment between OSH and REACH ahead of talks on future of REACH authorisation (Chemical Watch, 2021).

11. There is limited involvement of various sector organizations in the up- and downstream communication.

Several information sources in each of the work packages in this project indicate that supportive activities by sector groups or industry associations can be very useful to improve working conditions in end user companies. Sector organizations can combine knowledge and experience from multiple companies and can organize larger projects and activities for a large part of the sector. They usually also have a good overview of what is going on in the sector, although mainly the larger companies are a member of sector organizations and the knowledge of sector organizations of the smaller companies and their needs may be less. There is experience with (subsidized) projects by industry associations in the Netherlands and other countries that have led to substantial awareness and actions towards improved working conditions. Several sector groups also play an important role in the development of tools for REACH. However, not all sectors have a sector organization and not all companies within a sector are members of the sector organization. And not all existing sector groups and industry associations are very active in this field. One of the issues in this regard, is that they have no formal role/responsibility in REACH. Another issue is the fact that they are funded by their members, so if these members think that actions on this subject are not relevant, the sector organization may also not take the initiative to improve it.

12. The issues identified, partly via the case studies in this study in the Netherlands, are recognized by international workshop participants.

Although the case study interviews were only performed in the Netherlands, the general view from the workshop participants is that the findings in the Dutch case studies on a number of aspects are valid for the EU as a whole. Especially, the complexity of the REACH documents was internationally recognized. This finding is

supported by the (international) studies, analysed via the analysis of existing information, which largely resulted in the same issues.

13. REACH is an international (EU-wide) legislation, but the surrounding area (legislation, organisations and culture) is more national, which influences how REACH is perceived and implemented in practice.

REACH is EU-wide. However, the surrounding legislative, organizational and cultural area is partly more national. There is a perception, reported in some case studies, that some national legislations may not be harmonized with REACH and that this may lead to additional complexities. In some studies, a difference in support from national organisations in safe use of chemicals was suggested as a reason for differences in perception and/or implementation of REACH safe use information. Also quality differences between the EU countries regarding enforcement with the REACH legislation was mentioned. However, this was not clearly recognized during the workshops.

Overall, we conclude that the findings of our project provide very useful insights into a better understanding of how safe use conditions are presently derived and how they are communicated up and down the supply chain. This report provides a good overview of the needs of suppliers and downstream users related to information needed to enable them to derive, describe, implement and sustain safe use conditions. We have assessed the (sociological) factors that influence how information on safe use conditions (and the need for these) is comprehended by actors in the supply chain and how that affects the communication and use of this information. In the next chapter, we will indicate how the present methods and tools for communication of information on safe use conditions up and down the supply chain can be modified to improve the understanding and use of safe use information both in creating such information (for examples ESs) and in using it in the workplace.

6 Recommendations

Based on the results of this study and the conclusions in the previous chapter of this report, we provide below possible improvements related to safe use information in REACH. Some recommendations may have a higher priority than others. The research team has not ranked them. We consider it up to the actual stakeholders to decide on priority of the recommendations.

The following recommendations are provided.

- 1. Clarify the intended target group for the REACH documents, specifically the ES and ensure that the REACH documents are accompanied with understandable information adapted to the intended target group. It is recommended that ECHA in its guidance documents makes it very clear that REACH puts obligations on <u>companies</u> (as registrants or downstream users). And that this implies that responsible persons in those companies should arrange that these obligations are fulfilled. While it is in principle up to each individual company to arrange this, guidance by ECHA can more strongly indicate that sufficient chemical and occupational safety and health expertise is required, also in downstream user companies and that this expertise, if not in-house, should be found externally. The arrangement of the applications may require adaptation for the correct level of understanding in the company, which should also be clarified. National REACH helpdesks and sector groups are stimulated to support this message to those that seek their assistance.
- 2. To limit the length and complexity of REACH documents, specifically the ES, they should be simplified in format and content and, as far as possible, tailored to specific target groups.
 - a. Experts in large companies can work with complex technical documents
 - b. Responsible persons (usually the employer) in smaller and less technologically advanced companies should receive, in addition to the SDS, more tailored, pragmatic information in terminology understandable to them (e.g., use icons, less jargon and abbreviations, more tailored to the workplace, less pages, no conflicting information from different documents). However, these responsible persons should be able to understand and apply RMM to the workplace, or realise that something needs to be done and hire an expert
 - c. Therefore, responsible persons in end user companies could be educated (guidance and training) in the interpretation and use of (extended)Safety Data Sheets.

On both levels of technological complexity it is recommended to provide easy to use, simple documents. For the experts extra information or details can be added if necessary.

It is an obligation to actors in the supply chain (registrants, formulators, distributors) to supply useful information. It is therefore recommended that they should, as far as possible, send only those ES to specific end users or end user sectors that are relevant to them. And they should ensure that the content is understandable, e.g. by using dedicated wording or by providing additional explanation for standard (expert) wording. An option is also to invite the receiver specifically to ask for clarification if needed.

Education is specifically important for end user companies in SMEs and those in larger companies with lower technological advancedness. Authorities could stimulate end user sector groups to set up such education and an important element should also be obtaining insight in when external assistance would be needed.

- 3. Digitization of the documentation and the transfer (e.g., XML files), specifically of SDSs and ESs, can facilitate tailoring of information to target groups and updating documents in an automated way.
 - It is recommended that actors in the supply chains together with software builders search for proper ways to use digitization of information that will facilitate updating of documents as well as tailoring information. The initiative should be at the registrants, together with the formulators, because they have the need to send information further downstream. Involvement of end user representatives is recommended, because they will need to be able to work with the results.
- 4. The several potentially useful tools that already exist could be better implemented and aligned with the target audience. A more detailed study of why specific tools are not better implemented could be useful for this purpose. Implementation would be a shared responsibility of tool developers and groups of tool users (sector groups). DUCC could take the lead. It is recommended that (national) authorities support this e.g. via financial stimulus.
- 5. Arrangements should be made to ensure more and better feedback from receivers of safe use information (downstream) to the suppliers (upstream), that is:
 - The relevance of providing feedback should be made clear to downstream users;
 - b. Suppliers should actively ask for feedback;
 - c. Proper digitization may help in the provision of feedback;
 - d. Develop a standardized manner to implement the legal feedback structure up- and downstream which is already part of the REACH legislation.

The legal opportunity to provide feedback is part of REACH, but there is no obligation to either provide or ask for feedback. It is recommended that authorities (e.g., ECHA) in their guidance emphasise the relevance of feedback more. It is also recommended that the providers of information (registrants, formulators, distributors) regularly ask for feedback, specifically at the first sending of supplies with safe use information to their downstream users.

- 6. End users or their representatives should be more involved in the (further) development of safe use information in REACH and of the tools to communicate that information.
 - It is recommended that organisations of end users (*i.e.* users downstream of distributors and formulators) are actively contacted by the actors upstream (mainly formulators) to participate in further development of tools. It is also recommended that ECHA actively invites such end user organisations to their relevant working groups and networks, such as the ENES. Authorities (the EU Commission, national authorities) could stimulate such end user representation via discussing the relevance with local organisations and potentially financial stimulus.
- 7. It is recommended that not yet (very) active sector organizations play a larger role in the communication processes, specifically to support the smaller companies in their sector:
 - a. A legal role for sector organizations in the process might be useful;
 - b. Financial support for sector organizations e.g. from subsidies or innovation funds could be helpful;
 - ECHA could provide more guidance for sector organizations on how to improve the supply chain communication. An ENES like platform should be realized.

The legislators could consider whether it is possible to provide a legal role for sector organisations. Authorities and funds can support sector organizations

financially. ECHA can put more emphasis on participation in the development processes in their guidance and other communications.

- 8. A better harmonization should be arranged between the REACH and OSH regulations and documentations, both in the information as well as in the expertise.
 - a. OSH expertise should be involved in interpreting REACH information for end users, either via sector groups or external experts. Also vice versa would be beneficial.
 - b. OSH legal requirements (such as the mandatory hierarchy of control) should be respected under REACH information (Exposure Scenarios) provided to Downstream users. REACH and OSH language and measures need to be harmonized. Upstream communication of relevant data needs to be improved.
 - c. Bring REACH and OSH experts into contact with each other like in trainings and workshops.
 - d. Collaboration between REACH and OSH should be established at the national and European authority level.

For a, sector organisations such as CEFIC and DUCC should ensure (at their own level) or stimulate (at their downstream users level) that OSH expertise is involved in preparing and using REACH safe use information.

For b, there is a responsibility for authorities (e.g. ECHA and DG Employment) as well as sector groups to promote harmonisation.

For c, ECHA and authorities, but also e.g. Cefic or other sector organisations, can organise relevant meetings, trainings and workshops.

For d, both EU and national authorities are recommended to regularly ensure that REACH and OSH experts align their work and perspectives.

9. Promote using the insights from the social sciences in the REACH and OSH domain.

Insights from the behavior change literature, including determinants of behavior and techniques to change these determinants could be used to improve the safety behavior of employees (OSH), but also how users in the supply chain handle ES and SDS (REACH). For instance, to change the evaluation of ES (i.e., attitude) positive and negative consequences in the short and long term can be provided. To influence the social norm successful examples of companies that used an eSDS can be given. To learn a skill graded learning is advised, that is, start with a simple behavior (e.g., handling a simple SDS for one chemical in one's company) to more complex behaviors (e.g., an eSDS for a mixture). Examine in a company possible barriers in handling ES, like lack of expertise or lack of time, by adding a checklist to the eSDS with possible problems and solutions. Besides these conscious processes in behavior change, also unconscious processes are at work like nudges or habits. A nudge is a change in the environment that automatically promotes the wanted behavior. For instance, if a company receives an eSDS by mail, in the mail a picture shows a person who distributes the eSDS to other persons.

The supply chain consists of several sender-receiver dyads. Characteristics of each affects how the communication is processed. If a sender is not trusted or disliked the communication is not well received. Smaller companies may not trust large companies, because they think large companies only focus on their own profit and don't take into account the interests of small companies. Thus knowing who are seen as trusted senders by receivers is important, and not trusted senders' image should be changed (if possible).

Message design is also an important factor as described in the report (e.g. too long and complex ES). In the domain of patient education quite some attention is paid to how physicians communicate the scientific evidence regarding treatment described in guidelines to patients. One such research line is the communication of probabilties

of success or side-effects. For instance phrasing in verbal terms is not recommended, because these terms are interpreted quite differently by persons and events (e.g. a small chance of cancer related incidents is assessed as a lower probability than a small chance of rain). Numerical terms are advised, but then not in percentages but in frequencies using the same denominator especially in comparisons (e.g., 10 out of 100 versus 20 out of 100). Also visuals can promote the understanding of risks. In the Netherlands there is an institute (i.e., Pharos) dedicated to develop medical information that is also understood by persons with lower health literacy. Such an institute provides advice that is also useful in the REACH and OSH domain.

We have provided some illustrations why we recommend that insights from the social sciences is more used in the REACH and OSH domain. The present Cefic LRI B23 project is a good example how to implement this. Another manner is that large companies not only have OSH specialists but also social scientists to collaborate in handling REACH documents and transferring this to OSH fitted documents for their employees.

The findings of our project have provided a better understanding of how safe use conditions are presently communicated up and down the supply chain and how this can be further improved. We strongly suggest that the solutions provided in this report should be followed up by formulating a more concrete action plan for the various stakeholders in this complex process. We recommend in potential future research to use the generic information from the current B23 project and to focus on a smaller, but more homogeneous group, like SMEs in a specific sector, and to use further interviews and questionnaires to get a more specific picture of the REACH communication in that specific supply chain. The picture of this particular supply chain can subsequently be broadened by including SMEs from other sectors or other stakeholders from the same sector.

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8 Signature

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Appendix 1: Glossary

AISE International Association for Soaps, Detergents and Maintenance Products

ART Advanced REACH Tool
CAD Chemical Agents Directive

Cefic European Chemical Industry Council

Chesar Chemical Safety Assessment and Reporting tool CLP Classification, Labelling and Packaging

Concawe Environmental Science for the European Refining Industry

CoU Conditions of Use

CSA Chemical Safety Assessment
CSR Chemical Safety Report
DNEL Derived No-Effect Levels

DSD/DPD Dangerous Substances Directive / Dangerous Preparations Directive

DU Downstream User legally is a company. However, a company does not act, but responsible persons in a company act

and these vary. Depending on the size and kind of company the responsible person could be an OHSE officer,

occupational health contact person, team leader, or a foreman.

"Companies or individual workers who use chemicals are called downstream users in REACH and CLP. This includes companies who manufacture goods or offer services where chemicals are not the main element of their business, such as food, construction or cleaning companies. The chemicals used typically include paints, metals, adhesives, solvents

and cleaning agents.

DUCC Downstream Users of Chemicals Co-ordination Group

ECETOC European Centre for Ecotoxicology and Toxicology of Chemicals

ECHA European Chemicals Agency
EFH Exposure Factors Handbook
EGRET GES Risk and Exposure Tool

ENES Exchange Network on Exposure Scenarios

ES Exposure Scenario

ESCom XML Exposure Scenario data exchanger between IT system

eSDS extended Safety Data Sheet

FECC European Association of Chemical Distributors

FEICA Association of European adhesives and sealants manufacturers
FORUM Forum for Exchange of Information on Enforcement (ECHA)
GEIS Generic Exposure Information Sheet

GES Generic Exposure Scenarios
GHS Globally Harmonized System
HSE Health and Safety department
LEV Local Exhaust Ventilation
LCID Lead Component Identification

MS Member State

NVZ Nederlandse Vereniging voor Zeepfabrikanten

PNEC Predicted No-Effect Concentration

PROC Process Category
OC Operating Condition
OEL Occupational Exposure Limit
OHS Occupational Health & Safety
PBT Persistent, Bioaccumulative and Toxic
vPvB very Persistent and very Bioaccumulative

REACH Registration, Evaluation, Authorisation and Restriction of Chemicals

RMM Risk Management Measures

Safe use This is not a term used in REACH Regulation itself. The Guidance on information requirements and chemical safety assessment. Part A: Introduction to the Guidance document describes this as follows: (the chemical safety assessment

shall): "ultimately identify and document the conditions of manufacture and use which are needed for controlling the

risks to human health and the environment." These conditions are called 'safe use conditions'.

SCED Specific Exposure Consumer Determinant

SDS Safety Data Sheet

SME Small and Medium-sized Enterprise SPERC Specific Environmental Release Category

Study A study is any documented item that provides either research or practical experience or stakeholder opinion on how communication of information on safe use conditions is or should be functioning. Therefore, scientific studies fit within

communication of information on safe use conditions is or should be functioning. Therefore, scientific studies fit within this definition, but also descriptions of what the members of sector organisations experience as well as opinions of

stakeholders on what can or should be improved in the scope of communication of safe use conditions

SUMI Safe Use information for Mixtures sVHC substances of Very High Concern SWEA Swedish Work Environment Authority

Tool Indicates a wide arrange of items that are intended to contribute to the realisation of safe use of chemicals via

communication of information through the supply chain. In this broad definition, a legal instrument can be a tool, because it requires certain communication to be made. A guidance document on how to communicate information is also a tool in this definition. And finally, there are, of course, IT tools, such as software formats for information exchange.

TRA Targeted Risk Assessment

Appendix 2: Data extraction Table



Appendix 3: Tools

A.3.1. REACH Regulation

Goal

REACH (European Commission, 2006), issued on 18 December 2006, replaces a number of different EU chemical Directives or Regulations. The legislation, next to other elements, sets rules for downstream communication on chemicals. It indicates what needs to be communicated on safe use conditions downstream, as well as the formats for this communication, being the SDSs and ES. It also specifically provides the option for upstream communication if a specific use of a product has not yet been assessed by the registrant. It also regulates that for hazardous substances an ES is required, but that this is not obligatory for mixtures.

Publisher

European Parliament and Council in Brussels, Belgium and Strasbourg, France.

Target group

The regulation is targeted at all the stakeholders in the supply chain of chemicals that need to adhere to it. This group includes large or smaller chemical manufacturers, importers, Only Representatives (parties performing tasks within REACH on behalf of importers), formulators of mixtures and end users. In addition, REACH also gives tasks and responsibilities to central and local regulators and law enforcement. It is also very important to policy makers and associations/platforms focusing on the safe use of chemicals and consultancies that assist authorities, manufacturers or other stakeholders.

Relevant methods

Since the initial REACH legislative text was issued in 2006, several amendments have been published to account for newly registered substances, changes in restrictions, adjustments in testing requirements, adaptations needed for the implementation of Classification, Labelling and Packaging (CLP) etc. All these documents, as well as the latest consolidated version of REACH, are available to the public via the website of ECHA.

REACH has a very large number of methods by which it intends to ensure safe use of chemicals. These include the processes that are included in the acronym REACH: Registration, Evaluation and Authorization of CHemicals. Furthermore, REACH is the Regulation that governs and sets the criteria for SDS and for ES as a tool to communicate safe use information downstream. Those methods of REACH more directly aimed at communicating safe use information will be separately described below.

A.3.2. Chemical Safety Report

Goal

A Chemical Safety Report (CSR) (ECHA, 2018a) is a detailed report on the chemical safety assessment (CSA) that is a mandatory part of the registration dossier of a chemical substance. It is not per se intended as a tool for communication. However, because it is the starting point and also contains the ES, that are also (in the same or modified form) added to the (e-)SES, it is mentioned here as a tool anyway. The CSA gives an in-depth examination on whether the substance may lead to human health and environmental hazards and assesses the exposure, hence potential risks and consequences of using the substance. This leads to the determination on what use conditions and risk management measures are safe for different uses and these are described within the CSR in the format of Exposure Scenarios (ES). The CSR is used to communicate the safe use conditions to the authorities, to enable them to

evaluate whether the assessment is done correctly and to allow inspections to check these conditions in workplaces.

Publisher

European Chemicals Agency, ECHA, Finland

Target group

The CSR is to be written by registrants or consulting organisations and is to be evaluated by ECHA.

Relevant methods

The CSR can be generated by using Chesar, a dedicated CSA tool developed by ECHA. The use of Chesar results in a structured, harmonised and transparent report that includes the importing of substance-related data and the description of the uses. A thorough assessment of the exposure means including the conditions of safe use, related exposure estimates and demonstrating control of risks. From the CSR, the exposure scenarios included in the registration dossier can be retrieved as a text document for further communication.

A.3.3. Exposure scenarios

Goal

Exposure scenarios (ESs) are intended to systematically describe the operating conditions for the use of a substance or mixture throughout its lifecycle and is intended to help safeguard humans and the environment from exposure to hazardous compounds.

Publisher

ESs are published by the substance manufacturer or importer that has performed the CSA. For mixtures, this information may be provided by the formulator.

Target group

Formulators may use substance ESs to compose mixture SDSs. End users may use this information, either from the formulator or directly from a substance supplier, for doing their own safety assessments.

Relevant methods

Manufacturers and suppliers must make sure that substances that are put on the market in the EU are accompanied with an ES annexed to their SDSs. This is a requirement when the substance has been registered under REACH. These ESs are prepared for hazardous substances and reported in a chemical safety report (CSR) in the REACH dossier. The ES documents the conditions of use for a substance during its life cycle and the way in which the risks to human health and/or the environment can be controlled. Suppliers of mixtures must pass on information about the various ESs for the constituents in the mixture. DUs may use the information for assessing the safe use on site and thus the ES helps them to meet their requirements under REACH and other legislation (e.g. occupational health and safety, control of environmental emissions etc). Therefore it is important that DUs, both formulators and end users, understand and implement the ESs that have been provided to them by their suppliers.

A.3.4. (e)SDS and label

Goal

A Safety Data Sheet (SDS) is a standardised document for a chemical substance or mixture to inform about the potential hazards (health, environmental, fire, reactivity etc) and inform how to safely use (including transportation, storage and disposal) the

product. The SDS might also function as a vehicle for sharing exposure scenarios in so called extended SDSs (eSDS)s. SDS are regulated in the REACH Regulation. A product label contains some of the elements of the SDS typically together with commercial information in a printed form onto the product that serves to directly instruct the end user at the working place. The labels are regulated via the CLP Regulation.

Publisher

SDSs are issued by the manufacturers, importers or distributor of substances and/or mixtures. Labels are also made available by these suppliers.

Target group

SDSs and labels are targeted both at the workers that use these chemicals and others that are responsible for occupational safety. Both tools are considered to be legal documents and, depending on the positioning of the product in the market (e.g. as a biocide, cosmetic) may be part of a dossier, which is also relevant to authorities. Furthermore, personnel of poison control centres and doctors may also assess SDSs and labels in case of a medical accident. Information on how to deal with a fire caused by the chemical and the disposal of it is relevant to fire fighters and local authorities, respectively.

Relevant methods

Both the safety data sheet (SDS) and labels are directed via the Regulation on Classification, Labelling and Packaging of chemical substances and mixtures (CLP) (EC 1272/2008) and, depending on the nature of the chemical, may include information on harmonised hazard and precautionary statements, hazard pictograms and OC and RMM. SDSs and labels may both also provide additional information for instance on physicochemical properties and OCs and RMMs. The format of the SDS document is defined in REACH and is subdivided into 16 sections. Each section is described in detail in ECHA's guidance document products. Labels are typically attached to the package of a product and include at least the commercial name of the product, the manufacturer, CLP information in case of a hazardous product and usually the instructions for use. Depending on the intended use and (local) rules, additional information must be provided, for instance the active ingredients and shelf life in case of biocides.

A.3.5. ECHA Guidance in general

<u>Goal</u>

The ECHA Guidance (ECHA website) documents in general aim to help stakeholders in fulfilling their obligations under legislation, in this specific case REACH.

<u>Publisher</u>

European Chemicals Agency, ECHA, Finland.

Target group

The target groups for various guidance documents differ, depending on the specific Guidance document. Quite a substantial number of Guidance documents is aimed at registrants of chemicals under REACH and their advisors. These are large or smaller chemical producers, importers, Only Representatives and consultancies.

Relevant methods

The Guidance documents have different forms and different depth of description, depending on the subject and the target group. There are various types of guidance,

both in document form (PDF) as well as interactive web guidance (see Figure A.1). These are briefly described here.

- Navigator: interactive web-based guidance to help stakeholders determine their obligations under REACH
- Formats: (annotated) templates that can be filled in to perform part of the activities; there are e.g. annotated templates for Exposure Scenarios
- Guidance in a nutshell: relatively short guidance documents explaining obligations in simple terms, e.g. guidance in a nutshell for downstream users
- Practical Guides: slightly more extensive documents explaining relevant elements in the focus of the specific Practical Guide with text, flow diagrams, examples and case descriptions; example: Practical Guide 13: How downstream users can handle exposure scenarios
- Factsheets: very brief (e.g. 2-pager) document with very concise explanations, tips and links to further documentation, e.g. "Guidance and tools for downstream users"
- Guidance documents: in-depth documents with partly scientific guidance on specific subjects; for instance the Guidance for downstream users is 213 pages.



Figure A.1. Illustration of the interactive web-based guidance of ECHA on the safe use of chemicals.

A.3.6. ECHA Guide on Safety data sheets and Exposure scenarios Goal

The purpose of this ECHA guidance (ECHA, 2018b) is to provide more in dept knowledge in what SDSs and ESs should include and where to find all of this information. Hence, this guidance acts as a tool for using other tools.

Publisher

European Chemicals Agency, ECHA, Finland.

Target group

This guidance document is targeted at recipients end users (downstream users at the end of the supply chain, *i.e.* not being formulators or distributors/repackaging companies that supply chemical products to others, formulators and suppliers (distributors, wholesale companies) of chemical substances and mixtures.

Relevant methods

The document gives a detailed description of the SDS and ES per section, addresses the items that need special attention and what information must be included. Also

what the source of that information should be and where applicable references to the relevant regulation or other guidance documentation can be found. A few examples are given and a closer look is given for the both recipient and the supplier

A.3.7. eSDS: ECHA Fact sheet

Goal

This ECHA Fact sheet (ECHA, 2016) introduces DU to SDSs and ESs by describing what SDSs and ESs are, when they should be obtained and the DU actions needed upon receiving them.

Publisher

European Chemicals Agency, ECHA, Finland

Target group

This short document is targeted at industrial or professional end users and formulators of hazardous chemicals.

Relevant methods

This factsheet of 3 pages explains to DUs the relevance of SDSs and ES, what information must be included in the SDS and ESs and when and how DU can expect to receive this information for both substances and mixtures. Also described are the steps to take when the information is received and what to do when the use or conditions of use of the DU is not taken into account. And for more details references to additional information are given.

A.3.8. ESCom phrase catalogue

Goal

The ESCom phrase catalogue (Cefic, 2018) provides a standard set of phrases on the safe use of chemicals in the eSDS. It is intended to enable a consistent and harmonised way of communication of ES information resulted from a CSA throughout the supply chain and to improve the exchange of ES data between IT systems. The Ultimate goal is to ensure that the same wording is used by all actors in the supply chain for the same things, thereby minimising misunderstanding caused by terminology differences.

Publisher

The European Chemical Industry Council, Cefic, Belgium.

Target group

The phrase harmonisation tool designed with automation advantages is to be used by registrants (Manufacturers/Importers) but also formulators and end users benefit from the standardisation in the safe use communication. A further target group is the providers of IT tools for storing and communicating SDS and related information, that can include these standard phrases with codes to facilitate e.g. automated translation of phrases

Relevant methods

The ESCom phrase catalogue is an Excel spreadsheet with standard phrases and metadata. It can be retrieved free of charge from the download centre and there is also a version that is fully compatible with the latest version of ECHA's CSA tool Chesar. An XML format for the standardised and harmonised phrase package exchange is also available as well as guidance on how to submit new phrases to the catalogue using the Webtool. Examples of ESCom phrases are "Avoid carrying out operation for more than 1 hour.", "Ensure that the activity takes place in a downward

laminar flow booth with partial screens and fitted with glove ports" and "Ensure that worker is in a separated (control) room".

A.3.9. Generic Exposure Scenarios

Goal

Generic Exposure Scenarios (GES) (Money et al., 2011) have been developed to provide a consistent and efficient way of communicating across the supply chain. The scenarios, also known as GES use titles, and supporting use descriptors for workers, consumers and the environment, have been initiated by the European Solvent Industry Group (ESIG) in liaison with other sector organisations to align with solvent use information relevant to a wide range of sectors. This partnership (ESVOC), which contains a large number of formulator associations and some end user associations, ensures that GESs present REACH information including all relevant OC and RMM that are aligned with the practical situations at DUs and are presented in comprehensible terminology that can also be used for downstream communication of safe use in (e)SDSs.

Publisher

GESs are developed by the European solvents industry (ESIG) in Manufacturers and Importers in collaboration with other sector organisations, e.g. AISE, CEPE, FEICA, mainly representing formulator companies. The list of all GES titles and use descriptors is available on the ESIG website https://www.esig.org/reach-ges/. Outside of the solvents area, similar initiatives have resulted in the development of SWEDs or of similar overviews of conditions of use, not called GES, e.g. the EuPC Use maps v1.0 - Worker Conditions of use tool Annex.

Target group

Manufacturers and Importers may include the GES uses and conditions in their REACH dossier. Formulators may us the GES data for generating mixture SDSs. End users may use this information, either from the formulator or directly from a substance supplier, for performing their own safety assessments.

Relevant methods

GESs have been developed based on how exposure would commonly take place and to enable exposure assessors with evaluating, estimating or quantifying the exposure of a substance. In the development, several organisations of companies formulating or using solvents were cooperating. A GES is applicable to a group of substances with a similar risks and within one or more specific industry sectors. Each GES consolidates the relevant tasks/activities involving potential for exposure (Contributing Scenarios) which are linked to applicable use descriptor codes. Thus they describe the conditions of a recommended use for a substance and how to control the risk to human health and/or the environment. The GES use standard phrases (ESCom phrase catalogue, which are available in all European languages and are related to recommended expected exposure reductions proposed by exposure prediction models like ECETOC TRA. This information can be shared via (e)SDSs and allows DUs to determine the safe use on site. The GES concept and set-up have been endorsed by ECHA and CEFIC.

A.3.10. Use maps

Goal

Use maps (AISE website; ECHA 2020; Portugal, 2019) have been designed to give a sector-specific overview of the typical substance uses arranged by their life cycle stage and are created to inform the registrants about how their substances are used in the supply chain in a harmonised manner. Each 'use' has been given a 'use name'

together with a brief market description and a number of contributing activities are also listed.

<u>Publisher</u>

Use maps are issued by the various sector organisations and are also available on the website of ECHA.

Target group

Downstream user organisations can inform suppliers about the Use maps to give realistic and useful ESs in a harmonised and consistent way. This is in accordance with REACH Article 37.2. Registrants can use this information to fine-tune their CSAs and make it more representative for the downstream use sector.

Formulators will be able to more easily process the information received in the ESs from several substances in a mixture, as the conditions of use will be systematically expressed in the same way.

Relevant methods

Sectors' information on Use maps is typically captured in Excel sheets. These Use maps libraries contain the use description and the input parameters for workers exposure assessment. In some cases, they are mainly descriptions of uses and conditions in spreadsheet formats. In other cases they contain more structured descriptor sets, such as Specific Worker Exposure Descriptors, that can be directly used in exposure models (SWEDs), Presently, for those sector groups that procude SWEDs, the differentiation between Use maps and SWEDs appears to be largely the format and the fact that the Use Maps, next to SWEDs contain similar descriptor sets for consumers and the environment. Other sector groups only have Use maps without the descriptor sets. The Use maps are made available for the sector-specific uses. Currently, Use maps libraries have been initiated by individual sector organisations including the International Association for Soaps, Detergents and Maintenance Product (AISE); Fuels (Concawe); Cosmetics and personal care products (Cosmetics Europe); European Crop Protection Association (ECPA); European Federation for Construction Chemicals (EFCC); European Solvents Industry Group (ESIG); European Plastics Converters (EuPC); Association of the European Adhesive and Sealant Industry (FEICA), Fertilizers Europe and I&P Europe for Imaging and printing products.

A.3.11. SWEDs

Goal

Sector-specific Worker Exposure Descriptions (SWEDs) (ECHA website) are aimed to inform on conditions of use and respective risk management measure for products used by industrial and professional workers. Registrants can use the data as an input to their ESs and improve their CSA. SWEDs include suitable standard phrases that help registrants effectively communicate the exposure scenarios attached to the safety data sheet to the downstream user. The SWEDs are generally a part of the Use map system of a sector group and often provided also in an xml-format for direct integration in the Chesar software tool for exposure assessment published by ECHA.

<u>Publisher</u>

SWEDs are issued by the various sector organisations and are also available on the website of ECHA.

Target group

SWEDs are to be used by DU to channel information to their suppliers. This bottom up communication is often not done by the end users but by the sector organisation of the formulators.

The registrants may use the newly obtained information for updating their existing REACH dossiers.

Relevant methods

DUs can use smart Excel based SWED coded templates to indicate the conditions of use in practice. The recipient is the registrant who can link the information to ECETOC TRA or other risk assessment method. The registrants may use the newly obtained knowledge for updating their existing REACH dossiers and, if found safe, communicate the CSA outcome via an eSDS revision. If the use is not found to be safe, more stringent conditions could be communicated to the DUs.

A.3.12. SUMIs

Goal

Safe Use Mixture Information for end user (SUMI) (NVZ, 2018) is a tool to communicate safe use information in line with REACH article 31.7. This is done by simplifying and standardising the communication to professional and industrial users on operational conditions and risk management measures.

Publisher

In order to have relevant and understandable SUMIs, sector associations have developed their own, standardized set of SUMIs for generic uses. For instance for the detergents, the AISE (AISE at ECHA website) and the Dutch association for detergents, maintenance products and disinfectants (NVZ).

Target group

Formulators of mixtures can use the SUMI templates as practical tool to communicate tailor-made safe use information to the professional and industrial end users. DUs can use these SUMIs to understand the operation settings and RMM that have been found to be safe when using the mixture.

Relevant methods

End users will be informed per chemical (mixture) about the applicable SUMI templates which are about one A4 size that will give a short and standardized description on the operational conditions (e.g. maximum duration and linked to a SWED code) and risk management measures (e.g. use of specific personal protective equipment and sometimes also good practice advice and information depending on product composition. Pictograms on PPEs and good advice e.g. 'don't smoke' or 'wash hands after use', may also be included. SUMIs may be appended or may be referred to in the body of the SDS using the SUMI codes.

A.3.13. Supply Chain Communication Guidance (Cefic)

Goal

Cefic's Supply Chain Communication Guidance **Fout! Bladwijzer niet gedefinieerd.**(Cefic, 2009) is composed of a number of documents aimed to support manufacturers and importers with the downstream communication.

<u>Publisher</u>

The European Chemical Industry Council, Cefic, Belgium.

Target group

The documents are mainly targeted at substance manufacturers.

Relevant methods

These Cefic guidance documents inform on the ES development and supply chain communication, letter and fact sheet on use communication, messages to

communicate in the supply chain on eSDS for substances; a presentation on supply chain communication tools and Cefic's standard reply on use communication. The main points of interest are the Guidance on ES development and supply chain communication, the letter and fact sheet on use communication, messages to communicate in the supply chain on eSDS for substances and Supply chain communication tool – user interface constraints and xml format schema. This toolbox also informs about IT functional requirements to build IT tools to support supply chain communication, Cefic standard reply on use communication and Supply chain communication tool: interface constraint.

A.3.14. Blueprint of a coherent system for generating, communicating and receiving safe use advice for hazardous chemicals

Goal

The goal of the blueprint is to map the actions and tools to sustain and further improve the workability and quality of eSDSs (ECHA, 2018d).

<u>Publisher</u>

European Chemicals Agency, ECHA, Finland.

Target group

The blueprint is targeted at manufactures of substances, formators of mixtures and end users as described below.

Relevant methods

In the ideal situation for the stakeholders of ENES, the tools/standards for manufacturers are Chesar, ESxml and eSDS authoring, for formulators a formulator's tool box, sector SUMIs, ESCom phrase catalogue and sector Uses maps from the ECHA site. The end users assess/check whether or not their practice in the different activities with the chemical is covered by the risk management as mentioned in the SDS. The supplier's risk management advice would then play a major role in the OSH workplace risk assessment of the chemicals user.

The manufacturer has a role as the registrant to select and upload the relevant Use maps or other data, runs the CSA based on substance data and integrate data into an SDS. The formulator does a conformity check, selects relevant ES or generate it's own ES, integrates the mixture data into an SDS and checks again the relevance of the ES with an eSDS for the mixture as the result. The end users check the conformity and confirms, complement or substitute the data by own assessment and potentially apply changes in practice.

A.3.15. Workplace Instruction Cards

Goal

Workplace Instruction Cards (DGUV, 2012, 2019), also known as WICs, are made available by DU companies to inform their workers in a clear and brief manner how to safely handle hazardous substances or products. In addition to raising awareness on the safe use of chemicals, the WIC allows the DU company to comply their obligations under REACH, Transport regulations and Occupation Health and Safety regulations.

Publisher

Workplace Instruction Cards are issued by or on behalf of DU companies. They are usually company specific.

Target group

WICs are to be used by workers, e.g. a cleaner or painter, using hazardous chemicals on-site and who may need to work under defined operational conditions and/or wear

appropriate PPEs. WICs may also be used for educational and purposes and by trainees.

Relevant methods

WICs are product-specific short (typically an one-pager) risk and safety communication used by DU companies to instruct their workforce on-site. Although there is no formal data set requirements, the WICs typically describe the hazards and precautionary statements, the relevant PPEs and OCs, first aid measures and procedures in case of a calamity. Information for this could be gathered from the relevant (e)SDS, SUMI and/or own safety assessment using for example the exposure scheme Stoffenmanager. In the Netherlands, the RAS (Raad voor Arbeidsverhoudingen Schoonmaak- en Glazenwassersbranche) developed a handy tool where the GEIS (Generic Exposure Information Sheet), the predecessor of the SUMI used in the industrial and institutional cleaning and maintenance sector, could easily be converted a WIC, but with the introduction of the SUMI this tool is currently being adjusted. The format for the WIC could be a hard copy document, like a posters, and located in the main areas of the facilities that most of the employees access. Alternatively, an app for a mobile device like a cellular phone may be used at the workplace.

A.3.16. Lead Component Identification Methodology (LCID)

Goal

The goal of the LCID (CEFIC & VCI, 2019) is to present a method to derive safe use conditions for mixtures by evaluating which components determine the safe use conditions. These so-called lead components are generally the ones needed the most stringent use conditions to be used safely. The method describes how to evaluate what the lead components are.

Publisher

The developers and publishers of the LCID are Cefic and the VCI (Verband der Chemischen Industrie e.V.).

Target group

The evaluation of the safe use conditions for mixtures is mainly a task for formulators, because they have definitive information on the composition of the mixtures they produce. However, end users know how they will use the information and that is also relevant. Therefore, both groups are considered the target group.

Relevant methods

The method starts with identification of the composition of the mixture. Priority substances, often determining the safe use conditions, are identified, e.g. carcinogens and mutagens or substances that are persistent, bioaccumulating and toxic or very persistent and very bioaccumulating. Furthermore the classified substances with limit values (e.g. DNELs) are identified. It is identified which substances have additive effects, local effects or ozone depleting potential. Specific conditions affecting exposure, such as aerosol formation or embedding in a matrix are also taken into account. The concentration of the substances in the mixture is taken into account, as well as their limit values to rank the components in importance for setting safe use information. Once the lead components are defined, the safe use information is derived from the exposure to these substances.

The guidance also provides considerations for how to communicate the safe use conditions for the mixture, which were derived from the lead components, e.g. via integration in the body of the SDS or via an Annex similar to an Exposure Scenario.

Appendix 4: Studies

As indicated earlier, the phrase 'studies' is used in this report as an umbrella term for various types of communication and documentation in relation to scientific or practical studies of the communication of safe use information, the tools used therein and the opinions and perceptions of stakeholders on this subject. The form in which these 'studies' are published may be in scientific publications, study reports, workshop presentations, posters, articles in news media (e.g. Chemical Watch) and other forms.

To date, several of these studies have been performed to understand the outcome of the implementation of REACH and what might need to be done to further optimise this. In this project, a number of the studies that are available to date are presented. The focus is on studies related to the safe use communication instigated by REACH. There are also various studies related to costs of the REACH processes, exposure assessment tools used, etc. These are not the focus of this report. Studies on safe use communication not specifically related to REACH, but to e.g. Occupational Safety and Health legislation or other triggers for safe use communication that have also been gathered, if found.

Most of the studies have been carried out either by ECHA, Cefic or on behalf of a local authority in one of the Member States (MS).

In the subparagraphs below, a number of studies have been summarised in chronological order:

A.4.1. Study on the Communication of Information (2012)

Goal and methods

This ECHA study (ECHA, 2012) was carried out to assess how hazard communication is perceived by the general public and whether the new CLP labels (pictograms) were understood. For this purpose, data was obtained from two surveys and consultants' reports and from an extensive consultation by the Agency's Risk Communication Network. In the study more than 26000 European citizens from all Member States were interviewed and several competent authorities were involved in nominating participants, in particular from the European Chemical Industry Council (Cefic) and the International Association for Soaps, Detergents and Maintenance Products (AISE), for the consultation.

The evaluation and review of the risk communication was carried out by examining people's attitude in dealing with safety instructions, their understanding of hazard pictograms and the safety language as standardised by the CLP Regulation was also assessed.

Results and conclusions

Results showed that the levels of understanding of the risks related to chemical products was considerably different between MSs. It was clear that the public was familiar with some CLP hazard pictograms, but the level of their understanding - or what they considered to be 'understanding' - varied significantly. The level of understanding of the new hazard pictograms is relatively low. The perception and processing of hazardous information are not rational processes. The relationship between risk perception and safety behaviour was found to be rather low.

No actual connection between general safety beliefs and the frequency of use could be found. The reading of the directions of use (including warnings) is common practice, but varies immensely across chemical products. With little knowledge on chemical products and time pressure in decision-making, the majority of consumers will count on superficial and quick assessments, and make use of visual signals that are displayed on the product.

The authors proposed that the product appearance and packaging should be more aligned with the hazard information of labels. By doing that, the message on the label will be better understood and the appropriate safety behaviour in users will be encouraged.

The public seemed to lack the motivation and will to read information provided on the hazard labels and was found to be largely affected in their perception of hazards by the overall product packaging and by experience instead of the hazard label itself. It was suggested to strengthen the public's knowledge on CLP pictograms by targeted awareness-raising, but also particular behavioural patterns of specific groups of the general public.

A new analysis to investigate the impact of the CLP pictograms on EU citizens' behaviour and understanding was scheduled for 2015. Staff responsible for such communication and awareness-raising activities (both at an industry and MS Competent Authority level) should meet and discuss best practice.

Industry should be motivated to align product appearance and packaging more with the hazard information on labels to promote the appropriate safety behaviour in consumers.

A.4.2. REACH supply chain challenges (2013)

Goal and methods

In this Chemical Watch article (Chemical Watch, 2013), the opinions on exchanges of information on classifications, eSDSs and substances of very high concern were assessed just before the implementation CLP. These topics were addressed in relation to several stakeholders that perform activities, including communication on safe use conditions in the REACH supply chain. Task actions and opinions of the European Commission, ECHA, trade bodies and a few companies were gathered to get a better understanding of the status quo at that time.

Results and conclusions

In 2013, there were many issues that companies were facing with respect to supply chain communication. These were writing and understanding ESs; communicating changes in the hazard classification, aligning with other companies on classifications and informing stakeholders about the presence of candidate list substances in articles. The first two of these challenges were in particular related to mixtures. The actions to tackle some of these were described in the European Commissions' REACH Review report issued in 2013. It was already clear that firms will need to use more advanced IT systems to facilitate in the exchange information. Fortunately due to REACH, some small companies already participated in an overall European chemicals management system. The general perception at the time was that the quality of information in SDSs was improved, and further steps were to be expected. At a later stage less effort would be needed for DUs when verifying their uses and comparing their operational conditions and risk management measures to those recommended in the ES. However it was not the time yet to assess these benefits, and the financial burden was also a main concern, especially for Small and mediumsized enterprises (SMEs).

The Commission agreed with the notion of eSDSs being "too complicated and often too extensive", and that the existing use descriptor system, while being of great value to large companies, was "often too demanding" for SMEs. There was also "no clear obligation to elaborate and provide a mixture-specific exposure scenario". The Commission pointed out that new or amended guidance, IT tools and awareness projects should be coordinated by ECHA, in some cases in collaboration with industry or member state (MS) competent authority for support. Nevertheless, these were expected to take time before they would become in effect.

The technical and regulatory affairs director of detergents branch organisation, AISE, and a representative of the Downstream Users of Chemicals Coordination group (DUCC) indicated that understanding ESs, once the right one has been selected, could still be difficult. This because their format and content are not defined in the REACH Regulation and there is still a large variety of IT tools. In addition, DUs have yet to develop the necessary knowledge and also language could be a barrier in a few cases.

As there is no legal requirement for making ESs available for mixtures, it is expected that formulators will be reluctant in providing this information. This is supported by the legal text of REACH that states that only required 'relevant information' on mixtures needs to be distributed. Besides that DUs are often not sure whether the substances they buy will indeed be registered and it is therefore unclear if and when they could expect an eSDS.

ECHA's Exchange Network on Exposure Scenarios (ENES), which is "clearly becoming the key reference point for ESs," put a lot of effort in aligning the trade bodies and the agency. One of their topics is establishing the principles and boundaries that should be applied to the practice of "scaling" – a method used to recalculate the original assumptions in an ES so it matches the DU's own operating conditions or risk management measured. ECHA also observed that case studies on mixtures presented by the paints, lubricants and adhesives sectors may have a common approach in grouping, prioritising and focussing on risk-related substances. Applying this approach to other sectors is possible in principle, although certain sector aspects may determine which approach is to be taken.

In parallel, a lot of work is being carried out by a number of companies and trade association to develop SCEDs and SPERCs, and SPERC libraries and templates that can be used together with Chesar. But it may take many years before different sectors agree upon common formats and content for mixture ESs, warned the DUCC.

In an interview, the Hazard communication manager of Dow Chemical mentions that, in his experience, the enforcement across Europe are "well aware of the difficulties industry is facing" in this area and that currently the inspectors focus on ESs for mixtures.

Cefic's chemical regulation manager mentioned that it is crucial to address the issue of supply chain communication more widely. He also suggested ways in which substance manufacturers and importers can help address concerns of down stream users, for instance by understanding if the substances that they purchase will be registered or not, whether a specific use of a substance is taken into account by their supplier, if a substance is subject to authorisation, and if the supplier will apply for authorisation. Companies buying mixtures or components should also know if these products contain substances that will be regarded as a substances of Very High Concern (sVHCs) as further restrictions may apply.

At the time of these assessments, the formulators of mixtures were facing the issue of having two different classification and labelling systems due to the transition to CLP, i.e. those following the CLP Regulation and those adhering to its predecessors. The limitations of the EU classification and labelling inventory, such as different classifications for the same substance but also mistakes in hazard classification, have meant that companies had to invest in staff to help also customers (DUs) to deal with these challenges.

A.4.3. Quality and usefulness of (extended) Safety Data Sheets (2014) Goal and methods

This study (Marquart et al., 2014) evaluated the state (at the time of the study) of eSDS from the perspective of the DU's who need to maintain a safe and healthy working environment that originates from the national implementation of the Chemical Agents Directive (CAD).

In this study, 50 eSDSs were assessed by experts in occupational safety and health that focussed on a formal compliance with legal requirements of REACH Art. 31 and Annex II, the quality of the data, clarity of the communicated information and the usability of this information for risk assessment and management on site.

The evaluation of the quality of the eSDS was done via a direct comparison of the data requirements with the actual available information in the eSDS. The quality of data and clarity of information was assessed by checking the consistency between different sections and expert judgement on the adequacy of the given information. The general usefulness of the eSDS for the performing risk and management assessments at the workplace was assessed by expert judgement on a weight of evidence approach.

Results and conclusions

In the report the experts concluded that none of the studied eSDSs were fully compliant. Only in one case the non-compliance issues were considered "not too seriously limit to use the eSDS in the risk assessment for the workplace". In total twenty (40%) of the eSDSs were found to be not up-to-date and ten eSDSs (20%) were not entirely in the local (Dutch) language. It was also observed that necessary details for skin protection were missing (> 85% of the eSDSs).

The type of adequate respiratory protection was not given (when relevant) in 23 of the eSDSs. Another observed shortcoming was the absence of measures to prevent risks due to materials that were incompatible with each other: 85% of those eSDSs where incompatible materials were counted.

Inconsistencies in information within the body of the SDS or between the ESs and the body of the SDS was found in 11 SDSs (22%). These inconsistencies were considered a bottleneck for the adequate use of the eSDSs.

On the safe handling methods for specific uses the majority of eSDSs, 49 of 50, were considered not sufficient on methods for the specific uses. Some eSDSs did not report on methods for safe handling, others mentioned methods for safe handling that were not justified by the physicochemical and toxicological characteristics of the substance.

Overall, none of the assessed SDSs complied fully with the specific legal prerequisites or were insufficient with respect to the quality and usability of the eSDS. According to the authors, more than 95% of the eSDSs studied did not give sufficiently useful advice, aimed at the recipient, on safe handling and risk management measures in the body of the eSDS, i.e. Sections 7 (Handling and storage) and 8 (Exposure controls/personal protection). Almost in all cases, the recommendations mentioned in these sections were phrased in a way that could be considered unclear to DU for deciding on appropriate conditions and RMM.

In about 66% of the eSDSs, the ESs were of an understandable added value to the SDS, but of the other one-thirds of the SDS with ESs, the recommendations for operational conditions and RMMs were not specific enough to be of any relevance. An explanation for the lack of specificity is not available.

It is worth mentioning that not a very large set of eSDS was studied and that the scoring was partly influenced by whether specific information was present or absent in the eSDS. The data interpretation is largely determined by expert opinion on data quality and usefulness for DUs, from the perspective of experts with knowledge in occupational safety and health and REACH.

A.4.4. Implementation of the chemicals regulation REACH – Exploring the impact on occupational health and safety management among Swedish downstream users (2015)

Goal and methods

The aim of this scientific paper(Schenk & Antonsson, 2015) is to better understand how REACH has influenced the risk management of the occupational health and safety of chemicals at Swedish DU companies and how these firms comply to the regulation.

The authors Schenk and Antonsson interviewed several groups including seven occupational hygienists and workplace safety engineers, referred to as OHS personnel, four local and four regional safety representatives. Also one representative of the Swedish Work Environment Authority (SWEA) department for regulations, two labour inspectors and one member of the inspection units from Swedish Chemicals Agency participated in the study.

The information was gathered through semi-structured interviews and in Swedish. The target was to include all major areas and address key topics in a similar manner, but the order of questions could vary between interviews in response to the informants' answers to previous questions. This method also enabled the interviewer to request clarifications, more details and examples. The main topics discussed during the interview were:

- A) Awareness, use and view on occupational exposure limits (OELs).
- B) Experience with REACH, workplace(s)'s relation to REACH.
- C) Expertise and view on the impact of REACH on OHS management.
- D) Knowledge of and vision on the communication between suppliers and users.
- E) Informant's information seeking.
- F) Use and view on SDSs.
- G) Awareness, use and view on eSDSs and ES.
- H) Awareness, use and view on derived no-effect levels (DNELs).

Authority informants were also requested to share their experience with REACH inspection efforts. The prepared questions were predominantly open-ended and in a few cases were closed with follow-up probes.

Results and conclusions

The researchers observed that knowledge and experience of the different procedures under REACH varied between informants. The advantage of REACH noted by most informants was the increase of or availability to information on risk of using chemicals. This corresponded both with SDSs and other information routes like ECHA's dissemination activities. For example, the ECHA database on registered substances was mentioned as a valuable source of information by most OHS professionals. It was unclear whether this access of information had led to useful RMMs.

Despite the fact that finding SDSs improved since REACH, informants were usually not pleased with the SDSs, in particular with the RMMs proposed in the SDS. These were in most cases described as too general, unspecific and open to interpretation. It was stressed that the type of routines used for a certain general risk management measure such as the use of gloves has a huge effect on the protection offered. A recurring example was that the SDS may indicate the kind of glove to be used, but not mention any information about how often to replace the gloves.

More expertise is needed to comprehend SDSs and the instructions within. Many smaller companies do not have in-house expertise and the budget to hire consultants, or even the understanding that such expertise is needed. Regional safety

representatives and consulting OHS professionals mentioned little awareness and understanding of SDSs among smaller companies.

Informants familiar with ESs found them complicated, referring both to the total amount of information and the difficulties in translating the information. The mix of a large number of different ESs for substances in the eSDS and difficulties to determine which scenario is relevant for the company operations and use of mixtures makes up a first hurdle. A second obstacle is the interpretation of recommended operational conditions and RMMs, i.e. understanding how to follow ESs. Although doubtful about the current value of ESs, most informants considered ESs to have potential as an information trail for safe working practices.

The authorities in the survey mentioned that the SDSs were not adequate with regards to the RMMs as they were generally described as unspecific or vague and occasionally even conflicting. The informants were of the opinion that the RMMs in the SDSs were sometimes unnecessary and sometimes not sufficient. The inspection's point of view is that it is difficult to enforce unspecific and vague measures.

The combination of not receiving information from suppliers that is of sufficient quality and the limited resources of SMEs to use information is a well-known challenge that hinders effective risk management. The issue of vague and insufficient information about RMMs remains to be solved.

As the implementation of REACH is considered complicated, many informants have asked for additional guidance on how to conform to REACH requirements. The SWEA Inspectors pointed out the need for more expertise and skills in chemical safety management and the chemical legislation among SWEA inspectors. The number of workplace hazards are enormous and vary, but only a few of SWEAs inspectors are available to monitor chemical risks in the workplace. OHS professionals and safety representatives generally ask for more guidance from authorities, both SWEA and the Swedish Chemicals Agency.

Several OHS professionals would like suppliers to identify relevant ESs and only send these to them. Not more than a few of the informants seemed to be aware of the option to ask suppliers for explaining the SDS, those that knew were OHS professionals in larger firms. The two major constraints found to the concept of ES were that they currently do not reach the whole supply chain and that, they are mostly not available for mixtures. The survey also revealed that most informants were of the opinion that for safe use information of a substance or product neither the SDSs nor the attached ESs were sufficient. However, the informants believed that in the (near) future REACH would be more beneficial to OSH. The barriers to the REACH implementation are similar to those related to the implementation of OHS legislation; i.e. not enough awareness, understanding and/or incentives to take action. And in particular SME's may be understaffed to keep up.

All the informants were recruited by their own initiative, except for four authority informants. The informants were thus not representative of the Swedish working environment and it is likely that the participants in this study may have joined because of specific interest in chemicals risk management and REACH. This was also confirmed by the informants during the interviews. The low number of people that showed interest in participating in the interviews may imply that, compared to other occupational health topics, REACH implementation receives not enough attention from OHS professionals and safety representatives. Nevertheless, the different groups included allowed the authors to study a range of perspectives on OHS management among DUs.

Finally, it was concluded that the implementation of REACH was not seen as major factor in the DUs occupational risk management. The authors proposed that this is probably related to the finding that many companies, in particular SMEs, do not exactly know, or may not yet be aware of all their REACH responsibilities. With this, the introduction of REACH increased the availability and access to information about chemical risks, but not necessarily about chemicals risk management.

A.4.5. Quick Scan REACH and Safe Practice (2016)

Goal and methods

In this study, the authors Marquart and Dieperink-Hertsenberg (2016) assessed the Safe Practices after the implementation of REACH. 'Safe Practices' can be established to fulfil the obligation of determining the risks in workplaces in the Netherlands. If companies adhere to proven 'Safe Practices' they do not need to perform a specific risk assessment in their company. A "QuickScan" on three existing methods to derive Safe Practices was performed, based on REACH Exposure Scenarios, where the use of the product under a defined set of conditions does not result in a health hazard.

It was evaluated by the authors whether ESs by themselves can be used as a Safe Practice or source for a Safe Practice. This requires that it is proven that the ES leads to safe use and that it is sufficiently specific for a specific use. Subsequently, three methods were investigated where conditions and control measures for products (mixtures of substances) can be determined based on the Exposure Scenarios of individual substances.

The methods assessed are

- (A) SUMI DUCC; Safe Use of Mixtures Information for end user
- (B) SUMI generic: Safe Use of Mixtures Information for end users generic¹
- (C) LCID Lead Component Identification methodology

Results and conclusions

Both Exposure Scenarios and Safe Practices intend to lead to situations where the use of chemical products does not lead to risks.

ESs and Contributing Scenarios (sub-scenarios for specific tasks within an ES) can cover multiple circumstances. Safe Practices are for very specific uses. Therefore ESs and Contributing Scenarios are not always specific enough to derive Safe Practices for these specific uses.

ESs based on downstream Use maps from sector groups are often more specific and use terminology understood by the downstream users; they are also usually in agreement with actual practices at downstream users.

ESs based on measured data are valid for the use of the products that were used when the measurements were made. However, if the composition of products used is not sufficiently described, they cannot be used as basis for Safe Practices, because a user cannot check whether he uses the same products as used during measurements.

The tools such as specific worker exposure determinants and safe use of mixtures information (SUMI) are tools for translating the working conditions from downstream users to registrants (SWEDs) and the results of risk assessment back to DUs (SUMI) in an understandable format; whether this leads to actual safe use depends on whether the risk assessment that was the basis for the SUMI are valid and correctly identify the control measures needed to achieve safe use.

The LCID is a method to choose the critical component for a mixture; the operational conditions and risk management methods of this component are then considered to

¹ At the time of research, the SUMI system was not fully developed and a suggested format by a consultant was not fully compatible with the format by the DUCC

be applicable for the mixture as a whole; it is a risk assessment methodology - it does not directly influence appropriate implementation of safe use methods.

A.4.6. Supply Chain Communication Distributors' Experience (2017) Goal and methods

This presentation (Garmendia Aguirre, 2017) given at the Safety Day Symposium 2019 in Milan conveys the Distributors' experience with the communication in the Supply Chain. The chemical distributors' industry and its role in REACH, CLP and other legal requirements is given, challenges in the Supply chain communication are gathered and sector activities to help members in overcoming regulatory challenges are listed.

Results and conclusions

The FECC, the European Association of Chemical Distributors and the voice of the Chemical Distribution Industry in Europe, is linked to 15 national associations, 40 company members and 8 Associate members. In 2015, the organisation represented 869 chemical distributors and about 30000 employees. Distributors (including retailers) typically store and put chemicals on the market for third parties. Their REACH and CLP obligations are often limited to passing on the information in the supply chain.

Distributors play a major role in the communication in the supply chain. They can be considered as the bridge between the chemical manufacturers and DU by enabling the availability of chemicals on the market and providing information to ensure chemicals can be traced and quality control can be performed.

With the introduction of REACH, FECC's role as an importer meant interacting with DU, making inventories of key substances, communicating about substances that will not be registered and supporting DUs when the product availability on the market is at risk. Distributors are strongly involved in passing on information down the supply chain so they know (or should know) which uses are covered by the ESs in the eSDSs. This role also means informing upstream stakeholders on uses and use conditions where no ES is available yet.

The distributors actively share a copy of the (e)SDS from the supplier to their customers or provide their own (e)SDS consolidated from what has been obtained from suppliers. Here, consolidating e-SDS means that data from different suppliers of a substance is compared and grouped into one consolidated e-SDS.

A goal within the FECC's Supply chain communication is to set up an European library of ESs per substance, when different suppliers provide different sets of ESs. By applying defined and agreed measures, uses and Operating Condition (OC)/RMM can be compared and aligned and an European library may be created. The main challenge is to find the differences between the many suppliers' ESs for the same substance and the comparison with own operations (own uses, OCs, RMMs).

The authors of the presentation conclude that "Communication is key", legal obligations are given, but not always understood, "Alignment across supply chain needed", stress the need to improve the communication flow and move towards further harmonise and standardise the communication

A.4.7. Critical aspects and comments on the assessment and management of Exposure Scenarios (ES) with regard to worker exposure (2017)

Goal and methods

The aim of this Italian study (Federchimica, 2017) is to analyse the difficulties and critical aspects that DUs encounter with ESs and that may be an obstacle in the process of ES verification by DUs. For this work, an expert evaluation was performed

by Federchimica to evaluate the process and results, based on prior experience and critical analysis of the updated Guidance document R12 (on the use descriptor system).

Results and conclusions

The study reports on the following reasons for difficulties that Italian DUs face when implementing ESs:

- A. Insufficient skills in dealing with the technical language ("use descriptors"), the background of the CSA on which the scenario are based and that usually relates to REACH.
- B. The different rational of the ES assessment performed by the registrant under REACH in comparison to that done in the risk assessment under the local Italian Legislative Decree by the DU.
- C. Intricacy, immenseness, non-harmonised built of the ES, *i.e* they can be complex in structure, very large and in different formats.
- D. The practical work situation with all its difficulties is usually not taken into account. Or the reference to a local exhaust ventilation (LEV) in the risk assessment and hence eSDS/ES, is not motivated.
- E. Potential mismatches between ESs, for the identical substances, obtained from different suppliers.
- F. Updates of the SDS and accompanying ESs that may require a completely new assessment.
- G. Fixed timeslots for the evaluation of the ES, for the discussions with the supplier of any changes, for applying the required measures or for performing a DU chemical safety assessment for the working place.
- H. ES of mixtures is up to now simply the sum of the ESs of the hazardous substances in the mixture, but it is not clearly defined how this should be determined. SUMIs and LCID tool for all the mixture do not seem to be the completed answer to this.
- The RoadmapFout! Bladwijzer niet gedefinieerd. gives target dates for the implementation and updating of operational tools for stakeholders that are too far ahead to deal with the real and current needs of stakeholders involved in REACH.
- J. The large number of ECHA guideline revisions, including adjustments or updates of the consolidated documents.
- K. Assessing the need for Personal Protective Equipment (PPE) in REACH depends on single substances, while an employer needs to account for the full situation in the company - the assessments can be in contrast to each other.
- L. Not all thinkable risk management measures are considered in the REACH assessments and the effect of LEV is only used to calculate that there is no risk, restricting the options for using alternative risk management measures by DUs.
- M. All present ESs that DUs have must adhere to use the old use descriptor system, which cannot be found on the ECHA webpages anymore, as it is replaced by an update with modified description. Therefore there is a misalignment of between the "language" by the writer (registrants) and that of its audience (DUs).

A.4.8. Safe use of chemicals by professional users and health care specialists (2018)

Goal and methods

In this academic study performed by Margarita Apatsidou *et al.* (2018) the level of understanding of the hazard and risk communication and awareness with regards to the safe use of chemicals has been assessed for the first time among Greek

professional users and health care specialists eight years after the implementation of the respective EU legislation.

The approach was as follows:

A total of 1500 individuals (850 industrial workers and professional users of chemicals from 35 different SMEs, self-employed professionals included, and 650 health care specialists from 6 public and private hospitals/medical centres (40 private practitioners included) at different locations in Greece, were requested to participate in an anonymous validated, self-administered survey with 26 close-ended questions in 2016 - 2017.

In total 350 individuals (200 workers and professional users, 150 health care specialists) returned the survey (23.3%, within the range of the typical self-completed questionnaires).

The first section of the survey focussed on demographic topics (6 questions); the second addressed the risk/hazard communication of chemicals (14 questions); and the third looked at the use and application of personal protective measures (6 questions). An independent multidisciplinary expert group with a toxicologist, a regulatory officer, a representative from the industry and a psychiatrist reviewed the survey and provided input. The group gave input on the general content and face validity of the survey (content validity ratio = 0.993, P<0.05) which was shown to be complete and adequate for distribution. Statistical analysis was performed on the obtained data.

Results and conclusions

The demographic characteristics of the study population revealed that health care specialists and Professional users had a similar age (P=0.323) and work experience (P=0.224). Women were found more in the group of health care specialists, and men were more abundant in the professional workers group. Twenty different type of jobs were identified among the Professional users, including industrial workers (chemical products, pharmaceuticals, plastics, food industry and energy products/fuels), gas station employees, painters, carpenters, farmers, hairdressers and drivers. The majority of these professions ware part of the private sector (>80%). The education level in the Professional users group was considerably lower than health care specialists group, as expected.

Perception of Globally Harmonized System (GHS) pictograms, which are pictorial indications of hazards and control measures that occur on labels of products. Over 85% of the informants were not aware of the CLP Regulation, while 20% of professional users of chemicals are aware of REACH. Above 65% of the responders did not notice any differences in the labelling of the products being used. The most familiar pictogram that was seen is the old hazard symbol of a black cross on an orange background from the Dangerous Substances/Products Directives (DSP/DPD) (about 40%), which was replaced by CLP in June 2015. In general, 50-60% of professional users recognizes pictograms correctly, while for health care specialists the percentage was up to 80%. However, both groups knew only the corrosive hazard for the skin/eyes in pictogram GHS05 and only 8% in group 1 and 26% in group 2 also understood that the corrosivity for metals is given by the same pictogram.

About 33% of the professional users in this study mentioned to read the label as their primary source for product information, while for health care specialists the was even higher with 65%. More than 65% of the informants thought that pictograms GHS06 and GHS08 would correspond to a similar hazard for human health, and not more than 5% in Professional users group believed that carcinogenicity or reproductive toxicity to be communicated by using GHS08. Most responders (>75%) realise that hazardous products are being used during their daily life, but the perception of hazard and the seriousness fluctuated significantly between the two groups (P=0.012) and statistically related to the educational (P=0.022) and professional (P=0.014) level. In

general, hazards were perceived less adequately if the educational was lower and professionals perceived the hazards less adequately than (higher educated) health care specialists.

Hazard communication using product labels was not well understood by 7% in both groups. The professional users (18%) and health care specialists (23%) hardly used SDSs for assessing the safe use of chemicals. An observation was that 30% of the professional users who use PPE, only do this after they have been told to do so by their employer or the shift supervisor.

About 15% of the informants in both groups did not take any special safety measures regarding their work clothes at home, while younger (P=0.015) and more educated (P=0.035) end users of chemicals follow specific cleaning practices. Nearly 60% of the interviewed health care specialists have been informed on the safe use of chemicals or steps to follow in case of an accident. In that case, the National Poisoning Centre is the point of contact for further information, but 20% of the health care specialists have a preference for the SDSs. Based on the above and other literature the authors conclude that, age (P=0.02), work experience (P=0.025) and job (P=0.022) was linked to how well the CLP was known. However, they do not specify details, e.g. whether younger or older workers had more knowledge on CLP.

The authors state that pictograms are very important components in hazard/risk communication. It has been shown that training and education are needed to understand GHS pictograms and this will also be useful in developing skilled individuals in the use of SDSs. Workers in the cleaning sector that were not familiar with the pictograms had not been adequately informed on the safe usage of chemicals by their employers. It was proposed that age and educational level may affect the performance of workers and the cognitive process to understand pictograms as demonstrated in the present study. Some pictograms were more easy to understand, whereas others remain controversial, such as GHS05, GHS06 and GHS08, as shown in this study. Similar worries exist for the labelling of fragrances.

It was shown, that use of PPE was not directly related to the actual hazards of products worked with. Farmers that are highly exposed to pesticide toxic components do not use PPE. On the other hand, disposable latex gloves that are often used by gardeners do not provide sufficient protection even for contact with pesticides over a limited period of time. Hence, the focus should be more on awareness-raising activities and increasing the communication of chemicals hazard/risk.

In conclusion, on a national level in Greece, awareness-raising campaigns are essential, together with trade unions and health care professional associations, to train professionals on safe use of chemicals to protect human health and the environment.

A.4.9. FORUM REF-5 Project report on extended safety data sheets, exposure scenarios, risk management measures and operational conditions (2018)

Goal and methods

This ECHA study (ECHA Forum, 2019) was carried out to obtain an EU/EEA-wide understanding on how safe use information was collected, communicated or implemented, and whether the different aspects of information were coherent with one another, as required under REACH. It was not verified if this information was applicable, complete and/or suitable. REF-5 was aimed at various prerequisites for making safe use information from substance registration dossiers available to downstream users.

In this investigation, a total of 898 inspections were conducted in 29 EU/EEA countries. Since a number of the inspected companies having different roles in the supply chain, a total of 302 (28%) 'first level suppliers' companies, 270 (25%) 'suppliers', and 519 (47%) 'users' were inspected. Further, 375 different substances were checked, around 38% of substances were used creating mixtures.

The emphasis was on conditions of the workers that had to deal with the hazardous chemicals and whether they received safe use information. With respect to inspections in companies with an "end user" role, the focus was on the implementation of operational conditions and risk management measures as described in the exposure scenario the company had obtained.

Results and conclusions

Non-compliances (18%) were observed in companies that fail to gather their own eSDSs for the mixtures (1%), while the supplying an eSDSs in another language than that of the Member States where the substance was placed on the market was the most common form of non-compliance (12%).

In total, 296 violations were reported of which 42% were found in the 'first level supplier" companies, 29 % in the 'supplier' companies and similarly 29% in the 'users' companies.

In the majority of cases, these shortcomings (i.e. exposure scenarios in CSR, including "risk management measures that were not properly indicated") are copied through into the eSDSs (63% of communicated exposure scenarios are copies of the chemical safety report's ESs). This means that the information sent in the supply chain via the eSDSs is not of the desired quality with respect to accuracy/correctness, clarity, and usefulness. The substances checked most frequently in this project were sodium hydroxide (77x), ethanol (68x) and sulphuric acid (62x).

In conclusion, many of the duty holders, such as registrants and formulators, comply with the provisions of the regulation which concerns compilation, distribution and use of safety information in the form of the chemical safety report and exposure scenarios/extended SDSs for substances. Systems are in place to allow the transfer and communication of safe use information within the supply chain: where required, most of the SDSs for substances are provided and distributed with annexed exposure scenarios which are, in most cases, copies of all or of selected exposure scenarios from the chemical safety report.

At the same time, however, obvious quality deficits were observed in the chemical safety reports. Notable was the poor-quality information, including the lack of updates on harmonised classification of substances, missing/incomplete exposure scenarios, risk management measures that were not clearly specified, exposure models used outside their functional domain and disputable exposure estimates. Proposals made were on improving the quality of SDSs and communication between companies; prioritising the REACH Review actions on the quality of SDSs by the European Commission and on ECHA's role in working towards projects and campaigns on guidance information, validating chemical safety report content and improving cooperation between authorities.

A.4.10. Approaches and tools to better support consumer exposure assessment under REACH (2018)

Goal and methods

This study (Wijnhoven, 2018) aimed to identify shortcomings in tools and communication for the consumer exposure assessment within REACH. For this reason, the following approach was followed:

(A) Analysis of issues using an overview of ECHA observations on this topic, an overview of available information, and input from stakeholders obtained from a survey

and a workshop with stakeholders. The identified issues were labelled as 'supply chain communication', 'exposure scenarios' and 'tools for consumer exposure assessment'. Also, the main solutions for the issues were outlined in a first solution strategy.

- (B) Develop a strategy for improving the existing tools in order to fine-tune them for generating and exchanging information on how to use consumer product safely under REACH.
- (C) In a so called "reality check" the data set to be shared with formulators was assessed for a couple of product types and determine the relevance of the information for product design together with a group of formulators.

During the consultation, information was gathered via a workshop and a survey from formulators active in a wide range of sectors including the adhesives/sealants, coatings and paints, washing and cleaning, polishes and wax blends, cosmetics/personal care and lubricants/ greases industry.

In total 15 participants from companies and sector organisations joined the workshop and 30 small and large companies participated in the questionnaire.

Results and conclusions

The main observation related to communication on safe chemistry where:

- (A) No exposure scenarios are shared with the end use formulators for raw materials purchased as chemical mixtures.
- (B) Nearly half of the exposure scenarios that are provided do not cover the activities of the formulator, for instance relevant product type and/or the condition of use not mentioned.
- (C) Many formulators are capable of making their own quantitative exposure assessments, however the smaller companies accounting for half of the market are not able to do so.
- (D) The compiled data implied that the majority of exposure assessments are performed in house
- (E) There was a general dissatisfaction on REACH exposure scenarios as they were found to be too lengthy, relevant information is hidden, not easy to comprehend or confusing, the given advice was not realistic, contradicting information was found between different suppliers of same substance and for consumer mixture they do not have much added value to chemical safety.

A number of solutions were proposed including the need to raise awareness of the registrants to distribute ESs and with relevant information, encouraging SCEDs and ConsExpo fact sheets to improve the accuracy and usefulness of ES, harmonising the use conditions that are mentioned in the ES, irrespective of the tool used and improving the guidance for the different REACH tools

A.4.11. REACh2SDS – Assessing the availability and quality of risk and risk management information in Chemical Safety Reports (2018)

Goal and methods

This ongoing study carried out by Angela Kämpfer and co-workers (2018) focusses on assessing the availability and quality of information on risk management in the CSR of substances in the 100-1000 tonnes per annum band. At a later stage the analysis of the risk communication within the supply chain will be followed.

As a method several aspects (based on 19 markers) of interest were analysed within the CSR and these were categorised and presented on a poster as follows

- (A) compliant (fulfilling legal information requirements / being within the boundaries of a model),
- (B) non-compliant (i.e. not fulfilling legal information requirements / out of boundaries), or

(C) complex (detailed analysis/more information required).

Exempted from the analysis were intermediates, inactive registrations, and substances with environmental classification only.

Results and conclusions

The following results were presented as interim results in a poster.

At the early stage of the study, 247 of 1690 CSR documents were analysed, of which 18 remain to be concluded with a final result.

It was found that 40 CSRs have been categorised as non-compliant.

The main reasons for non-compliance of legal aspects included: 'no details on personal protective equipment', 'absence of manufacturing processes for non-imported substances' and 'absence of the CSR'.

For non-compliance of (risk assessment) model aspects were mainly due to: 'model limitations', 'discrepancy risk management measures versus process' and 'inadequate reduction factors / efficiencies' (of risk management measures).

In this study 11 CSRs were indicated as 'Complex' and were categorised as such as they disregarded model limitations (e.g. use of TRA for carcinogenic substances), used insufficient reduction factors (e.g. gloves with 99% protection), or had discrepancies between the process and risk management measures (e.g. local exhaust ventilation in closed system, low dustiness for fine powder).

There are no final conclusions yet for this running project. Nevertheless, so far a clear quality difference was found between the individual reports, e.g. due to the frequent absence or inadequate use of information. This caused an overall high occurrence of non-compliant or complex cases. A rating system has been suggested to further characterise non-compliant CSRs, depending on the severity of the information gap for occupational safety and health.

A.4.12. Downstream users' information needs under REACH Summary of market studies in 2017-18 (2019)

Goal and methods

This report (ECHA, 2019) summarises several studies that were done to better understand the current flow of information on hazardous substances and mixtures in the supply chain, and also how useful it is to companies in the metalworking and engineering industry in Finland and a number of industry sectors in Italy. The Italian study has recently also been published in a scientific journal (Tranfo et al., 2020).

In this two-year market study, a semi-structured interview methodology was used to obtain information from different Finnish companies in 2017 on their inventory of chemicals, the exchange of information in the supply chain, risk management and the awareness of ECHA's guidance and tools. In the following year, the gathering of information focussed on received safety information, the communication with suppliers; the use data on chemical safety, ES and SUMI, and the information sent to customers.

In another study an online survey developed in cooperation with five Finnish industry associations. Here, the questionnaire was made to analyse information that was received by company, information then shared by the company and the respondent's views on the available guidance and support.

In another online survey of Italian companies developed by a national institute, a sector organisation and ECHA, assessed the chemical risk management in companies; the flow of REACH information, how SDS are used and what the quality of the SDS was.

Finally, labour inspectors from different EU MS were interviewed on their opinion on the quality of information in the supply chain; ESs and ECHA's tools and guidance.

Results and conclusions:

From early onward the studies revealed that the Finnish industries in general lacked sufficient understanding on ESs and related terminology. They did not know what to expect from an eSDS and were not sure on their obligations under REACH. In the interviews in Finland in 2018, most end users considered themselves knowledgeable on the legal responsibilities under REACH and CLP. Nevertheless, they were not fully aware of their actions related to ESs. Nearly 40% of respondents was not familiar with the concept of ESs. Labour inspectors reported differences in the amount of awareness across industries, with larger chemical corporations being well prepared and SMEs in user sectors sometimes not even aware that REACH applies to them.

In Finland, most customers preferred to receive SDS by email or via a database. And in both Finland and Italy end users were of the opinion that the 16 sections of the SDS contain enough information to guarantee safe handling. Many found that the required information is easy to find in the document. The majority of Finnish responders also demanded SDSs for non-hazardous chemicals.

Interestingly, nearly half of the end users in the 2018 Finnish survey mentioned not to have received any eSDSs, while the other half received this information for less than 25% of their substances. In Italy, the majority of companies received at least some eSDSs. In Finland, a couple of bottlenecks were observed in the flow of eSDSs at formulator/distributor level.

The studies in Italy and Finland also showed that most of the received attachments with ESs where less than 20 pages, but the longest attachment in Finland was up to 200 pages long. Labour inspectors noted that ESs may add value to large companies that have dedicated employees for safety issues, but that the information may be challenging for SMEs without necessary specialists.

At the time of these Finnish studies, no experience with SUMIs was gained yet by end users.

The sections on hazards (Section 2) and personal protection (Section 8) of the SDSs were checked most often by recipient companies. Only 15-23% of Italian companies used process descriptions and exposure information in the eSDS. In Finland, some end users indicated that they rarely consult or use the ESs or take follow up action. Most end users did not understand that their uses needed to be supported in the REACH registration and therefore needed to be known to their suppliers. Finnish respondents indicated that they use information from the SDS for their workplace risk assessments and formulators also mentioned to use the ES for that purpose. However, no details were provided on the information elements that they specifically use.

Updating the workplace risk assessment after receiving new information in a SDS was done by about a fifth of Italian companies. In large companies, the main reason for such an update was triggered by new classification information, in SMEs the motivation was exposure-related information in 20% of the cases. According to the study in Italy, almost half of the companies applied the risk management measures in the eSDS as mentioned, but a comparable fraction of the companies integrated them with other measures. Communication on PPEs in the SDS was taken in 60% of the companies.

Only a small portion of end user companies used derived no-effect levels (DNELs) for their workplace risk assessment and usually only if there was support from external experts. The researchers concluded that "it would be beneficial to enhance the companies' knowledge of the use of DNELs in workplace risk assessment". Scaling of ESs, which is the modification of one control measure or condition mentioned in the ES towards higher exposure levels, but at the same time modifying

another control measure or condition mentioned in the ES in the opposite direction in a structured way, by DUs was hardly ever performed. It allows the DU to demonstrate that the actual use conditions at the working place are covered in the obtained ESs from their supplier, even if there are some variations in the (condition of use) parameters. The scaling options should be provided by the substance supplier.

While in Finland most companies almost exclusively used electronic archives to share SDSs with workers, the information is also printed in smaller companies. In contrast, most Italian companies used hard copies to share safety information. In Finland, more than half the suppliers produced their own workplace safety cards and some sent them to DUs too. In Italy, about 10 % of companies created workplace safety cards. No information was reported on whether one way of sharing was more effective than the other.

Formulators mostly entered information on substances manually into their IT systems. They use it for their own workplace risk assessments and as data for SDSs for mixtures. The management of ESs and use information is usually integrated into the information management systems that are originally designed for SDSs.

Finnish end users rated the clarity and level of understanding of SDSs on average 3.4 out of 5. Labour inspectors scored this as 4 for large companies and only a 2 for SMEs. In addition, the quality of information was found to be rather variable between suppliers.

In Italy, around 30% of respondents considered the conditions of use and risk management measures as the easiest segments to be identified in an eSDS, while use descriptors and exposure estimates were more difficult to find. In about a third of the SDS, some information was missing.

Finnish respondents noted that safe use information in two placeholders (ES and Section 8 of the SDS) is not ideal and difficult to absorb and manage. The extent of information also makes it more cumbersome to trace relevant data. The perspective of the companies is that ESs are too lengthy and written in a language that is only of use to technical experts. Also, they were of the opinion that important information, e.g. on PPEs, was already given in the body of the SDS or in chemical databases. Consistency and high quality information were considered more relevant than the extent of information. Italian companies had similar points of view. They argued that ESs provided only a few advantages and that retrieving information from them was a demanding task. Labour inspectors suggested that information in the ESs should be kept as simple as possible.

Communication between DUs and suppliers normally takes place via phone or email and was considered to work well. The main reason for contact is to request an update of the SDS or for a version in the local language as required by REACH. Close to half of the Finnish companies also mentioned to have given feedback on the quality of the eSDSs to the suppliers. In Italy however, most end users did not take any action or communication, even if the information in the eSDS did not match the operational conditions at their site.

A number of companies provided information on uses to their suppliers, but not all suppliers were found to be interested in this type of information. Use-related contacts were mainly related to PPEs.

Suggestions for improvement of information and its flow generally were "in the direction of clear, easy to understand and short documents in a local language and harmonised structure". Information should be practical and consistent. Acronyms

should be clarified, templates should be harmonised and classification should be aligned between suppliers.

In the metalworking and engineering supply chain, the awareness of end user in Finnish companies on the guidance provided by ECHA and the available tools was 64-90%, and in the lower range for small companies. But the awareness of guidance and tools from Industry was much lower still (i.e., 18-67%). Interestingly, companies were mostly aware of information and tools published by the Finnish Safety and Chemicals Agency (90-100%). Respondents mentioned that an IT tool for assessing compatibility of ESs with local conditions at site would be helpful and that practical guidance and realistic examples should be promoted. Labour inspectors also were not aware of all existing tools in the supply chain.

End users do consult databases, such as on national OEL lists, ECHA's C&L Inventory and the International Labour Organisation's International Chemical Safety Cards for information to assist in their chemical risk management, specifically to identify hazards. The databases are appreciated for their practical information in a consistent format.

On page 6 of the report, the authors conclude on the following challenges in supply chain communication:

- "1. End users are not fully aware of their duties related to the extended safety data sheet.
- 2. Information is not yet flowing down the supply chain as intended and upstream communication on uses is limited.
- 3. The information in the extended safety data sheet is not meeting the needs of the recipients.
- 4. There is a lack of IT solutions that facilitate the transfer of exposure scenario information from company to company."

A.4.13. Relevance of ENES for REACH and for REACH Review Action 3 (2019)

Goal and methods

The aim of this review by Veronika Jezso (2019) is to recap on the finding of the Scoping phase of REACH Review Action 3, and thereby reporting on the need for improving the risk management measures at the workplace and also the communication and transparency in the supply chain. The relevance of ENES for REACH and for REACH Review Action 3 during ENES12 was also highlighted.

Results and conclusions:

The second REACH review observations regarding safe use were that REACH delivers results related to the improvement of the risk management measures at the workplace and also on the communication and transparency in the supply chain. For instance, the information on substances has extended significantly, the phasing-out of substances of very high concern (SVHC, substances with one or more specific hazards considered to be very serious, such as carcinogens) is up and running and improvements have been made in the risk assessment management at the working place. The supporting role of ECHA on the implementation of REACH was also mentioned.

However, with respect to the eSDS there are still a number of activities to work on. For example, the information is perceived as too extensive and not practical enough, thus there is a need to make more use of harmonised formats and IT tools to support all uses and dissemination. In addition, inadequate information in the ESs is considered to hinder the formulators responsible for SDS for mixtures.

It was concluded that in developing further action, the focus should be on further improving the use and quality of eSDSs. Concrete action points will involve MSs, ECHA and the Commission, the industry and other stakeholders with a key role for ENES. It was also proposed that more industry sectors should engage in creating and using harmonized formats and IT tools. The industry and ECHA are supportive in the use of ENES tools.

The Commission will consider giving the minimum set of conditions for the ES for substances and mixtures in SDSs. For that activity, there will be a leading role for the Commission, while others will contribute e.g. ECHA and the Industry (via ENES). And lastly, the Commission will ask ECHA to create a methodology for improving the workability and quality of mixture eSDSs.

A.4.14. DUCC Sector Use maps (2019)

Goal and methods

This overview (Portugal, 2019) presented during ENES12 focusses on the advantages of using Use maps and addresses why, by / for whom, how, what and where to find them and stresses the benefits of using Sector Use maps.

Results and conclusions

Laura Portugal explained that Use maps should be used because when a substance is registered, its expected uses (identified uses) are to be evaluated by the registrants and the outcome will then be communicated via the SDS and the ESs. The Use map is also the dedicated tool for DUs for making all used known to registrants, and thus complying with REACH art. 37(2) and art. 37(3).

The Use maps should be embraced by sector associations as they have the extensive knowledge on how the products are used in that industry.

To develop Use maps there is a need for volunteers and sector associations to lead discussions with their member companies. In that process the relevant uses can be identified, relevant activities (the objective is to cover 80% of the market) can be planned and a description can be given of the uses along with the contributing activities, that is, the operational conditions and risk management measures. The latter can be accomplished by using Use Descriptors and the standard set of phrases from the ESCom Standard Phrases Catalogue. Other (internal) guidance might also be needed.

In a Cefic/DUCC Pilot on Use maps (2018-2019), a number of proposals for development were made and these are to be further discussed and/or implemented. The main observation was that a CSA based on sector-specific Use maps worked well in practice at tier 1 level (Chesar, ECETOC TRA) and leads to a reliable outcome and effective work-flow. Formulators are also pleased with having all ESs based on a sector Use map.

In an overview given on page 9 of the presentation, the authors conclude that the advantages of using the Sector Use maps are

- (1) "Quality: good use descriptions will lead to realistic conditions in the ESs
- (2) Harmonisation: description of uses + information in the ES
- (3) Clarity: standard phrases
- (4) Representativeness: covering most uses in a sector / agreed by the involved industry
- (5) Internal procedures: formulators can use them for internal mapping of uses
- (6) Automation: available in Excel and Chesar format
- (7) Efficiency: avoids unnecessary communication in the supply chain"

Forthcoming plans for Use maps involve more interaction with DUs and different sectors, also when no sector-specific Use maps are available yet, to encourage their sector organisation to develop Use maps and to engage in the activities for your uses to be included. Sectors should make resources available and encourage their members to use Use maps.

A.4.15. Communication on safe use of chemicals in the supply chain – basic principles and next step (2019)

Goal and methods

This ECHA presentation by Kevin Pollard (2019) was given during ENES12 in 2019, to address the communication on safe use of chemicals in the supply chain and to propose the next basic pillars of chemicals legislation and other coming aspects.

Results and conclusions

The "basic pillars of the chemicals legislation", according to the presenter, on the safe use of chemicals are expertise, regulatory participation for about "10%" of substances and communication in supply chain on hazards, uses, use restrictions and safe use advice.

The eSDS with ESs should contain task-specific advice on safe use for hazardous substances and mixtures rather than "ensure appropriate ventilation where needed" and "avoid contact with skin". The eSDS should present DNELs in line with the classification (in particular, relevant where no OEL exists) and trigger responsibilities on the recipient's side as the received recommendations are to be followed or an own assessment is to be performed at the workplace.

The challenges that were seen are:

- the registrant is expected to determine the safe use advice for the identified uses in the life cycle of the substance
- the registrant is expected to take into account the range of operational conditions and also clearly instruct on the RMM that fit the use and sector of use.
- the registrant should also clearly communicate the relevant advice in a language that can easily be understand by the recipients.

Another challenge in the supply chain is that the formulator is expected to use substance level from ESs and use these for giving safety instructions for the mixture. And thus several thousands of ESs from hundreds of suppliers will need to be assessed for creating SDS for 10,000 and more mixtures.

Another issue is that REACH added ESs from the CSA to the front end of companies' existing SDS IT systems without giving guidance how to integrate the information and the minimum requirements for the content and structure.

It is good to realise that the above use information has to be obtained from a complex, diverse and competitive market. It was proposed to create a blueprint for the desired flow of safe use information for manufacturers of substances, formulators of mixtures and end users with the relevant tools. See also Appendix A.3.13.

Establishing the minimum requirements for ESs would help with finding a single holistic /consistent system for all actors in the supply chain: Synchronising the system would be of great value here. For moving ahead, further development of methods will be needed and tools might help in closing the current gaps, in particular at the site of formulators. Digitalisation of safety data will be essential to make IT systems more efficient. REACH could satisfy the need for end user information and rolling out REACH ES to OSH and Industrial Emissions (IED) communities would in the long run also be interesting and effective.

A.4.16. Industrial End user Of Chemicals: Chemical Plant Risk Assessment & Exposure Scenarios" (2019)

Goal and methods

This presentation given by Evelyn Tjoe Nij (2019) highlights the DU perspective and activities regarding risk assessment and ESs with the DU being a chemical plant. In an overview, the advantages and disadvantages for DU assessments are mentioned, the learning points from the detailed ES checks at chemical plants, proposed high level ES checks and discussion points from Industry as DUs during ENES12.

Results and conclusions

The advantages of the REACH and availability of ES as a result of performing a risk assessment are the availability of additional information, and improved SDS and label with more information on limit values, when no regulatory or company Occupational Exposure Limits (OELs) are present. ESs also guarantee that the risks have been investigated for identified uses, the ES data can be used for screening risks for considering new chemicals and sector organisations give more support on how to use chemical products safely.

Contrary to that, the drawbacks are administrative burden and the resemblance with Occupational Safety and Health (OSH) regulation, although OSH is much more focussed on the workplace risk assessment and deals with complex chemical environments and the mandatory hierarchy of control measures.

Learning points for checking ESs extensively at chemical plants are that the check did not result in different workplace conditions. In general, it could be concluded that the workplace conditions were of a higher safety standard in comparison to the ES. It was also concluded that listing the possible industrial activities (in comprehensible wording) and their Process Categories (PROC) codes was helpful when doing the ES check at plant level. A mandatory workplace risk assessment done by the Chemicals Agents Directive (CAD), is believed to be sufficient to control workplace hazards by trained occupational hygienists and labour inspectors in several European countries.

To further improve the communication it was proposed to make a sector specific/company specific conversion from PROCs to text that can be understood more easily. In addition, exposure control measures that are applied to all activities with the substance should be specified only once (e.g. in section 8.2 of the SDS), and not repeated multiple times within and across the ESs.

Another point to be addressed was on the expectation in REACH that DUs should use the full spectrum of control measures identified in the SDS. But if undisputable and acceptable arguments (i.e. the RMMs are not 'appropriate') are given, then it is not a breach of REACH to take other measures. In these cases, DUs should be able to show how the other measures give the same effective level of protection. DU should also report in their risk assessment the reasons for not following the REACH controls. DUs should also mention any inappropriate risk management activities to their supplier.

A.4.17. REACH-Weiterentwicklung Auswertung der Online-Befragung zum REACH-Review 2017/2018 (2019)

Goal and methods

This study the authors (Reihlen & Jepsen, 2019) carried out to gain more knowledge in how REACH stakeholders are affected by the legislation and what their opinions and proposals are for improving the REACH implementation in Germany.

The method used is an online survey among the national REACH stakeholders. In total 159 respondents answered questions on how their work was affected by REACH and gave their views how the implementation of the REACH could be improved. The participants included 27 manufacturers/importers of substances, 35 formulators, 30 end users and in addition distributors, retailers, consultants and people affiliated with sector organisations, governmental and non-governmental organisation.

Results and conclusions

Overall, the main difficulties still are creating and communicating ESs, as well as reconciling them with the main part of the SDS (consistency). In addition, many actors see, at least in part, a problem in the fact that there are few incentives to pass on good information in the supply chain. The supply market of chemicals changes due to the registration, restriction and authorisation processes, which partly initiates substitution.

Some of the actors have already been inspected on their REACH implementation, their dossiers had been checked or their substances evaluated.

According to the opinions of the participants in the survey, the REACH text should not be changed and the REACH implementation should be improved via a simplification of requirements, an increase of the processes' efficiency as well as the provision of good practice examples and additional information and support.

A.4.18. ENES 12 Some conclusions (2019)

Goal and methods

This presentation (ENES, 2019) summarises the conclusions drawn at the ENES 12 event particularly on how to spread the word and priorities for closing gaps and improving tools to further facilitate the implementation of REACH and thereby improving the safe use of chemicals.

Results and conclusions

'It is all about risk management communication' is how this presentation kicks off. The amount of data generated since REACH is increasing enormously. Nevertheless it is not always evident how the information can be used for determining the correct use of chemicals. One reason for this is the complexity of the supply chain. And also the lack of knowledge of end users plays a role as many of them do not have the scientific and technical skills to fully comprehend all of the information they receive. In order to tackle these issues eSDSs are needed of high quality, that are easy to understand and to use for implementing risk management measures. Given the tremendous amount of data, information should be targeted and related to the actual risk. In assessments, objective and robust decisions should lead to effective RMMs. These RMMs should be implemented throughout the working place, they should also be objective and relevant in all relevant sectors of employment. The reality however is complex and there might be the need to simplify and translate the outcome for the non-technical end user 'workers. The main objective here is that 'workers should not be harmed by their work'

Where are we now and what does the future look like? ENES started back in 2011 with developing practical REACH tools. 'It is a long road but if we do not start walking we will not get there'. The key players are already actively involved. The focus should also be on the less technically aware people, possibly SME employers and representatives of workers' organisations. They might need support as much of the information is still technically detailed. It is still a challenge to simplify the content without losing the message. And thus the question that was raised whether an ENES Communication Strategy is needed.

It was suggested that the "house of REACH" was built on three pillars (i.e. generating knowledge about chemicals, information in the supply chain and regulatory action

(where needed). Ideally, the emphasis should be on (gaining) substance information and communicating this within the supply chain, rather than the need for substance-specific regulatory actions where risks cannot be adequately controlled. The further improvement of IT tools would be beneficial here to make sure that actors can 'speak to each other'.

As one of the final remarks more effective risk communication to end users is needed and for instance digitalisation or a video would help. Other remaining questions are how eSDS recipients recognise/demonstrate compliance and how can we make better use of REACH info in OSH RA/RM? At the moment there is no process to recognise the interplay between REACH DU CSR and OSH RA, would that help? The outcome should always be that a safer and healthier workplace is created and the occupational health is improved.

A.4.19. 34th Meeting of Competent Authorities for REACH and CLP (CARACAL) Open session (2020)

Goal and methods

The meeting Jezso (2020) at the 34th CARACAL concerning the REACH review Action 3 (eSDS) was organised to improve the workability and quality of eSDS. For this reason industry sectors were encouraged to develop and use harmonised formats and IT tools. These would give more relevant information to the user, make the preparation and use of eSDS easier and support the electronic distribution of information. In this 'study', the Commission summarised the responses received from CARACAL members on the findings of the 'Scoping Phase', the presented 'Call for support' document and also a few proposals for the next steps are given. In this meeting, micro- and SME end user companies, their advisors (e.g. occupational hygienists), OSH authorities and representatives from workers' organisations were brought together to discuss the current issues and actions to be taken for improving the different steps in the communication chain.

Results and conclusions

CARACAL members supported the development of a system to further improve the information flow in the supply chain via eSDSs. More work is needed in order to better comprehend the implications of the changes/improvements as a result of digitalisation. The Exchange Network for Exposure Scenarios (ENES) was recognised for being the right platform for looking into the necessary technical development and to involve all relevant interest groups.

The members indicated that more discussion would be needed on the REACH DU duties for recipients of mixture SDSs. But there are also concerns for instance on potential administrative and cost burden for SMEs.

A number of members requested more involvement of the Occupational Safety and Health (OSH) 'community', as their participation is essential for the provision of user information. There was also a strong request to discuss the needs and concerns of micro- and SME companies, as registrants and formulators falling into this category often lack sufficient awareness, resources and expertise to fulfil certain regulatory requirements. Bringing the different stakeholders on board and establishing a fruitful collaboration seems to be essential. For the coming Development phase, potentially novel, more efficient and workable solutions would be established and tested in collaborations with multiple actors.

A.4.20. ECHA proposal for SDS standardisation comes under fire (2020) Goal and methods

This Chemical Watch article (Buxton, 2020) focusses on the exchange of information using obligatory communication formats and phrases. In particular, the view of authorities in Austria and Sweden and also trade body SMEunited is given in this article.

Results and conclusions

Upstream parties mostly have extensive chemical/toxicological expertise about 'their' chemical substances and mixtures, but unfortunately have little knowledge about the actual downstream uses. DUs are faced with very concrete, often even varying exposure circumstances and framework conditions, where they need very targeted, specific advice. More formalisation of the ES would be not much help to them. In Sweden experience from enforcement has shown that standardised phrases often lead to less specific, more general information.

SMEunited said not to be in favour of a compulsory formalisation of SDSs as it would not solve the existing shortcoming in the communication. It argued that 'this information is often not appropriate for the target group [downstream users]. Instead of a regulatory intervention, this communication style should be adapted step by step.' SMEunited expected improvements through guidelines and training courses, which are 'much better suited for this purpose than renewed intervention in the safety data sheet format, which is associated with extensive organisational and financial expenditure'.

Austrian authorities suggest that workshops in member states – if possible with ECHA experts present – with targeted upstream to downstream users from the same supply chain could help overcome communication problems.

Cefic concluded that "it's important to keep in mind that requirements might differ between safe use advice for substances as such and, to some extent, for substances to be used in mixtures.' Furthermore, the procedure for communicating safe use advice 'might also be different, for example mixture safe use information embedded in the SDS core body or attached'.

The SME trade body also mentioned that integrating risk-based information from the ES, and with the information in the respective sections of the SDS main body 'might be a key element to make the safe use communication on substances and mixtures more consistent'.

A.4.21. DUCC/CEFIC pilot on exposure scenario and supply chain communication Registrants testing Use Maps and formulators testing the SUMI selection method (2020)

Goal and methods

The study (ENES, 2020) is aimed to determine whether the structure and extent of harmonisation initiated by the sector's Use maps and SUMIs results in expected benefits to both registrants and formulators. It was also assessed whether the guidance available to companies allows for correct use of the tools.

For this purpose, CEFIC and DUCC together with a couple of their members tested sector-specific Use maps and the related SUMIs with representative substances and mixtures. In the first phase, 10 registrants used Chesar to perform CSAs based on the Use Map information for 7 different test substances. The most up-to-date version of the ESCom standard phrase library was used and the testing was mainly targeted at exposure assessment for workers. The Use map information and their substance exposure scenarios (ES) were communicated to formulators. In the second phase, 35 formulators used this information, together with their own mixture recipes, to select relevant information that could be shared in the mixture SDS to end users. Feedback on the experience was collected and the project core team analysed on a number of issues that affect both registrants and formulators.

Results and conclusions

In total about 20 eSDS with about 330 ESs were generated. The Use maps and SWED/SUMI concepts seem to work efficiently where testers followed the instructions, and where they remained within the boundaries given in the Use map. Under these circumstances, the outcome among registrants is largely the same and

many formulators found it easy to proceed, ESs have harmonised format and applicable SUMIs can be chosen.

But some cases the registrants deviated from the Use map data and/or derived the assessment information (e.g. highest safe concentration or amount). The obtained ES no longer enables the formulator to select the SUMI efficiently. Identified arguments for diverting from the Use map input are:

- Adding risk management measures to cover qualitative hazards
- Modifying inputs as it not feasible to show safe use in the safety assessment
- Registrants used different starting points for substance concentration and/or different risk characterization ratio target values to decide on safe use.

Based on the feedback on the experience in this study, it was proposed to further harmonise and improve the ES for communication in terms of data structure and layout, for a more efficient processing of the information by formulators. In more details

- The Chesar format for the ES communication is effective and should be used as a reference towards harmonisation, also by other tools owners.
- The Table of Contents of the ES Annex could be improved so that formulators can find the ES that apply their mixture type more easily
- The title section of the ES could include the SWED code for each listed contributing activity as well as the highest safe concentration of the substance under the defined SWED conditions, so that formulators can more quickly check compliance for their mixture.

Appendix 5: Overall workshop attendance

		affiliation	country	type	Α	В	С
1	Giovanna Tranfo	INAIL	IT ,	authority/research	Х		
2	Andreas Ahrens	ECHA	FI	authority	Х		
3	Renske Beetstra	RIVM	NL	authority	Х		
4	Jessica Meyer	BAuA	DE	authority	Х	Х	
5	Helena Niemelä	Concawe	BE	industry association	Х		Х
6	Nicoletta Godas	BAuA	DE	authority	Х		Х
7	Andrew Murray	ECHA	FI	authority	Х		Х
8	Marten Kops	NVZ (Dutch Detergents Association)/AISE	NL	Sector Organisation	Х		Х
9	Hans Thore Smedbold	Occupational Hygienist, St Olavs Univ Hospital, Norway	NO	research	Х	Х	Х
10	Carolin Dumke	BAuA	DE	authority	Χ	Χ	Χ
11	Abdulqadir M. Suleiman	Norwegian Labour Inspection Authority	NO	authority	Х	Х	Х
12	Ottar Madslien	KIWA	NO	consultant	Х	Х	Х
13	Andrea Spinazze	Universiteit Insubria	IT	research		Х	
14	Henri Heussen	Cosanta - Stoffenmanager	NL	consultant		Х	
15	Christopher Dobe	Syngenta	SW	industry		Х	Χ
16	Daniela Gecelovská	Slovak National Labour Inspectorate	SK	authority		Х	Х
17	Dag Rother	BAuA	DE	authority		Х	Χ
18	Joost van Rooij	Ceasar Consult and Chemrade BV	NL	consultant		Х	Х
19	Albert Hollander	Cosanta - Stoffenmanager	NL	consultant		Х	Χ
20	Thomas Vanfleteren	Cefic, Technical Manager	BE	authority			Х
21	Pete Kines	National Research Centre for the Working	DK	research			Х
22	Monica Gherardi	INAIL (Italian worker's compensation authority)	IT	research			Х
23	Margaret Wouters	RIVM	NL	authority			Х
24	Ioana Alexandra Blaj	HSSE Manager at Cefic	BE	authority			Х
25	Rokus Renirie	policy officer, Ministry of Social AffairsT	NL	authority			Х
	Monitoring team						
26	Dook Noij	ex-Dow, industrial hygienist	NL	industry	Х	Х	Х
27	Evelyn Tjoe Nij	Dow, chair of CEFIC Safe Use Communication NoE	NL	industry	Х	Х	Х
28	Wouter ter Burg	RIVM	NL	authority/research	Х	Х	Х
29	Celia Tanarro	ECHA	Fl	authority	Х	Х	Х
30	Urs Schlüter	BAuA	DE	authority		Х	Χ

Appendix 6: Report workshop A

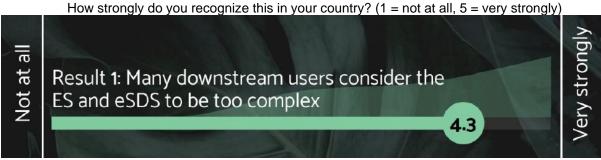
During workshop A, we shared a quick recap of the results of WP 1 (international literature review) and WP 2 (empirical case studies). Insights reflected on how upand downstream users deal with REACH legislation and documents (i.e., Safety Data Sheets and Exposure Scenarios), how the communication about working safely with hazardous substances runs through REACH and to what extent this actually promotes safe use conditions in the workplace. The discussion focused on generalization of the Dutch results to other EU countries: are these European or more national issues that need to be addressed? How can these issues be solved and on which (inter)national level?

The goals of this workshop were to:

- Identify similarities and differences between the Netherlands and other EU countries with respect to the results
- Identify good practices and ideas on improvement/how to handle the concerns raised by the results

Six statements were polled during the first plenary of the workshop with MentimeterÒ. The question for each of these statements was: How strongly do you recognize this in your country? 1 = not at all, 5 = very strongly. Next, the statements were discussed in breakout rooms. Two sessions with each three breakout rooms, after the first session participants changed to another breakout room in the second session. As such each of the six statements was discussed in one breakout room. Per breakout room about 4 to 6 persons from different countries and different stakeholder groups (research, regulator, industry) participated and each breakout room lasted 20 minutes. Each breakout room had a facilitator and note taker from the project team. In the plenary session afterwards, the results of the break out rooms were presented and discussed in 45 minutes. Below the results of the MentimeterÒ poll, the discussion in the breakout room and following plenary session are presented per statement.

Statement 1: Many downstream users consider the Exposure Scenarios and eSDS (if they know them) as too long, too complicated and too technical in terminology



Mean = 4.3, min = 3, max = 5, 14 respondents

score	1	2	3	4	5
responses	0	0	3	4	7

Solutions/Best practices

- No country specific solutions yet
- · Identify the intended users of the ES and eSDS. Who is the target audience?
- Facilitate collaboration between REACH people and OSH people.

- Communicate REACH hazard information to downstream users, who can then work on reducing the exposure.
- However, If end users do not have experience to understand REACH safe use information, how can we think they have expertise to reach safe use conditions only based on hazard information?
- The e(SDS) and REACH in general already allows a DU to make their own assessment (DU CSA) if the information received does not include relevant workplace situations. But indeed, many DUs (especially end users) do not have the expertise to do this.
- Limit the information in the SDS and ES so that they can be used in practice.
 Remove safe use information, focus on hazard information. However, hazard information was already available for many years, thus then there is no new information from REACH if you remove the safe use information.
- Educate downstream users on basic information on REACH (how to read eSDS and ES).

Statement 2: Although the inherent complex nature of the safe handling of hazardous substances is acknowledged, almost all interviewees believe the complexity of the REACH legislation and documents (e.g., safety data sheet) may result in a less safe working environment, because resources can only be spent once.

How strongly do you recognize this in your country? (1 = not at all, 5 = very strongly)

Result 2: Resources spent to REACH can better be spent to really improve safe working conditions

2.7

Mean = 2.7, min = 2, max = 4, 13 respondents

score	1	2	3	4	5
responses	0	5	7	1	0

Summary

- Main goal is to work safely, so there should not be a competition between REACH and OSH.
- Different in different countries. In Norway not many resources spent on REACH. Focus on OSH regulations (as done before).
- It depends on the company size. In bigger companies resources are in place for REACH implementation. In smaller companies REACH is not very visible, while REACH was also set up to support smaller companies in improving working conditions.
- REACH information is too general and not directly applicable at the workplace.
 Conflicting information can induce risk.

Solutions/Best practices

- Workplace specific initiatives: Safety information/instruction card (short version of the eSDS).
- Translate information from eSDS in combination with local workplace information into workplace instruction protocols that can be used in the workplace.

- Sector organisation can assist in this process.
- Exposure assessments not for all companies.
- Need better quality of hazard information.
- Company check how to handle RMM based on this exposure assessments.

Statement 3: Characteristics of downstream users like size of the company, organization of the sector and expertise/experience of employees have a strong impact on dealing with REACH requirements.

How strongly do you recognize this in your country? (1 = not at all, 5 = very strongly) Result 3: The one-size-fits-all approach of REACH hinders effective communication for specific companies, like SMEs 3.1

Mean = 3.1, min = 1, max = 5, 13 respondents

score	1	2	3	4	5
responses	1	4	3	3	2

Summary

- It's not only the size, it's also the role within the supply chain (registrant, formulator, etc).
- Larger companies have better trained personal, e.g. occupational health specialists that could contribute.
- The organisation behind the company is also relevant, e.g. trade body.
- Small companies don't have the knowledge / capability to deal sufficiently with REACH.
- Is REACH a problem or part of the solution?
- OSH is organised on a national level, REACH more on EU level.
- In many SMEs we still struggle on having the SDS available at the workplace. This has to be solved before we can start using the hazard information. Next level is to use the hazard information as a proxy for risk. Then when the company is large enough to have employed HSE professional we can start focusing on enhancing the risk assessment including exposure assessment.
- SMEs do hire accountants for their financial problems so why not also experts for implementation of safe use advice?

Solutions/Best practices

- Increase the role of the sector organisations to guide the sector in the appropriate "language". Enforce sector organizations, because now it is all voluntary work in the sector organizations. Local sector organizations should be supported by European sector organizations.
- More SME assistance in knowledge/resources.
- Initiatives, workshops may help, or tools like Work instruction cards.
- Guidance needs to be translated. Not only translation, but also country specific, because guidance documents are translated.

Statement 4: There are few feedback loops in the communication process. It seems mainly a top-down communication flow that the document developers

are not in contact (either direct or indirect) with the users, resulting in a mismatch in information and poor understanding.

How strongly do you recognize this in your country? (1 = not at all, 5 = very strongly)

Result 4: Feedback is lacking, especially from end users to upstream users

3.5

Mean = 3.5, min = 1, max = 5, 12 respondents

score	1	2	3	4	5
responses	1	1	3	5	2

Summary

- · Registrants argue that they lack sufficient feedback from DU.
- Questionnaires about eSDS, issue was the (local) language or absence of applicable uses (in IT).
- Special kind of product à good knowledge.
- · But more general products (paint) à than less knowledge on work floor

Solutions/Best practices

- · Recognizing the need for feedback.
- DU should be convinced / incentivized about the benefits.
- DU may be approached directly about the use and processes of substances (by authorities).
- (Further) establish the communication structures in the supply chain: more direct communication to suppliers (upwards).
- Encourage DU and suppliers to get in touch with one another. Supplier is not always willing to participate e.g. in case of new uses, DU may need to take more initiative.
- Issues when DU and registrants are competitors, in that case no data sharing by DU: as a solution DU may make their own dossier.
- Sector Use maps haven been used, more sectors should be involved.

Statement 5: There seems to be a diffusion of responsibility in the supply chain. End users and formulators point upstream that registrants do not deliver correct or sufficient information, while registrants point downstream that end users lack the knowledge, skills and resources to correctly interpret and use the information that registrants provide.

How strongly do you recognize this in your country? (1 = not at all, 5 = very strongly)

Mean = 3.4, min = 2, max = 5, 12 respondents

score	1	2	3	4	5
responses	0	2	5	3	2

Summary

- What is meant by diffusion? Or do you mean dilution?
- People point towards each other. But they do not know who the other is.
- Is there something wrong about the communication about the hazard? Or about safe working?
- The whole process is slow. We have long supply chains: registrant upstream
 has no clue who buys their products and the same other way around. Sector
 organizations, who work as intermediates.
- They are concerned about putting a product on the market. Not about safe work. The focus of why we do this is being corrupted in the supply chain.
- The info needs to be written in the way the end user can understand.
 Communication up and down needs to be improved. Need more easy understandable information. Who should help the downstream users in understanding and implementing?
- Issue in scaling in exposure scenarios. Need more transparency in models.
- There are only few sector organizations who really dive into this. There may be
 a role for authorities. Sector organizations have not an official role in REACH
 legislation. Membership of SO, too diffused, then they don't request help. Single
 companies are responsible. DU responsibilities are not clearly spelled out in
 REACH legislation. (legal) responsibility à parties can solve it, but have no
 responsibility.
- Sector organizations, SUMI principle. OSH for end users. Responsibility triggered SUMI development. Safety assessment obliged by OSH. Motivated use info collected by REACH. The stick (OSH law) we need to work safely. End user à OSH à REACH.

Solutions/Best practices

- Strengthen sector organizations that work as an intermediate for communication into the supply chain.
- Explore what is needed to help end users to better understand the message.
- Role for authorities to help sector organizations set this up better: strengthening knowledge. For instance, that authorities subsidize sector organizations (is practice in the Netherlands).
- · Role for authorities in quality control
- There should be better options to fit the exposure scenarios to the real scenario

Statement 6: Even if REACH information is communicated to an end user in the workplace there are psychological factors that influence if an end user will work safely with hazardous chemicals, like underestimation of risk, social norms, habits.



Mean = 4.6, min = 2, max = 5, 13 respondents

score	1	2	3	4	5
responses	0	1	0	2	10

Summary

- REACH cannot have a big impact to the solution to this question. Its more about culture.
- Role for sector organizations. But question is: why do these organizations not already take this role? They work 'for' their members, the companies in the sector. So if they don't think it's important it will not be a priority.

Solutions/Best practices

- Employer should ensure employees take the risks seriously and they have enough time to take protective measures. Employer responsible for this culture.
- Role for sector organizations in developing a harmonized approach to communicate to end users. Also, cooperation of different sector organizations within the supply chain.
- Remove discrepancies between REACH and other legislations (like OSH).
 Make sure REACH is in line with other legislation. No competition. REACH dossier information can be used by OSH.
- Translation of information to visuals and or other languages (provide language lessons). Translated by people close to the workers themselves. The basic info should be simple and understandable.
- Cleaning up recipes (remove dangerous substances as much as possible from mixtures)

Additional remarks from the final plenary session

- Is REACH just a piece of paper without proper communication?
- Who is the intended target group for the REACH information?
- REACH is for substances. Annex 2 in format SDS. Chemicals are mostly mixtures. There are a lot of Issues with mixtures, especially outside of EU. What to do for mixtures? Are mixtures part of the scope?
- OSH already existed before REACH on dealing with chemical substances.
 What is the added value of REACH?.
- The introduction of REACH has provided more data and paper.
- REACH resulted in more info on chemical hazards and how to deal with it.
- Bigger companies have done their own assessments.
- Verify whether OSH legislation is still in line with new info from REACH.
 Companies having trouble, put responsibility to consultants.

Workshop slides [1st plenary session]

CEFIC LRI B23 project

Optimizing the benefit of REACH worker exposure assessments: ensuring meaningful health risk communication

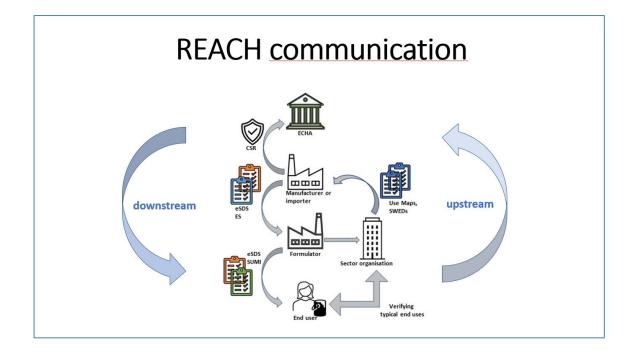












CEFIC LRI B23 project overview

Four work packages

- Literature study: Analysis of previous developments, existing processes and tools on communication of (safe) use conditions up and down supply chains
- Empirical study: Analysis of present communication practices up- and downstream and needs of
- Workshops in which recommendations for improvement of processes, methods and tools are discussed
- 4. Reported in report, scientific paper and core presentation / core poster











Introduction Project and monitoring team



Wouter Fransman



Henry Boumann Triskelion



Katharina Preuhs



Rianda Gerritsen







Hans Marquart



Wilma Otten



Dide Reijmer

Monitoring team present

- Dook Noij
- Evelyn Tjoe Nij
- Wouter ter Burg
- Celia <u>Tanarro</u>

Introduction Goal of workshop A

Discuss results up- and downstream communication under REACH in Dutch case studies

- Identify similarities and differences between the Netherlands and other EU countries with respect to the results
- Identify good practices and ideas on improvement/how to handle the concerns raised by the











Introduction

program

9.00 - 9.15Opening and introduction participants

9.15 - 9.45Plenary: Results up- and downstream communication under REACH

Coffee Break 15 minutes

10.00 - 10.20 Round 1 breakout rooms

10.25 - 10.45 Round 2 breakout rooms

Coffee Break 15 minutes

11.00 – 11.45 Plenary: presentation and discussion Breakout Rooms

11.45 - 12.00 RECAP

12.00 Closure

Introduction

Getting to know each other briefly

Use your phone or second display for login to Menti

Go to Menti.com and use code 1508 4617

Or use the link in chat or QR code:



Keep mentimeter open during the rest of the workshop











Methods

WP 1 Literature study

SEARCH for tools and studies

- · Expert knowledge of project- and monitoring team
- Define keywords
- Databases <u>Pubmed</u> & Google <u>scholar</u>
- Websites of some institutes, like ECHA and the UK Health and Safety (HSE)
- 'Snowballing'
- → 44 relevant documents in data extraction table

Tools

- 13 tools selected from a broader set
- Three categories
 - o EU legal tools (REACH, CSR, ES, SDS)
 - o ECHA guidance documents
 - o else: Use Maps, SWEDS, SUMI, ...

Studies

- 21 studies 2012-2020
- · Three categories
 - 'scientific studies'
 - o posters/presentations stakeholder meetings
 - o else: news articles, summary reports, meeting summaries

Methods WP 2 Empirical study

Interviews

- 6 <u>use</u> cases <u>representing</u> down stream users (companies)
- 2 sector organizations, 2 registrants

Recruitment, privacy and consent

- Recruitment through network project- and monitoring team
- Independent TNO ethical committee approval
- Non <u>Disclosure</u> Agreement <u>with</u> 4 companies
- Informed consent
- Separate feedback report per use case
- Reports of interviews approved by companies/interviewees
- 4-7 months between 1e contact and last interview

Interview protocol use cases

- REACH documents for a specific substance
- Questions based on McGuire's communication and persuasion matrix

	Overview use cases WP 2								
	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6			
Number of employees	Ca. 100	> 1000	< 10	10-50	> 1000	Ca. 400			
Technological sophistication	High	High	Low	Low to medium	Low to high	Medium			
Sector	Machine building & Packaging	Electrical & electronic equipment	Specific construction company	Formulation of chemical products	Road and tunnel building	Formulation of cosmetics and cleaning agents			
Organisation of sector	Machine Building: well organised, Packaging: Unknown	Well organised	self-employed with contacts in sector organisation	Well organised	Well organised	Well organised			
Knowledge of org. and env. Health	Present	Present	Limited to none	Limited	Present	Present			
Number of interviews & Interviewees	A. technical sales manager B. HSE specialist C. sales director Benelux	A. team leader B. senior operator C. two HSE managers D. contact person Health and Safety + HSE coordinator E. SHE database administrator F. senior operator	self-employed handyman	Group interview with 4 persons: representatives of 2 sector organisations, 1 formulator paint, 1 formulator glue and sealant	A. purchas-ing director B. manager safety C. QSHE advisor/safety expert D. employee QSHE department + manager purchasing dept. E. building contractor	A. manager R&D, Legal affairs B. employee dept regulatory affairs			
Nr of documents (input interview)	18	6	1	NA	5	7			

WP 1 and WP 2 Results of our research activities

Results and conclusions of WP 1 and 2 are comparable

Workshop A Focus on WP 2 <u>results</u>: Dutch or European concerns in <u>communication process</u>

WP 2 communication perspective COMMUNICATION MODEL SENDER Channel MESSAGE FEEDBACK Noise Noise Sustained use Reinforcement Sustained use Reinforcement

Main result - 1

The message

Many downstream users consider the Exposure Scenarios and eSDS (if they know them) as too long, too complicated and too technical in terminology.

"The extended safety data sheet is often very long and unnecessarily complex. The reality has been translated into REACH language, but only few people understand this REACH language, so the document has largely fallen on deaf ears."

Poll

"Many downstream users consider the ES and eSDS to be too complex."

How strongly do you recognize this in your country? 1 = not at all to 5 = very strongly

Please go to Menti.com and enter the code: 1508 4617

Main result - 2

The message

Although the inherent complex nature of the safe handling of hazardous substances is acknowledged, almost all interviewees believe the complexity of the REACH legislation and documents (e.g., safety data sheet) may result in a less safe working environment, because resources can only be spent once.

"I absolutely understand the added value of REACH and that the legislation certainly contributes to working safely with hazardous substances. However, I also think that the legislation is extremely complex and the rules are often 'overshot'."

Poll

"Resources spent to REACH can better be spent to really improve safe working conditions."

How strongly do you recognize this in your country? 1 = not at all to 5 = very strongly

Please go to Menti.com and enter the code: 1508 4617

Main result - 3

Receiver

<u>Characteristics</u> of downstream users like <u>size</u> of <u>the</u> company, <u>organization</u> of <u>the</u> sector <u>and</u> expertise/experience of employees have a strong impact on <u>dealing with</u> REACH requirements.

"This missing expertise becomes more severe as the company in question gets smaller. Smaller companies are less likely to employ experts who have the knowledge to properly understand a safety data sheet."

Poll

"The \underline{one} -size-fits-all approach of REACH $\underline{hinders}$ effective communication for specific companies, like \underline{SMEs} ."

How strongly do you recognize this in your country? 1 = not at all to 5 = very strongly

Please go to Menti.com and enter the code: 1508 4617

Main result - 4

Supply chain: sender-receiver

<u>There</u> are few feedback loops in <u>the communication process</u>. It seems mainly a top-down communication flow that the document developers are not in contact (either direct or indirect) with the users, resulting in a mismatch in information and poor understanding.

"We have established a number of working groups with a number of factory sites to assist with tools we are developing. But in practice, I think we have too little contact with the operators on the workplace to really have a picture of what is going on there."

Poll

"Feedback is <u>lacking</u>, <u>especially from</u> end users <u>to</u> upstream users."

How <u>strongly</u> do <u>you recognize this</u> in <u>your</u> country? 1 = not at <u>all to</u> 5 = very strongly

Please go to Menti.com and enter the code: 1508 4617

Main result - 5

Supply chain: sender-receiver

There seems to be a diffusion of responsibility in the supply chain. End users and formulators point upstream that registrants do not deliver correct or sufficient information, while registrants point downstream that end users lack the knowledge, skills and resources to correctly interpret and use the information that registrants provide.

"Producers who supply directly to the market are under a magnifying glass by controlling authorities. ... At the supplier of the raw materials, things are often not in order and we have to take care of that, because we are checked."

Poll

"There is a diffusion of responsibility in the supply chain."

How strongly do you recognize this in your country? 1 = not at all to 5 = very strongly

Please go to Menti.com and enter the code: 1508 4617

Main result - 6

Receiver

Even if REACH information is <u>communicated to an</u> end user in <u>the workplace there</u> are <u>psychological</u> factors that influence if an end user <u>will work safely with hazardous chemicals</u>, like <u>underestimation</u> of risk, <u>social norms</u>, <u>habits</u>.

"I see some added value in attention for working with hazardous substances. On the one hand my health is important, on the other hand taking protective measures is often at the expense of pragmatism or efficiency."

Poll

"REACH information is <u>just one</u> of <u>the</u> factors promoting <u>working safely by</u> end users in <u>the workplace</u>."

How strongly do you recognize this in your country? 1 = not at all to 5 = very strongly

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Appendix 7: Report workshop B

The exposure tools (both models, such as ART, and wider tools, such as Chesar) play a pivotal role in the whole process of communicating safe use conditions. This is due to the upstream communication being used to provide input to exposure tools while the downstream communication is fed by the output of exposure tools. During workshop B, expert users and developers of existing exposure models discussed the implications of the results of the project. These concern results of an international literature study and an empirical study interviewing up- and downstream users on how they deal with REACH legislation and documents (i.e., safety data sheets and exposure scenarios), how the communication about working safely with hazardous substances runs through REACH and to what extent this actually promotes safe working in the workplace.

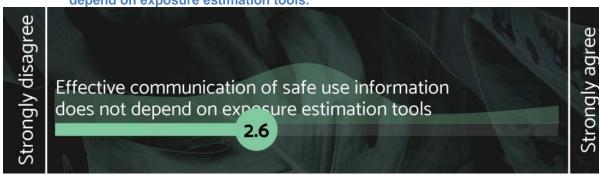
The goal of this workshop was to:

 Identify improvements of exposure tools to enable more effective derivation, communication and implementation of safe use scenarios related to our results, needs of end users (terminology, format), links of parameters of the tools in relation to the end user specifics, pitfalls of the tools and what needs to change in the tools to improve the up/downstream communication.

Four statements were polled during the first plenary of the workshop with MentimeterÒ. The statements related to the results emerged during the literature and empirical study. Statements were polled with the response options ranging from 1=fully disagree, to 5=fully agree. Some statements were followed up with open questions, whose answers are also described under that specific statement.

After the poll, these statements (including follow up questions) were discussed in breakout rooms of each 5-6 participants with variation in professional background and country. By means of shuffling participants, each participant got the chance to discuss two separate statements in two different breakout rooms. As such, each of the four statements was discussed twice per breakout room, getting input from different participants. Each breakout room lasted 20 minutes. Two breakout rooms had a facilitator and note taker from the project team, and in two breakout rooms one member of the project team facilitated and took notes. In the plenary session afterwards the results of the break out rooms were presented and discussed in 45 minutes. Below these results are presented per statement.

Statement 1: Effective communication on safe use information does not depend on exposure estimation tools.



Mean = 2.6, min = 1, max = 5, 17 respondents

score	1	2	3	4	5
responses	4	3	7	1	2

Breakout rooms

Are the conditions and risk management measures in exposure estimation tools (e.g. ECETOC TRA, EMKG tool, ART, etc.) sufficiently understandable and specific for end users? Why / why not?

- Some input parameters in the tools are not understandable by end users (e.g. "ventilation with 80% efficiency"), further down the chain information is not always clear
- The output from tools does not reach the end user
- Tools require considerable expertise in occupational hygiene
- Miscommunication on terminology in tools (e.g. exhaust ventilation)
- Registrant has the responsibility to provide the necessary information
- Too much focus on industrial applications but not so much for the end user.
- Most workplaces prioritize on the hazard information, with less focus on exposure (reduction) (i.e. control banding)
- Workers are exposed to a mixture of chemicals, while REACH focuses on single substances
- Input parameters need guidance to facilitate the correct choices.
- Tools try to cover everything in generic models.

How can the results (i.e., conditions and risk management measures related to exposure levels) of exposure estimation tools be made more useful for end users?

- Several responses referred to the guidance to understand tool input parameters (pictograms, visuals, etc.) and on how to work safely with hazardous substances (RMM).
- Tools should provide more guidance on how to (practically) implement RMM in addition to control banding.
- Translate tool output to action plan.
- Make the tool easily understandable.
- Measurements to verify control measures efficiencies.
- Translate knowledge from exposure tools to workforce (Similar to discussion on translation from eSDS to workplace instruction protocols).
- Several responses referred to translation of general information from tools to the specific workplace is needed (and to specific sectors).

Notes plenary sessions relating to statement 1

- REACH RA is not specific but general. Should be valid for all comparable workplaces in Europe. Specific workplace RA is only valid for one company/workplace where the work is done.
- There are always needs to get additional information to make sure the information you have in SDS is accurate.

Statement 2: End user representatives should be more involved in development of exposure tools.



Mean = 3.8, min = 1, max = 5, 16 respondents

score	1	2	3	4	5
responses	1	2	2	5	6

Open question: [If yes,] in what part of the process and how should end users be involved in the development of exposure tools?

- From the start.
- Need to understand input parameters and (if relevant) output for communication.
- Interpretation between workplace description and tool input parameter.
- SUMI development.
- Involvement as end user of exposure tools and developer/advisor for those tools.
- In gathering the information on specified use through direct communication between registrants and users.
- · Risk assessment of their activity.
- Output design stage and presentation.
- Appropriate language (potentially sector specific).
- Ensure feedback loops.

Breakout rooms

For what type of exposure tools is more involvement of end user representatives beneficial?

- Tools for upstream communication of exposure information (e.g. Use maps).
- Tools for exposure estimation (e.g. ECETOC TRA, ART).
- Tools for downstream communication of exposure information (e.g. Exposure Scenarios, SUMI).

How can more involvement of end users be organized / stimulated?

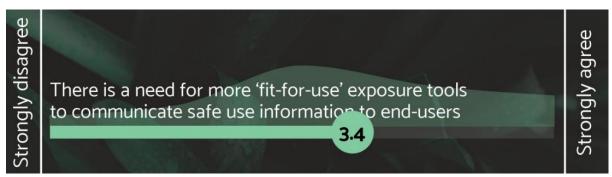
- Inclusion in all aspects: upstream, downstream, and exposure estimation.
- Important to distinguish which users we are talking about: at the workplace, HSE in companies, purchase in companies, legal requirements. All have different needs and hence should be involved differently.
- This goes from more generic REACH tools to company specific OSH tools that promote working safely in the workplace.
- It is about how to transfer the information from one level to the next level. Users also talk different languages. It is about interfacing.
- Several responses said it depended on who is the user of a tool, because you need to make it fit for purpose. Like it's impossible to make an exposure scenario without end users.
- Not only provide information, but also collect feedback via a helpdesk, provide training, YouTube videos. Implementation is more than providing information: Need not only give a tool, also train them how to use it in the proper way.
- Not sure if end users need to be involved in the most upstream / abstract level.
- Occupational hygienists need to be involved in development of tool. In each step it's impossible to not involve them.
- Upstream communication should be improved. Obligation of employers to do this. In order to write good scenarios (feedback not only from professionals but also workers).
- 6 steps, you do not involve all employees at every step.
- Right information needs to reach the right person (filtering mechanism).

Notes plenary sessions relating to statement 2

 What are responsibilities of tool owner? Extremely important point, should be some kind of requirement of tool development that developers have some kind of business model on how to improve and maintain the model within relevant time frame and how to help users and provide information. In some cases we have no scientific background of the models as it is not nicely/transparently documented. Also part of the business model of the tool: take into account when developing aspects like training, helpdesk, YouTube video. If you do not have any kind of these things, then he has personally doubts concerning reliability of the model.

- Tools always require a translation to a specific work field by an occupational hygienist.
- Use of the same tools for OSH and REACH possible. Only the aim is different:
 OSH is to justify that something is safe, while REACH provides safe use advise to the rest of the supply chain.

Statement 3: There is a need for more 'fit-for-use' exposure tools to communicate safe use information to end users.



Mean = 3.4, min = 1, max = 5, 16 respondents

score	1	2	3	4	5
responses	1	2	6	4	3

Open question: Why is there (no) need for more fit-for-use exposure tools?

- To get more close to reality data than the generic data used.
- These tools are already there.
- For a better understanding of the control measures.
- If the result of the exposure assessment is connected to the safe use advice this can be used together for the communication in the supply chain.
- Tools seem not to be the main issue/problem, but the right choice of input for a workplace situation (translation from workplace to tool input).
- Tools tend to be too general. This makes interpretation hard. It is a challenge to understand the limitations of each tool for different application
- There is a need for more fit for use SUMI, if SUMIs are to be considered as exposure communication tools.
- I am not sure if it is the tools; it is the system or the user that needs to be more fit for use.
- Systems can be adapted to convert the tool input in safe use advice without changing the tool itself. Problem comes if some of the inputs are not recognized by end users.
- Difference between expert exposure language and workers language. Local language being the most obvious one. WIC should be in simple language, user based formats. Not one size fits all.
- Issue would appear to be not so much the existing tools, but tailoring for end
 users, and mostly an issue for substances sold into many sectors/uses.
 Presumably part of the problem is traceable back into the SDS delivery systems
 and sales systems.

Breakout rooms

- Try to develop generic SUMIs which is easy if you have non-hazardous products, for more hazardous products they are useless, you need more tailormade output.
- End user point of view: challenge due to varied competencies, to have a fit-foruse exposure tool for communication, both should get something out of it.
- If tool is complicated or unclear what is communicated, the goal of the tool is wasted.
- Several responses referred to making information further up in the supply chain easier understandable.
- Also several responses said: Relate to who to fit this to: top registrants? DU?
 Therefore keep competencies and needs in mind.
- E.g., use generic SUMI method (A generic SUMI tool has already been developed and published. This can be used)
- Not clear what legislation is saying about requirements.
- 3-4 pages for all uses. Seems digestible.
- Real evaluation process needed for proper risk assessment (find balance between general and specific).
- REACH dossiers, depending on process they are very (too) generic, often only one situation therefore not general at all.
- Description of sufficient use should be kept more realistic (don't be too optimistic).
- Practical wording for information which is understood (e.g. gloves, mask).
- Common framework of knowledge, better sharing knowledge/information concerning ES.
- On regulatory/institutional level: activities/projects to create a widely accessible and widely shared.

Notes plenary sessions relating to statement 3

- Do not see need for additional tools, for instance in STOFFENMANAGER one
 can already create understandable information. It is already there and if you
 look at tools for chemical agents, most tools enable the making of WIC. These
 are already a step forward to making information accessible for employees.
 Needs translation, but it is already available. Layout can be different. No point
 in coming up with new tools to do this.
- Need to find easier way to find and share limits.
- Train user to use tools in proper way.

Statement 4: There should be a closer link between REACH and OSH-expertise.



Mean = 4.5, min = 3, max = 5, 16 respondents

score	1	2	3	4	5
responses	0	0	1	6	9

Open question: [If yes,] on which specific aspect should this closer link between REACH and OSH-expertise exist?

- Same or more harmonized wording (closer to end user).
- Agreed concept on when/how REACH data can be used for OSH and vice versa.
- SDSs should be made for the same purposes to be a help at the workplaces.
- Knowledge on the regulations and understanding that they both aim to improve the worker health and protect the environment.
- Easy reuse of data.
- On application of the different tools of exposure communication, agreeing on the usefulness and implementation.
- Exposure assessment (realistic conditions), understandable language in output and communication.
- Workplace assessments and measurements should be transferred to REACH and other way round the REACH information should use the language from OSH and translate to wider regions.
- The requirements of OSH legislation must also be met in compliance with REACH.
- Risk assessment. Exposure limits. Wording.
- If OSH risk assessment is available and checked by registered IH REACH ES check should not be necessary. Avoid double work.
- Identification of real work situations rather than theoretical simplified scenarios (both on complex exposure and mixture situations. Ensure agreement with EN-689.
- Best available techniques should merge into REACH.

Breakout rooms

- One problem is the fact that the tools often end up in PDFs or other non-transferable format.
- Even within larger companies there is still a gap in knowledge, expertise and language between REACH experts and OSH-experts; training may help.
- Often information is stuck in the range of formulators; they have less expertise than those who create the ES (and SDS).
- Most relevant information (from SDS/ES) to be put in electronic transferable format so that formulators can use it to create new safe use information for end users.
- More sector organizations should create SUMI or SUMI-like 'tools'.
- End user sectors can further translate into really practical info from SUMI.
- Maybe we should consider the OSH expert as the 'end user' of the exposure tool output.
- Older registrations were made under enormous time pressure and without sufficient tools, so quality could have been better.
- The information to be used is more important than the tool.

Notes plenary sessions relating to statement 4

- Information is never the key to behaviour change. We talked about comprehension. If the information is about behaviour change, then people should also see the benefits and see people around them to adopt the new behaviour and feel able to do that. And they should also have training but there could also be constraints for them to do it such as "speed up" and they feel that they cannot do it.
- Conscious decision making, there are also habits. If someone has done it for a long time a certain way, this requires a different approach, here the focus is on the message and understanding the information / knowledge transfer.

• Clear that there is a need to use the proper expertise from people downstream in creating documentation and translating it to DU via tool or directly, there is also a clear view that implementation is very important and needs more than information. Also there are options to make life simpler by linking tools to each other electronically so that copying of information can be made simpler. Would be great if more sector organizations would feel more responsible but have no obligations and therefore should be incentivized to play a greater role. Sending info downstream that is understandable.

Conclusions

There is reasonable agreement that end users should be more involved in development (and use) of exposure tools to ensure that the results are useful for them. Several 'fit-for-use' tools, or tools that can be made fit for use, are already available and can be used more effectively. Practical wording and a common understanding of information would help. There was much agreement about the fact that there should be a closer link between OSH and REACH, because (for worker safety) they have the same goal and because OSH-experts know the real situations and understand technical wording. However, information itself is not the key to (behaviour) change. Other aspects, e.g. seeing benefits, feeling able, are very important. Information is already there (in one form or another), but implementation of safe use advice should be improved.

Screenshots slides (1e plenary)

CEFIC LRI B23 project

Optimizing the benefit of REACH worker exposure assessments: ensuring meaningful health risk communication

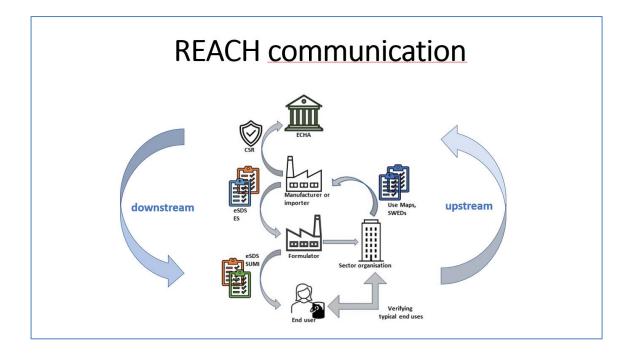












CEFIC LRI B23 project

overview

Four work packages

- Literature study: Analysis of previous developments, existing processes and tools on communication of (safe) use conditions up and down supply chains
- Empirical study: Analysis of present communication practices up- and downstream and needs of stakeholders
- Workshops in which recommendations for improvement of processes, methods and tools are discussed
- 4. Reported in report, scientific paper and core presentation / core poster











Introduction Project and monitoring team



Wouter Fransman TNO



Henry Boumann Triskelion



Katharina Preuhs





Rianda Gerritsen





Monitoring team present

- Dook Noij
- Evelyn <u>Tjoe Nij</u>
- Wouter ter Burg
- Celia Tanarro
- Urs Schlüter



Wilma Otten



Goal of workshop B

Identify improvements of exposure tools to enable more effective derivation, communication and implementation of safe use scenarios related to our results, needs of end users (terminology, format), links of parameters of the tools in relation to the end user specifics, pitfalls of the tools and what needs to change in the tools to improve the up/downstream communication











Introduction

program

13.30 – 13.45 Opening and introduction participants

13.45 – 14.15 Plenary: Results up- and downstream communication under REACH

Coffee Break 15 minutes

14.30 - 14.50 Round 1 breakout rooms

14.55 – 15.15 Round 2 breakout rooms

Coffee Break 15 minutes

15.30 – 16.15 Plenary: presentation and discussion Breakout Rooms

16.15 - 17.00 RECAP

17.00 Closure

Introduction

Getting to know each other briefly

Use your phone or second display for login to Menti

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Or use the link in chat or QR code:



Keep mentimeter open during rest of workshop











Methods

WP 1 Literature study

SEARCH for tools and studies

- · Expert knowledge of project- and monitoring team
- Define keywords
- Databases Pubmed & Google scholar
- Websites of some institutes, like ECHA and the UK Health and Safety (HSE)
- 'Snowballing'
- ightarrow 44 relevant documents in data extraction table

Tools

- 13 tools <u>selected from</u> a <u>broader</u> set
- Three categories
 - o EU legal tools (REACH, CSR, ES, SDS)
 - o ECHA guidance documents
 - o else: Use Maps, SWEDS, SUMI, ...

Studies

- 21 studies 2012-2020
- Three categories
 - 'scientific studies'
 - posters/<u>presentations</u> stakeholder meetings
 - o else: news articles, summary reports, meeting summaries

Methods WP 2 Empirical study

Interviews

- 6 use cases representing down stream users (companies)
- 2 sector organizations, 2 registrants

Recruitment, privacy and consent

- Recruitment through network project- and monitoring team
- Independent TNO ethical committee approval
- Non <u>Disclosure</u> Agreement <u>with</u> 4 companies
- Informed consent
- Separate feedback report per use case
- Reports of interviews approved by companies/interviewees
- 4-7 months between 1e contact and last interview

Interview protocol use cases

- REACH documents for a specific substance
- Questions based on McGuire's communication and persuasion matrix

Overview use cases WP 2						
	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6
Number of employees	Ca. 100	> 1000	< 10	10-50	> 1000	Ca. 400
Technological sophistication	High	High	Low	Low to medium	Low to high	Medium
Sector	Machine building & Packaging	Electrical & electronic equipment	Specific construction company	Formulation of chemical products	Road and tunnel building	Formulation of cosmetics and cleaning agents
Organisation of sector	Machine Building: well organised, Packaging: Unknown	Well organised	self-employed with contacts in sector organisation	Well organised	Well organised	Well organised
Knowledge of org. and env. Health	Present	Present	Limited to none	Limited	Present	Present
Number of interviews & Interviewees	A. technical sales manager B. HSE specialist C. sales director Benelux	A. team leader B. senior operator C. two HSE managers D. contact person Health and Safety + HSE coordinator E. SHE database administrator F. senior operator	self-employed handyman	Group interview with 4 persons: representatives of 2 sector organisations, 1 formulator paint, 1 formulator glue and sealant	A. purchas-ing director B. manager safety C. QSHE advisor/safety expert D. employee QSHE department + manager purchasing dept. E. building contractor	A. manager R&D, Legal affairs B. employee dept regulatory affairs
Nr of documents (input interview)	18	6	1	NA	5	7

WP 1 and WP 2 Results of our research activities

Results and conclusions of WP 1 and 2 are comparable

Workshop B Background/Definition

'Exposure tools': present information on uses, conditions, RMM upstream, make exposure estimates and send information on safe use conditions downstream

- Upstream exposure tools: e.g. Use maps
- Exposure estimation tools: e.g. ECETOC TRA, ART
- Downstream exposure tools: e.g. SDS, exposure scenarios, SUMI

This workshop aims to discuss improvements of tools to improve communication of safe use conditions \rightarrow safer use by end users

It is <u>not</u> to discuss the validity of exposure estimation tools!

Result 1 Use maps, SWEDs End users Registrants Safety data sheets / Exposure scenarios SUMI SDS / Product label

Statement 1: Effective communication of safe use information does not depend on exposure estimation tools (scores: 1 <u>fully disagree to 5 fully agree</u>)

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Result 2

- Most effort of REACH stakeholders in tools for upstream communication
 - Exposure <u>estimation</u> tools have a <u>communication</u> aspect
 - Assisting tools are used, e.g. standard phrases
- End-user $\underline{\text{involvement}}$ in development / $\underline{\text{use}}$ of these tools not $\underline{\text{really visible}}$

Statement 2: End-user <u>representatives</u> <u>should</u> <u>be</u> more <u>involved</u> in development of exposure tools (scores: 1 <u>fully</u> <u>disagree</u> <u>to</u> 5 <u>fully</u> <u>agree</u>)

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Result 3

- Awareness / understanding of REACH very low at end-users
- Improved hazard data thanks to REACH driver for modifications in workplace safety
 - End-users mainly use info from body of SDS and labels largely on PPE
 - These tools already existed before REACH
- REACH / SDS / exposure scenarios considered too complex and not all parts relevant to end-users
 - Making REACH practical to end-users appears to be missing

Statement 3: <u>There</u> is a <u>need for more 'fit-for-use'</u> exposure tools to <u>communicate</u> safe <u>use</u> information to end-users (scores: 1 <u>fully disagree</u> to 5 <u>fully agree</u>)

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Result 4

- Quite some work done on digitisation and harmonization
- Pros: consistent wording; efficient upstream communication; facilitates consistent interpretation
- Cons: <u>Harmonised</u> garbage in, <u>harmonised</u> garbage out; one size does not fit all; <u>harmonised</u> 'registrants'-wording not understandable for end-users
- More involvement of occupational safety and health expertise can help to make REACH more useful for end-users

Statement 4: <u>There should be</u> a closer link <u>between</u> REACH <u>and</u> OSH-expertise (scores: 1 <u>fully disagree</u> to 5 <u>fully agree</u>)

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Appendix 8: Report workshop C

Workshop C started with a short recap of methods and results from earlier activities of the project (WP1, international literature review and WP 2, empirical case studies). Furthermore, findings of workshop A and B were brought up, forming the concerns to be discussed in workshop C as they emerged as reoccurring or relevant topics from workshop A and B.

The goal of this workshop was to:

 Identify and prioritize aspects to improve communication concerning processes, tools, methods, formats, relevant stakeholders and drivers and barriers related to REACH.

Based on the previous two workshops, 5 concerns and possible improvements were formulated by the project team and each of these concerns / improvements was discussed in a 45 min Breakout room (BOR). Based on the experiences with the previous two workshops we decided to have a longer more in-depth discussion with the same participants in one breakout room. Per breakout room about 4 to 5 persons from different countries and stakeholder groups participated. Each breakout room had a member of the project team that took notes on a PPT slide that was displayed on the screen during the breakout room meeting, so that the participants could check if their remarks were written down correctly. One breakout room had two members of the project team to facilitate and take notes. In the 45 minute plenary session afterwards the PPT results of the break out rooms were presented and discussed. For each concern the following points were discussed for each improvement in the BOR and written down on the PPT slide.

- Pre-conditions
- Barriers/Promoters
- Key stakeholders
- Next steps to take

Concern 1. There is insufficient communication on the provided documentation and information within the supply chain

Suggested improvements

- 1. Establish a communication structure/feedback mechanism in supply chains.
- 2. Enforce feedback loops within the supply chain to ensure responsibility.

Breakout room

At the start of the breakout room it became clear that there already was a communication structure in the supply chain required by REACH. Therefore a new improvement was formulated.

Improvements

A legal feedback structure is already available up- and downstream. Question is does it work? Improvement should focus on support to meet this legal feedback structure. Suggestion is to have this legal standard supply chain communication in a standardized letter and also include a process how to use this letter in a timely manner in order to get feedback in time (mentioning legal responsibilities).

Preconditions

- Accepted by actors in chain.
- Now legal requirement that something physically is communicated, so digital format (e.g. XML) is questionable.
- · Resources for ECHA.

 Incentive for registrant to update CSR after registration deadline? Also efficiency gains to use this process.

Barriers/promotors

Promotors

- Having XML-format for the timing
- Legal structure feedback
- Needs time for existing solutions to really work. No add-ons. Make existing things more accessible.
- Sector Use maps

Barriers

- Legal barrier, see precondition for XML.
- Experienced benefit: What's in it for me when I take the effort to provide feedback.
- Complexity of supply chain (length and cross border)
- No format for key information for upstream communication.

Key stakeholders

- ECHA
- Registrants
- End users
- Formulators
- European Commission
- Sector Organizations
- (IT-providers if XML)

Next steps

- Discuss further in Exchange Network on Exposure Scenarios (ENES)
- CEFIC or DUCC (Downstream Users of Chemicals Coordination Group) ask for meeting ENES
- Assess options to help DU to have their uses implemented as identified uses of substances in CSR.
- See how improvement of standardised communication can be implemented.

Plenary session regarding concern 1

The problem is the complexity of the supply chain, not the supply chain itself. When looking at a standardized format users can add to existing formats to make it easier to include additional uses in the chemical reports.

There is a need for distinction between downstream communication eSDS and SDS which is a legal requirement and for which many things have been arranged compared to communication upstream.

When talking about electronic data exchange there is already a lot going on, even though it is not yet close to completion. A lot of work has been done there, but also to send information upstream. Electronic data format in XML is something which is not legally required. According to the current legislation one needs to send something physical, and XML is officially not accepted now.

What are actions to simplify or assist the simplification? There are so many actors of which some are not even informed about potential solutions. Supply chain cannot be simplified but changing the standardized format may help to speed up the process. It is essential to elaborate whether subjects in supply chain lack understanding of REACH in general.

Are end users that do not formulate products, sufficiently involved in ENES?. According to some participants of the workshop, end users have been present in ENES. have highlighted their concerns and have been party to the discussions in

ENES. However, it seems that in reality actual end user organizations have hardly been involved.

Currently configuration of developing groups doesn't involve actual end users and their organizations, but quite some formulator sector organizations needs are filled in, many of whom know their end user communities very well so in an indirect way there is a platform. Involvement of actual end users would be next step to make sure all relevant inputs are taken on board.

Concern 2. Exposure scenarios and (e)SDS are too complex

Suggested improvements

- 1. Simplify information: Select most important information that has to be provided through the supply chain and provide that in an easy-to-use way
- 2. *Improve knowledge/expertise*: Better implementation of information via improved education, training, to-the-point guidance, video, etc.

Breakout room

Improvement 1

Simplify information: Select most important information that has to be provided through the supply chain and provide that in an easy-to-use way

Preconditions

- · Separate sending and receiving
- Quality of the eSDS needs to be improved
- Remain current eSDS, and at the receiver extract the information you need
- Special attention to workers with low education and language problems

Barriers/promotors

Promotors

Make eSDS information transferable in XML

Barriers

eSDS are in pdf and not easily electronically transferable

Key stakeholders

- The sender (registrant) is responsible for transferring the right information
- ECHA has a role in this

Next steps

- Digitalisation: Make sure that the downstream (eSDS) information is correct and transferable (not pdf but XML)
- Improve REACH guidance based on lessons learned
- Harmonize language to improve digital communication

Improvement 2

Improve knowledge/expertise: Better implementation of information via improved education, training, to-the-point guidance, video, etc.

Preconditions

- SMEs need clever systems to assist them in interpreting eSDS
- Depends on training/schooling between EU countries

Barriers/promotors

Promotors

OSH experts need to assist in translating information from eSDS to work floor Barriers

None discussed

Key stakeholders

- The receiver has local workplace information
- SMEs can be assisted by sector organisation

Next steps

- Intermediate (sector organization) transfer this information to the workplace
- · Create videos, to-the-point guidance
- Train the trainer

Plenary session regarding concern 2

One could argue that an eSDS must be even more complex in such a sense that it should provide information that suits the need of a variety of sectors that uses the eSDS. The sector then can extract and use the information it needs from the eSDS. The eSDS thus needs to have information about the model behind it, calculations and how to scale your exposure calculation, etc.

Concerning language problems: the docs are meant for experts to interpret it and translate to work instructions for workers themselves who may have lower education and language problems.

General comment on the topic of 'exposure scenarios and (e)SDS are too complex': IT-providers are also important key stakeholders to make XML-method of sending (e)SDS possible, in particular at the receiving end.

How to realize this? The issue is that it needs to be translated for a specific sector. Should be sector organizations that take into account specifics and how to best train the audience, this is what we saw in NL. Potentially create leaflet with ideas for sector organizations following this workshop.

This issue needs to be financed. Promoter EU funding to realize this? Making funds available to outsource training to relevant parties would be very valuable indeed.

Concern 3. Existing exposure tools insufficiently lead to useful results for end users

Suggested improvements

- 1. Clarification: Better clarify and define the target audience per exposure tool
- 2. Specific results: Create (additional) tools to translate to more practical and (sector) specific results
- 3. OSH-expertise: Ensure involvement of OSH-experts in interpretation and use of results

Improvement 1

- Better clarify and define target audience per exposure tool.
- Audience SDS is wide: company managers, workforce, HSE people, technicians, assisting personnel, poison centres.
- ES: target responsible people for HSE at work floor, responsible for risk assessment, workers involved. According to law employer is target should make info available in understandable form.

Preconditions

Clarity what bits and parts are for what target audience.

Barriers/promotors

Promotors:

training of workers in SDS reading (required?)

Barriers:

None discussed

Key stakeholders

- Employers
- Employees
- Authorities

Next steps

Digitisation can split up parts to be sent to specific targets.

Improvement 2

Create (additional) tools to translate to more practical and (sector) specific results

Preconditions

- Need expert input
- Proper information coming from suppliers
- Clarity on target and what is understandable
- What problem to be solved

Barriers/promotors

Promotors:

- Commercial solutions already exist (for substances) not per se supported
- Digitalisation

Barriers:

Lack of money

Key stakeholders

- Employer
- Formulators
- Suppliers
- End users

Next steps

Official translation of terminology

Improvement 3

Ensure involvement of OSH-experts in interpretation and use of results

Preconditions

No differences in countries between (OSH-)legislation

Barriers/promotors

Promotors:

Rules to ensure involvement of experts at workplace

Barriers:

None discussed

Key stakeholders

- Employers
- Experts

Next steps

There was insufficient time in the break out room to discuss next steps

Plenary session regarding concern 3

Who has the responsibility to digitalize the process?

Difficult to define/interpret, probably the party that sends out SDS is the substance supplier and 2nd instance formulator. Responsibility for digital version is on them, but

could also be on IT companies as there are several IT companies making SDS and then of course the proper expertise should be involved to enable format so that someone can also choose what to say to specialist or person who buys the product etc. IT specialists are probably stakeholders.

Legal requirements to transfer something 'physically' in supply chain potentially preventing digitalization? Law might need to be changed.

Not everyone agrees that it's a legal requirement to have paper / PDF format sent, review legal text to check on what is required and if XML package would also be acceptable? (Best done by lawyer)

Depending on the country this legal requirement is enforced differently. There still seems a lot of unclarity and no agreed way on enforcement in EU countries. Would help if there were some enforcement group that could make a statement on what would be acceptable in all countries in the EU, that could already help.

Does anybody know what is the reason/intention behind that it should be physical at least? And the fact that it should be sent physical doesn't withhold one to sending it in XML. E-mail is also considered physical. Apparently there is some guidance to refer to.

Agree that it should be active deliverance, not physical but *active*. In many member states they accept electronic supply of SDS. XML is part of electronic deliverance, can be different from country to country, they only think electronic is not accepted if someone sends a link where the user must look up the SDS this is not acceptable, but when the link goes directly (to the information) it is acceptable. This is written in manual of conclusion.

In NL an SDS can be delivered electronically.

Concern 4. REACH and OSH cooperation

Suggested improvements

- Bring more sector organizations with internal or external OSH expertise to work on sector specific input for registrants and sector specific output for end users (e.g. SUMI); preferably by cooperation between formulator sector and end user sector
- 2. Increase motivation to make use of external REACH and OSH expertise (on use of REACH information): Better support systems for organizations (external support), e.g. via sector organizations

Improvement 1

Bring more sector organizations (SO) with internal or external OSH expertise to work on sector specific input for registrants and sector specific output for end users (e.g. SUMI); preferably by cooperation between formulator sector and end user sector

Preconditions

- Well organized sector organisations
- Harmonized safe use information from registrants
- Expertise of those using the models required
- More guidance by ECHA

Barriers/promotors

Promotors

• If OSH is done right, then REACH is mostly covered

Barriers

- Not all companies are represented by a sector organisation
- REACH is not high on the agenda
- Big organisations have a bigger say in the SO, but the small ones have a bigger need for help

 Those doing assessments in dossiers need sufficient background on using models

Key stakeholders

- Industry and formulators have to get active: facilitate the development of information for mixtures
- ECHA
- Sector organisations
- Authorities

Next steps

- Show when either of one is of value, e.g. through publications
- Bring OSH and REACH together on the authority level
- Bring OSH experience by asking OHs for feedback on REACH dossiers (authority good practice?)

Improvement 2

Increase motivation to make use of external REACH and OSH expertise (on use of REACH information): Better support systems for organizations (external support), e.g. via sector organizations

Preconditions

- There needs to be a strong need
- It needs to seem doable

Barriers/promotors

Promotors

- Automated processes
- · Economic driver

Barriers

- Organisations (companies) feel they have done it (OSH) and have to do the same again (REACH)
- Fear for need to take products off the market

Key stakeholders

There was insufficient time in the break out room to discuss next steps

Next steps

There was insufficient time in the break out room to discuss next steps

Improvement 3

Formulators get the responsibility / legal obligation to provide SUMIs (not registrants)

Other aspects not discussed.

Plenary session regarding concern 4

Having to overdo efforts: Not specific sector organizations but also companies or SME, they have already shown that processes are safe on OSH and now they need to check again that Safe use conditions apply to them, it may feel for them that this was already done so there is no motivation to look any further.

Every year there are reports on cancer cases as a consequence of exposure to hazardous substances, while every company claims to have OSH well done. So is it really true that companies have shown that processes are safe? How is this helping the cooperation between REACH and OSH?

Should there be more cooperation on authority level? Is that legislation or execution? As they need to get in contact with each other.

Example Germany: One problem we have to deal with is that we are not always thinking that OSH and REACH is something that could work together and that we should do that. We think we should work together. Everyone working under OSH thinks everything under REACH is an additional workload. REACH is something new and other people only working on REACH see that part. There are only a few people connected to both, we are still trying to point out the advantages of both systems.

Might be formal reasons for that. REACH is European legislation valid in all member states. OSH has a high national part in it. There is an authority side, only little connection due to historical reasons between REACH and OSH reasons. The same is true for industry, REACH and OSH people don't talk to each other much, 2 years ago a workshop was organized to bring them together and people who attended told me later that half of the workshop they tried to find a common language because they use words differently so there is a lot of improvement possible and a lot of people already understand that and we are on a part of the solution already. They need to talk to each other better.

In a number of member states, OSH and REACH competence are in different authorities, and may have different priorities. That is why they may need to cooperate. Even at EU level there is a differentiation between DG Employment (OSH) and ECHA (REACH). Different authority groups also tend to 'compete' regarding competences and power.

Concern 5. SMEs do not have the expertise, experience, knowledge, capacity to understand, use and adapt the information

Suggested improvements

- 1. Increase 'internal' expertise
- 2. Obtain 'external' knowledge/expertise

Improvement 1

Education, training, to-the-point guidance, video, etc. specifically for SMEs

Preconditions

Information should be more

- Accessible/readable/attractive format inform
- Simplified
- Also (more) training is needed (selecting ExpScenarios)

Barriers/promotors

Barriers

- Insufficient knowledge/awareness
- Motivation/behaviour/attitude
- Too much info
- reliance in whole sale dealers

Promotors

- + Safer environment
- + Compliance

Key stakeholders

- -SME
- -Authorities/Inspection
- -Sector organization (training)
- -National helpdesks (translation guidance)

Next steps

- More focus on awareness, flyers from authorities

- Making available (translated) supporting information
- Propose incentives?

Improvement 2

Organise access to external REACH & OSH expertise (on use of REACH info) Better support platforms for SMEs, e.g. sector organisations. Encourage using external REACH & OSH expertise use of REACH info).

Preconditions

Sufficient awareness (realize support is needed)

Barriers/promotors

Barrier

Budget/finance

Promotors

- Outsourced (more time)
- Compliance
- Safer environment
- Subsidies

Key stakeholders

- SME
- Sector organisations
- Consultancies
- (local) government / enforcement
- Supply chain

Next steps

More focus on <u>awareness</u>

Plenary session regarding concern 5

Help SMEs realize that they can get help to get out of the data that's available.

Also we were thinking of awareness of the obligations that you know you have some obligations and another thing we have discussed is the awareness and the motivation to do something about it.

How about construction companies who get their stuff from construction markets. Is there not a role for them to inform the small handymen and small companies? They probably get information via SDS or label. Not sure if they actively inform their consumers about changes. Possible channel for small companies?

Concerning retailers for public market: if products are also accessible for professional market they should already cover for this. Obligations are different. Main information is electronic SDS as a way to simplify them or split parts of them up to different target audiences. Where does responsibility lie to ensure information is still complete? If you simplify information who is responsible for it?

Especially higher up in the supply chain you might need more information than your supplier may think you might need. Yesterday in my course on REACH and eSDS first thing I showed an eSDS with 500 pages and show you need 15-20 at max. At the end if you look at communication to end users it should be done in a constructive way. Should be in main body of SDS, or SUMI. This should be done as sector organizations which is keyplayer. Need to harmonize to communicate and SUMIs go into that. If you do not have a SU you can have a general format.

On responsibility... ideal in creating understandable information but it's clear that the party sending product to DU is responsible for correctness of information. Employers are responsible that workers are informed by proper information and working safely. Sector organizations can help here.

In Germany if you buy specific kind of pesticides for professional uses, make sure that it is a professional user and not a consumer. So they are locked behind bars of some kind.

Final Remarks

It seems sector organizations have a lot to do as solution for all our problems but seem not to be directly responsible for implementation of REACH legislation. Medicines for patients have use instructions (in Dutch: "bijsluiter"), but they translated them in small videos presenting most important information (in Dutch: "kijksluiter"), that could be an example to use for REACH documents.

Awareness is a keyword in last concern we discussed. We had 2-year campaign in the Netherlands on awareness, not on REACH but working on hazardous substances.

Most things focused on process generators and which don't fall under most of what we discussed today and other ways to inform SMEs. E.g. gamification, toolbox meetings, something which is appreciated more than a bunch of text, work more with pictures and films also for same reason. Currently, project with RIVM trying to disclose for small SMEs if the information in REACH for them via infographics. Something to yield results beginning next year that they can share and might be a major overlap.

Set up a discussion group and share knowledge? Few steps in right direction, in a structured way.

Screenshots slides (1st plenary session)

CEFIC LRI B23 project

Optimizing the benefit of REACH worker exposure assessments: ensuring meaningful health risk communication

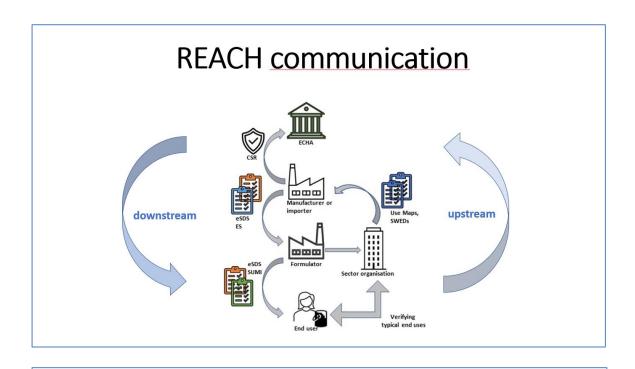












CEFIC LRI B23 project overview

Four work packages

- 1. Literature study: Analysis of previous developments, existing processes and tools on communication of (safe) use conditions up and down supply chains
- Empirical study: Analysis of present communication practices up- and downstream and needs of stakeholders
- Workshops in which recommendations for improvement of processes, methods and tools are discussed
- 4. Reported in report, scientific paper and core presentation / core poster











Introduction Project and monitoring team



Wouter Fransman



Henry Boumann



Katharina Preuhs



Rianda Gerritsen





Monitoring team present

- Dook Noij
- Evelyn <u>Tjoe Nij</u>
- Wouter ter Burg
- Celia Tanarro
- Urs Schlüter



Hans Marquart



Wilma Otten



Dide Reijmer

Introduction Goal of workshop C

Identify concrete next steps on how to improve communication concerning processes, tools, methods, formats, relevant stakeholders and drivers and barriers related to REACH











Introduction

program

13.30 – 13.45 Opening and introduction participants

13.45 – 14.05 Plenary: topics workshops A + B

Coffee Break 10 minutes

14.15 – 15.00 Breakout room discussions (45 min)

Coffee Break 10 minutes

15.10 – 16.20 Plenary: presentation and discussion Breakout Rooms

16.20 – 16.30 RECAP 16.30 Closure

Methods

WP 1 + WP 2

WP 1: Literature Study

SEARCH for tools and studies

44 relevant documents in data extraction table

- ightarrow 13 tools selected (EU legal tools, ECHA guidance docs, else e.g. SUMI, Use Maps)
- → 21 studies from 2012-2020 (scientific studies, poster/presentations, news articles & summary reports)

WP 2: Empirical Study

Interviews with relevant stakeholders

6 use cases (down stream users: companies)

- → variety in number of aspects e.g. size, knowledge, etc.
- 2 sector organizations
- 2 registrants
- ightarrow based on McGuire's communication & persuasion matrix
- ightarrow REACH documents for specific substance

Workshop A – European concerns?

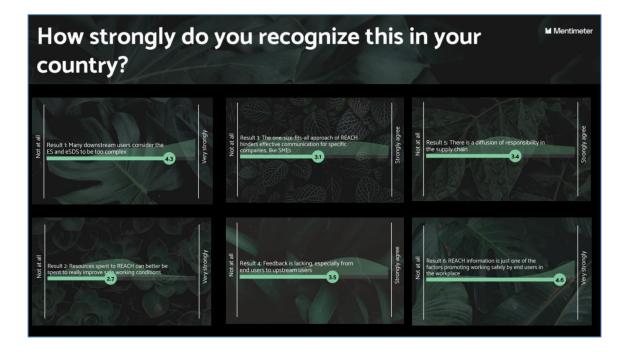
Goal:

Discuss results up- and downstream communication under REACH in Dutch case studies

- Identify similarities and differences between the Netherlands and other EU countries with respect to the results
- Identify good practices and ideas on improvement/how to handle the concerns raised by the results

Results from:

- Mentimeter:
 - "How strongly do you recognize this in your country? 1 = not at all to 5 = very strongly"
- Breakout room discussions



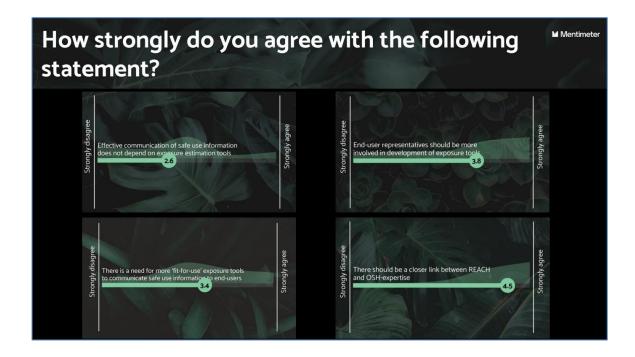
Workshop B – results exposure tools

Goal:

<u>Identify improvements of exposure tools</u> to enable more effective derivation, communication and implementation of safe use scenarios related to our results, needs of end users (terminology, format), links of parameters of the tools in relation to the end user specifics, pitfalls of the tools and what needs to change in the tools to improve the up/downstream communication

Results from:

- Mentimeter:
 - "How strongly do you agree with this statement? 1 = strongly disagree to 5 = strongly agree"
 - Some explanatory open questions
- Breakout room discussions



Concerns & Improvements

Concern 1: There is insufficient communication on the provided documentation and information within the supply chain

Improvements

- 1. Establish a communication structure/feedback mechanism in supply chains.
- 2. Enforce feedback loops within the supply chain to ensure responsibility.

Concern 2: Exposure scenarios and (e)SDS are too complex

Improvements

- Simplify information: Select most important information that has to be provided through the supply chain and provide that in an easy-to-use way
- 2. Improve knowledge/expertise: Better implementation of information via improved education, training, to-the-point guidance, video, etc.

Concerns & Improvements

Concern 3: Existing exposure tools insufficiently lead to useful results for end-users

Improvements:

- 1. Better clarify and define the target audience per exposure tool
- 2. Create (additional) tools to translate to more practical and (sector) specific results
- 3. Ensure involvement of OSH-experts in interpretation and use of results

Concern 4: Cooperation between REACH and OSH

Improvements:

- Bring more sector <u>organizations</u> with <u>internal</u> or <u>external</u> OSH expertise <u>to work</u> on sector <u>specific</u> input <u>for registrants and</u> sector <u>specific</u> output <u>for end-users</u> (e.g. SUMI); <u>preferably by cooperation between formulator sector and end-user sector</u>
- 2. Increase motivation to make use of external REACH and OSH expertise: Better support systems for organizations (external support), e.g. via sector organizations

Concerns & Improvements

Concern 5: SMEs do not have the expertise, experience, knowledge, capacity to understand, use and adapt the information

Improvements

- Increase 'internal' expertise: Education, training, to-the-point guidance, video, etc. specifically for SMEs
- Obtain 'external' knowledge/expertise: Organise access to external REACH and OSH
 expertise (on use of REACH information): Better support systems for SMEs (external
 support), e.g. via sector organisations. Increase motivation to make use of external
 REACH and OSH expertise (on use of REACH information).

Breakout Room discussion

For <u>each improvement</u>

- 1. Pre-conditions
- 2. Barriers/promotors
- 3. Key stakeholders
- 4. Next steps