

Downstream users' information needs under REACH

Summary of market studies in 2017-18

June 2019

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Table of contents

1.	. EXECUTIVE SUMMARY	5
2.	. INTRODUCTION	7
	2.1 BACKGROUND	7
	2.2 OVERVIEW OF THE STUDIES	8
3.	. DATA COLLECTION	.10
	3.1 INTERVIEWS OF FINNISH COMPANIES	.10
	3.2 FINNISH ONLINE SURVEY	.12
	3.3 SURVEY OF ITALIAN COMPANIES	.12
	3.4 LABOUR INSPECTOR STUDIES	.13
	. ANALYSIS OF THE DATA	
5.	. FINDINGS	.14
	5.1 COMPANIES	
	5.2 CHEMICALS IN USE	.16
	5.3 KNOWLEDGE ABOUT SUPPLY CHAIN COMMUNICATION	
	5.4 INCOMING INFORMATION	
	5.4.1 GENERAL	
	5.4.2 FLOW OF EXTENDED SAFETY DATA SHEETS	
	5.4.3 EXPOSURE SCENARIOS	.23
	5.4.4 SUMI - SAFE USE INFORMATION FOR MIXTURES	.24
	5.4.5 CHECKING OF INCOMING INFORMATION	.24
	5.4.6 WORKPLACE RISK ASSESSMENT	.25
	5.4.7 USE OF DNELS AND SCALING	.29
	5.4.8 SHARING SAFE USE INFORMATION WITH WORKERS	.29
	5.4.9 INFORMATION MANAGEMENT	.30
	5.5 QUALITY OF INFORMATION	.30
	5.5.1 BODY OF THE SAFETY DATA SHEETS	.30

5.5.2 EXPOSURE SCENARIOS32
5.5.3 LANGUAGE VERSIONS34
6. COMMUNICATION WITH SUPPLIERS34
6.1 GENERAL34
6.2 USE INFORMATION35
7. HOW TO IMPROVE THE INFORMATION AND ITS FLOW
8. SUPPORT37
8.1 TOOLS AND GUIDANCE37
8.2 DATABASES39
9. CONCLUSIONS AND RECOMMENDATIONS39
10. CONSIDERATIONS FOR FUTURE STUDIES40
11. ATTACHMENTS43
11.1 GUIDE TO THE INTERVIEWS OF FINNISH COMPANIES IN 201743
11.2 GUIDE TO THE INTERVIEWS OF FINNISH COMPANIES IN 201846
11.3 FINNISH ONLINE SURVEY QUESTIONNAIRE51
11.4 QUESTIONNAIRE OF THE ITALIAN SURVEY IN 201855
11.5 GUIDE TO THE INTERVIEW OF OSH EXPERTS IN 201759
11.6 OUESTIONNAIRE OF THE OSH EXPERTS SURVEY IN 201860

1. Executive Summary

Background

Throughout 2017 and 2018, the European Chemicals Agency (ECHA) conducted six studies with partners to understand how aware companies are about extended safety data sheets, how they use them and what they expect from them. An extended safety data sheet contains a main 16-section body and exposure scenarios annexed to it.

REACH introduced a requirement to extend the safety data sheet with an exposure scenario annex for hazardous substances¹ registered in quantities of 10 tonnes or more per year. The extended safety data sheet would be a means to communicate relevant information from the registrant's chemical safety assessment. The information included in exposure scenarios should support users of chemicals to take necessary measures to protect human health and the environment.

The studies in this report provide feedback both on the new exposure scenario attachment and the body of the safety data sheet that has already been a requirement for all hazardous substances and mixtures for decades.

The studies were conducted under the Exchange Network on Exposure Scenarios (ENES) programme². They covered different stages in the supply chain from the manufacturers of substances to formulators of mixtures, as well as distributors and users of chemicals in Finland, and in five industry sectors using chemicals in Italy. In addition, views of labour inspectors on the extended safety data sheets and the potential use of their content in workplace risk assessment were collected.

Studies

Two rounds of company interviews were organised in Finland, the first in spring 2017 and the second in early 2018. Thirty-seven companies participated, the majority of which were large and medium-sized enterprises. The aim was to understand how information on hazardous substances and mixtures is currently flowing in the supply chain, and how well it meets the needs of companies in the Finnish metalworking and engineering industry.

The first round of interviews in 2017, collected information, in addition to the topics mentioned above, on how aware companies are of ECHA's support material (guidance and tools for downstream users).

In late 2017, ECHA also cooperated with five Finnish industry associations on a survey. The survey complemented the interviews and collected feedback from 45 companies on the flow of information, how supply chain communication could be improved, and questions on the available guidance and tools to support companies with their REACH and CLP duties. Responses came from companies operating at different levels of the supply chain, including small, medium and large companies manufacturing substances, formulating mixtures, distributing chemicals or using them in the metalworking and engineering industry.

A survey of Italian companies was also carried out by the Italian National Institute for Insurance against Accidents at Work (INAIL). This survey studied the flow and quality of extended safety data sheets and how companies use safety data sheet information in their workplace risk assessment. It was conducted together with the Italian Federation of the Chemical Industry and five associations covering the wood processing, textile, paper and cardboard, tanning of leather, and plastic and rubber sectors. In total, 683 companies (mainly small and medium-sized) across these five sectors completed the survey in early 2018.

¹ Including those that are persistent, bioaccumulative and toxic; very persistent and very bioaccumulative; and Candidate List substances.

² https://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios

The aim of the labour inspector studies was to understand what occupational health and safety authorities consider useful information for users of chemicals in the extended safety data sheet. Representatives from 10 labour inspection authorities were interviewed in late 2017 and 20 EU Member States responded to a survey in spring 2018. They were contacted through the Committee of Senior Labour Inspectors' (SLIC) Chemex Working Group.

Summary of key findings and recommendations

Four types of challenges were identified in the studies.

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

The **limited knowledge of companies on extended safety data sheets**, the related regulatory duties and the support available for companies is evident from the studies.

In general, suppliers of chemicals (especially large companies) are well aware and resourced to comply. Despite this, almost half of the end-user companies in Finland and Italy had not received or had not noted receiving extended safety data sheets. However, end users of chemicals mainly use mixtures and the inclusion of exposure scenario information in the mixture safety data sheet is not yet a common practice.

A clarification on how exposure scenario information should be communicated in the mixture safety data sheet is expected to be developed under REACH Review Action 3. In addition, many end users of chemicals indicated that they are not well aware of the duties related to exposure scenarios. This clearly indicates a need for continued awareness-raising activities on extended safety data sheets at the lower part of the supply chain.

ECHA has already published extensive support material on extended safety data sheets, including simple guides and examples to support companies. The majority of these publications are available in 23 EU languages and can, therefore, be easily accessed and used by any stakeholder to raise awareness about the topic. The material can be found in the downstream user sections³ of ECHA's website. Practical examples on exposure scenarios are available in the support section⁴ of the website.

The Finnish, Italian and labour inspector studies reported gaps in **the flow of the extended safety data sheet** along the supply chain. Exposure scenarios received by companies were noted to be typically reasonable in length - less than 30 pages - but they do not always reach the lower part of the supply chain because of practical difficulties (e.g. due to IT systems or translations) in distributing them. However, all actors in the supply chain should remember that it is a REACH duty to pass on the exposure scenario information and companies at all levels of the supply chain are entitled to receive this information.

The studies in this report clearly indicate that **upstream communication** with suppliers on userelated information is **still limited** and that it focuses mainly on classification-related questions

³ https://echa.europa.eu/regulations/reach/downstream-users

⁴ https://echa.europa.eu/support/practical-examples-of-exposure-scenarios

and personal protective equipment. Upstream communication on uses and use conditions to registrants as well as contacts with suppliers on the quality of the extended safety data sheet takes place on an *ad hoc* basis and is mainly done by larger companies. The findings of the Finnish and Italian studies indicate that structured communication would facilitate the channelling of understandable information on uses and use conditions upstream. The use maps developed under the ENES Programme can be a solution for this at industry sector level.

Various **shortcomings in the quality of the extended safety data sheets** were listed in the studies. Companies and labour inspectors agree that exposure scenarios only add value if they are well prepared. The noted shortcomings include information being missing, unclear or too generic to be useful. A lack of harmonised document structure, inconsistency of information and ambiguous terminology were commonly mentioned issues. In addition, the survey showed that the lack of a national language version for the exposure scenarios and partial or poor quality translations of extended safety data sheets were common. These quality issues undermine the value and usability of the extended safety data sheets and should be addressed as a priority.

It is important to remember that the extended safety data sheets are expected to be used by a range of companies that vary from professional craftsmen to large companies with departments dedicated to chemical safety and legal compliance. The distribution of safety data sheets with exposure information in PDF or hard copy formats makes it challenging to meet the information needs of a diverse group of recipients while keeping the documents manageable and easy to understand in the European multilingual environment. Therefore, many companies expressed a wish for **modern IT solutions** that would facilitate their work. They would like to have IT solutions that would allow company-relevant information to be filtered. In addition, solutions for the electronic transfer of information from incoming extended safety data sheets into recipients' IT systems would be welcome. Introducing such tools would improve the efficiency of handling safety data sheet information, and reduce errors caused by time-consuming manual handling of data.

The six market studies provide valuable insights into the flow of extended safety data sheets in the supply chain and the impact of exposure scenarios at the end-user level in 2017 and 2018. Therefore, the findings will facilitate the planning of ENES activities on enhanced supply chain communication and they will contribute to REACH Review Action 3⁵ on the workability and quality of extended safety data sheets. Some of the collected information is also relevant to the development work under REACH Review Action 12.1 on the interface of REACH and Occupational Safety and Health legislation and REACH Review Action 14 on support to small and medium-sized companies.

2. Introduction

2.1 Background

Under REACH, companies are responsible for collecting information on the properties and uses of the substances they manufacture or import above one tonne a year. They also have to assess the hazards and potential risks presented by the substance. This information is communicated to ECHA through a registration dossier containing hazard information and, where relevant, an assessment of the risks that the use of the substance may pose and how these risks should be controlled. Relevant information from the registration is also communicated to downstream users of the substance to ensure its safe use.

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0116&from=EN

Users of substances for which a chemical safety report has been prepared (hazardous and registered above 10 tonnes) receive safe use information from the registrant's chemical safety report in the extended safety data sheet, which consists of 16 sections as defined in Annex II to REACH plus exposure scenarios in an annex. The exposure scenarios should be relevant to the recipients' uses. The users of chemicals with extended safety data sheets must make sure that their uses and conditions of use are covered by the information received. They also have the right to make their uses known to their supplier by submitting appropriate information upstream in the supply chain.

Clear, practical and understandable information in the extended safety data sheets is critical for recipients of chemicals (substances or mixtures) to ensure their safe use. The extended safety data sheets are intended, in addition to the fulfilment of REACH obligations, to facilitate compliance with other pieces of legislation such as occupational health and safety, environment and product safety. Therefore, it is important to understand how REACH information currently flows and how it could be improved to support the end user of chemicals, in particular, small-and medium-sized companies.

ECHA⁶ and industry have been working together since 2011 to support the chemical safety assessments in companies and the development of useful exposure scenarios under ENES⁷. The purpose of this work is to provide tools and guidelines for actors in the supply chain from registrants to users of chemicals so that they can efficiently produce and use the exposure scenarios that are part of extended safety data sheets.

2.2 Overview of the studies

This report summarises the main aspects and key findings of six studies that were carried out in 2017 and 2018 to better understand what kind of safety information, generated under REACH, is helpful to companies, how well the system currently works and how the extended safety data sheets could be improved.

Attention was paid to how information generated under REACH could be used under the occupational safety and health (OSH) legislation for workplace risk assessment. The knowledge that companies have about their duties related to extended safety data sheets and their awareness of the available support material were also studied.

ECHA carried out five of the studies. These included two rounds of interviews and one survey of Finnish companies and two studies of labour inspectors in various EU Member States. The National Institute for Insurance against Accidents at Work (INAIL⁸) conducted the Italian study together with the Italian industry. An overview of the industry sectors covered in the studies is given in Table 1 and Table 2 lists the studied topics.

Table 1 – Industry sectors covered in the six studies.

⁶ https://echa.europa.eu/about-us

⁷ https://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios

⁸ https://www.inail.it/cs/internet/multi/english.html

Study Finnish interviews Finnish Finnish Italian survey 2017 interviews online Sector 2018 survey **Chemicals** √ \checkmark Paint and printing inks √ √ **Cleaning products Engineering industries** √ **Distributors** Paper and cardboard \checkmark √ Plastic a rubber √ **Tanning of leather Textiles** √ **Wood processing**

Table 2 – Topics covered in the six studies.									
		Finnish		Italian	Labour inspectors				
Study Topic	Interviews in 2017 Interviews in 2018 Online survey			Survey	Interview	Survey			
Knowledge about extended safety data sheets	✓	√	√	√	√				
Supply of chemicals	√	√	√						
Chemical inventory	\checkmark	√		\checkmark					
Incoming information	√	✓	√	√	√				
Use of information	\checkmark	√		\checkmark	√	√			
Information management	✓	√	√	√					
Communication with suppliers	√	✓	√	√	√				
Information shared with workers	✓	✓							
Quality of information	√	√	√	\checkmark	√				
Guidance and tools			√	✓	√				
Enforcement					√	√			

The market studies were conducted to better understand the information needs of companies at

the lower end of the supply chain for safety information on chemicals.

These findings will help ECHA to focus its future activities on supply chain communication, in collaboration with stakeholders through ENES, to those tasks that are most likely to deliver benefits to end-user companies.

In addition, the collected information will be valuable for the work that will be carried out under REACH Review 2018 Action 3 on the workability and quality of extended safety data sheets. Some of the findings are also relevant to REACH Review Action 12.1 on the interface of REACH and Occupational Safety and Health legislation and REACH Review Action 14 on support to small and medium-sized companies.

The report also contains some general information about the chemical supply chain and provides typical numbers of hazardous chemicals in various end-user sectors in Finland and Italy. In addition, some numbers of suppliers per customer in the Finnish metalworking and engineering industry are given.

3. Data collection

The studies carried out in Finland were supported by the Chemical Industry Federation of Finland⁹, the Association of Finnish Paint Industry and Printing Ink Companies¹⁰, the Finnish Cosmetic, Toiletry and Detergent Association¹¹, the Association of Finnish Technical Traders¹², the Technology Industries of Finland¹³, and the Finnish Safety and Chemicals Agency (Tukes)¹⁴.

3.1 Interviews of Finnish companies

A semi-structured interview methodology was used. The contractors developed an interview guide together with ECHA for both interview rounds. The 2017 guide (Attachment 11.1) and the 2018 guide (Attachment 11.2) contain two questionnaires. The first one addressed duties for suppliers and the second one those for end users of chemicals under REACH.

The questions in both questionnaires were aligned with the specific duties for these REACH roles. In 2017, the questions focused on:

- 1. the company's inventory of chemicals;
- 2. the flow of information in the supply chain;
- 3. the risk management of chemicals in the company; and
- 4. the awareness of ECHA's guidance and tools.

In 2018, the focus was on:

⁹ https://www.kemianteollisuus.fi/en/

¹⁰https://www.kemianteollisuus.fi/en/about-us/contacts/association-of-finnish-paint-industry-and-finnish-printing-ink-association/

¹¹ http://www.teknokemia.fi/fin/in english/

¹² http://www.tekninen.fi/the-association-of-finnish-technical-traders/

¹³ https://teknologiateollisuus.fi/en

¹⁴ https://tukes.fi/en/frontpage

- 1. the incoming information and communication with suppliers;
- 2. the use of safety information;
- 3. the exposure scenario¹⁵ and SUMI¹⁶; and
- 4. the outgoing information and communication with customers.

In addition, interviewees were asked to express their views on how the flow of information could be improved. The first round of interviews took place in early 2017 and the second one a year later.

In 2017, the first six interviews were used to test the interview guide. The lessons learned during these interviews were integrated into the guide by slightly modifying it to facilitate the interviewee's understanding of the questions. The most significant change was the addition of examples of the CLP¹⁷ hazard pictograms¹⁸, exposure scenarios and SUMIs in the questionnaire, so that they could be shown to help the interviewees understand the terminology used. The chosen method provided structure to the discussions but gave sufficient freedom to interviewees to present additional thoughts. The guides were implemented as online forms.

The target sectors for the studies were the Finnish metalworking and engineering industry and their suppliers. Companies for the interviews were selected from a list of companies that have their manufacturing sites in Finland. Companies that based on information accessible to the contractors seemed to supply or belong to the metalworking and engineering industry were contacted by email or telephone to ask if they would be willing to participate in the study. The Technology Industries of Finland association facilitated this process.

Before the interviews, the companies were contacted to check the relevance of their processes for the scope of the study and to help them prepare for the interview. During these contacts, it was underlined that the interview was not connected to any inspection campaign. In addition, the companies were informed how the findings of the study may lead to actions that are beneficial to them.

Two interviewers performed the face-to-face interviews by using the aforementioned interview guides. The interviews took place in the premises of the participating companies in southern and central Finland and lasted 45-90 minutes. The interviewees were mainly Health, Safety, Environment and Quality (HSEQ) experts in the companies. However, other professionals with relevant knowledge were also interviewed in some of the companies. The number of interviewees per company was one or two. ECHA participated in about one third of the interviews. Three quarters of the interviews were conducted in Finnish and the remaining quarter in English. To ensure proper understanding and effective communication, terminology was often translated during the interviews from one language into the other.

The findings of the interviews were discussed with the participating companies, Finnish authorities and industry association representatives in workshops at the end of each study. The participants of these events agreed that the findings were representative of the situation in the field.

¹⁷ The Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008)

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¹⁵ Exposure scenarios are a set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life cycle and how the manufacturer or importer controls, or recommends downstream users to control exposure of humans and the environment. These exposure scenarios may cover one specific process or use, or several processes or uses.

¹⁶ Safe Use of Mixtures Information

¹⁸ https://echa.europa.eu/regulations/clp/clp-pictograms

3.2 Finnish online survey

The online survey was developed in cooperation with the five Finnish industry associations mentioned earlier that are active in manufacturing and importing chemicals, formulating mixtures, distributing chemicals and using chemicals in the production of articles in the metalworking and engineering industry.

The questionnaire (Attachment 11.3) focused on:

- 1. the information received by the company;
- 2. the information supplied by the company; and
- 3. the respondent's views on the available guidance and support.

Companies replied to about 20 or 30 questions – depending on their answers – most of which were multiple choice. Free text answers were available for 10 questions.

The survey was carried out in Finnish through a web survey tool. The participating industry associations mailed the link to the survey questionnaire to their members on 23 November. In total, 405 companies were contacted. The recipients received two reminders about the questionnaire before it closed on 31 December 2017. Forty-five recipients completed the survey and submitted their replies. Most of the respondents (>90 %) were HSEQ/technical experts.

3.3 Survey of Italian companies

The National Institute for Insurance against Accidents at Work (INAIL) developed the questionnaire (Attachment 11.4) together with ECHA and Federchimica¹⁹. It was tested with six companies before the online survey was launched.

The questionnaire contained 24 multiple choice questions and was divided into four sections:

- 1. the chemical risk management in the company;
- 2. the flow of REACH information;
- 3. the use of safety data sheets; and
- 4. the quality of safety data sheets.

The survey was carried out in Italian by using Computer Assisted Web Interviewing (CAWI) by providing companies with a dedicated and customised link. INAIL sent the link to the companies by email. The email explained the scope and purpose of the study and highlighted the importance of the survey. Two reminders were sent by email, the first one week after the initiation of the survey and the second 11 days after the first reminder. The survey started on 19 February 2018 and was open for about two months.

In addition to the survey emails, information about the study objectives, the characteristics of the questionnaire and the expected outcome of the study were published on the participating organisations' websites. These associations were the wood processing (Federlegno²⁰), plastic and rubber federation (Federazione Gomma Plastica²¹), textiles (Moda Italia System²²), paper

21 http://www.federazionegommaplastica.it/

¹⁹ https://www.federchimica.it/en/federchimica/about-us

²⁰ http://www.federlegnoarredo.it/

²² https://www.confindustriamoda.it/en/homepage/

and cardboard (Assocarta²³) and tanning of leather (UNIC²⁴). This promotion played a key role in motivating companies to participate and increased the number of responses significantly. The participating companies are located in the Lombardy and Tuscany regions.

3.4 Labour inspector studies

A semi-structured interview methodology was adopted as the research approach for the interviews of the labour inspectors in 2017. The questions covered:

- 1. the quality of information in the supply chain;
- 2. the exposure scenarios; and
- 3. ECHA's tools and guidance (Attachment 11.5).

The questions were tailored to gather the labour inspectors' views on supply chain communication. About half of the 22 questions required simple answers and the other half allowed inspectors to openly respond, giving suggestions and ideas on how to improve the current situation. An example of an exposure scenario and a SUMI were also shown for comments.

Interviewees were invited to participate through the Senior Labour Inspectors' Committee (SLIC²⁵) Chemex Working Group. Of the 12 members of the Chemex Working Group, 10 agreed to be interviewed. They were the representatives of Belgium, Cyprus, Germany, Finland, Ireland, Hungary, the Netherlands, Slovenia, Sweden and the UK. The interviewees were all labour inspectors or inspection coordinators, and therefore experts in the OSH legislation with different levels of knowledge about REACH. The interviews were carried out in English in autumn 2017 and they lasted approximately 60-75 minutes.

An online survey of the labour inspectors took place in 2018. Its aim was to find out which information from the extended safety data sheets the national labour inspectors consider most relevant and useful for workplace risk assessments. The survey was carried out in English through a web survey tool and contained eight questions (Attachment 11.6). The questions set were posted onto the SLIC's KSS exchange portal, where a contact point in each Member State labour inspection authority completed it in spring 2018.

In total, 20 responses from the following Member States were received: Austria, Belgium, Bulgaria, Croatia, Cyprus, Denmark, Estonia, Germany, Greece, Hungary, Ireland, Lithuania, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia and Spain.

Note: The Forum for Exchange of Information on Enforcement (the Forum²⁶) was running a project (REF-5) on exposure scenarios, the extended safety data sheet, risk management measures and operational conditions, in parallel to these market studies. The findings of the REF-5 project²⁷ were published in December 2018 and are reflected in the conclusions and recommendations of these studies in Section 9.

²³ http://www.assocarta.it/en/about-assocarta.html

²⁴ http://www.italiantannerysuppliers.it/directory/unic/

²⁵ https://oshwiki.eu/wiki/Senior Labour Inspectors Committee

²⁶ https://echa.europa.eu/about-us/who-we-are/enforcement-forum

https://echa.europa.eu/-/enforcement-project-calls-for-improved-safety-information-to-protect-workers-from-chemical-hazards

4. Analysis of the data

The information collected in the Finnish studies in online forms was automatically aggregated. However, the answers to the open questions needed to be grouped before they could be analysed. Aggregated findings were analysed for differently sized companies (small, medium and large) and for different REACH roles (manufacturers of chemicals, formulators, distributors and end users). The differences between the groups, if any, are noted in the findings.

Due to the small numbers of small- or medium-sized companies that took part, these groups were combined in the interview studies for the analysis and reporting. In the online survey, the companies were grouped by the REACH role that reflected their core business by using the roles they indicated, their association membership and information available online about their business as a guide. This needed to be done because many companies indicated in their feedback that they had more than one REACH role.

In the Italian study, the responses were analysed statistically for the individual questions and a series of related questions. The differences were reported in relation to the size of companies, type of employees carrying out the assessments and the industry sectors as absolute values (frequencies) or percentages (relative frequencies).

The notes taken during the labour inspector interviews, as well as the online survey feedback, were consolidated. Commonalities and differences in replies were noted. The answers to the open questions needed to be grouped before they could be analysed.

5. Findings

5.1 Companies

The willingness of companies to participate in the studies varied. In Finland, 11 % of the recipients responded to the online survey. In Italy, the response rate was exceptionally high²⁸ and almost half of the recipients (43 %) of the survey's link submitted their feedback. On the other hand, 30 % and 10 % of the Finnish companies that were contacted agreed to take part in the 2017 and 2018 interviews respectively.

Almost half of the 82 companies that participated in Finland are large²⁹ (46 %) followed by medium³⁰ sized (30 %) and small³¹ (24 %) companies. However, it is worth noting that while the company size in the studies was based on the number of employees, some of the companies that are listed as small are actually national affiliates of large corporations. The number of Finnish companies by size and REACH role are listed in Table 3.

Over half (55 %) of the Finnish companies that participated in the studies in 2017 and 2018 are end users. The rest were chemical suppliers. Almost half of the 45 Finnish companies that responded to the online survey had several roles under REACH. Over 30 % of them indicated two roles and 13 % indicated three REACH roles.

²⁸ Typically, the response rate in online surveys is 10–15 %.

²⁹ Large >250 employees

³⁰ Medium 50-250 employees

³¹ Small <50 employees

Table 3 – Number of **Finnish** companies that participated in the studies by REACH role and company size.

		Respondents by company size								
Company role		2017 (n=17) terviev M			2017 (n=45) ine s ur M		(2018 n=20) erview s M		Average (n=82) %
Manufacturers		1		3	1	5			2	15 %
Formulators			1	3	3	2	1		3	16 %
Distributors				3	2	4		2		14 %
End users	3	6	6	2	6	9	4	3	5	55 %
Share %	18 %	41 %	41 %	26 %	28 %	46 %	25 %	25 %	50 %	
% in all Finnish studies	Small	24 %	ı	Medium	30 %		Large	46 %		

S =Small <50 employees, M = Medium 50-250 employees, L = Large >250 employees

In Italy, INAIL and Federchimica selected five sectors for the study that represent the Italian end users well. These were the wood processing, textile, paper and cardboard, tanning of leather, and plastic and rubber industries. The survey targeted mainly small and medium-sized companies. The researchers decided to include companies that had at least 10 employees because they were more likely to have sufficient knowledge to be able to respond to REACH-related questions.

Table 4 – Number of **Italian** companies that participated in the survey by industry sector and company size.

	Res	%		
Sector	Small Medium (<50 employees) (50-250 employees)		Large (>250 employees)	(n=683)
Wood Processing	109	19	-	19 %
Textiles	92	34	4	19 %
Paper and cardboard	87	28	4	17 %
Tanning of leather	116	13	-	19 %
Plastic and rubber	111	64	2	26 %
Share %	75 %	23 %	1.5 %	100 %
Total	515	158	10	

Three quarters (75 %) of the 683 companies that completed the Italian online survey were small. The remaining quarter (23 %) being medium-sized. Less than 2 % of the respondents were large

companies. The companies that participated in the study represent the five industry sectors (Table 4) fairly evenly. However, companies in the plastic and rubber industry provided slightly more replies than the other sectors.

5.2 Chemicals in use

Most of the Finnish companies that participated in the studies had from 50 to over a 1 000 chemicals in their inventory. The number of chemicals purchased by the end users interviewed in 2017 varied from 25 to 100 for small companies and 100 to 1 000 for large companies, and in the 2018 interviews, the range was from less than 5 to a 1 000. The findings of the Finnish online survey are similar and they are presented in Figure 1. In that study, 78 % of the companies indicated that they had at least 50 chemicals.

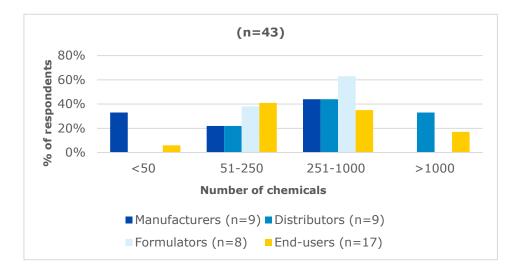


Figure 1: Number of chemicals purchased by different company roles according to the Finnish online survey.

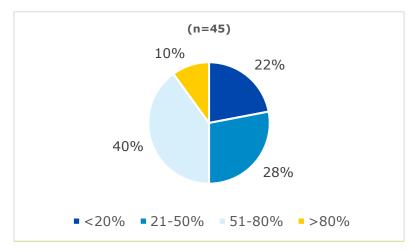


Figure 2: Percentage of hazardous chemicals in the company inventory according to the Finnish online survey.

The percentage of hazardous chemicals in a company inventory in the Finnish online survey was for half of the companies 50 % or more (Figure 2). Among the Finnish companies interviewed in 2017, the percentage was 50 %. In 2018, it was 75 %.

A typical proportion of hazardous chemicals for the Finnish manufacturers of chemicals and formulators is 20-80 % and for distributors 50-80 %, while the end users have somewhat fewer hazardous chemicals in their inventory (Table 5). The size of a company did not seem to correlate with the percentage of hazardous chemicals in the company's inventory.

Table 5 – Percentage of hazardous chemicals in the inventory of companies by REACH role according to the Finnish online survey (n=43).								
	<20 %	21-50 %	51-80 %	>80 %				
Manufactures/importers (n=9)	0 %	36 %	50 %	14 %				
Formulators (n=8)	13 %	50 %	38 %	0 %				
Distributors (n=9)	0 %	0 %	71 %	29 %				
End users (n=17)	47 %	24 %	24 %	6 %				
Average %	22 %	29 %	40 %	9 %				

In the Finnish online survey, the ratio of substances and mixtures varied somewhat from the suppliers to the end users (Figure 3). As can be expected, the end users have more mixtures in their portfolio than suppliers. The findings of the Finnish interviews in 2018 indicated that the substance to mixture ratio was 20:80.

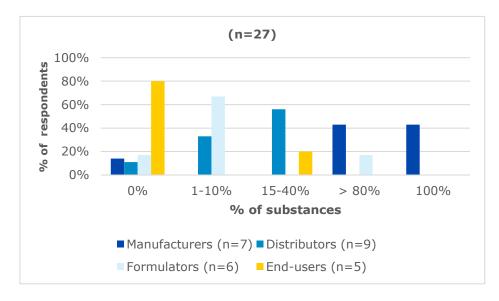


Figure 3: Percentage of substances in the companies' chemical inventories according to the Finnish online survey.

In Italy, 65 % of the companies that responded to the survey used less than 20 hazardous chemicals (mixtures or substances). A quarter of these companies (25 %) used between 20 and 100 hazardous chemicals and only 10 % of them used more than 100 (Table 6). In this study, larger companies seemed to have a larger number of hazardous chemicals. The researchers considered that this reflects the increasing complexity of the processes involving chemicals in larger companies.

Table 6 – Number of hazardous chemicals used in Italian companies by company size (n=683).								
Hazardous chemicals	Small	Medium	Large	Average (n=683) %				
Less than 20	71 %	49 %	30 %	65 %				
20 - 100	21 %	37 %	30 %	25 %				
More than 100	8 %	14 %	40 %	10 %				

The number of hazardous chemicals used in the five Italian end-user sectors is smaller than in the Finnish sectors. This is likely to be due to the differences in the usage of chemicals in the sectors studied in Finland and in Italy. The Italian survey also noted differences between each sector it covered. For example, 80 % of textile companies used less than 20 hazardous chemicals while the typical number for plastic and rubber companies was 20-100, and for tanning of leather companies over 100 (Table 7).

Table 7 – Percentage of companies in the Italian study using a certain number of hazardous chemicals by industry sector.										
Hazardous chemicals	Wood processing	Textile	Paper and cardboard	Tanning of leather	Rubber and plastic	Average (n=683) %				
Less than 20	63 %	81 %	78 %	50 %	59 %	65 %				
20 - 100	25 %	12 %	19 %	26 %	37 %	25 %				
More than 100	12 %	7 %	3 %	24 %	4 %	10 %				

The number of chemical suppliers per Finnish company reported in the 2018 interviews ranged from 10 to 500 for the manufacturers of substances and the formulators of mixtures. For end users of chemicals, this number varied from less than five to over 50 (Figure 4). The same study reported that the number of customers per chemical supplier ranged from 100 to 5 000.

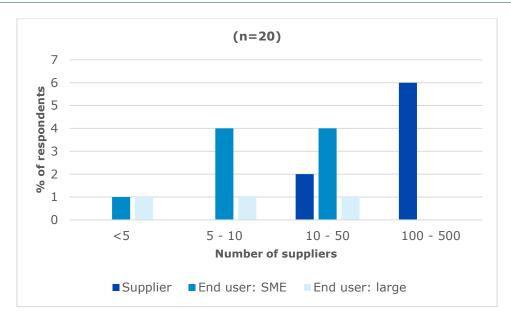


Figure 4: Number of chemical suppliers per REACH role and size according to the Finnish interviews in 2018.

The number of chemicals supplied varied between companies. However, due to the limited sample size, it is not possible to draw any conclusions on differences based on the size of the companies or their REACH role (Table 8).

Table 8 – The number of chemicals the Finnish respondents supply by company size and by REACH role.										
	Respon	dents by co	ompany	Respon						
Number of chemicals supplied	Small (n=7)	Medium (n=6)	Large (n=14)	Manufacturers (n=7)	Formulators (n=6)	Distributors (n=14)	Average (n=27)			
<50	29 %	33 %	43 %	55 %	20 %	25 %	30 %			
51-250	43 %	0 %	7 %	22 %	20 %	13 %	19 %			
251-1 000	29 %	67 %	14 %	11 %	40 %	49 %	41 %			
>1 000	0 %	0 %	36 %	22 %	20 %	13 %	11 %			

5.3 Knowledge about supply chain communication

All studies indicated that end-user companies are not yet fully familiar with the extended safety data sheet and the exposure scenario concept. During the Finnish interviews in 2017, a general lack of understanding about the exposure scenario and related terminology was noted. The companies in the metalworking and engineering industry did not know what information the extended safety data sheet contained and admitted that they are not sure about their related duties under REACH. Some of them even thought that REACH does not apply to them.

It was also clear that these companies are not familiar with REACH terminology. For example, the difference between a chemical substance and a mixture or what is considered a hazardous

chemical was not always understood. Many of the companies also admitted that they do not know when a safety data sheet or an exposure scenario should be provided.

During the Finnish interviews in 2018, most of the end users (67 %) considered that they are quite well aware of their legal obligations under REACH and CLP, but they admitted that they are not completely sure about their duties related to the exposure scenario. Similarly, 40 % of the companies that responded to the Finnish online survey were not familiar with the exposure scenario concept. It seems that many companies do not know that their uses need to be covered by the supplier's extended safety data sheet and that they have a right to communicate information on their uses upstream in the supply chain.

The labour inspectors interviewed in 2017 also reported differences in the levels of awareness across industries. Large chemical companies that have personnel dedicated to REACH are well prepared while small and medium-sized companies in sectors using chemicals may not even know that REACH applies to them.

The findings of all these studies underline the importance of continued awareness-raising activities on REACH duties related to extended safety data sheets, especially among end users of chemicals.

5.4 Incoming information

5.4.1 General

Finnish suppliers of chemicals provide their customers with extended safety data sheets, but do not yet provide safe use information for mixtures using the SUMI format. The information is delivered by email to customers or it is sent to a service provider that manages safety data sheets on the customer's behalf. The documents are typically sent by email in PDF-format or uploaded on a website. The customers' preference to the different ways of receiving the safety data sheet according to the Finnish online survey can be seen in Table 9. About a quarter of the respondents to the Finnish online survey indicated that their customers want to receive paper copies of the safety data sheet. Suppliers provide the hard copies and safety data sheets for non-hazardous chemicals only upon the customer's request.

Two third (60 %) of the Finnish end users noted during the 2018 interviews that they do not always automatically receive update documents, especially the extended safety data sheets.

Table 9 – How Finnish customers want to receive safety data sheets according to the online survey.						
	% of replies (n=27)					
Electronic version by email	89					
Electronic version uploaded to a database (other than the customer's database*)	37					
Electronic version uploaded to the customer's database	11					
Paper version by mail/with the delivery of goods	26					
Access to safety data sheets on the supplier's website	7					
Customers do not want to receive safety data sheets	4					
* for example a database maintained by a safety data sheet service provider						

In general, the Finnish and Italian end users seem to consider that there is sufficient information in the 16 sections of the safety data sheet to ensure safe handling of the chemical. Many of the companies considered that the necessary information is easy to retrieve from the 16 sections of the safety data sheet. However, companies also reported contradictorily that the information is too generic and sometimes too conservative and according to the Finnish interviews in 2017, 80 % of end users indicated that the information is hard to extract.

It is noteworthy that a few of the Finnish suppliers interviewed in 2018 do not send safety data sheets to their customers but make them available on their website. Some of these companies indicated that, in such a case, information about how to access the safety information is included in the sales documents of the chemical but it was not apparent for the other companies how they inform the customers about the safety data sheets available on their website.

In the Finnish online survey, the majority (87 %) of the respondents indicated that they request safety data sheets also for non-hazardous chemicals they purchase. There were no differences between different sized companies or REACH roles in this practice. The main reasons for requesting safety data sheets for non-hazardous chemicals were to confirm the 'non-classification' or that this is required by the customer's chemical inventory or quality system. This practice of requesting safety data sheets for non-hazardous chemicals may partially explain why many end users report that safety data sheets are not automatically distributed.

During the Finnish studies, some suppliers also mentioned that there are still companies that do not want to receive safety data sheets.

5.4.2 Flow of extended safety data sheets

All six studies indicated that extended safety data sheets have started to flow in the supply chains. According to the Finnish interviews in 2018, the number of extended safety data sheets received varied between suppliers and end users. All suppliers had received them but about half of the end users reported that they had not received any extended safety data sheets.

The other half of the end users had received the documents for less than a quarter of their substances. Similarly, in the Finnish online survey all manufacturers and distributors had received exposure scenarios for some of the chemicals they purchase, but almost half (43 %) of the end users noted that they had not seen these documents (Table 10).

Table 10 – Percentage of Finnish respondents by REACH role who have received exposure scenarios for chemicals they purchase according to the Finnish online study.									
Number of chemicals	0	1-20	21-50	51-100	>100				
Manufacturers (n=9)	-	44 %	44 %	12 %	-				
Formulators (n=8)	-	38 %	24 %	25 %	13 %				
Distributors (n=9)	-	11 %	56 %	22 %	11 %				
End users (n=17)	43 %	43 %	14 %	-	-				
Average (n=43)	16 %	35 %	32 %	12 %	5 %				

In Italy, more than half (53 %) of companies have received at least some extended safety data sheets. However, more than half (52 %) of the small companies that responded to the survey indicated that they have not received any exposure scenarios. For the medium-sized and large companies, the percentages were 35 % and 10 % respectively. In total, 14 % of the respondents stated that more than 30 % of the safety data sheets contain exposure scenarios.

Some differences were noted between industries in Italy (Table 11). The percentage of companies that had not received any exposure scenarios was highest in the textile sector (55%) and lowest in the tanning of leather sector (36%).

Table 11 – Percentage of safety data sheets having exposure scenarios annexed by industry sector in **Italy**.

Safety data sheets with exposure scenarios	Wood processing	Textile	Paper and cardboard	Tanning of leather	Plastic and rubber	Average (n=683) %
None	51 %	55 %	51 %	36 %	44 %	47 %
More than 30 %	16 %	19 %	14 %	14 %	10 %	14 %
Less than 30 %	32 %	25 %	35 %	50 %	47 %	16 %

The Finnish studies identified some bottlenecks in the flow of extended safety data sheets at the formulator/distributor level. These actors do not always forward exposure scenarios to their customers or make them to meet the customers' needs (i.e. include only those exposure scenarios that are relevant). According to the Finnish online survey, up to 35 % of the suppliers did not distribute exposure scenarios to their customers (Table 12).

Table 12 – Percentage of respondents in the **Finnish** online survey who supply chemicals with exposure scenarios by company size and role.

	Respondents by company size		Respon	All Respondents			
Number of chemicals supplied with exposure scenarios	Small (n=7)	Medium (n=6)	Large (n=14)	Manufacturers (n=7)	Formulators (n=6)	Distributors (n=14)	Average (n=27) %
0	14 %	50 %	36 %	29 %	33 %	35 %	35 %
1-10	43 %	0 %	0 %	14 %	17 %	7 %	7 %
11-50	14 %	17 %	43 %	29 %	33 %	29 %	29 %
>50	29 %	33 %	21 %	29 %	17 %	29 %	29 %

Unfortunately, the Finnish online survey did not ask for the rationale why companies do not send exposure scenarios. During the 2018 interviews, suppliers however indicated the following reasons for not supplying the documents:

- customers do not want too much information;
- exposure scenarios do not help the customers to carry out their workplace risk assessment;
- processing of exposure scenarios requires lots of manual work because IT systems do not yet work together; and
- transferring information from one format to another takes a lot of time and is prone to errors.

According to the labour inspector interviews, anecdotal information indicates that one reason why distributors are not forwarding exposure scenarios may be related to the high costs of translating the exposure scenarios to the national language.

The researchers of the Finnish interviews noted that the finding that small companies receive fewer exposure scenarios might be somewhat misleading because those respondents who are not familiar with the concept might have received those documents without noticing it.

5.4.3 Exposure scenarios

In the Italian study, the majority of the companies (85 %) that had received extended safety data sheets responded that the attachments are less than 20 pages. This is in line with the Finnish online survey that indicates that the exposure scenario annexes are typically 11-30 pages.

The Italian study noted that there are differences in the length of documents received. In the tanning of leather sector, almost 29 % of the companies reported receiving annexes of over 20 pages, compared to the company average of 15.5 % (Table 13). In Finland, the longest exposure scenario annexes were reported to be up to 200 pages long.

Table 13 – Percentage of extended safety data sheets having an annex that is under or over 2	20 pages
by industry sector in the Italian survey.	

Number of pages	Wood processing	Textile	Paper and cardboard	Tanning of leather	Plastic and rubber	Average % (n=683)
Less than 20	85 %	89 %	90 %	71 %	86 %	85
More than 20	15 %	11 %	10 %	29 %	14 %	15

In the Finnish online survey, about a third (29 %) of the respondents considered that exposure scenarios can be useful. The respondents who had a positive view of the exposure scenario included companies with all sizes and REACH roles, although the majority of them manufacture, distribute or formulate chemicals. In their view, if these documents are well prepared, they provide useful additional information that facilitates the workplace risk assessment and, therefore, safe use.

The Italian study indicates that a fifth (20 %) of the companies have used exposure scenarios for workplace risk assessment. However, there is a big difference between the average percentage and the percentage for large companies (23 % vs 50 %). According to the

researchers, this may suggest that it is difficult for smaller companies to carry out workplace chemical risk assessment. The finding that small companies commonly use external experts (consultants) for this task supports this conclusion.

The labour inspectors interviewed in 2017 indicated that exposure scenarios were clear to them and could add value to large companies that have personnel dedicated to handle safety issues, while small and medium-sized companies may find the information challenging due to a lack of knowledge, expertise and resources.

The labour inspectors also mentioned that even if the exposure scenario they were shown was concise, it was only 1 of 22 relevant exposure scenarios for the substance. With a two-page exposure scenario for each use, this would mean nearly 50 pages if all exposure scenarios are delivered. If a company uses 10 such substances, this means potentially 500 pages to review as part of a workplace risk assessment.

5.4.4 SUMI - Safe use information for mixtures

The three Finnish studies also covered the safe use information for mixtures (SUMI)³². It was challenging to get feedback on this topic because companies did not have any practical experience on these documents.

During the 2018 interviews, the SUMIs of the Finnish translations of the European Council of the Paint, Printing Ink and Artists' Colours Industry (CEPE)³³ allowed interviewees to give their first impressions on the SUMI template. The interviewees considered the two-page format user-friendly but wondered whether SUMIs would contain any new information. They also noted that these documents might have a potential to be used by workers, since they appeared to be reasonably short and clear. In the Finnish online survey, SUMIs were suggested as a potential way to enhance supply chain communication but the respondents did not give any reasoning why they thought so.

On the other hand, concerns regarding SUMIs were also raised. For example, several suppliers indicated that the increasing number of documents would add to administrative burden and risk that all received documents are not properly read. They also questioned whether the SUMI's introduction would improve the safety of mixtures to an extent that would justify the increased workload and complexity.

5.4.5 Checking of incoming information

According to the 2018 interviews in Finland, the information in the safety data sheets that end users most commonly check is Section 2 on Hazard Identification. They also pay attention to Section 8 on Exposure controls/Personal Protection – especially personal protective equipment – and Section 7 on Handling and Storage. During the 2018 interviews, the suppliers also listed these sections as the most important ones for their customers, together with Section 15 that contains national regulatory information.

The Italian survey indicated that over 60 % of companies use safety data sheets to identify the hazards (Section 2) of a chemical and 30 % of them check the personal protective equipment in Section 8. Only 6 % of these companies use the safety data sheets for information on engineering controls. The researchers assumed this is because the engineering controls are more fixed, designed before an activity starts, and rarely changed. The use of information on engineering

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³² In this report, SUMI refers to DUCC's SUMI approach. During the Finnish interviews, some examples of SUMIs translated into Finnish were shown to interviewees for commenting.

³³ http://www.cepe.org/

controls increases with company size (small 5 %, medium 8 % and large 15 %).

Process descriptions and exposure information in the extended safety data sheets are used by less than a quarter (15-23 %) of the Italian companies. Some of them (5 %) indicated that they do not use any information in the extended safety data sheets for their workplace risk assessment. For this, there were no significant differences between the five industry sectors.

Such behaviour was also noted in Finland during the 2018 interviews. Some of the interviewed small end users indicated that they review some sections of the safety data sheets but hardly look at or use the exposure scenarios or take further actions. The reason why some companies do not use any information from the safety data sheets is that they have used these substances in the same way for a long time and consider that they know how to use them safely.

When Finnish companies were asked in 2018 whether they make sure that their suppliers supported their use, it appeared that most end-user companies were not fully aware of what this means. Some companies indicated that they make sure that the uses that involve large quantities of a chemical are supported, but they do not check that chemicals used in small volumes or for short periods of exposure are supported.

5.4.6 Workplace risk assessment

According to the Finnish interviews in 2017, over half of the end users (60 %) keep a record on how they use chemicals. These companies also use the information in the safety data sheets in their workplace risk assessments. A fifth (20 %) of them gather information for some chemicals and the remaining fifth (20 %) indicated that they do not collect information on chemicals they use.

In the study, the interviewees did not provide detailed information on the types of data gathered. However, in the 2018 interviews, the companies elaborated that they assess the information they receive from suppliers and have a process in place to compare it with their on-site conditions. Some of these companies showed the interviewers how they map their uses and categorised them under process categories (PROCs) to facilitate the extraction of relevant information.

According to the 2018 Finnish interviews, most of the formulators seem to use exposure scenario information for their workplace chemical risk assessments. However, it is not clear which information elements they use and how this information influences their assessments. When companies handle a new chemical, their HSEQ specialist commonly assesses the information in the extended safety data sheets (at least in the main body) and discusses its relevance with production managers. Companies consider that they know how to use a chemical safely if they have been using it for a long time. In their opinion, additional information from suppliers is not needed for these chemicals. Most companies mentioned that their workers have annual medical checks that include the monitoring of their exposure (e.g. through blood samples) for relevant chemicals. However, end users think that authorities do not expect them to carry out a quantitative exposure assessment. One-third of the interviewed end users mentioned that they have tools in place to perform risk assessments, but they did not elaborate on what these tools are.

In Italy, more than a fifth (23 %) of the companies indicated that they have updated a workplace risk assessment after receiving information in a safety data sheet. Such actions were more common in large companies out of which 50 % indicated they have done so. No differences were noted between industry sectors. The main reason for the updates had been a change in the classification information (66 %). In large companies, the updating was always induced by a change in substance classification, while in small and medium-sized companies the reason was exposure-related information in 20% of the cases.

According to the Italian survey, the risk management measures communicated in the extended safety data sheet are applied as such in 47 % of the companies, but in 44 % of the cases, they are integrated with other measures that are additional to those included in the exposure scenarios. The communicated risk management measures are implemented most commonly in the paper and cardboard, wood processing and textile sectors. In the tanning of leather and plastic and rubber sectors, the communicated risk management measures are integrated with sector-specific measures that are considered more appropriate and responsive to the business needs. It was also noted that larger companies are more likely to implement the communicated measures.

In the Italian study, half (49 %) of the respondents use the information in Section 8.1 of the safety data sheet to check the exposure limit values ($OELs^{34}$ and $DNELs^{35}$). While the other half (46 %) also consult other sources of information to check the validity of the information received. A small percentage (5 %) of the respondents rely solely on other sources. The researchers assumed that the reason why the plastic and rubber sector might be most keen to verify the information on the extended safety data sheet is that these companies use some substances of very high concern (SVHCs³⁶).

The findings of the Italian study indicate that personal protective equipment communicated in the safety data sheet was adopted in the majority (60 %) of companies. However, the findings also demonstrate that the information provided about personal protective equipment should be improved. In more than a third (36 %) of the companies, an in-depth assessment was required to complement the received information. In a few (4 %) companies, the received information was not considered sufficiently detailed. Larger companies indicated more commonly that they need further information and company-specific assessments.

For more than half (60 %) of the surveyed Italian end users, the expert who carries out the workplace risk assessment also performs REACH-related duties. The percentage is lowest in the textile industry (50 %) and highest (69 %) in the wood processing industry. No significant differences were noted between different sized companies. In more than half of these companies (55 %), internal experts are assisted by consultants to fulfil their REACH and OSH obligations. A third (30 %) of the companies rely solely on external expertise. The use of such experts for both activities is 32 % in small companies and 24 % in medium-sized companies. The findings of the Finnish interviews are similar and indicate that contractors assist many small Finnish end users in conducting their workplace risk assessment.

The findings of the Italian study suggest that companies with in-house expertise are more likely to use information in the extended safety data sheets than contracted professionals are. This highlights the importance for these companies to know how to find qualified consultants who are sufficiently knowledgeable about both REACH and OSH legislation.

The labour inspectors considered that the safety data sheets contain a sufficient amount of information to allow companies to manage risks at their sites. However, some of them were concerned, just like the Finnish companies, that there might be too much information for small and medium-sized companies to handle. In addition, they considered the information not to be specific enough and that it does not seem to respect the hierarchy of the control measures principle under OSH legislation. The Chemical Agents Directive³⁷ has been transposed into national legislation, leading to slight differences in its implementation across Member States.

36 Substances of very high concern under the REACH Regulation are substances that are CMRs category 1 or 2, PBTs or vPvBs or those that have endocrine-disrupting properties

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³⁴ Occupational exposure limit

³⁵ Derived no-effect level

³⁷ <u>Directive 98/24/EC - risks related to chemical agents at work</u>

Some of the differences can be seen in the findings of the 2018 labour inspector survey.

The labour inspectors in all of the 20 countries that responded confirmed that identifying hazardous substances is the starting point for workplace risk assessment. A quantitative exposure assessment may be required in 18 of them if there is a national binding occupational exposure or biological limit value and nine may require it when there is a CMR³⁸ substance without a threshold (Figure 5).

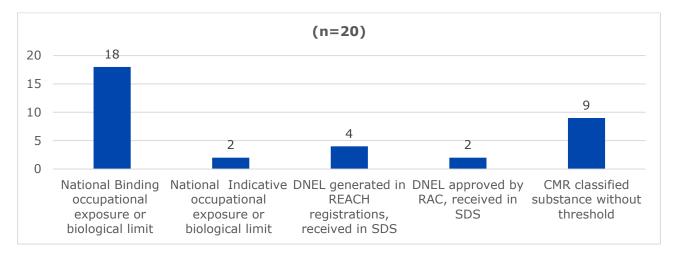


Figure 5: When the employer is expected to carry out a quantitative exposure assessment according to the 2018 labour inspector survey.

The acceptable methods to evaluate the exposure to hazardous substances as part of the workplace risk assessment are given in Figure 6. Those where a quantitative assessment is not expected are presented in Table 14.

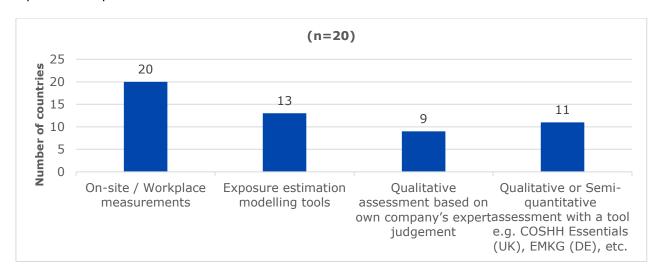


Figure 6: Acceptable methods to evaluate exposure to hazardous substances as part of workplace risk assessment according to the 2018 labour inspector survey.

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³⁸ Carcinogenic, mutagenic or toxic for reproduction

Table 14 – Acceptable methods to evaluate exposure to hazardous substances as part of workplace risk assessment when a quantitative assessment is not expected according to the 2018 **labour inspector** survey (n=20).

	No. of countries
By following substance- or process-specific guidance issued by sector of industry	11
By following substance- or process-specific guidance issued by the national Occupational Safety and Health authority	14
By applying an authority approved qualitative risk assessment e.g. COSHH Essentials (UK) or EKMG (Germany)	9
By relying on own company expert judgement	10

Figure 7 shows the situation in which a workplace risk assessment update is triggered. The option least selected was the receipt of new information on a control parameter such as a DNEL.

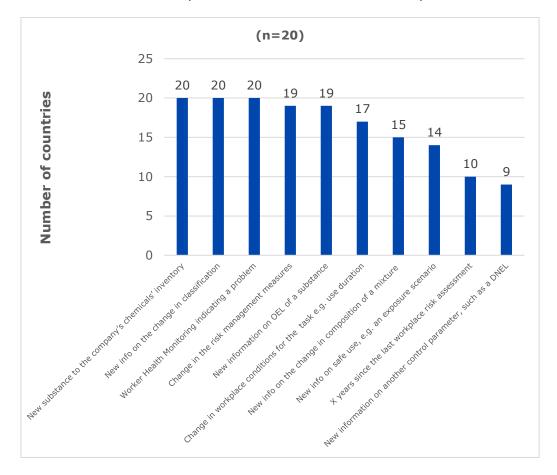


Figure 7: What is triggering an update of an employer's workplace risk assessment according to the 2018 labour inspector survey?

When labour inspectors carry out a workplace inspection on hazardous substances, 14 of 20 respondents indicated that they sometimes ask the employer if the exposure scenarios annexed to the safety data sheets have been taken in to account in the workplace risk assessment. Five of them indicated that they always do so, and one does so in specific cases.

More than half (60 %) of the respondents indicated that they sometimes accept the exposure scenario as a relevant contribution to the employer's workplace risk assessment, if well documented and simultaneous exposure to other substances is of no concern, while four respondents never do so.

5.4.7 Use of DNELs and scaling

The Finnish end users interviewed in 2018 indicated that they have not used derived no-effect level (DNEL) values in their workplace risk assessment unless they had access to external support such as an occupational health physician. Similarly, only a few Italian companies (8 %) reported that they used DNELs. The use was most common in the plastic and rubber sector. Otherwise, there were no differences between the Italian industry sectors or company sizes. According to the researchers, this is most likely due to the Italian legislation that stipulates the use of Occupational Exposure Limit values (indicative or binding) or risk assessment, with the decision to use DNELs being left up to the company. They however note that this finding indicates that it would be beneficial to enhance the companies' knowledge of the use of DNELs in workplace risk assessment.

In Italy, 98 % of companies have not used the scaling procedure. It allows the user of a chemical to show that the actual use conditions at the site are covered in the exposure scenario received from their supplier even if there are some differences in the (condition of use) parameters. Where relevant, the scaling procedure can be provided by the supplier of the hazardous substance.

The labour inspectors who were interviewed in 2017 believed that DNEL information could be useful if there is no OEL, and according to the 2018 survey, DNEL is not commonly used in workplace audits. The labour inspectors also felt that companies would assume that following the exposure scenario would mean that their risks are managed. Some bigger and more experienced companies may find the DNEL information useful for scaling, but according to the labour inspectors, this approach is not yet commonly in use.

5.4.8 Sharing safe use information with workers

In Finland, companies commonly use electronic archives to share safety data sheets with their workers. In small companies, the information is also printed and placed in folders that are located in the work area. In some large Finnish companies, workplace safety cards are produced inhouse or received from suppliers or external service providers.

In Italy, the situation is different. More than half (56%) of the companies that responded to the survey used hard copies of safety data sheets as a way to share safety information with their workers. This approach is most common in small companies. Only a quarter (26%) of the Italian companies use electronic documents for this purpose. In Italy, about 10% of companies produce workplace safety cards. These are mainly produced and made available to workers in larger companies. The difference between the countries is likely to be due to the more limited use of electronic filing systems in small Italian companies than in Finland.

More than half (63 %) of the Finnish suppliers that were interviewed in 2018 produced workplace safety cards for their own use and some of them (38 %) also send these documents to their customers. The customers of these suppliers highly appreciate these documents. So much so that a quarter (25 %) of the suppliers expressed that these documents were part of their competitive advantage.

5.4.9 Information management

In Italy, approximately one-third (32 %) of end-user companies have an IT system to manage incoming safety data sheets. However, there are differences in the use of IT systems between the sectors and different sized companies. A quarter (25 %) of the small companies use them while they are almost twice as common in medium-sized (49 %) and large (40 %) companies. These systems are most common in the tanning of leather (44 %) sector and least common in the wood processing sector (20 %). More than half (57 %) of companies enter the received information manually, accounting for more than 70 % if only medium-sized companies are considered.

In Finland, companies that formulate mixtures mostly transfer the incoming information manually into their IT systems. They use this information for their own workplace risk assessment and as an input for their safety data sheets for mixtures. Some of the companies interviewed in 2018, use external service providers³⁹ to manage their safety data sheets. The main reason for this is that managing a large number of safety data sheets in-house is very time and resource intensive. In addition, the service providers have more integrated systems that are practical for companies belonging to a group to manage these documents centrally. The service companies can also produce workplace safety cards that are based on the safety data sheets. The reasons not to use service providers included the small number of documents to manage (<100 safety data sheets) and the cost of these services for a large number (>1 000) of safety data sheets.

The findings of the Finnish online survey indicate that companies have mainly integrated the management of exposure scenarios and use information into the tools developed for safety data sheets. The respondents expressed a need for further IT development in this area.

The majority (80 %) of the companies that supply chemicals in Finland fulfil their duties related to the extended safety data sheets by carrying out the assessments and authoring the documents in-house.

5.5 Quality of information

5.5.1 Body of the safety data sheets

During the 2017 Finnish interviews, the end users rated the clarity and comprehensibility of the received information in the safety data sheets as 3.4 out of 5. The feedback provided by the 2018 Finnish and the labour inspector interviews were very similar (Figure 8). However, the labour inspectors would not score the information the same for all audiences. Half of the interviewees indicated that they would score the information as a 4 for large companies and 2 for small and medium-sized companies, giving an average score of 3 overall.

According to the Finnish and Italian studies, most companies think that the information provided is sufficient to manage the chemical risks at their site. The view of the labour inspectors is that the 16 sections of the safety data sheet are appropriate in size (max 10 pages). However, both companies and authorities agreed that the quality of information varies considerably between suppliers.

³⁹ External safety data sheet providers are services provided by independent companies to receive, keep an inventory, manage and perform other SDS-related tasks.

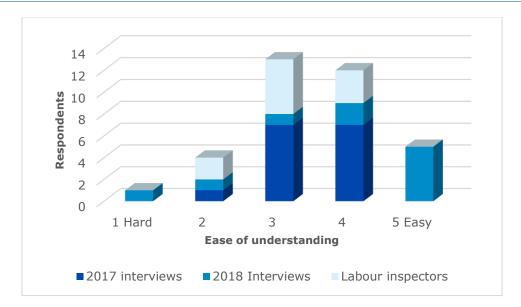


Figure 8: Clarity of the information in the safety data sheets according to the Finnish and the labour inspector interviews.

In Italy, respondents indicated that the conditions of use affecting exposure (29 %) and risk management measures (29 %) followed by use descriptors (17 %) and exposure estimates (14 %) are the easiest pieces of information to identify in the extended safety data sheets. There were no significant differences in the responses between small and medium-sized companies or industry sectors.

Italian companies reported that, on average, for 30 % of the safety data sheets they receive some information is missing (i.e. a section is empty). The lack of information was most commonly reported in the wood processing, tanning of leather, and plastic and rubber sectors (Table 15). Medium-sized companies reported more deficiencies in the safety data sheets than small companies did.

Table 15 – Percentage of companies in Italy that have noted that a section in a safety data sheet does not contain information.						
Information missing in a safety data sheet	Wood processing	Textile	Paper and cardboard	Tanning of leather	Plastic and rubber	Average (n=683)
No	66 %	79 %	71 %	67 %	65 %	69 %
Yes	34 %	21 %	29 %	33 %	36 %	31 %

A third (30 %) of the Italian companies that reported empty sections in the safety data sheet felt that this could be justified only in about 10 % of the cases. In more than a quarter (28%) of the cases, the missing information was subsequently provided after contacting the supplier. In 24 % of the cases, it was not considered relevant for the workplace risk assessment. Over a third (37 %) of the companies had consulted other sources of information to obtain related data.

Different sectors in the Italian study also value the relevance of the missing information differently for workplace risk assessment (Table 16). The paper and cardboard, tanning of leather, and plastic and rubber sectors commonly contact their suppliers while the wood processing and textile sectors use other sources to obtain the missing information for their risk assessments.

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Information missing in a safety data sheet	Wood processing	Textile	Paper and cardboard	Tanning of leather	Plastic and rubber	Average (n=683)
The lack of information was formally justified	14 %	29 %	6 %	6 %	3 %	10 %
The lack of information has been overcome by contacting the supplier	18 %	7 %	41 %	40 %	31 %	28 %
Other information sources have been used	48 %	46 %	21 %	40 %	34 %	37 %
The missing information was not considered relevant for the chemical risk assessment	20 %	18 %	32 %	14 %	32 %	24 %

Table 16 – The relevance of missing information to the workplace risk assessment by sector according to the **Italian** survey.

The Italian companies reported that the label elements are in general in line with the information in the safety data sheets (Section 2.1 and 2.2). Only 4 % of the companies reported inconsistencies in this area. If inconsistencies were noted, the large majority (93 %) of the companies contacted the supplier and only 7 % consulted databases for this purpose.

5.5.2 Exposure scenarios

The Finnish end users interviewed in 2018 think that the safe use information communicated in the exposure scenario and in Section 8 of the safety data sheet is not ideal. Having similar information in the 16 sections of the safety data sheet and in the attached exposure scenarios makes it burdensome to digest and manage.

Another recurring comment in the study was that the increasing amount of information received makes it more difficult for recipients to find relevant data. Therefore, the interviewed companies criticised the exposure scenario for being too long and written in a language that is meaningful only for technical experts. In addition, they felt that the relevant information (e.g. on personal protective equipment) is already available in the 16 sections of the safety data sheet or in chemical databases that they commonly use.

Similar concerns were expressed during the Finnish online survey. The deficiencies listed included lack of harmonisation, variable legibility – for example, due to the terminology used and poor translations – the limited perceived benefits and increased administrative burden (Table 17).

The companies stressed that it is more important to receive consistent, good quality information than more information. A commonly mentioned example of the problem is the inconsistency of the classification and labelling of a substance between suppliers. Some also stated that reducing the quantity of information communicated in the extended safety data sheet could be helpful.

Poor layout (no index, page numbers and/or version numbers)

exposure scenarios/information refers to other sources

Too much repetition/information scattered across the safety data sheet and

Information is overlapping/contradicting with the body of safety data sheet

OSH/environmental legislation

Additional administrative burden

Poor translations

Table 17 – Views of the Finnish companies and the labour inspector on scenarios.	the shortcoming	s of exposure
Reasons	Companies	Labour inspectors
Unclear information/too many acronyms/too much information	√	√
Too long/difficult to identify relevant information	√	√
For specialists	√	√
Not in line with the terminology and assessment requirements in	√	√

In total, a quarter (24 %) of the Italian companies encountered difficulties in finding information within the exposure scenarios and they felt that the document provided limited benefits. A few (3 %) of the small companies were not able to identify any information in the exposure scenarios and they considered the risk management measures communicated in the documents incomprehensible and difficult to implement. The researchers assumed that the use of safety data sheets is very difficult for these companies.

The labour inspectors were of the opinion that the exposure scenario, generated by Chesar that they reviewed, was quite good in terms of its conciseness and readability (Figure 9). Their comments on the quality focused on the usability of the data in workplace risk assessment but were otherwise very similar to the views expressed by Finnish companies (Table 17).

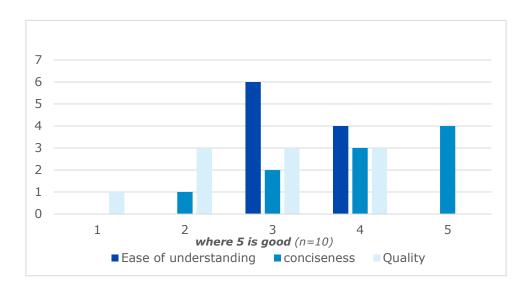


Figure 9: Labour inspectors' view of an example exposure scenario generated by Chesar.

A general feeling echoed by a number of the labour inspectors was to try to keep the information in the exposure scenarios as simple as possible. If the information is confusing, then the recipients will handle the chemical as they have done previously. The result being that useful information generated under REACH is not being used.

5.5.3 Language versions

The companies that participated in the Finnish and Italian studies indicated that it is not always easy to get safety data sheets and their updates in their local language. Documents in a foreign language are problematic because they typically have regulatory information (e.g. OELs) that is not relevant to the recipient. More than half (70 %) of the Finnish companies interviewed in 2018 said that they receive safety information both in Finnish and English and only a fifth of the respondents (20 %) indicated that they receive all safety data sheets in Finnish.

In Italy, 27 % of companies indicated that they had received some safety data sheets in another language than Italian in the past three years. There are differences between the Italian sectors. In the plastic and rubber sector, almost half (49 %) of companies had received documents that were not in Italian. The medium-sized companies reported receiving more safety data sheets that were not in Italian than small ones.

If the Italian companies received a safety data sheet that is not in Italian, more than half (54 %) of them, use it as received. This is most common in the wood processing (74 %) and textile (66 %) sectors. About one-third (34 %) of the companies that had received safety data sheets in another language had requested an Italian version but not received it. Only in 11 % of cases when an Italian language version had been requested and received was the translation considered adequate. This finding is in line with the Finnish studies that recorded complaints about the Finnish translations. Sometimes, the documents were noted to contain more than one language or to be very poor quality machine translations.

According to the interviewed labour inspectors, the safety data sheets they see are mainly in the national language. However, they were concerned about the quality of the translations, leading to incorrect information on national requirements in some of the sections (e.g. the UK OEL in Section 8 instead of the national one) and the fact that many exposure scenarios were in English or not annexed.

6. Communication with suppliers

6.1 General

In Finland, communication between the users and suppliers of chemicals mainly takes place by phone or email. According to the 2017 interviews, most (70 %) companies are in contact with their suppliers and considered the communication to work reasonably well (Figure 10). The frequency with which end users are in contact with their suppliers depends on the ease of communication. Contacts are more regular when the supplier is proactive and organises site visits and trainings or nominates a contact person for chemical safety matters.

In Italy, communication with suppliers seems to work well on questions related to classification and labelling for which over 90 % of the participating companies contacted their suppliers if there were any concerns.

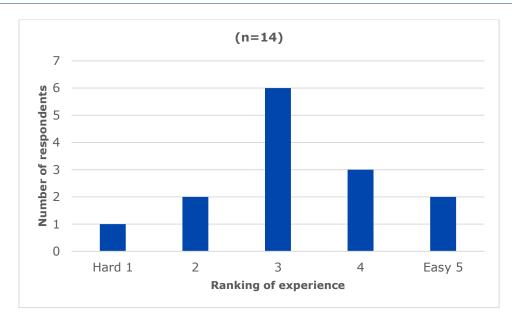


Figure 10: Users of chemicals' overall ranking of receiving requested information from their suppliers according to the 2017 Finnish interviews.

According to the Finnish interviews in 2018, the most common reasons to contact suppliers were to ask for an updated safety data sheet or a document in the local language. Another common reason was to clarify the classification and labelling information. About half of the companies interviewed in 2018 had given feedback to their supplier on the quality of extended safety data sheets. Similarly, 58 % of the respondents to the Finnish online survey contacted their suppliers in relation to the safety data sheets and just under half of the end users (42 %) said they have given feedback on the quality of the information they received on the extended safety data sheets. According to Finnish interviews in 2017, almost half (47 %) of the end users had not had a need to contact their suppliers because they could manage their compliance tasks with the information received.

The Italian study indicates that it is common for end users to not take any action or communicate with the supplier even if the information provided in the extended safety data sheet does not match with their conditions at the site. According to the Finnish online study, the manufacturers and distributors seemed to contact their suppliers more actively (60-71 %) than end users and small companies (45-50 %).

The findings of the Italian study indicated that larger companies are more inclined to contact their suppliers when they have questions on the extended safety data sheets. Small companies seemed to prefer to change their supplier or to substitute the substance if the received information is not in line with their operational conditions.

The labour inspectors' opinion according to the 2017 interviews is that smaller companies are not actively communicating with their suppliers and only do so when inspectors instruct them to.

6.2 Use information

These studies indicate that the upstream flow of use information can be improved. The Finnish interviews in 2018 reported that over half of the companies (60 %) had communicated use related information to their suppliers. In the Finnish online survey, the percentage of companies that contacted their suppliers was lower. Less than half of the respondents (42 %) provided information about the uses to their suppliers and only 37 % of those respondents who supply

chemicals received information about their customers' uses.

According to the Finnish online survey, the three main situations in which companies have communicated about their uses are:

- 1. before the relevant registration deadlines;
- 2. on an *ad hoc* basis when the exposure scenarios received do not match the intended use; and
- 3. during research and development work.

However, some respondents indicated that not all suppliers were interested in receiving such information. The companies interviewed in Finland in 2018 noted that there is not an efficient way to handle the upstream communication on the quality and appropriateness of the use information. One of the reasons being the differing understanding of the terminology in companies, for example, terms such as "unsupported use" and "use conditions".

According to the study, the use-related contacts were commonly related to personal protective equipment. Suppliers were also contacted and asked about the availability of less hazardous substitutes.

In Italy, 13 % of the companies that participated in the survey were not able to find their uses in the extended safety data sheets. In 10 % of cases, they did not find their use conditions and in 24 % of them, half of the companies (50 %) did not take any action in such a case. For those that do, 11 % contact their supplier, 9 % substitute the substance, 7 % adjust the production process to be in line with the safety data sheet, 1 % declare that they have changed the supplier and 23 % undertake other unidentifiable actions.

7. How to improve the information and its flow

The studies with the Finnish companies and the labour inspectors provided suggestions on how to improve the extended safety data sheet and make exposure scenarios more useful and easier to manage. The respondents' suggestions fall into three categories:

- 1. document structure and content;
- 2. support; and
- 3. information technology (Table 18).

The needs commonly noted by companies are to have clear, easy to understand and short documents in a local language with a harmonised structure – including a table of contents, version and page numbers. The findings also underline the need for practical and consistent information that can be used to support regulatory duties under other pieces of legislation such as the workplace chemical risk assessment.

Recurring ideas on how to improve the flow include:

- 1. making the safety data sheets easier for users to understand (e.g. clarify acronyms used in Section 8);
- 2. having harmonised extended safety data sheet templates and information, which would make the information easier to retrieve; and
- 3. improving the consistency of classification between suppliers.

Additionally, end users would appreciate more training sessions on the extended safety data sheets.

Some respondents would prefer safety documents to be made available in an online database for consultation rather than being distributed to customers. In addition, companies were interested in having more information on substances of very high concern (SVHCs) and their substitutes on the safety data sheets.

The companies and the labour inspectors both noted that if the information is confusing, then the recipient will handle the chemical as they have done previously.

Table 18 – Suggestions noted during the **Finnish** studies and the labour inspector interviews on how to improve exposure scenarios and make them easier to use.

1. Document structure and content

Short documents (the safe use information for a substance or mixture in a use, maximum two pages in length)

Harmonised template with an index/table of contents and page and version numbers

Changes in information content clearly indicated in updated safety data sheets/exposure scenarios

Easy to understand (documents in layman language or explanations of technical terms and acronyms included in the document)

Relevant information (e.g. OSH/environmental limit values)

Improved legibility (i.e. layout and harmonised template) and translations

Information should be embedded in the main body of safety data sheets

Safe use information for mixtures (SUMIs)

2. Support

Guidance and helpdesk services

Easy to navigate guidance web pages

Practical examples on how to author exposure scenarios and use the information they provide

Support material in local language

Training sessions in local language

3. Information technology

Up-to-date safety data sheets/exposure scenarios available online (e.g. on ECHA's website) for downloading

DNEL/PNEC not included in the safety data sheet sent to the customer but made available online

Possibility to filter the document e.g. by PROCs that are relevant for the company

Information on substitutes for SVHCs provided on safety data sheets or online

8. Support

8.1 Tools and guidance

The Finnish end users in the metalworking and engineering sector interviewed in 2017 were not

aware that ECHA provides guidance on how to comply with REACH obligations and tools that help companies to carry out their duties. Therefore, this topic was included in the Finnish online survey to gain further insights on how well companies were aware of the support material that ECHA and national authorities have made available online.

Another challenge noted during the 2017 interviews was that it is not easy for companies to find out what is available, where the material can be accessed and how to select the most relevant material for a particular purpose because ECHA has published so much information online. The labour inspectors who were interviewed in 2017 also noted this challenge. As a follow up to these findings, ECHA has developed and published a *Downstream User guidance and tools* factsheet⁴⁰ to facilitate access to relevant material.

Almost all of the companies (98 %) that participated in the Finnish online survey are familiar with the material published by the Finnish Safety and Chemicals Agency (Tukes). Over three-quarters (78 %) of the respondents know some of ECHA's material and nearly half of them (44 %) are aware of industry material. Unfortunately, the respondents did not indicate in their replies any specific support material beyond Tukes's REACH helpdesk and web pages and ECHA's guidance and web pages. Small companies and end users seem to be less knowledgeable about the material as can been in Table 19.

Table 19 – Awareness in the metalworking and engineering supply chain about to	the
guidance and tools published by ECHA and the Finnish authorities.	

	Small (n=11)	Medium (n=13)	Large (n=21)	Manufacturers (n=9)	Formulators (n=8)	Distributors (n=9)	End users (n=17)	Average (n=45)
ECHA	64 %	82 %	90 %	78 %	88 %	89 %	65 %	78 %
Tukes	91 %	100 %	100 %	100 %	100 %	100 %	94 %	98 %
Industry	27 %	38 %	57 %	44 %	75 %	67 %	18 %	44 %

The majority of Finnish companies listed email news by the national competent authority Tukes and ECHA as good channels for authorities to keep them informed, but the role of industry organisations as a way to reach companies was also highlighted.

Other popular channels for informing companies are ECHA's and Tukes's websites and helpdesks, regular training sessions by national authorities, industry organisations and consultants as well as ECHA's webinars. Companies that provide safety data sheet or chemical database services and professional networks for HSEQ-professionals should also be considered as potential channels for REACH-related information.

An IT tool that could be used to assess the compatibility of the received exposure scenarios and the conditions of use at the site was also mentioned. Additionally, simple practical guides and examples on how the extended safety data sheets can be used should be promoted. ECHA's downstream user factsheet is designed for such awareness-raising activities. Finally yet importantly, the flow of information between companies that do business together was mentioned as a way the regulatory information is already (or should be) flowing in the supply chain.

The labour inspectors were not very aware of all the tools developed to support communication in the supply chain. However, they know ECHA's website, the substance search facility, and

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⁴⁰ https://echa.europa.eu/documents/10162/21332507/du_in_brief_en.pdf

specific guidance that they are interested in such as the ECHA *Guidance on the compilation of safety data sheets* and *Guidance for downstream users*. In addition, many of them check specific guidance that they are interested in, mainly the interactive *Guide on safety data sheets and exposure scenarios* and the *Practical Guide on the downstream user chemical safety report*. All these documents can be accessed through the publication section⁴¹ of ECHA's website.

8.2 Databases

The companies in Finland and Italy highlighted the role of databases (e.g. national OEL lists, ECHA's C&L Inventory⁴², ECHA's dissemination site⁴³, ILO's International Chemical Safety Cards⁴⁴ or commercial databases) in their chemical risk management. They appreciate the databases for practical information in a consistent format. The databases are consulted, for example, when the information received from different suppliers is inconsistent.

In Italy, a third (35 %) of the companies indicated that they complement the safety data sheet information by consulting chemical databases when they identify the hazards of a substance. There were some differences between the Italian sectors in the use of databases and their use was noted to decrease with increasing company size. In the plastic and rubber sector, half of the companies (50 %) use databases for hazard identification. When the Italian companies check the limit values (OELs and DNELs), also in this case almost half (46 %) of them consult databases and a few (5 %) rely solely on databases.

9. Conclusions and recommendations

The six market studies provide valuable insights into the flow of extended safety data sheets in the supply chain and the impact of exposure scenarios at end-user level in 2017 and 2018. The findings are directly relevant to the planning of the ENES activities on enhanced supply chain communication and they contribute to REACH Review Action 3.

There are four types of challenges in supply chain communication:

- 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.

The discussion on these challenges and recommendations can be found in the executive summary.

⁴¹ https://echa.europa.eu/publications

⁴² https://echa.europa.eu/information-on-chemicals/cl-inventory-database

⁴³ https://echa.europa.eu/information-on-chemicals

⁴⁴ https://www.ilo.org/safework/info/publications/WCMS_113134/lang--en/index.htm

Similarly, to the studies in this report, the Forum's REF-5 project⁴⁵ and a study contracted by the European Commission⁴⁶ on the *Approaches and Better Support for Consumer Exposure Assessment under REACH* indicate that awareness in the supply chain about the extended safety data sheets is still limited and continued awareness-raising activities are needed. In line with the Finnish studies, the Commission's study reported that exposure scenarios do not always reach the lower end of the supply chain.

The findings of the Forum project are more positive, indicating that the transfer of information up and down the supply chain takes place and that required information is integrated into the relevant sections of the extended safety data sheets and/or in exposure scenarios. However, all studies stress that the quality of the information is not yet satisfactory in terms of accuracy, clarity and usefulness. Both of these studies considered ENES tools e.g. sector use maps⁴⁷ as a way to enhance supply chain communication. The use of modern IT tools was also suggested. These recommendations are in line with the findings of this report.

10. Considerations for future studies

The methodologies used for the six studies in this report worked well. However, lessons were learned during the studies that can be beneficial information for future work, for example, under a proposed 10-year monitoring programme of extended safety data sheets across Europe that is being considered under the ENES Work Programme to 2020.

The lessons learned are listed below under the three main steps of a study: planning, implementation and reporting.

PLANNING

- Attention needs to be paid to the design of clear and well-structured questions and questionnaires. This will ensure that the time needed to reply is minimised and the questions are understood.
- It is important to test the questions with the target audience (e.g. six members) to verify their understanding and to get information on how much time is needed to complete the exercise.
- Companies, especially small end users, do not use the same terminology (e.g. substance, mixture and hazardous chemical but paint, cleaner etc.) as regulators do. Therefore, it is critical to review the questions with appropriate industry experts to ensure a correct understanding.
- Use of visual aids, e.g. hazard pictograms, exposure scenarios and SUMIs, can facilitate the understanding of the questions.
- For multiple-choice questions, realistic ranges or options for answers need to be established, preferably with relevant industry experts.
- It is important to ensure that the people who participate in the study in a company are knowledgeable about the substance matter. Industry associations and professional networks can be potential channels to reach such experts.

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⁴⁵ The <u>REF-5</u> project inspected extended safety data sheets in almost 900 companies in 29 States in the European Economic Area.

⁴⁶ The <u>Commission study</u> collected <u>feedback</u> from several sectors that formulate mixtures and provided feedback on the flow of exposure information they receive from REACH registrants in extended safety data sheets.

^{47 &}lt;a href="https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library">https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library

 Collaborating with organisations that are known to the respondents is critical for a successful study.

IMPLEMENTATION

- It is important for a good response rate to schedule a study so that it is not conflicting with any competing activities (e.g. holidays).
- Well-prepared pre-study information (e.g. what the study is about, what is needed to respond and why it is worth participating) shared with the experts to be interviewed or recipients for an online survey can play an important role in getting a good response rate.
- Companies usually need to be reminded about online surveys and follow-up calls are part of setting up interviews with companies.
- 45-90 minutes is typically needed for a face-to-face interview. However, it may be difficult to motivate people to spend more than 10-15 minutes to complete an online survey.
- Six to eight weeks is normally a sufficient period for the recipients of a survey link to fill in and submit their feedback.
- The semi-structured interviews used with the companies and labour inspectors worked well. This methodology provided a sufficient structure to carry out the interviews but also enough freedom for the interviewees to add topics that they considered relevant.
- The set-up of interviews with Finnish companies was not appropriate for getting detailed feedback on exposure scenarios and SUMIs in the one-hour session. Such discussions would have required a dedicated time slot (e.g. 30 minutes) and an interview guide specifically developed for that purpose.
- It is important that the interviewers are sufficiently proficient about the substance matter
 to be able to collect quality information and to be able to explain the terminology (e.g.
 safe use, exposure scenario, unsupported use, scaling) when that is not clear to the
 interviewees.
- Interviewees are commonly indicating ranges when questions concern, e.g. numeric values. Therefore, the interviewers should prepare reference answers with relevant ranges for such questions before the interviews. This will facilitate the processing and analysis of the interview data.

REPORTING

- When studying the use of chemicals in a sector, it would be beneficial to have a general
 description of the chemicals (substances and mixtures) typically used in the sector. This
 can facilitate the interpretation of the findings, especially if the researcher is not very
 familiar with the studied sector.
- Multiple-choice questions give well-structured and easy to interpret information about topics covered if the questions are well prepared. They can be used for topics that are easy to understand and where the range of answers is known.
- If open questions are used in an online survey, the analysis of the findings can be challenging because the researcher needs to group the responses. Interpreting the responses can be difficult because respondents often do not write full sentences. This can potentially make the narrative feedback quite cryptic, especially if the answers need to be translated from one language into another.
- It is good to include questions that can be used to cross-check the consistency of the answers.

• If detailed information about the use of support material and tools is needed, then the study needs to list all relevant material because respondents rarely mention names of any documents or tools beyond indicating e.g. ECHA guidance, helpdesk website.

11. Attachments

11.1 Guide to the Interviews of Finnish companies in 2017

Understanding the information needs for using chemical products safely and proposal for the elements of a marketing plan to promote the use of ECHA's tools and services

1. Questionnaire for Downstream Users This is a working translation of the interview guide in Finnish

General Background Information

Company name: Company size: Amount of people using/handling chemicals: Main Products: Are you a Member of industry/trade association(s)? If yes, which?

Purchasing and Inventory of Chemicals and Substances

- 1. Who is responsible for purchasing chemicals/keeping an inventory?
- 2. Does this person/unit cover the whole chain from purchasing the chemicals, to storing and keeping an inventory, safe use, and finally, disposal of the chemicals?
- 3. What kind of instructions/protocols/quality systems do you have for purchasing chemicals?
- 4. On which basis do you select your suppliers?
- 5. Can you tell us your main supplier?
- 6. How many chemicals are used in this company/facility/unit?
- 7. How many of those chemicals are classified as hazardous substances/chemicals or mixtures?
- 8. Do you have an inventory or register for all the chemicals that are stored, handled or used in your company?
- 9. How is this inventory/register used for handling of chemicals?
- 10. Has there been any change in your inventory of chemicals over the last 5 years?
 - a. If yes, in what way has it changed?
 - b. If yes, what triggered that change?

Supply Chain Communication

- 11. What information do you receive when purchasing hazardous substances from suppliers?
- 12. How many of these hazardous substances in use (Q. 5b) have Exposure Scenarios?
- 13. What information do you receive when purchasing hazardous mixtures from formulators (suppliers)?
- 14. How many of these hazardous chemicals in use (Q. 5b) have SUMI's?
- 15. Do you receive these documents (SDS, ES, SUMI) automatically from the supplier?
- 16. Do you think that the information provided is sufficient to help you manage risks from chemicals at your site/facility/company?
 - a. If no, what is missing?
- 17. In what language(s) is the information supplied?
- 18. Is this received information clear and easily understandable?
- 19. What could be the main areas that need to be improved? Any suggestions as to what could be improved?
- 20. Do you communicate any information needs concerning specific hazards and exposure relevant in your activities, back to the supplier/formulator?
 - a. If yes, how?
 - b. If no, why not?
- 21. Do you gather information on how chemicals are used in your facility/factory/unit?
- 22. Do you communicate any information needs about Safe Use back to the supplier?
 - a. If yes, how?
- 23. Have you determined whether the actual use and conditions of use match the conditions described in the Exposure Scenarios received?

- a. If yes, how?
- b. If no, why not?
- 24. How would you rank your overall experience in terms of receiving requested information from your suppliers?

ECHA Tools and Services

- 25. Are you familiar with ECHA services and Roadmap/Exchange Network Exposure Scenario (ENES) tools?
 - a. If yes, how did you find out about ECHA services and tools?
 - b. If no, where do you go for help? (Skip to Q. 31)
- 26. What tools/services are you familiar with?
- 27. How often do you use these tools/services?
- 28. With what purpose and how often do you use these tools?
- 29. How useful do you find these tools/services?
- 30. What would you suggest to be improved?
- 31. (*If they have not used the tools/services*) Would you be interested in learning more about the tools/services and the benefits they may bring to you?
 - a. If not, why not?
- 32. (*Skip if they have used the tools/services*) Where/how would you search for these tools and how to use them?

Risk Management, Communication and Monitoring

- 33. Have you used Exposure Scenarios received in the annex to a Safety Data Sheet in your management of substances at your company/site/facility?
 - a. If yes, for what purpose?
- 34. How readable and understandable do you find the Exposure Scenarios?
- 35. How concise do you find the Exposure Scenarios?
- 36. How would you rank the overall quality of the Exposure Scenarios?
- 37. What could be improved in the Exposure Scenarios?
- 38. Safety data sheets contain limit values for hazardous substances. (For instance, derived no-effect limits (DNEL) for effect on humans, predicted no-effect concentration (PNEC) for effects on the environment). How do you use that information?
- 39. Who is responsible to ensure that hazardous substances and/or mixtures are used safely in your company?
- 40. How do you keep your employees informed about chemical safety procedures?
- 41. Have any changes occurred within last 5 years with respect to handling chemicals and managing risks from hazardous substances and/or mixtures in your company/site/ facility?
 - a. If yes, which?
 - b. If yes, what triggered such a change?
- 42. Do your employees follow the instructions given to manage risks?

Comments and feedback

43. Do you have any other comments, feedback or would like to address anything else in specific?

Debrief seminar

44. Would you be interested in attending a debriefing seminar on the project's findings?

Thank you for your time!

2. Questionnaire for Supplier - General Background Information

Company name: Company size: Main Products:

Safety communication

- 1. How many of your raw materials are substances which are labelled hazardous?
- 2. How many of these have an annex with Exposure Scenarios? (Hazardous substances include chapter 3.1. in the SDS)
- 3. What safety information do you provide to your customers?
- 4. How do you decide what information to provide to your customers?
- 5. How do you deliver this information to your customers?
- 6. Is there an appointed person/unit that ensures that the customer is provided with the required information on the chemicals you supply?
- 7. How do you ensure that all the updates (i.e. updated SDS) reaches the customers?
- 8. What kind of system do you use to generate the safety information?
- 9. Do you think that the information on the chemicals you pass to your customers is sufficient, if not, what could be improved?
- 10. Have you received any feedback from your customers on the information you provide them?
 - a. If yes, what kind of feedback?
- 11. If a lot of feedback, in what parts of the SDS do you feel your customers have been unsatisfied with?
- 12. How could "providing the information of safe use to the customers" be made easier?
- 13. Have you received any request from your customers to provide additional information or clarification or have you been requested to provide missing information or material?
 - a. If yes, what?
 - b. If yes, how?

Comments and Feedback

14. Do you have any other comments, feedback or would like to address anything else in specific?

Debrief seminar

15. Would you be interested in attending a debriefing seminar on the project's findings?

Thank you for your time!

11.2 Guide to the Interviews of Finnish companies in 2018

Finnish Research on how formulators and end users process safe use information for chemical products in the metalworking and engineering industries

2.a INTERVIEW - SUPPLIERS This is a working translation of the interview guide in Finnish

2a.1 Introduction (Background) Available at: https://goo.gl/forms/GoSgVCAs8Uq6YpQv2

This research project is commissioned by the European Chemicals Agency (ECHA) and it is conducted by us, Giovanni Chaurand and Lassi Kervinen (*Short self-introductions*). The purpose of this project is to understand how suppliers of chemical products:

- 1. Process internally SDS and extended SDS
- 2. Handle the communication on Exposure Scenarios
- 3. What they perceive are their information needs and the needs of their customers (end users)

How are we doing this?

We expect that by visiting suppliers in various industry sectors (industrial coatings, metal cleaning and metal cutting fluids) and conducting interviews, we could discuss how safety information is processed, for example by discussing:

- The procedure of receiving safety information from the manufacturers
- How is this information processed internally?
- What type of communication exists with your customers and suppliers?
- How do you see this whole process?
- Etc.

Here is a rough scheme of these above-mentioned topics that we wish to discuss:



Figure 1. Process of information flow

All the information obtained in the interviews is disconnected from the company's name, will be kept confidential and it will be used only for the purposes of this study. This information will not be used for law enforcement or any other equivalent purpose.

2a.2 Background Information (Questionnaire style, short answers)

- 1. Company name
 - a. Your role in the company?
- 2. Company size
- 3. Could you tell us about your company? What type of products do you have? In what type of sectors, etc.?
- 4. What is your role(s) under REACH
- 5. Is the company member of an industry association e.g., Technology Industries of Finland (Teknologiateollisuus), Chemical Industry Federation of Finland (Kemianteollisuus), Association of Finnish Paint Industry and Printing Ink Companies, the Finnish Cosmetic, Toiletry and Detergent Association, Technology Industries of Finland and the Association of Finnish Technical Traders?
 - a. If yes, which?
 - b. If yes, do you communicate with them? Are you active? What and how do you participate?
- 6. How many suppliers do you have?
- 7. Do you source products outside of the EU?
 - a. If yes, to which extent (% of total)
- 8. How many customers do you have?
- 9. How many raw materials do you receive?

- 10. How many hazardous raw materials do you receive?
 - a. How many of those are classified (hazardous) substances?
 - b. How many are classified (hazardous) mixtures?
 - c. How many of the received- mixture-SDS have an Annex (SUMI or ES), or an extended section 7/8 in the SDS main body with DNELs/PNECs and measures for exposure controls?
- 11. How many SDS without annex do you receive? (*substances*)
- 12. How many SDS with annex do you receive? (substances)
- 13. How many products/recipes do you have?
- 14. Do you use external SDS service providers e.g., to author, manage or distribute SDS/eSDS?
 - a. If yes, why do you use it/how do you benefit from them?
 - b. If no, why did you decide to have this as an internal process?

2a.3 Incoming information and communication with suppliers (Open questions, discussion)

- 15. Could you show some examples of the Safety Information (SDS & eSDS) that you receive from manufacturers/suppliers?
- 16. How do you receive this information?
- 17. How often do you communicate with your suppliers?
 - a. How do you communicate with your suppliers?
 - b. Why do you communicate with them? What led you to communicate with them? Was something unclear? What?

2a.4 Exposure Scenario and SUMI Examples

- 18. How do these examples look to you? Are they informative and easy to understand?
- 19. How would you go on retrieving information from these documents?
- 20. Do you think you and your customers would benefit from receiving these documents? Would they make a difference?

2a.5 Processing of information (Open-ended questions, discussion)

- 21. What happens to SDS information when it arrives to your company? (*How is this information processed internally?*)
- 22. How do you integrate the incoming information into your system to generate SDS? (*external service providers?*)
- 23. How do you check that the design and use of your product is consistent with the information that you receive? For example, you design a recipe for a product with a concentration of 20%, but the conditions of use of the ES you receive is for 10%.
- 24. How do you solve this? Do you do the assessment yourself or ask your supplier?
- 25. How often did you experience a mismatch (from incoming/outgoing information)?
- 26. How did you handle it? (Change recipe, supplier, did not do anything?)
- 27. What approach do you use to create eSDS for mixtures? Do you use any tools (e.g., LCID) or templates (e.g., SUMI)? (examples of ENES tools)
- 28. Do you market your product outside Finland?
 - a. If yes, how do you handle translations? Do you use standard translations or other tools?
 - b. If yes, to what extent (% of sales)?

2a.6 Outgoing information (generation of information) **and communication with customers** (Open-ended questions, discussion)

- 29. How do you generate the "safe use" information (e.g., SDS, TDS, eSDS) that is provided to your customers? (and what?)(This covers SDS and TDS and focus on safe use.)
- 30. On what basis do you decide what information to provide to your customers?
- 31. How is this information delivered to your customers and to which part of the customer's organisation?
- 32. What type of communication channels do you have with your customers?
 - a. How do you make sure that the customer's use is correctly supported?
 - b. How are updates pushed to your customers?

33. Have you received feedback on the quality or quantity of the information you provide to your customers? (what?)

2a.7 Needs, suggestions and discussion (Open-ended questions, discussion)

- 34. What do you perceive to be the needs of your customers (in regard to safety information)?
- 35. In your experience, how does the communication with your customers/suppliers work? Do you have good/bad examples?
- 36. Is there anything in the communication process that could be improved?
- 37. What would you do differently if you could, in regard to the quality of information that you provide to your customers? (and what prevents you from doing it?)
- 38. Anything else to add? (And/or discuss other issues that may arise during the interview)

1a.8 Thank you

We would like to thank you again for agreeing to participate in this project. We expect to write a report on the findings by the beginning of March.

- 39. Would you like to receive this report?
- 40. Would you like to participate on a seminar where the main findings would be discussed?

2b. INTERVIEW - DOWNSTREAM END USERS

2b.1 Introduction (Background)

This research project is commissioned by the European Chemicals Agency (ECHA) and it is conducted by Giovanni Chaurand and Lassi Kervinen (*Short self-introductions*). The purpose of this project is to understand how end users of chemical products can benefit from SDS + eSDS in order to meet their obligations under the Finnish occupational health and safety and REACH legislation, for example:

- 1. How and what safety information is retrieved from SDS + eSDS for the workplace chemical risk assessment and how well it meets OSH requirements.
- 2. How is safety information handled in the workplace and working site?

How are we doing this?

We expect that by visiting end users of chemical products in various engineering sectors with different industrial processes (coatings, cleaning of metal parts before or after surface treatment and metal cutting fluids) and conducting interviews, we could discuss how safety information is received, processed and used, e.g., by discussing:

- The procedure of receiving information from the suppliers
- How is this information processed and used internally?
- What type of communication exists with your suppliers?
- How do you see this whole process?
- Etc.

Here is a rough scheme of these above-mentioned topics that we wish to discuss:

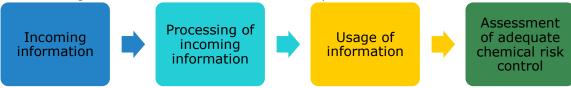


Figure 2. Process of information flow

All the information obtained in the interviews is disconnected from the company's name, will be kept confidential and it will be used only for the purposes of this study. This information will not be used for law enforcement or any other equivalent purpose.

2b.2 Background Information (Questionnaire style, short answers)

- 1. Company name
- 2. Your role in the company? (Interviewee)
- 3. Company size
- 4. Could you tell us about your company? What type of products do you have and for which type of sectors, etc? Who are your customers?
- 5. Role(s) under REACH
- 6. Is the company member of an industry association e.g., Technology Industries of Finland (Teknologiateollisuus), Chemical Industry Federation of Finland (Kemianteollisuus), etc.?
 - a. If yes, which?
 - b. If yes, what type of communication do you have with this associations?
- 7. Which of the following types of chemicals do you use, in which approximate amounts per year?
 - a. Paints and coatings
 - b. Metal cutting fluids
 - c. Chemicals for cleaning metal parts/surfaces (before or after surface treatment)
 - d. Other
 - e. In what kind of equipment/machinery
- 8. How many suppliers (of hazardous chemical products) do you have?
- 9. How many chemicals are used in this factory?
- 10. How many hazardous chemical products do you handle?
 - a. How many of those are substances?
 - b. How many are mixtures?
- 11. What percentage of your incoming hazardous substances include annexes?
- 12. What percentage of your incoming hazardous mixtures include an annex?
- 13. How do you store and keep an inventory of SDS locally in your company?
- 14. Do you use external SDS providers e.g., to author, manage or distribute SDS/eSDS?
 - a. If yes, why do you use it?
 - b. If no, why don't you use one?

2b.3 Incoming information and communication with suppliers (Open-ended questions, discussion)

- 15. What information do you receive from your suppliers?
- 16. How do you receive this information?

Could you show some examples of the safety information related to the safe use of chemicals (exposure controls) you have received from manufacturers/suppliers?

- 17. What type of communication channel do you have with your suppliers?
 - o How do you make sure that your use is supported?
 - o How do you receive updates of SDS?

Could you show us examples of what you think is a good and bad SDS? (collect them if possible?)

- 18. What makes them good or bad? (*Note for interviewers: look for possible annexes*)
- 19. Have you given feedback to your suppliers on the quality of the information that you have received?
 - a. If no, why not?

2b.4 Processing and usage of information (Open-ended questions, discussion and walk around premises, see workstations)

- 20. What happens to this information when it arrives to your company? (How is this information processed internally?)
- 21. How do you retrieve the meaningful information from SDS + eSDS?
- 22. What do you consider is the most important information in SDS and eSDS?
 - a. How easy it is to retrieve this important information?
- 23. How do you convert the information given in SDS + eSDS into actionable guidelines for your workers? (How do you make sure that OHS requirements are met, when you receive SDS? Is the information sufficient?)

- 24. Do you use external help to produce your chemical risk assessment?
 - a. If yes, what or who?
- 25. If you have received DNELs for the substances used (as such or in mixture) how to you make yourself aware that exposure in your company is below these values?
- 26. If you have received exposure scenarios or extended safe use advice in section 7/8 of the SDS, do you systematically compare this with the actual practice in the company and how?
- 27. Is such information helpful to establish safety at workplace?
- 28. Do the authorities expect you to quantify inhalation and dermal exposure at the workplace for all hazardous substances used to demonstrate safety?
- 29. Do you have any tools you use to combine them? (incoming info and site assessment)
 - a. If yes, what tools?
- 30. How are workers able to find information on safe use relevant to them?

2b.5 Exposure Scenarios and SUMI Examples (Show eSDSs)

- 31. What comes first to your mind when you see these examples?
- 32. How would you go on retrieving information from these documents?
- 33. Do you think you would you benefit from receiving these types of documents? Would they make a difference?
- 34. Are you following SVHCs in substances and mixtures that you use in your processes?
- 35. Have you discussed this with your suppliers?

2b.6 Needs, suggestions and discussion (Open-ended questions, discussion)

- 36. What do you consider to be the most important information that you receive from your suppliers?
- 37. What are your main needs when receiving safety information from your suppliers?
- 38. How easy has it been to get this important/relevant information that you need/want?
- 39. How could it be made easier and better?
- 40. In your experience how does the communication with your suppliers work? Do you have good/bad examples?
- 41. Is there anything in the communication process that could be improved? Do you have improvement suggestions in the communication style? And process?
- 42. What would you do differently if you could, in regard to the quality of information that you receive from your suppliers?
- 43. Hypothetically, would you rather have the supplier send you the information they think is relevant to you, or search it yourself from a database where most uses would be covered?
- 44. Are you aware of your legal obligations under REACH/CLP Regulation?
- 45. Anything else to add? (And/or discuss other issues that may arise during the interview)

2b.7 Thank you

We would like to thank you again for agreeing to participate in this project. We expect to write a report on the findings by the beginning of March.

- 46. Would you like to receive this report?
- 47. Would you like to participate on a seminar where the main findings would be discussed?

11.3 Finnish online survey questionnaire

Online survey – cover page (the original Finnish version is available upon request)

The questionnaire consists of about 30 questions and takes 15 to 20 minutes to complete. The questions marked with an asterick are compulsory. You do not need to answer all open questions. However, we hope your

that yo		e written feed	back, as that i	s the best wa	y to highlight the challenges y
	ponses will be treate European Chemicals				will feed in to the work progran t EU level.
<u>Secti</u>	on 1 -Company	<u>information</u>	<u>on</u>		
1.	Contact informati	ion			
	Company: Email address:			Name: Phone numbe	er:
2.	Your role in the c	ompany			
Techn	ical/HSEQ expert $\ \square$	Sales/market	ting 🗆 Managen	nent 🗆	Other
3.	Company size (Nu	umber of emplo	oyees)		
Micro ((<10) Small (<50) □ Medium (·	<250) 🗆 Large ((>250) □	
4.	Company's REAC	H role (Select	all that apply)		
5.	(Select all that ap Chemical Industry Association of Finni Finnish Cosmetic, T Technology Industr Association of Finni	res ter of articles g. industrial cl (representative of a y organisation ply) Federation of F sh Paint Indus oiletry and De ies of Finland sh Technical T	leaning) third manufacturer of s ns is your com Finland try and Printing tergent Associa	npany a mem Ink Companie	ber of:
	Federation of Finnis Our company is not Other		any organisatio	on	
<u>Secti</u>	on 2 - Informa	tion receive	ed by your	company	
6.	How many che	emicals (subs	tances or mix	tures) does v	our company buy?
	<50 □	51-250 □	251-1000	-	>1000 □
7.	What percenta Regulation?	ge of these o	chemicals are	classified as	hazardous under the CLP
	<20 % □	21-50 % 🗆	51-80 % 🗆	>80 % □	
8.	Do you reques chemicals?	t safety data	sheets from y	our supplier	also for non-hazardous
	Yes □	No □	Please explair	n briefly why:	

9.	How often does your company contact suppliers, for example, in relation to their safety data sheets?
	a. Regularly
	b. Only in exceptional cases
10.	The most common reasons for contacting suppliers are (Select all that apply)
	 a. The safety data sheet requested for a non-hazardous chemical b. The safety data sheet is missing for a hazardous chemical c. The safety data sheet is not in Finnish/Swedish d. A request for an up-to-date version e. The safety data sheet is not in compliance with EU requirements f. The information is insufficient/not easy to understand g. The exposure scenario has not been provided h. Other reason
11.	For how many chemicals have you received an exposure scenario as an annex to the safety data sheet?
	0
12.	 How long are the exposure scenarios that you have received? shortest pages typical pages longest pages
13.	What proportion of the exposure scenarios do you get: as an attachment to the safety data sheet?% as a separate document/file/link?%
14.	Do the exposure scenarios provide you with the information needed to meet the requirements set by your national occupational safety and/or environmental legislation?
	Yes □ No □
	I am not familiar with the REACH exposure scenarios
15.	Please explain briefly, why exposure scenarios do or do not provide you with useful information.
16.	Please explain briefly, what would make exposure scenarios more useful and easier to use in your company.
17.	Do you have tools and/or methods in your company that enable the management and efficient use of REACH-compliant extended safety data sheets?
	Yes □ No □ Please explain briefly:
18.	Do your customers provide you with information on how they/their customers use chemicals?
	Yes □ No □ If yes, please explain briefly:

Section 3 - Information supplied by your company

19.	Do you prov use chemica	-	ippliers with informat	tion on how you/your customers
	Yes 🗆	No □	If yes, please explai	n briefly:
20.	Do you supp	ly chemica	ls to other companies	s?
	Yes 🗆	No □	If no, move to ques	stion 27
21.	How many c companies?	hemicals (substances or mixture	es) are you supplying to other
	<50 □	51-25	251-1000 🗆	>1000 🗆
22.			tances / and ures	
23.	Do you supp	ly chemica	ıls classified as hazarı	dous under the CLP Regulation?
	Yes 🗆	No □		
24.	How many o	f the chem	icals you supply have	e an exposure scenario or SUMI?
	0 🗆	<10 🗆	11-50 🗆 51-100) □ >100 □
25.	In what form	-		receive the safety data sheets
	Paper ver	sion by ma	il/with the delivery of go	oods
	Electronic	c version by	e-mail	
	Electronic	version up	loaded to the client's da	ntabase
		version up ease explai	loaded to another datab n briefly:	oase
26.	-		equirements for safet ur products?	ty data sheets and other safe
		oany uses a ts	service provider that m	icals and prepares the documents akes the estimates and prepares the

Section 4 - Guidance and tools

	that support	the safe us	se of chemicals (e.g. SUMI)	?
	ECHA's too	ols and guid	lance:	Yes □ No □
	National R	EACH and C	CLP Helpdesk support:	Yes □ No □
	Industry to	ools and gui	idance	Yes □ No □
28.	Do you use so	ome of the	tools, guidance and/or ser	vices?
	Yes 🗆	No □		
	Please mention support mate		ones you use, or explain why	you do not use the available
29.	knowledge of	safety da	pport material available, hat a sheets, exposure scenariof chemicals (e.g. SUMI), or	os or other documents
	Yes 🗆	No □	Please explain briefly:	
30.	author or use	safety da	instructions would help you ta sheets, exposure scenari ety (e.g. SUMI)?	-
	Please explain	briefly:		
31.	companies ab	out the avexposure s	re good channels for autho vailable tools, guidelines an scenarios and other docume SUMI)?	d advice related to safety
	Please explain	briefly:		
32.	Are you willing topic?	g to answ	er any possible further que	stions from ECHA on this
	Yes □	No □		

27. Are you aware of the support material and services that are available for the authoring and use of safety data sheets, exposure scenarios and other tools

11.4 Questionnaire of the Italian survey in 2018

This is a working translation of the Italian online questionnaire

QUESTIONNAIRE

|--|

1.	Who is in charge of the chemical risk assessment in your company, as foreseen in the national OSH legislation (Legislative Decree 81/2008)? the employer who plays the role of RSPP an internal RSPP an external RSPP internal and external resources of the company
2.	Do the same people also deal with the REACH obligations? ☐ Yes ☐ No
3.	How many hazardous chemicals (substances and mixtures) are used in your company? ☐ Less than 20 ☐ Between 20 and 100 ☐ More than 100
4.	How many safety data sheets of the substances include an annex with exposure scenarios (extended safety data sheet, e-SDS)? ☐ None ☐ Over 30% ☐ Less than 30%
5.	As a general rule, how long are the annexes to the safety data sheets received for the substances? Less than 20 pages More than 20 pages
6	As a general rule, which of the following information is easily identifiable in the annexes to the e-SDS?(It is possible to choose more than one answer) conditions of use that affect exposure use descriptors exposure estimate risk management measures None of the above
7.	For the purpose of the chemical risk assessment, does the company have an information system for managing the information contained in the safety data sheets? □ No □ Yes
If	so, how is the information reported in the SDSs uploaded? ☐ Manually ☐ Electronically
8.	In your company has the need ever occurred to inform the supplier of a use not covered by the e-SDS? $\hfill \square$ No $\hfill \square$ Yes
9.	In your company has the need ever occurred to inform the supplier about risk management measures indicated in e-SDS and considered inappropriate? $\begin{tabular}{l} \square & \text{No} \\ \square & \text{Yes} \end{tabular}$

B. <u>Information flow</u>

10. In the last 3 years did you receive an SDS in a language other than Italian? ☐ Yes	
□ No	
If Yes: ☐ It has been used as such	
$\hfill\Box$ It has been requested in Italian but has not yet been received $\hfill\Box$ It was requested but the Italian translation is inadequate	
11. In your company do the current use and / or conditions of use of the chemicals, for who an e-SDS has been received, match those ones in the exposure scenarios described there	
a) Yes, always b) No, never	
c) Yes, sometimes In cases b) and c), which action has been taken? (It is possible to choose more than one answer)	
☐ The supplier has been informed of the lack ☐ You have changed supplier	
☐ The substance was removed / replaced	
 □ The production cycle has been adapted to what is indicated in the sheet □ Other (describe any other actions taken: e.g. the drafting of an own CSR) □ No action 	
12. Have you ever used the scaling procedure to show that the current use of substances /	
mixtures matches those ones covered?	
□ No	
13. How are the SDSs (or the information contained therein) made available to workers?	
(It is possible to choose more than one answer) □ Through a paper inventory	
☐ Through an IT inventory	
\Box The crucial information is shown in a summary sheet affixed on site \Box Other (describe other ways)	
C. Technical information	
C. <u>I Centiledi Information</u>	
14. In your company has the need ever occurred to update the chemical risk assessment du to the acquisition of an e-SDS?	е
□ No	
☐ Yes If so, the update was necessary on the basis of information concerning:	
(It is possible to choose more than one answer)	
☐ Classification of substances / mixtures☐ The exposure scenarios provided for in the e-SDS	
☐ The authorization / restriction system for substances	
15. Which information in the e-SDS is used for the chemical risk assessment in your compar	ıy?
(It is possible to choose more than one answer) ☐ Description of the process and intended use shown in the exposure scenario	
\square Information on concentration / frequency and duration of exposure	
 □ Information on engineering control measures □ Information on personal protective equipment (PPE) 	
☐ Exposure estimates (when available)	
□ None	
16. Normally the risk management measures reported in the exposure scenarios:	
 □ They are applied as reported □ They are integrated with other measures considered more responsive to business needs 	
☐More restrictive measures than those reported are adopted ☐ They were not understandable and difficult to implement	

	To identify the dangerousness of the substances handled in your company, reference was made to:
	\square Exclusively to sections 2.1 (classification) and 3.2 (composition of mixtures) of the SDS \square Section 2.1 and 3.2 of the SDS and databases
	☐ Exclusively to databases (indicate which ones)
18.	For the purpose of the chemical risk assessment, do you refer to the exposure limit values
	given in section 8.1 of the SDS?
	 ☐ Yes, without referring to other sources ☐ Yes, but we preferred to check its validity through other information sources (eg databases,
	annexes to Legislative Decree 81/2008, European directives in the transposition phase) □ No: other information sources have been used
19.	For the purposes of the chemical risk assessment, have you ever used DNELs? ☐ Yes
	□ No
20.	For the purposes of choosing Personal Protective Equipment (PPE), has the information reported in the SDS (section 8.2.2) been adequate? Yes: the PPE with the performance characteristics detailed in the sheet has been chosen Partially: for the purposes of the selection, an in-depth analysis was necessary, bearing in mind the actual conditions of use
	☐ No: detailed performance characteristics were not described
	D. <u>Strengths / Weaknesses of Safety Data Sheet</u>
21.	Have you ever noticed that a section of the SDS did not report information?
	□ No □ yes If yes:
	☐ the lack of information was formally justified
	 □ the lack of information has been overcome by contacting the supplier □ other information sources have been used
	\Box the missing information was not considered relevant for the chemical risk assessment
22.	For substances and mixtures handled in your company, has any inconsistency been found between the label elements and the classification of the substance / mixture (sections 2.1
	and 2.2 of the SDS)?
	□ No, never □ yes
	If yes, the critical issue was managed:
	 □ communicating it to the supplier □ consulting Data Banks
22	For the purposes of the chemical risk assessment addressed to health, which of the
23.	following sections of the SDS do you consider not relevant/helpful?
	(It is possible to choose more than one answer)
	☐ Section 2 (hazard identification) ☐ Section 3 (composition / information on ingredients)
	☐ Section 7 (storage manipulation)
	☐ Section 8 (exposure controls / Individual protection)
	☐ Section 9 (physical and chemical properties) ☐ Section 11 (toxicological information)
	□ Section 15.1 (legislative and regulatory provisions)

24.	For the purposes of the chemical risk assessment addressed to safety, which of the
	following sections of the SDS you do not you consider helpful?
	(It is possible to choose more than one answer)

(It is possible to choose more than one answer)
☐ Section 2 (hazard identification)
☐ Section 3 (composition / information on ingredients)
☐ Section 4 (first aid measures)
☐ Section 7 (storage manipulation)
☐ Section 8 (exposure controls / Individual protection)
☐ Section 9 (physical and chemical properties)
☐ Section 10 (stability and reactivity)
☐ Section 15.1 (legislative and regulatory provisions)

11.5 Guide to the interview of OSH Experts in 2017

Interview of labour inspectors/coordinators working in the OSH field on information in the supply chain

General questions

- 1. Role Experience related with REACH and information in the supply chain
- 2. Differences in compliance between company types (small vs large, industrial vs professional setting, chemical vs other sectors)

Questions on quality of information in the supply chain

- 3. Do you request (extended) safety data sheets from the companies you inspect? Before/during/after inspection and for what purpose?
- 4. In what languages are they supplied?
- 5. Do you think that the information provided in the extended safety data sheet is sufficient to help companies manage risks from chemicals at their site/facility/company?
- 6. Is the information provided in the extended safety data sheet clear and easily understandable, taking into account the specific needs and knowledge of the user audience? Scale 1-5 (1: unclear, 5: clear) Info understandable
- 7. What could be the main areas that need to be improved?
- 8. Do you know if companies communicate any information needs concerning specific hazards and exposure relevant in their activities, back to their supplier/formulator? Does your office get questions on this from companies and what to do how often does the question arise?

Checking Exposure Scenarios

- 9. Have you checked companies that have used exposure scenarios received in the annex to a safety data sheet in their management of substances at their company/site/facility?
- 10. Have you determined for any site whether the actual use and conditions of use match the conditions described in the exposure scenarios received? Please see attached example of an exposure scenario, generated by Chesar
- 11. How readable and understandable do you find this exposure scenario? Scale 1-5
- 12. How concise do you find this exposure scenario? Scale 1-5
- 13. How would you rank the overall quality of this exposure scenario? Scale 1-5
- 14. How does it compare with other exposure scenarios you have seen in your work?
- 15. What could be improved in these exposure scenarios?
- 16. Safety data sheets contain limit values for hazardous substances. (For instance, derived no-effect limits (DNEL) for effect on humans, predicted no-effect concentration (PNEC) for effects on the environment). Do you think that information is useful?
- 17. Have any changes occurred within last 5 years with respect to handling chemicals and managing risks from hazardous substances and/or mixtures in your Member State?

Questions on Tools and Guidance (if sufficient time)

- 18. Are you familiar with ECHA services and Roadmap/Exchange Network Exposure Scenario (ENES) tools to improve communication of safe use information in the supply chain?
- 19. What tools/services are you familiar with?
- 20. If have used the tools, why? How often? How useful do you find these tools/services?
- 21. What would you suggest to be improved?
- 22. If you have not used the tools/services would you be interested in learning more about the tools/services and the benefits they may bring?

11.6 Questionnaire of the OSH experts survey in 2018

To establish for different Member States' OSH authorities:

Study on workplace (chemical) risk assessment and the role of REACH-generated information on safe use of substances

au Ex da	equirements on scope, methods and tools for workplace (chemical) risk assessment: What do OSH of thorities expect the employer to do in practical terms? It pectations of national authorities how REACH safe-use information included (or annexed to) the safety otalities that the methods and tools used for (chemical) risk assessment at property or the property of the
1.	For the workplace risk assessment, is there an expectation for the employer to identify hazardous substances (purchased as substances or in mixtures) used in the workplace/tasks in the company?
	□ Yes □ No
2.	If No, then what is the expected starting point for an employer for carrying out an on-site assessment?
	(Free text answer)
3.	For which of the following do you expect the employer to carry out a quantitative exposure assessment
	 □ National occupational exposure or biological limit value that is binding □ National occupational exposure or biological limit value that is indicative □ Derived no-effect levels (DNEL) generated in REACH registrations and communicated in the safety data sheet
	 □ Derived no-effect levels (DNEL) approved by RAC and communicated in the safety data sheet □ CMR classified substance without threshold □ Other (please state)
4.	In such cases, what methods are acceptable to evaluate the exposure to hazardous substances as part of the workplace risk assessment? (select one or more)
	☐ On-site / Workplace measurements ☐ Exposure estimation modelling tools ☐ Qualitative assessment based on own company's expert judgement ☐ Qualitative or Semi-quantitive (control banding) assessment with a tool e.g. an authority
	approved tool such as COSHH Essentials (UK), EKMG (DE), etc. (please give details) \Box Other (please state)
5.	For hazards where you don't expect a quantitative assessment, how would that employer be expected to demonstrate adequate control of risk?
	 □ By following substance- or process-specific guidance issued by sector of industry □ By following substance- or process-specific guidance issued by the national OSH authority □ By applying an authority approved (or recommended) qualitative risk assessment tool⁴⁸ for the hazardous substance e.g. COSHH Essentials (UK), EKMG (DE), etc. Please identify the tool
	□ By relying on own company expert judgement □ Other (please state)

⁴⁸ Based on type/level of hazard and exposure potential categories, the appropriate risk management strategy is determined (control banding). A comparison between exposure estimate and OEL (or DNEL) does not take place.

6.	Which of the following is expected to trigger an update of an employer's workplace risk assessment? (select one or more)
	 □ A new substance being purchased, and added to the company's chemicals' inventory □ The receipt of new information on the occupational exposure limit of a substance already used on site, (i.e. SDS indicating this change in Section 8) □ The receipt of new information on another control parameter, such as a DNEL (i.e. SDS indicating this change in Section 8) □ The receipt of new information on the change in classification of a substance already used on site (e.g. an SDS indicating this change in Section 2) □ The receipt of new information on the change in composition of a mixture already used on site (i.e. an SDS indicating this change in Section 3) □ The receipt of new information on safe use, e.g. an exposure scenario (annexed to a SDS) □ A change in workplace conditions for the task e.g. length of time a worker uses a substance or mixture □ A change in workplace conditions in the risk management and control measures, e.g. the installation of a new ventilation system □ Monitoring of worker's health indicating a problem, or an occupational disease is diagnosed among employees X years since the last workplace risk assessment □ Other (please state)
7.	When Inspectors carry out a workplace inspection on hazardous substances, to what extent do they ask the employer if they have taken into account the exposure scenario(s) annexed to the safety data sheet in their workplace risk assessment?
	□ Never □ Sometimes □ Always □ Depending on (please specify)
8.	Do you accept the exposure scenario49 annexed to the safety data sheet for a hazardous substance as a relevant contribution to the employer's workplace risk assessment? In other words: If an employer ensures that the supplier's advice in the exposure scenarios for a substance is practically implemented, do you accept this as fulfilling the workplace risk
	assessment obligation for that substance for the given use ⁵⁰ ?

⁴⁹ The exposure scenario describes the conditions of use by which adequate control (of risk) can be achieved for a given use. It accompanies the safety data sheet provided by the supplier and is generated by a competent person.

⁵⁰ Note: Nevertheless the employer will need to make his own assessment for taking into account simultaneous exposure to multiple substances and other risk factors

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