ECHA
EUROPEAN CHEMICALS AGENCY
Forum For Exchange Of Information On Enforcement

Forum

REF-5 PROJECT REPORT

Extended safety data sheets, exposure scenarios, risk management measures and operational conditions

Adopted on 23.11.2018

Disclaimer

This publication is solely intended for information purposes and does not necessarily represent the official opinion of the European Chemicals Agency. The European Chemicals Agency is not responsible for the use that may be made of the information contained in this document.

This report presents the results of inspections made under the Forum enforcement project. Duty holders and substances selected for checks were those that were relevant for the scope of the project. The project was not designed as a study of the EU-EEA market. The number of inspections for individual countries is varied. Accordingly, the results presented in the report are not necessarily representative of the situation in the EU-EEA market as a whole.

Version	Changes	
1.0	23.11.2018	First Edition

FORUM REF-5 PROJECT REPORT
Harmonised Enforcement Project REF-5 on extended safety data sheets, exposure scenarios, risk management measures and operational conditions
Reference: ECHA-2018-R-24-EN
ISBN: 978-92-9020-900-3
Cat. Number: ED-05-18-129-EN-N
DOI: 10.2823/671313
Publ.date: December 2018
Language: EN

If you have questions or comments in relation to this document please send them (quote the reference and issue date) using the information request form. The information request form can be accessed via the Contact ECHA page at:
http://echa.europa.eu/contact

European Chemicals Agency
Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

Table of Contents

1. Executive summary

1.1 Content of the project

The REF-5 enforcement project focused on the compilation, communication and implementation of safe use information in the supply chain. Target substances were those registered and for which exposure scenarios were required. Depending on their role under REACH, the duty holders targeted for this project were:

- First level suppliers, i.e. registrants (Cluster 1).
- Suppliers, i.e. downstream users including formulators, distributors (Cluster 2).
- Users, i.e. downstream end-users (Cluster 3).

REF-5 aimed to investigate and enforce a variety of legal provisions under REACH, the most relevant stipulated in Articles 14, 31 and 37 of REACH. In addition, duty holder's internal control routines to collect, process and use the information provided by their customers also made up part of the project.

REF-5 focused essentially on substances as such. Although extended safety data sheets (SDSs) for mixtures were not part of the project, it was checked whether formulators have procedures and tools in place to handle information received from their suppliers when preparing extended SDSs for mixtures.

The quality of the safe use information in the extended SDSs regarding accuracy/correctness, clarity, usefulness and verifiability was not checked during the inspections. Therefore, the current report only indicates whether some safe use information was compiled, communicated or implemented, and whether the different information elements were consistent among each other, as required under REACH. It was not checked whether this information was relevant, complete and/or fit for purpose. Nevertheless, some insight into the quality of the exposure scenarios in the chemical safety report, as the source for the extended SDS, was gained (Chapter 2.10).

1.2 Main results and conclusions

In total, 898 inspections were conducted in 29 EU and EEA countries. With some of the inspected companies having more than one role, a total of 302 (28 %) "first level suppliers" companies, 270 (25 %) "suppliers", and 519 (47 %) "users" were inspected.

Further, 375 different substances were controlled, a number of which were controlled in several Member States, giving 1 435 as the overall number of substances controlled. Around 38 % of substances were used in mixtures.

Due to the nature of the "users" (they could be "professional" or "industrial" users or even producers of articles), special attention was given to the conditions of the workers that handled the hazardous chemicals and if they received safe use information. Therefore, in the "user" inspections, 325 labour inspectors and 115 environmental inspectors were involved, alongside REACH inspectors.

Of the companies inspected, 655 (73 %) were in manufacturing, 139 (15 %) were in wholesale and retail trade and 104 (12 %) in other activities. The companies inspected were of varied sizes, based on the number of employees. A total of 71 % were small and medium-sized enterprises (SME) inspected, 28 % were non-SMEsand 1 % were unknown. The sector with the most reported non-compliances was wholesale and retail trade (31 %). Further, sectors of manufacturing of chemicals and related

products (NACE unit A, in this report) had 20 % non-compliances, with manufacturers of chemicals and chemical products accounting for 73 % of the total non-compliances found in the manufacturing sectors.

The substances controlled the most number of times were sodium hydroxide (77 inspections), ethanol (68), and sulphuric acid (62). However, it was styrene that had the most number of reported non-compliances (16), followed by ethanol (10) and acetone and methanol (both with 8 non-compliances reported).

On non-compliances, 168 companies (18 %) were reported to have at least one infringement. In total, 296 infringements were reported of which 42 % were found in the "first level supplier" companies, 29 % in the "supplier" companies and similarly 29 % in the "users" companies.

Looking at the level of non-compliance with specified REACH provisions within the scope of this project, a range between 1 and 12 % of non-compliances was reported for the relevant provisions across all three company roles. Failure to compile their own extended SDSs for the mixtures they prepare had the lowest rate (1 %), while the non-translation of the extended SDSs into the language of the Member States where the substance was placed on the market had the highest non-compliance rate (12 %).

For the total 296 infringements, altogether 665 enforcement measures were taken, of which 36 % were verbal advice, 33 % were written advice, 16 % were administrative orders and 4 % were fines. Some cases (21) were transferred to other Member States.

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

At the same time, however, significant quality deficits were observed in the chemical safety reports. Further, during the operational phase, a designated ECHA support team looked into the chemical safety reports, and observed poor-quality information, including lacking updates on harmonised classification of substances, missing/incomplete exposure scenarios, risk management measures that were not clearly specified, exposure models used outside their functional domain and questionable exposure estimates (Chapter 2.10 and Annex 2, table A6).

In the majority of cases, these deficits are copied through into the extended SDSs (63 % of communicated exposure scenarios are copies of the chemical safety report's exposure scenarios), meaning that the information transferred through the supply chain via the extended SDSs is not of satisfactory quality in term of accuracy/correctness, clarity, and usefulness. This is also confirmed by the inspectors' observations during the inspections (see Chapter 2.10.2).

1.3 Main recommendations resulting from the project

There are several recommendations made for industry in relation to improving the quality of safety data sheets (SDSs) and communication; to the European Commission including prioritising the REACH Review actions on the quality of SDSs; ECHA Secretariat and Forum in working towards projects and campaigns on guidance information, validating chemical safety report content and improving cooperation between authorities. For national authorities, it is recommended to put in place work programmes that support the implementation of the REF-5 objectives.

All detailed recommendations can be found in Chapter 3.2.

2. Detailed results of the project

2.1 General overview

Project overview

In 2015, at the 21st plenary meeting of the Forum for Exchange of Information on Enforcement (Forum)[1] it was agreed that the fifth REACH-EN-FORCE (REF-5) coordinated enforcement project would focus on the extended communication duties of actors in the supply chain introduced by the REACH Regulation.

This would be accomplished by examining: i) the coherence of extended safety data sheets (extended SDSs) with the chemical safety report, ii) the availability and distribution of extended SDSs/exposure scenarios[2] throughout the supply chain and iii) the implementation of the risk management measures and the operational conditions described in the exposure scenarios at workplaces, ensuring the safe use of substances.

REACH registration duties had already been the focus of two previous REF projects conducted by the Forum since 2010 (REF-1 and REF-3), while REF-2 was the Forum's REF project with a focus on communication across the supply chain with the SDSs.

The REF-5 project complemented Forum's previous coordinated activities of national enforcement authorities on the registration duty and on the communication requirements of an extended SDS and, thus, all registration-related duties under REACH have been addressed by at least one coordinated enforcement project of the Forum.

The aim of the project was primarily to raise awareness about the extended SDSs and to get a synopsis of the situation in the EU and in EEA countries with regard to how effectively extended SDSs are passed on and communicated all the way through the supply chain, i.e. from manufacturers of chemicals to the users. Another important objective was to ensure that workers handling hazardous chemicals received the required safety information, by examining the use and implementation of the requirements in the exposure scenario at workplaces. A follow-up of enforcement actions at inspected companies would improve compliance, thus promoting health and environmental protection.

REF-5 targeted various obligations for making safe use information from substance registration dossiers available to downstream users. With duties related to communicating safe use information stipulated in REACH for each actor in the supply chain, REF-5 aimed to investigate and enforce a variety of legal provisions in REACH, as given in Chapter 2.6 of this report.

The project focused on registered substances for which the tonnage criterion for 10 tonnes/year per registrant was met, and had a hazard profile or was assessed to be persistent, bioaccumulative and toxic substances (PBT) or very persistent and very bio-accumulative (vPvB). For these substances, a chemical safety assessment and a chemical safety report are required, thus falling within the scope of project.

---

[1] More information can be found at: http://echa.europa.eu/forum

[2] Exposure scenarios: the set of conditions, including operational conditions and risk management measures, that describe how the substances is manufactured or used during its life cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use, or several processes or uses as appropriate (REACH Article 3(37)).

Extended SDSs: a safety data sheet (SDS) with the relevant exposure scenarios included as an annex for a substance for which a company in the supply chain has carried out a chemical safety assessment under REACH. Exposure scenarios provide information on how the exposure of workers, consumers and the environment to hazardous substances can be controlled during use.

The REF-5 project addressed all duty holders as to make available safe use information for chemicals from registration dossiers, a continuous process and systematic actions need to be followed by all duty holders along the supply chain. Therefore, for the purposes of this project, to allow national enforcement authorities the flexibility to cover the duty holders located in their areas of competence and to give room for national priorities, the duty holders were divided into three distinct clusters.

Cluster 1 - **First level suppliers**. Registrants with the obligation to perform the REACH chemical safety assessment belonged to this cluster. This cluster consisted of manufacturers, importers of substances, "importing DUs"[3], only representatives or re-importers. Only companies that had the obligation to provide an extended SDS were relevant for this cluster.

In this cluster, inspectors checked for the presence of the required information in the relevant sections of the extended SDS, exposure scenario and chemical safety report. Assessment of the quality and usefulness of the information provided for the recipient was not planned in the present project. Another aspect of compliance checked in the REF-5 project was to assess the consistency between the information in the extended SDS and its annexed exposure scenario and the exposure scenario in the chemical safety report.

Examples of what was assessed as being non-compliant can be seen in table A1, in annex 2.

Cluster 2 – **Suppliers**. This cluster comprised of the suppliers in the supply chain of relevant registered substances as such and substances in mixtures, who needed to provide safe use information further down the supply chain to the users. Apart from the main role of distributor, suppliers could additionally be formulators, re-fillers, or re-importers.

It is important to note that extended SDSs compiled for mixtures fell outside the scope of this project. However, formulators' practices in handling substance information received from their suppliers when preparing their own mixtures' extended SDSs for supply was covered in this cluster.

Cluster 3 – **Users**. This cluster included the industrial and professional users of registered substances. This "users" cluster was included in the project's scope to assess the implementation of requirements for the safe use information that is communicated down the supply chain.

For this cluster in particular, Member States were encouraged to involve not only national REACH enforcement authorities, but also national enforcement authorities with competence in occupational safety and health (without prejudice to Occupational Safety and Health enforcement), environmental protection and other authorities, by conducting joint inspections.

Furthermore, for the inspected companies belonging to clusters 1 and/or 2, the REF-5 project also paid attention to the duty holder's internal control routines, by assessing whether the companies had adequate systems in place to generate and handle the information for the exposure scenarios and SDSs, which needed to be in place to enable them to fulfil their duties laid down by REACH in relation to safe use information.

[3] "Importing downstream users (DUs)" are included as a target group for enforcement due to the findings in the REF-3 project where they were identified as a risk group. For more information on cooperation with customs, see information from the REF-3 report: http://echa.europa.eu/documents/10162/13577/ref_3_report_en.pdf

Overview of the operational phase of REF-5 project

The operational phase of the project started in January 2017 and continued throughout the year. Only inspections carried out on-site were reported and one questionnaire (annex 1) per company was filled in. The participating inspectors could control up to five substances per inspected company. The responses given in the questionnaire reflected the assessment of all the inspected substances at the company.

The grouping of duty holders in clusters and the existence of internal control routines were reflected in the structure of the questionnaire. Depending on the role of the company in the supply chain, inspectors filled in the corresponding cluster section of the questionnaire. Where the company had more than one role in the supply chain, inspectors had the option to fill in more than one cluster section of the questionnaire. However, national enforcement authorities and or inspectors were free to decide which roles they wanted to inspect, since there was no obligation to control all the roles applying to each inspected company.

In the course of the operational phase, 898 inspections were conducted by 29 EU and EEA countries. A total of 375 different substances were examined. Many of these substances were investigated in more than one inspection, thus an overall of 1 435 checks of substances took place, of which approximately 38 % of the substances checked were used in a mixture.

With regard to the different duties and roles in the supply chain:

- 302 inspections were carried out in "first level suppliers" companies (cluster 1).
- 270 inspections were carried out in "suppliers" companies (cluster 2).
- For the roles that comprised "users" (cluster 3), 519 inspections were carried out.

Note that some companies had more than one role, i.e. company's duties could be investigated for more than one cluster and, therefore, their results would be reported under more than one cluster.

Regarding inspections in companies with an "end user" role (cluster 3), the focus was on the implementation of operational conditions and risk management measures prescribed in the exposure scenario the company had received. From the 519 inspections, labour inspectors were involved in 325 inspections while 115 inspections had the participation of environmental inspectors.

Project results and its reporting

The statistics presented in this report are based on the data recorded in the questionnaire (Annex 1) by the inspectors during their visits to the companies. Some of the questions in the questionnaire were optional and hence some inspectors opted not to reply. Therefore, the statistical results used in this report should be read as the "result reported for that particular question". When a percentage is provided, the total of the replies reported for that question is given (n=y): x % of the total number of reported cases y.

2.2 Coordination of the project

The project was prepared by a Working Group of the Forum. A national coordinator was appointed by each participating country. The task of the national coordinator was to provide national information and guidance on the project's methodology and its timeline. Additionally, the national coordinators were responsible for liaising with the appointed contacts from the other relevant authorities (*e.g*. labour and environmental inspectorates)

to identify the potential target companies and which clusters each of the participating authorities will focus on. At the end of the operational phase of the project, the national coordinators collected the national results and submitted them to the Forum Working Group. The data collected from all national coordinators was the basis for this report, which was prepared by the Working Group, consulted and approved by the Forum.

The project focused on the enforcement of both worker and environment exposure scenarios. Depending on the participating country's institutional structure, distribution of competencies and on the duty holders targeted, multiple authorities (labour inspectorates, environmental inspectorates or other) participated in the operational phase of the project, either individually or in cooperation. Table 1 presents the data collected concerning the collaboration between inspectorates when inspecting duty holders with the "user" role (cluster 3).

Table 1: Number of cluster 3 inspections done by singular inspectorates or in cooperation with multiple inspectorates

Enforcement authority (inspectorates)	Number inspected companies
Labour	265
Environmental	57
Other*	16
Labour + Environmental	39
Labour + Other*	4
Environmental + Other*	2
Labour + Environmental + Other*	17
Total	400

* *"Other" includes* inter alia *maritime, health, SEVESO, food and consumer products authorities*

In 119 cluster 3 inspections, there was no report of cooperation taking place.

2.3 Participation and number of inspections

Table 2 lists the participating countries, the number of national inspections reported and also presents the role of the company under REACH, which correlates with the supply chain levels, per Member State. Note that the same company could have more than one role in the supply chain.

Each participating country decided for itself which clusters to control and how many inspections to conduct during the operational phase of the project, since the project had not defined a minimum number of inspections.

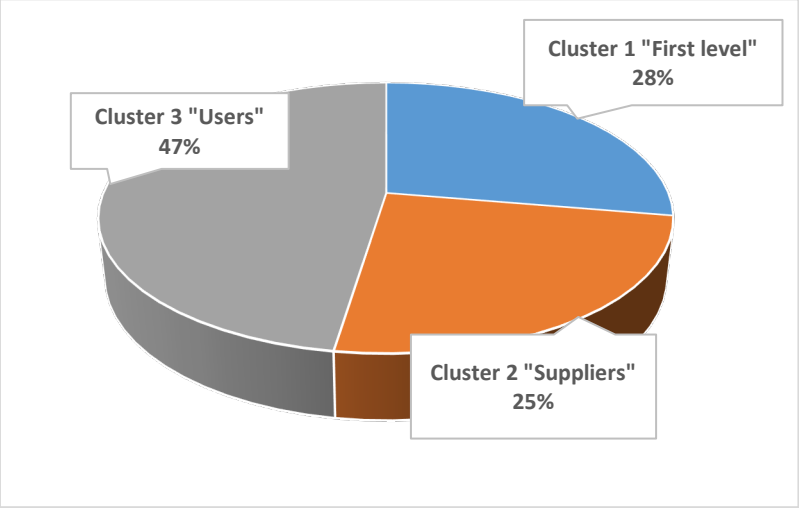
TABLE 2: NUMBER OF REPORTED INSPECTIONS PER PARTICIPATING COUNTRY PER ROLE

Country	Companies inspected	Companies with "First level supplier" role	Companies with "Supplier" role	Companies with "User" role
AT	9	2	5	4
BE	14	0	0	14
BG	54	24	8	35
CY	9	3	9	0
CZ	20	13	5	7
DE	126	61	33	44
DK	20	0	12	8
EE	21	6	5	10
EL	14	7	6	11
ES	18	8	10	8
FI	9	3	1	8
FR	30	8	6	27
HR	8	1	4	4
HU	37	16	21	8
IE	12	6	4	9
IT	55	9	17	31
LI	3	1	2	1
LT	20	4	4	20
LU	2	0	2	2
LV	15	9	5	3
NL	24	14	1	11
NO	66	7	25	44
PL	149	45	46	99
PT	22	20	3	1
RO	30	13	7	19
SE	30	10	15	19
SK	16	2	5	9
SI	64	10	8	63
UK	1	0	1	0
Total	**898**	**302**	**270**	**519**

2.4 Type of companies targeted by the project

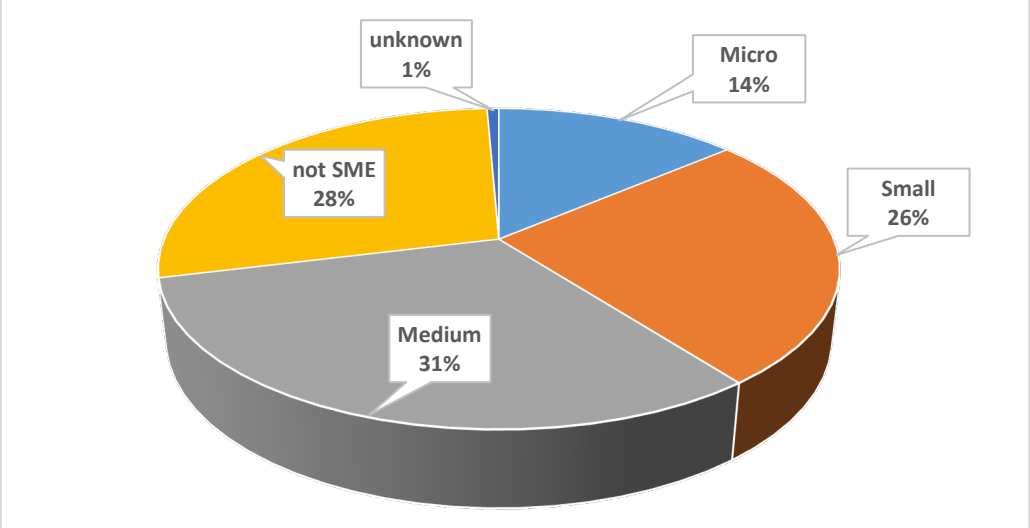
The participating countries had the possibility to target relevant duty holders in different levels of the supply chain (clusters) and check the fulfilment of their correspondent obligations. Of the 898 inspected companies, some of them had multiple roles and therefore were investigated under more than one cluster. The sum of the number of checks in all three clusters is 1 091, even though only 898 companies were inspected. Of the companies inspected, 28 % had a first level supplier role (cluster 1), 25 % had a supplier role (cluster 2) and 47 % had a user role (cluster 3).

FIGURE 1: DISTRIBUTION OF THE COMPANIES INSPECTED PER CLUSTERS/ROLES



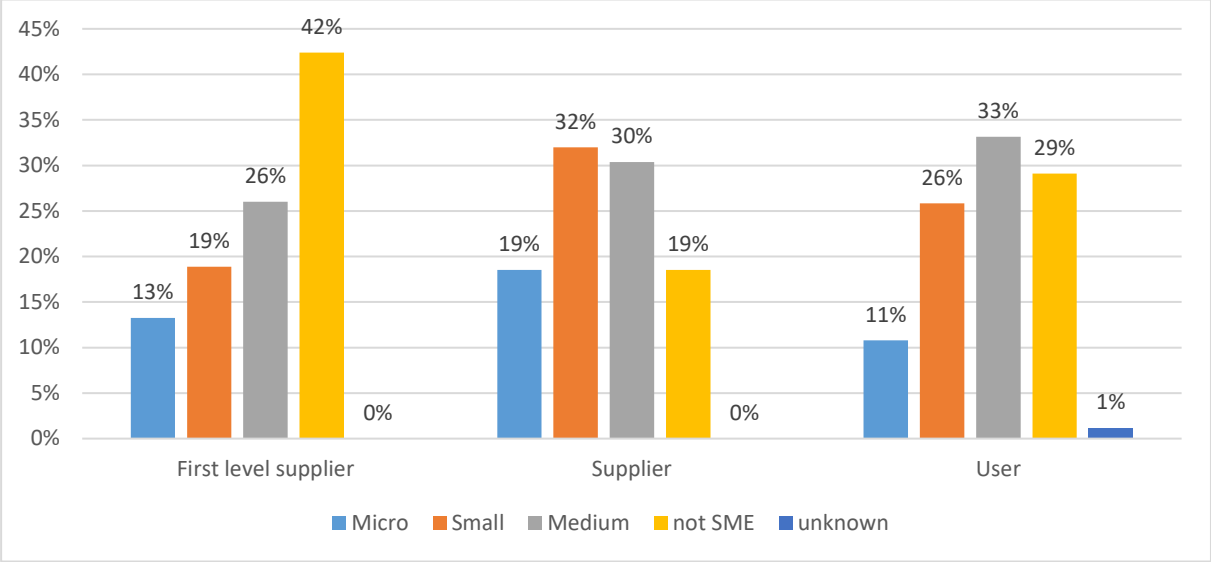
The distribution of the size of the 898 companies recorded in the project can be seen in figure 2.

FIGURE 2: DISTRIBUTION OF THE SIZE OF THE INSPECTED COMPANIES



The size of the companies inspected distributed according to their role/cluster is depicted in Figure 3.

FIGURE 3: DISTRIBUTION OF THE SIZE OF THE COMPANIES INSPECTED PER ROLE



It is clear from Figure 3 that in each cluster/role, the inspections had good coverage of companies in relation to company sizes.

NACE[4] codes were reported for all the 898 inspected companies and 50 different NACE codes have been reported. These codes have been grouped, solely for the purpose of this report, into four key NACE units (A-D) and are summarised in Table 3. For further details of all the economic sectors inspected, see table A2 in Annex 2.

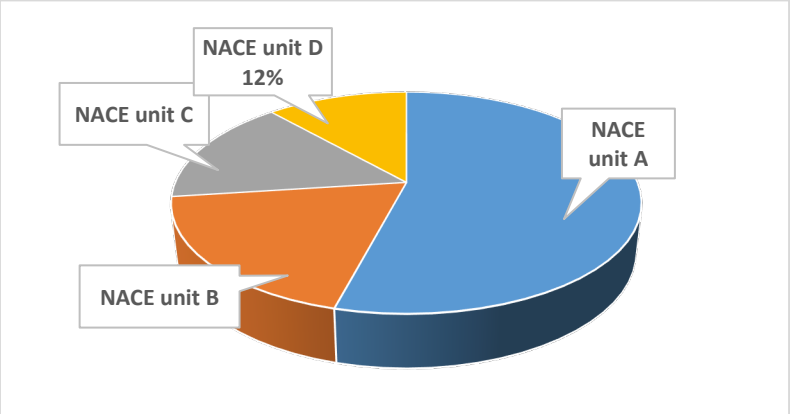
The inspections were conducted in a wide range of economic sectors, the majority of them belonging to the manufacturing sector.

TABLE 3: THE DIFFERENT SECTORS INSPECTED DURING THE OPERATIONAL PHASE

NACE unit	NACE divisions	Sector	Number of NACE divisions	Number of Inspections
A	10-22 (except 18)	Manufacturing of chemicals and related products	11	486
B	23-32	Manufacturing of fabricated metal, electrical and other products	10	169
C	45-47	Wholesale and retail trade	3	139
D	Various	Others	26	104
Total			**50**	**898**

[4] NACE-Code (statistical classification of economic activities in the European Community): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:393:0001:0039:EN:PDF

Figure 4: Percentage of inspections done in the nace units A-D



The companies belonging to the NACE units A and B (manufacturers) have the highest number of investigations.

2.5 Substances investigated in the project

Since more than one substance could be investigated per company (maximum five), 1 435 substances in total where checked for compliance during the 898 inspections, which corresponded to 375 different substances and their extended SDSs investigated. Due to the vast array of substances investigated, Table 4 summarises only the most frequent substances checked. For a more expansive list of the substances investigated in this project, see Table A3 in Annex 2.

Inspectors indicated that the substances investigated were used in mixtures in 549 out of the 1 435 cases.

The substances controlled most frequently in this project were sodium hydroxide (77 times), ethanol (68) and sulphuric acid (62). These three substances account for 55 % of all different substances controlled.

TABLE 4: SUBSTANCES MOST FREQUENTLY INSPECTED IN THE PROJECT

Substance	No. of investigations
Sodium hydroxide	77
Ethanol	68
Sulphuric acid	62
Hydrogen chloride	49
Toluene	48
Acetone	39
Ammonia	38
Formaldehyde	38
Styrene	36
Nitric acid	32
Sodium hypochlorite	32
Xylene	30

2.6 Legal obligations

REF-5 covered different parts of the REACH Regulation as it is presented in Table 5.

TABLE 5: REACH PROVISIONS ENFORCED UNDER THE REF-5 PROJECT

REACH provisions (Article and Annexes)	Summary
10 (a) (v)	Information regarding the safe use of hazardous substances has to be available in the registration dossier as it makes part of the registration.
14(4) (6) (7) For Art. 14(4) see also Art. 10 (b) For Art. 14(7) see also Art. 22 (1) (g)	CSA for hazardous substances includes ES. Registrants must include measures to adequately control risks identified in the CSA and recommend them in the extended SDS.
31(1) (2) (7) (9)	Selected extended SDS requirements – provision of extended SDS to recipient of substance; inclusion of relevant ES in extended SDS annex; update after new information affecting RMM or hazard are available / authorisation is granted or refused / restriction is imposed.
32 (1)(d)	Duty to communicate down the supply chain available information to enable RMM, for substances that don't require extended SDS.
34 (b)	Duty to communicate up the supply chain information to enable RMM identified in the extended SDS.
35	Access to information for workers.
36 (1)	Obligation to keep information.
37 (1)	DU to provide information to help prepare the registration.
37 (2) (3)	DU has the right to make the use known to the supplier with the aim of making it an identified use in the manufacturer's chemical safety assessment.
37 (4)	Duty of the DU to prepare a CSR and eventual exemptions from this obligation.
37 (5)	Duty to identify, recommend and apply RMM.
37 (7)	Duty of DU to keep own chemical safety report up to date and available.
38 (1)	Obligation for DU to report information.
39 (1)	Deadline for DU to comply with the requirements of Article 37.
39 (2)	Deadline for DU to comply with the requirements of Article 38.
Annex I, 0.7	Requirement to attached relevant ES with RMM and OC to the extended SDS.
Annex II	Requirements for the compilation of SDS.
Annex VI, section 5	Requirements of Art 10(v), section 5 of Annex VI: guidance of safe use to be given in the extended SDS.

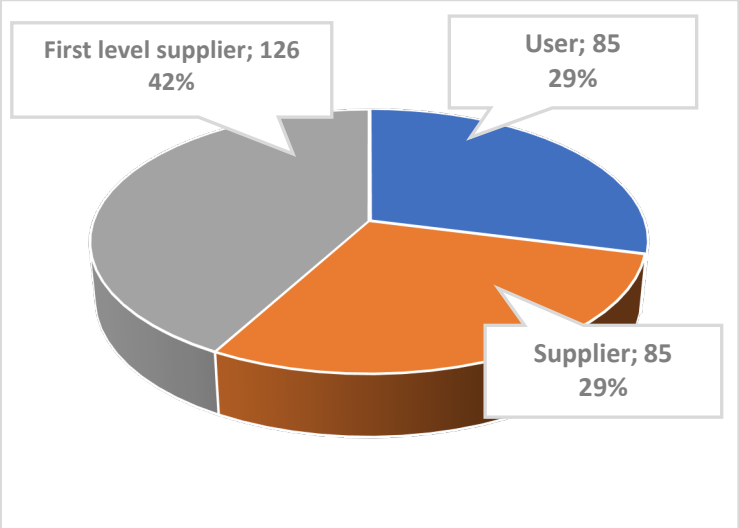
2.7 Infringements related to specified legal provisions of the REACH Regulation

As mentioned earlier in the report (Chapter 2.1), when a percentage is provided, the total number of the replies reported by the inspectors is given (n=y). The results are to be read as x % of the total y.

From the 898 inspected companies, 163 companies (18 %) were reported to have at least one non-compliance with the obligations listed in Table 5. A total of 296 infringements were reported for these 163 companies.

Most of the non-compliances were encountered in the "first level suppliers", while for "suppliers" and "users", an equal number of non-compliances was reported. Figure 5 shows the distribution of the non-compliances per role.

FIGURE 5: NUMBER AND PERCENTAGE OF COMPANIES WITH AT LEAST ONE NON-COMPLIANCE PER ROLE



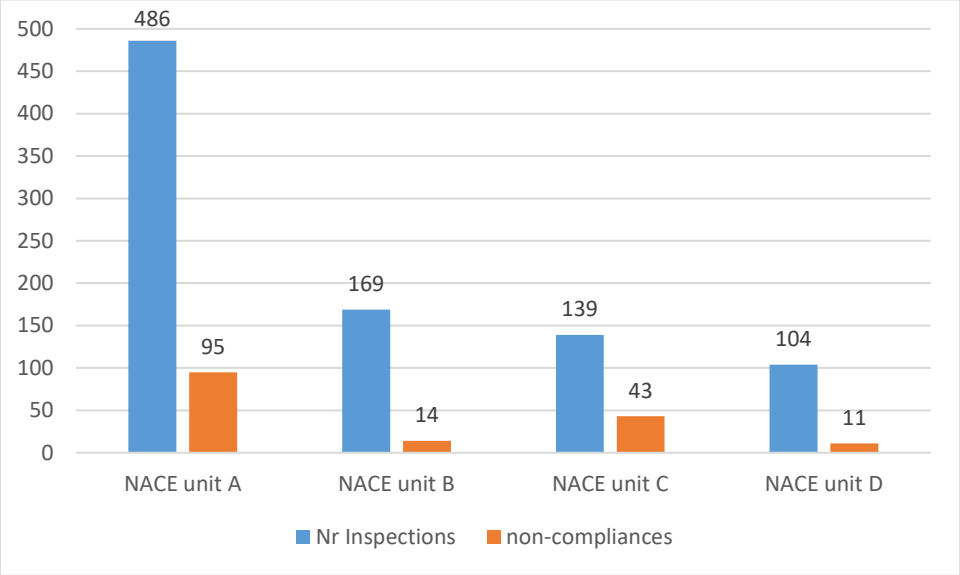
It was observed (see Table 6) that the sector with most non-compliances was the wholesale and retail trade (NACE unit C) with 31 % non-compliance.

TABLE 6: NON-COMPLIANCES FOUND IN THE DIFFERENT NACE UNITS

NACE units*	Sectors	Rate of non-compliant companies
A	Manufacturing of chemicals and related products	20 % (n=486)
B	Manufacturing of fabricated metal, electrical and other products	8 % (n=169)
C	Wholesale and retail trade	31 % (n=139)
D	Others	11 % (n=104)
Total		18 % (n=898)

*see Table A2

FIGURE 6: NUMBER OF INSPECTIONS AND NON-COMPLIANCES DISTRIBUTED BY NACE UNIT



Note that companies falling under NACE division 20 *"Manufacture of chemicals and chemical products"* were responsible for 80 of the 95 non-compliances reported in NACE unit A.

On the other hand, companies involved in the manufacturing of fabricated metal, electrical and other related products reported the lowest levels of non-compliance.

Altogether, 1 453 extended SDSs corresponding to 375 different substances were checked in total during this project. 243 of them had at least one non-compliance i.e. required information was missing.

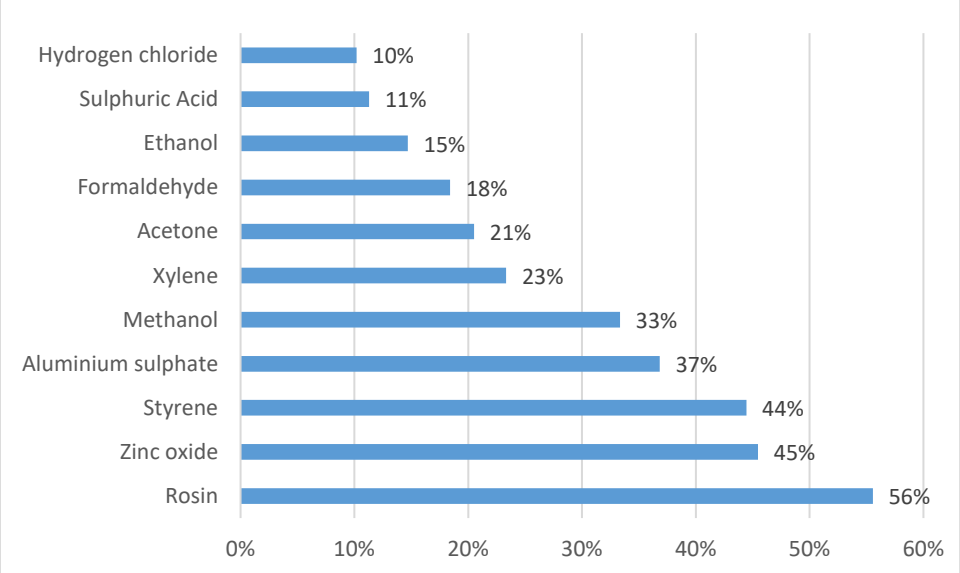
The most non-compliances were reported for styrene (16 cases) and for ethanol (10 cases). Both substances are, according to the registration statistics from ECHA, among the 20 most frequently registered substances. Table 7 gives an overview of the substances for which most frequently (at least five times) an infringement was reported.

For both styrene and ethanol, the most reported non-compliance was related to the failure of a "supplier" company to inform their own supplier about additional information that should be included in the SDS received. This indicates that these substances are being used in different conditions or with other purposes than the ones expected.

TABLE 7: SUBSTANCES WITH 5 OR MORE NON-COMPLIANCE

Substance	No. of non-compliance / no. of controls
Styrene	16/36
Ethanol	10/68
Acetone	8/39
Methanol	8/24
Xylene	7/30
Formaldehyde	7/38
Sulphuric acid	7/62
Aluminium sulphate	7/19
Hydrogen chloride	5/49
Zinc oxide	5/11
Rosin	5/9

FIGURE 7: RATE OF NON-COMPLIANCES WITHIN THE HIGHEST NON-COMPLIANT SUBSTANCES



It was observed that even for common substances such as ethanol, acetone and methanol, which were expected to have good data, there was a substantial non-compliance rate. Although few inspections were done on rosin, which is not a very common substance, it was found that this substance had a high rate of non-compliance. This is a good indication that focus should be put into such type of substances.

Inspectors under this project checked whether exposure scenarios have been communicated with the extended SDS for substances registered with a chemical safety report, in companies with "first level supplier" and/or "supplier" roles. For 7 % (n=455) of the companies, this was not the case[5]. Among the other important issues checked was whether the identified uses, stated in Section 1 of the substances' extended SDSs, corresponded to those given in the exposure scenarios. In 6 % (n=452) of the extended SDSs, the intended uses were found to be different from what was given in the chemical safety report[6].

In 12 % (n=297) of the applicable reported cases where a substance was placed on the market in another Member State by the company inspected, the company did not compile/translate the extended SDS in the language(s) of the other Member State[7].

The lowest non-compliance was observed on the provision related to the obligation to keep safe use information for substances that the company ceased using/producing/supplying in the last 10 years. It seems that this obligation is well implemented by companies since non-compliances were observed in only 3 % (n=338) of the applicable reported cases[8].

Non-compliances in each role/cluster

First level supplier/Cluster 1

Workers' protection

It seems that the information on workers' protection is relatively well integrated in Sections 7 and 8 in the extended SDS, as well as in the exposure scenarios.

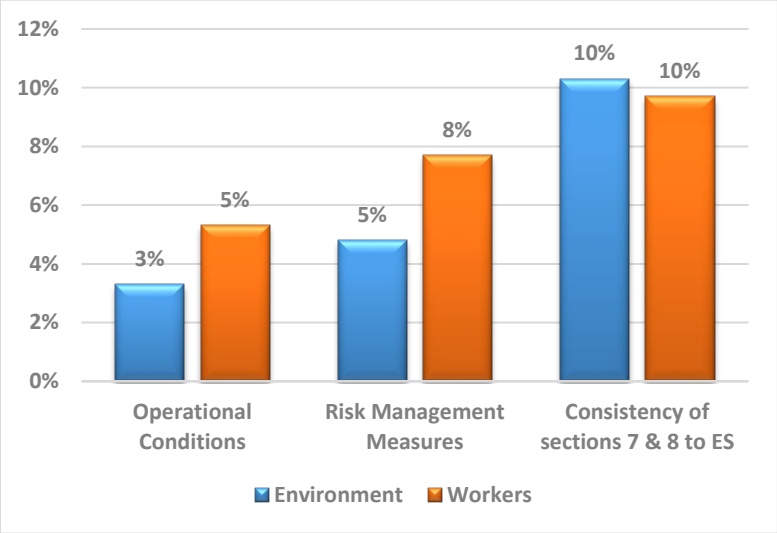
The exposure scenarios did not recommend operational conditions for the identified uses of the substance(s)[9] in 5 % (n=284) of the checked exposure scenarios. Risk management measures for workers' protection were not described[10] in 8 % (n=285) of the checked exposure scenarios. However, in 10 % (n=257) of the cases, discrepancies were observed between the information on workers' protection provided in Section 7 and Section 8 of the extended SDS with those given in the exposure scenarios for communication annexed to the extended SDS[6].

Environmental protection

Information on environmental protection seems to be slightly more often present in the extended SDSs compared to information on workers' protection. Where operational conditions were provided, those for the protection of the environment were not given[10] in 3 % (n=272) of the reported extended SDS checks. Only in 5 % (n=284) of the inspections reported, did the exposure scenarios not describe the risk management measures to ensure that the releases for the environment were adequately controlled[10]. Similarly to the workers' protection issue described above, in 10 % (n=273) of the reported checks, an inconsistency was observed between the information about environmental protection provided in Section 8 of the extended SDS and the one given in the exposure scenario for communication annexed to the extended SDS[6].

[5] Infringement of REACH Article 14(4).
[6] Infringement of REACH Article 31(2) and Annex II, Section 0.1.2.
[7] Infringement of REACH Article 31(5).
[8] Infringement of REACH Article 36(1).
[9] Infringement of REACH Article 14(6).
[10] Infringement of REACH Annex I, Section 5.1.1.

FIGURE 8: SUMMARY OF THE NON-COMPLIANCES FOUND IN CLUSTER 1 CONCERNING ENVIRONMENT AND WORKER'S PROTECTION



Consumers protection

In relation to the provided information on consumers' protection, it was found that conditions of use in the exposure scenarios related to consumer uses/products were not described in 2 % (n=264) of the cases[10].

Suppliers/Cluster 2

Incoming SDS and use

Companies with roles as downstream users/formulators/re-fillers or as distributors, use the information from extended SDSs received when compiling extended SDSs for their own products in the vast majority of the cases. Non-compliances were found in 3 % (n=256) of the cases[11].

In 18 % (n=246) of the reported cases, the inspected companies identified that the recommended risk management measures in the exposure scenario were inappropriate or not necessary. Only in 2 % of these cases (n=45), did the company fail to inform its supplier about it[12]. Suppliers in general responded to companies on that, failing to do so in 11 % (n=44) of the cases and 8 % (n=40) of the companies did not receive an updated extended SDS.

Outgoing SDS

For the companies which make changes, additions to, or translate to other languages, the extended SDSs of the substances they received and then supply them downstream as such or in mixtures, the changes were found to be not documented and traceable in only 3 % (n=94) of the cases reported[13].

[11] Infringement of REACH Article 37(5).
[12] Infringement of REACH Article 34.
[13] Infringement of REACH Article 31(1).

Only 1 % (n=189) of the inspected formulators responded that they did not compile their own extended SDS for the mixtures that they prepare and supply downstream[13]. 7 % (n=183) of these formulators did not make use of the relevant exposure scenarios of the constituent substances when preparing the extended SDS for their mixtures[14]. The relevant DNELs/PNECs and OELs[15] or other relevant national parameters from the incoming substance's extended SDS were not included in the mixture's extended SDS[16] in 7 % (n=183) of the reported cases.

In cases where risk management measures were mentioned in the exposure scenario or in the main body of the extended SDS, the risk management measures especially for workers protection (technical measures and PPE) were not sufficiently specified in 3 % (n=184) of the reported cases[16]. Note that checking the correctness of such measures was not part of the scope of this project.

For substances in mixtures, the registration numbers from the received substance's extended SDSs were not indicated in the mixture's extended SDS[17] in 4 % of cases.

Upstream communication

14 % (n=256) of the companies responded that they possessed additional information, which should be included in the extended SDS they received but 9 % (n=35) of them did not inform their supplier about that[12].

Users/Cluster 3

In 24 % (n=519) of the cases, companies did not receive an extended SDS for the hazardous substance they use from their supplier and in 10 % of these cases no information on safe use was made available to the workers[18].

In comparison with the situation described above, in 2 % (n=382) of the cases where extended SDS were received from their supplier, the extended SDSs were not made accessible to their workers and their representatives[18].

In the 3 % (n=381) of cases where the company's use of the substance was not an "identified use" and in the 2 % (n=372) of cases where the correspondent exposure scenario was not annexed to the SDS, the inspectors reported that none had prepared their own downstream user chemical safety report[19].

[14] Infringement of REACH Article 31(2).

[15] DNEL - Derived no-effect level.
PNEC - Predicted no effect concentration.
OEL - Occupational exposure limit.

[16] Infringement of REACH Annex II, Section 8.

[17] Infringement of REACH Annex II, Section 3.2.4.

[18] Infringement of REACH Article 35.

[19] Infringement of REACH Article 38(1).

2.8 Other findings of the project

The use of tools and structure in companies (internal control routines)

”First level supplier” and “supplier” companies were investigated to assess whether they had adequate systems in place to generate, keep, collect, process, utilise and communicate the “safe use” information provided in the supply chain, generated by the REACH Regulation.

Companies were asked if exposure scenarios had been generated and communicated for substances for which an exposure assessment had been carried out under REACH. In 93 % (n=455) of the cases, it was done.

Generally, 71 % of the companies (n=466) had procedures laid down and executed in the company’s internal control routines which made the generation of the extended SDSs possible in accordance to REACH. Further, 64 % of these companies (n=464) used specific tools/methods to facilitate the generation of extended SDSs.

Moreover, the availability of tools/methods for communication of safe use information in extended SDSs was examined and 63 % of the companies had them in place.

Annex 3 gives an overview of the tools and methods for generating and communicating about the extended SDSs that were reported as being used in the inspected companies.

Distribution of extended SDSs has to be done according to REACH Articles 31 (8) and (9). The results from the inspections show that majority of companies (90 %, n=471) have systems/instruments which make the distribution of the extended SDSs in accordance to REACH possible. The vast majority (86 %, n=302) of the companies that supply to other Member States have procedures in place for checking if the extended SDSs provided downstream are in line with the respective national legislation of the Member State of the customer.

The results also show that 58 % (n=459) of the companies do take steps to match or select the relevant exposure scenarios for their customers’ uses.

The majority of companies (77 %, n=456) reported that they supply the same exposure scenario annex to all customers, whether they take steps or not to match or select exposure scenarios relevant for their customers. From those that were sent to the customers, 67 % (n=327) of the extended SDS supplied contained 1-10 different exposure scenarios, 31 % (n=327) contained 11-50 and a small number (2 %, n=327) reported to have more than 50.

To make it easier for the downstream user to find the exposure scenario most relevant to his needs/uses, a recommended approach is to include a table of contents with the titles of all the exposure scenarios annexed to the SDS. This was the case in 64 % (n=326) of the extended SDSs with several exposure scenarios. In 63 % (n=190) of the checked chemical safety reports, the exposure scenarios annexed to the SDS were an exact copy of the chemical safety report. This, to a large extent, can corroborate the earlier reported consistencies between the chemical safety report and the exposure scenarios in the extended SDSs.

When checking for correspondence of the identified uses in Section 1 of the SDS and that which give exposure scenarios, there was an almost total agreement between these two (94 %, n=452).

Further, 80 % (n=468) of the inspected companies have systems/instruments in place to handle information received from their downstream customers according to REACH Article 34 or Article 37(7). Some inspectors reported on the issue and number of enquiries the companies received from their customers (Table A4, Annex 2).

First level suppliers /Cluster 1

The inspectors had the possibility to compare the information given in the exposure scenario with the corresponding information in the chemical safety report. The results showed that the information was almost identical with regards to both worker protection and environmental protection (92 % in both cases). An explanation for the relatively high compliance is that, in many cases, the information given in the exposure scenarios are an exact copy of the information in the chemical safety report. However, this does not say anything about the quality of the information (this is explained further in Chapter 2.10 of this report).

Suppliers/Cluster 2

Incoming SDS and use

Supplier companies receive documentation for the substances and/or mixtures they use, mix or distribute. In this project, 11 % of the inspected supplier companies supplied only substances, 41 % supplied mixtures only and 48 % supplied both substances and mixtures.

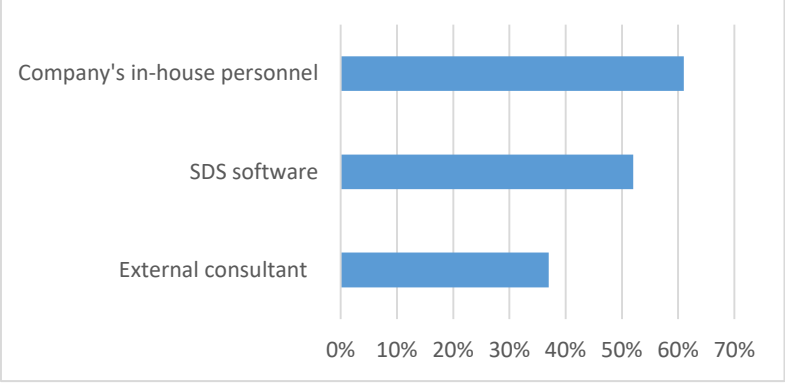
Almost all of the companies (96 %, n=256) had received SDSs from their supplier for all the inspected substances/mixtures. Of the 4 % that did not receive SDSs, 56 % returned to their supplier and demanded to be provided.

When receiving the substances' SDS from their supplier, 87 % of the companies (n=256) have routines for checking if the registration number of the substance was given. In the cases where the registrations numbers are not given, 85 % (n=123) of the companies ask the supplier for the reason. A similar investigation was done on the presence of the exposure scenarios for the identified uses attached to the substances' SDS. In general, 81 % (n=253) of the companies do that check. In the cases where it was not attached or safe use information was not included, 86 % (n=139) of the inspected companies asked the supplier for the missing information.

Outgoing SDS

The supplier companies are also obliged to provide SDSs and exposure scenarios to the next level downstream users. Except for one company, all others compiled the SDSs for the mixtures they supplied downstream (n=188). In 61 % of them, the SDSs were compiled by the company's in-house experts, 52 % by using different kinds of SDS software and 37 % using an external consultant. Note here that some companies reported more than just one option.

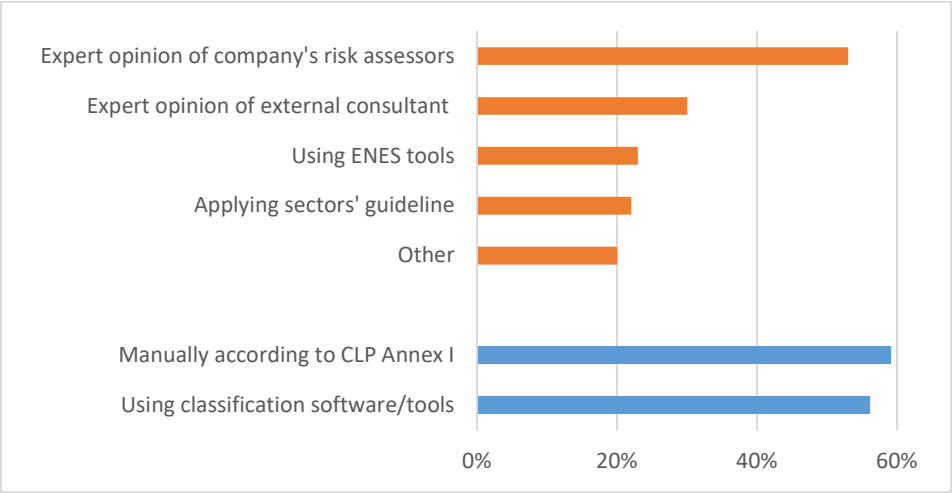
FIGURE 9: REPORTED TOOLS USED BY COMPANIES FOR THE COMPILATION OF SDS



In the supplied SDSs, the relevant risk management measures were identified in different ways. In 53 % of these companies, they reported to use an expert opinion by the company's risk assessors, 30 % used an expert opinion of an external consultant, 23 % used products developed under the joint ECHA-industry-Member State's initiative (the chemical safety report/exposure scenario roadmap, also known as "ENES tools") and 22 % applied available economic sector's guidelines. In addition, 20 % indicated use of other alternative ways/procedures to identify the risk management measures (note that some companies reported more than just one option).

Further, to determine the classification of the mixtures supplied, 59 % of the companies do it manually according to the CLP provisions, while 56 % used classification software/tools (some companies reported more than just one option).

FIGURE 10: REPORTED TOOLS USED BY COMPANIES TO IDENTIFY THE RISK MANAGEMENT MEASURES (ORANGE) OF THEIR MIXTURE AND ITS CLASSIFICATION (BLUE)



The majority (78 %) of the inspected companies that prepare their own mixtures and supply them downstream, communicate the information on safe use (operational conditions and risk management measures) by integrating them in the respective sections of the main body of the SDSs, while 24 % of these companies communicated this information as an attachment to the SDSs in a consolidated form, primarily in the language of the Member State where their customer is located. The remaining used the "safe use of mixtures information" template (SUMI) and other templates/tools developed by sector industry groups (6 %) and 7 % used other mixture exposure scenarios not developed by industry (note that some companies reported more than just one option). More information on the tools and methods used by the companies is included in Annex 3.

In 79 % (n=183) of the companies investigated, they were able to prove that there is control of the content and of the consistency between the different sections of the SDSs for the mixtures they prepare and supply.

Upstream communication

REACH Article 37(2) describes the right of the downstream users to make it known to their supplier if their uses are not covered in the "identified uses" supplied to them. In 43 % (n=258) of the cases, the reported companies identified a use that was not covered in the "identified uses" provided by the supplier. However, 70 % (n=110) of them did not inform their supplier about it. In general, about half the inspected companies (53 %, n=256) kept records when handled or passed information upstream.

Users/Cluster 3

Of the 519 inspected end-user companies, 76 % reported that they had received the substances' extended SDSs from their suppliers.

Of the companies that receive the extended SDSs from their supplier, 90 % (n=391) stated that they keep records on these substances (more information on the records kept by the companies is described in Table A5, in Annex 2) and 79 % reported to have procedures and routines for implementing the operational conditions and risk management measures described in the exposure scenarios.

Of the companies reported, 75 % (n=328) have implemented the operational conditions and risk management measures described in the exposure scenarios without any changes, while the rest reported to have used scaling based on information given by the supplier. 46 % (n=362) of the companies reported to apply additional safety measures, most often complementary to the measures for control of workers' exposure given in the exposure scenarios.

Almost all of the "user" companies inspected (98 %, n=381) claimed that the received exposure scenarios were relevant for the company's use of the substance and a considerable number (71 %, n=353) have records to demonstrate their implementations. Only 10 % (n=364) of the reported companies were found not to use the substance within the conditions described in the exposure scenarios received but only one company reported that they, for this reason, had prepared their own downstream user chemical safety report.

"User" companies stated that they had not received any exposure scenario for the substances used in 24 % of the cases (n=519). It is notable that the majority (92 %, n=131) of these companies had not asked their suppliers about the reason why, but 93 % (n=133) of them had received a "normal" SDS (without an exposure scenario annexed).

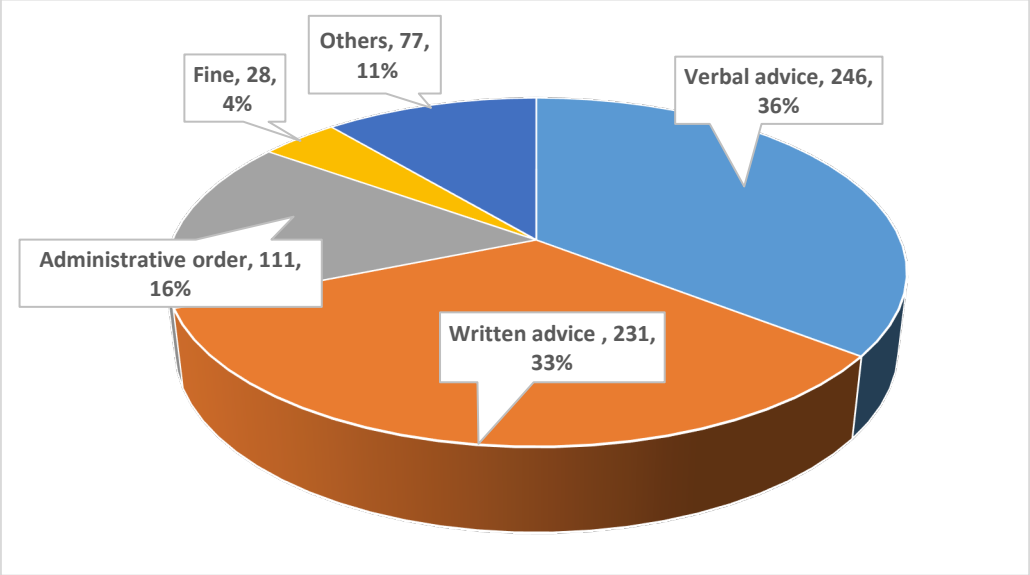
Companies declared to have systems to keep records and document the implementations of the information given in the SDSs in 72 % (n=132) of the cases. Companies also claimed to have procedures in place to ensure compliance with other chemical regulatory requirements such as work and environment regulations in 85 % (n=130) of the situations.

2.9 Results of follow-up action

Out of the 296 reported infringements for the 163 non-compliant companies, 21 cases were forwarded to Member States other than where the inspection was conducted.

Different measures have been imposed by the enforcing authorities and often more than one measure could be imposed for each non-compliance, depending on the national procedures of each Member State. In total, 665 measures were reported to have been imposed due to non-compliances with REACH obligations in the scope of this project. Most of the measures were either verbal or written advice (246 and 231 respectively). In addition, 111 administrative orders were issued and 28 fines were imposed. No criminal proceedings/prosecutions were initiated for the non-compliances found and reported here.

FIGURE 11: DISTRIBUTION OF ENFORCEMENT MEASURES



By April 2018, which was the reporting deadline for this project, two-thirds (almost 600) of the follow up activities for the 898 inspected companies were completed by the inspectors. About a third of the follow-up activities were still on-going when the results were reported by the national coordinators.

2.10 Additional information on the project

2.10.1 Quality of the chemical safety report

Within the REACH framework, registrants' chemical safety assessments/chemical safety reports must demonstrate adequate control of risk for those uses of the substance (as such, in mixtures, or in articles) they intend to support and which they therefore include in Section 3.5 of the IUCLID dossier.

The extended SDS is the main mechanism to communicate the outcome of the suppliers' chemical safety assessment to the users of chemicals, to enable the assessment to be verified against reality and to support safe handling and control of exposure. Ensuring the consistency between the IUCLID technical dossier, the chemical safety report and the extended SDS is therefore crucial and even a legal requirement.

The extent to which the information presented in the extended SDS is useful and reliable for ensuring adequate control of risk when using the substance was outside the remit of the REF-5 project's inspections.

While supporting the REF-5 inspections, ECHA examined selected registration dossiers and chemical safety reports to produce substance profiles and to extract exposure scenario information from the chemical safety report for the inspectors to compare with the information communicated. While doing so, ECHA identified a number of recurring serious issues/shortcomings and quality problems in the chemical safety reports such as incorrect exposure estimations, mismatches between estimation of exposure and operational condition/risk management measure, different versions of the chemical safety report in the same joint submission, non-sector specific information (details in Table A6 in Annex 2). Other recurring issues, include *inter alia* different versions of a chemical safety report within the same joint submission, information in the chemical safety reports being totally

unrelated and detached from the information jointly submitted by the lead registrant (e.g. hazard, uses covered by the joint submission, etc.).

Examining selected registration dossiers showed that individual use and maintenance of the chemical safety report does not work in practice (e.g. the chemical safety report was not updated after a change in harmonised classification and labelling or after the lead registrant has removed uses from its registration). Incomplete registration dossiers (e.g. missing chemical safety reports), chemical safety reports with missing exposure assessment, as well as inconsistencies between the IUCLID dossier and the chemical safety report contents were also noted.

ECHA's REF-5 support exercise looked at 42 substances, 50 different chemical safety reports and 82 exposure scenarios that have been opened and scrutinised for specific uses. The exercise covered a limited number of substances, but it was nevertheless instrumental in identifying and providing an overview of the common pitfalls.

In general, the poor quality of the examined chemical safety reports, specifically the lack of operating conditions and risk management measures specifications does not support confidence in the chemical safety assessment's conclusions and therefore does not support the generation of an accurate, understandable, verifiable and useful exposure scenario for communication to the (downstream) users of the substance.

2.10.2 Inspectors' experiences

Beyond the realm of REF-5, inspectors and the REF-5 national coordinators have expressed during the operational phase, and more particularly during a REF-5 inspection workshop (organised in Helsinki in September 2017), the weaknesses and quality defects encountered in the exposure scenarios inspected.

Inspectors and national coordinators have reported a number of recurring issues such as exposure scenarios available in English only, or with poor translation quality, potentially creating misunderstandings or even introducing errors.

Inconsistencies have also been observed between the information available in the main body of the SDSs, and the exposure scenarios attached to the SDSs: e.g. DNELs having different values in the core body of the SDS, in the exposure scenario and in the risk management measures.

With regard to the uses, tasks, operating conditions and risk management measures, inspectors and national coordinators have indicated that the descriptions and standard phrases used in the exposure scenarios were too generic and vague to be practically understood by the recipients. Also it was commented that some of the conditions were expressed in a manner that makes them not verifiable by the downstream user (e.g. efficiency of local exhaustion ventilation (LEV) expressed as a percentage of exposure reduction).

Although the scope of REF-5 did not include mixtures, during inspections, inspectors reported that there were challenges associated with extended SDSs for mixtures. Inspectors' experiences show that extended SDSs for mixtures were of poor quality, lacked required information, or the uses were not covered. This makes it difficult for the recipients of the SDSs to see the added value of the extended SDSs. Further, it was indicated that implementing requirements in received extended SDSs in some cases result in not fulfilling requirements according to OSH[20].

[20] Occupational Safety and Health Regulations

3. Conclusions and Recommendations

3.1 Conclusions

First level suppliers (Cluster 1)

Even though cluster 1 companies had the highest relative rate of non-compliances compared to the other clusters, it can still be concluded that most of the suppliers who are also registrants comply with the requirements of the REACH Regulation. There are few reported cases where some information was missing in the inspected chemical safety report and/or extended SDSs. Further, information communicated down the supply chain was to a great extent consistent with that given in the chemical safety reports. Both operational conditions and risk management measures are in general given in the extended SDSs for substances communicated to the users down the supply chain.

However, the quality of the information was shown to be of much concern as there were observed serious shortcomings in the quality of the information in the chemical safety report. The same poor-quality information is therefore relayed down the supply chain. The impact of this relaying of poor quality information is that the purpose of the chemical safety report and exposure scenario is not attained.

Suppliers (Cluster 2)

Many of the inspected second level suppliers comply with their duties, using the information received from their suppliers in their compilation of the extended SDSs of the products they then supply downstream. There is good integration of the information in the relevant sections of the extended SDSs, as well as in the exposure scenarios. A range of different methods are employed by the companies when compiling the extended SDSs.

Users (Cluster 3)

Most of the cluster 3 companies inspected had received exposure scenarios as part of the extended SDS for substances from their suppliers, and the workers and their representatives had access to this information. Those who did not received exposure scenarios for substances, as part of the extended SDSs, had received "normal" SDSs.

The project shows that awareness and knowledge of the tools/methods available to support registrants and downstream users exists albeit at a low level. This is not surprising as the tools are still relatively novel.

This project focused on a small number of substances in relation to the number of registered substances. Hence, the findings of this report are to be interpreted only in the context of the scope and conditions of this project.

3.2 Recommendations

Some recommendations can be suggested based on the results of the project:

To industry

- Ensure that registration dossiers and the associated chemical safety reports are periodically updated as appropriate, and as a consequence of this, the extended SDSs are also updated.

- Registrants should put more effort in proposing functional (clear and practical, use-specific and self-explanatory) risk management measures as part of the chemical safety reports and the corresponding exposure scenarios in the SDSs. The usefulness of the information is necessary to positively support the needs of the downstream users to manage the risks from the substances supplied. Compilation of good practice examples of "harmonised safe use information" and training will help to increase the quality of the safe use information.

- Taking in to use the available tools, such as those generated by ENES, can contribute in improving the quality of the exposure scenarios/extended SDSs. This is also one of the actions proposed by the Commission's REACH review (Action 3 "Improving the workability and quality of extended safety data sheets"). However, these tools do not yet cover the full spectrum of the supply chain needs.

- Downstream users should work more to improve the communication up the supply chain, in terms of providing feedback to their suppliers on incorrect or inappropriate information in the extended SDS they receive. This will support the improvement of the quality of the information for all those in the downstream supply chain.

- The "Manufacturers of chemicals and chemical products" and "Wholesale and retail trade" sectors were reported as the most non-compliant. Hence, it would be beneficial for the relevant industry organisations to start a discourse on the way forward towards better fulfilment of their REACH duties.

To the European Commission

- From the results of the project, it seems that transfer of information up and down the supply chain takes place. However, not very much is attained as there are still significant gaps on the quality of this information. Action 1 in the Commission's REACH Review[21] ("Encourage updating of registration dossiers") calls for the Commission, ECHA and industry to propose ways to improve the update of the dossiers. The REF-5 experience confirms the need to install more effective mechanisms to update chemical safety reports regarding both, new information and better quality.
- Some of the challenges experienced during REF-5 have their basis in the REACH Regulation itself, where wording and equivocal declarations in the regulation lead to difficulties in enforcement. The Commission could start a discourse with Forum on how to work towards attaining the objectives and practical enforcement of the regulation in the issues explored in REF-5.

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

- Experiences from REF-5 on cooperation between inspectorates has shown that closer integration of REACH with other legislation (OSH/Environment) would be a more meaningful and effective way to reach the objectives of all the relevant legislation.

- The Commission could support SMEs in improving their chemical safety report. Over 50 % of the inspected companies in the project with the "first level supplier" role were SMEs. A number of SMEs may not be members of industrial sector organisations and may, therefore, not have the same resources as their organisations-members counterpart.

- In light of Action Point 3(2) in the REACH Review where the focus for the Commission will be to "consider including minimum requirements for the exposure scenarios for substances and mixtures in safety data sheets and request ECHA to develop a methodology for safety data sheets of mixtures", it is recommended here that this work be given priority to ensure a quick transition into improving the workability and quality of SDSs.

- The Commission should consider establishing a binding format and content requirements for exposure scenarios, similar to what applies to safety data sheets (EU Regulation 2015/830, *Requirement for the compilation of safety data sheets*). At the same time, it is important to clarify the role of the exposure scenario annex in relation to Sections 1.3, 7 and 8 of the main body of the safety data sheet (see REACH Review Action 3.2). This would help to move towards harmonisation, clarity and verifiability of the communicated information.

To ECHA Secretariat

- ECHA should consider making an information campaign explaining the possibilities and the available guidance to make more meaningful exposure scenarios and to use more effective ways to reach the objectives of all the legislation aiming to ensure safe use of chemicals. Together with industry, good practice examples could be worked out on exposure scenarios which meet the needs of downstream users.

- To design and implement measures that ensure some automatic validation of the content of the chemical safety reports during the completeness check of registration dossiers.

- There is need to follow-up more effectively on the quality of the registrants' chemical safety reports.

- To make some campaign on the importance of ensuring dossiers and chemical safety reports updated.

To Forum

- Forum should consider repeating such a project either as a REF or as pilot in a few years, focusing more on the quality of the information of the extended SDSs. It may be necessary in such a case that prior arrangements are made to train inspectors to be more knowledgeable with the content of chemical safety reports/exposure scenarios and to enforce the requirements of REACH. At that time, investigation of the extended SDSs of mixtures could be considered.

- The good cooperation established between the Member States' national authorities responsible for different aspects of safe chemicals' management such as labour, environment, and consumers should be further promoted. Thus, future REF projects should be designed in a way that is attractive for other authorities to take part.

To NEAs/Member States

- National work programmes should be designed to support the implementation of the scope of the REF-5 project and recommend to be included as part of national enforcement activities.

- To address the fact that many downstream users further down the supply chain still did not receive exposure scenarios, national campaigns to improve the understanding of the legal requirement to supply exposure scenarios are recommended. This will foster the distribution and use of the safe use information.

- It can be recommended to start initiatives aiming at understanding how to ease practical use of the exposure scenarios. Experiences and documentation prepared for this project could be used by the inspectors for this purpose.

- National enforcement authorities should work on further measures to ensure that both exposure scenarios and extended SDSs are of good quality. There is a need to improve the quality of the information in the provided exposure scenarios/extended SDSs to ensure the usefulness of the information so that "users" can improve their management of the risks from chemicals.

.

Annex 1: Questionnaire

- Inspectors submitted **one questionnaire** per inspected company.

  It is not practical where several substance are controlled to have one questionnaire for each substance, since the extended SDSs are handled in a similar way, collectively. Only a few questions in Cluster 1 are specifically substance oriented. In these questions, where not all extended SDSs are fully compliant, "partially" is given as a response alternative. Furthermore, the number of non-compliant substances can be indicated (optional).
- The questionnaire is intended to be a reporting tool for inspectors and thus it is compact.
- While investigating a case, an inspector might wish to look deeper into compliance with other duties but only questions that directly link to the scope of the REF-5 project are in the questionnaire.

The questionnaire is intended only for the use of authorities and shall not be distributed to inspected companies.

Both results of inspections based on desktop checks (only for Cluster 1) and company visits should be reported and submitted to the working group.

Sections shaded in grey are only for internal/national use and are not to be reported to project management.

The inspectors should fill in the questionnaire according to Table 2.

Table 2: Indication of the questionnaire sections to be filled in relation to the cluster that the selected company belongs (see Chapter 2b for the description of the duty holders in each cluster):

Section\Clusters	**Cluster 1**	**Cluster 2**	**Cluster 3**
Section 0	X	X	X
Section 1	X	X	X
Section 2	X	X	-
Section C1	X	-	-
Section C2	-	X	-
Section C3	-	-	X
Section 3	X	X	X

Forum Project REF-5
QUESTIONNAIRE

Fill out one questionnaire for each company inspected.
Please note that one or more cluster may apply for the same company.

Table of Contents of the Questionnaire

Section 0 - General Information about the inspection

0.1. Participating country:

0.2. Person in Charge: **0.3.** Date of inspection: **0.4.** File reference:	For internal use – do not submit data

Section 1: General information about the inspected company

1.1. Name of company: **1.2.** Name of the contact person: **1.3.** Contact person's role:	Only for internal use – do not submit data
1.4. Company's NACE-Code(s):	

1.5. According to Commission Recommendation 2003/361/EC the company qualifies as:
◯ Micro ◯ Small ◯ Medium ◯ not SME

Micro: <10 employees
Small: <50 employees
Medium: <250 employees

1.6. Roles of the company under REACH (multiple responses, and across clusters possible):

☐ Importer ☐ Manufacturer ☐ Importing DU ☐ OR ☐ Re-importer	**Answer questions for Cluster 1 (Section C1)**
☐ DU/Formulator ☐ DU/Re-filler ☐ Distributor	**Answer questions for Cluster 2 (Section C2)**
☐ User ☐ Professional use ☐ Industrial use ☐ Producer of articles	**Answer questions for Cluster 3 (Section C3)**

Relevant articles

Art 3.9 of REACH
Art 3.11 of REACH
Art 3.13 of REACH
Art 3.14 of REACH
Art 8.1 of REACH

Cluster 2's DU is a DU other than an importer covered by an OR

1.7 Approximate number of substances the company operates with, for which an ES can expectedly be received or generated:_____	Note: An interval (range) of the number is sufficient (Please give the interval of not more than 5 *e.g.* 5-10; 20-25). The inspector can control maximum 5 of these substances.

1.8 Details of the substances controlled

	Substance name (Controlled)	CAS-no/EC-no.	Registration number	Yearly consumption if known (ton)	Substance used in mixture? (Y/N)	Wt % in mixture
1						
2						
3						
4						
5						

Section 2 - Tools and structure (internal control routines) (applicable only for Cluster 1 and 2)	The questions in this Section investigate whether there are adequate **systems** in place to collect, process and utilise new information provided by the DU customers.
Generation of exposure scenarios and safety data sheets	
2.1 Have exposure scenarios (ES) been generated and communicated for substances registered with the chemical safety report (CSR)? ◯ Yes ◯ No (Infringement of Art. 14(4)(a) of Reg. 1907/2006, REACH)	Including Chapter 9 and 10
2.2 Does the company have procedures laid down and executed in the company's internal control routines which make the generation of the extended SDS in accordance with the REACH Regulation possible? ◯ Yes ◯ No **2.3** Does the company use tools/methods that facilitate the generation of extended SDS in accordance with the REACH Regulation? ◯ Yes Which one(s)? ☐ Use Map information from (downstream) sectors ☐ Use Map information from (downstream) companies ☐ For mixtures: Lead Component IDentification (LCID) methodology ☐ For mixtures: Safe Use of Mixtures Information (SUMI) ☐ ESCom standard phrases ☐ Exposure scenario generation from CSA via Chesar ☐ ES template given in guidance document ☐ Others (not specified above) ◯ No	
2.4 Does the company use tools/methods available that facilitate the communication of safe use information in extended SDS in accordance with the REACH Regulation?	

◯Yes ☐ For substances: ES template given in guidance document ☐ For mixtures: Safe Use of Mixtures Information (SUMI) ☐ For mixtures: Lead Component IDentification (LCID) methodology ☐ Other ◯No	
Handling the information required for the exposure scenario and safety data sheet	
2.5 Can the company provide an extended SDS/other information required for substances the company ceased using/producing/supplying in the last 10 years? ◯ Yes ◯ No (Infringement of Art. 36(1) of Reg. 1907/2006, REACH) ◯ Not applicable	Manufacturers/importers have the duty to retain all information related to their registration of the substance
2.6 Does the company have systems/instruments which make the distribution of the extended SDSs in accordance with the REACH Regulation possible? ◯ Yes ◯ No	Articles 31(8) and 31(9).
2.7 Does the company have systems/instruments to handle information received from their downstream customers according to REACH Art. 34 or Art. 37(2)? ◯ Yes ◯ No	.
Supplementary question to 2.7 (optional): **2.7a)** For the substance(s) inspected, how many enquiries from downstream customers have been received per year by the company covering: • Uses in ES annex ☐ 1-10 ☐ 11-50 ☐ >50 • Hazard information ☐ 1-10 ☐ 11-50 ☐ >50 • Operational conditions in exposure scenarios ☐ 1-10 ☐ 11-50 ☐ >50 • Risk management measures in the exposure scenario(s) ☐ 1-10 ☐ 11-50 ☐ >50 • If any, which fraction of such inquiries has lead to an update of registration dossier/CSR	
2.8 Does the company check if the extended SDS provided downstream are in line with the respective national legislation of the Member State of the customers? ◯ Yes ◯ No ◯ Not applicable (*i.e.* not supplied to other MS)	Sections of the SDS where national provisions can be relevant: 1.3 1.4 8.1.1.1-8.1.1.4 13 15.1
2.9 Does the company compile/translate extended SDS in languages of other Member States where the substances are placed in the market? ◯ Yes	The ES for communication annexed to the SDS is required to be translated alongside with the SDS into the respective national

◯ No (Infringement of Art. 31(5) of Reg. 1907/2006, REACH) ◯ Not applicable (*i.e.* not supplied to other MS)	languages of EEA countries where the substances are placed on the market
2.10 Does the company take steps to match or select ESs so that they are relevant to their downstream customer's identified uses? ◯ Yes ◯ No	*E.g.* does the company send all ES to all customers, or do customers (customer groups) receive sub-sets of ES specifically relevant to them. .
2.11 Does the company supply all customers with the same ES annex? ◯ Yes **2.11 a)** Does the ES annex include a Table of Contents (ToC) with titles of the exposure scenarios that can help the different DUs to identify the ES relevant to them? ◯ Yes ◯ No **2.11 b)** How many ESs does the annex contain? ☐ 1-10 ☐ 11-50 ☐ >50 **2.11 c)** Is the ES annex an exact copy of the CSR? ◯ Yes ◯ No ◯ Not checked ◯ No	*E.g*. does the company provide a Table of Content to the ES annex to help their DU select the ESs relevant to them or does the supplier use market data or other information to select the ESs to put in the ES annex that are relevant to a DU, rather than simply duplicating all the ESs from the CSR. Simply duplicating all the ESs results, a downstream user receives information that may not be relevant to their uses and making it difficult for the DU to identify the information most relevant to them.
2.12 Do the identified uses stated in Section 1 of the substance(s) extended SDS correspond to those given in the ES? ◯ Yes ◯ No (Infringement of provision in Section 0.1.2 of Annex II and Article 31(2) REACH)	.

QUESTIONNAIRE – CLUSTER 1 – First level suppliers	
Worker protection	Mark the "Partially" box, if the obligation is not fulfilled for all the substances investigated
C1.1 Do the exposure scenarios recommends the operational conditions (OC) for the identified uses of the substance(s)? ◯ Yes ◯ No (Infringement of Art. 14(6) of Reg. 1907/2006 REACH) ◯ Not relevant ◯ Partially *a) If partially, number of substances controlled for which the exposure scenarios do not describe OC that reflect safe use of the substance (optional): [reference to the substance table 1.8]*	It must be clear from the text which are the operational conditions. OC are normally given in the second part of ES.
C1.2 Do the exposure scenarios describe the Risk Management Measures for worker protection? ◯ Yes [Answer C1.2a] ◯ No (Infringement of provision 5.1.1, annex I in Reg. 1907/2006 REACH) [Go to C1.3] ◯ Not relevant [Go to C1.5] ◯ Partially [Answer C1.2a] *a) If answered partially, what are number of substances controlled for which the exposure scenarios do not describe the RMM for use of the substance (optional): [reference to the substance table 1.8]*	Risk management measures are normally given in the ES. However there might be cases where they are not required, for example if the operational conditions ensure for safe use. .
If answer to C1.2 is '**Yes**' or '**Partially**': **C1.2.a** (Only for those RMM that are mentioned in the ES or extended SDS): Are the RMM for worker protection (technical measures and PPE) sufficiently specified and given in a consistent form in the exposure scenario and/or the main body of the extended SDS? ◯ Yes ◯ No ◯ Not checked ◯ Partially	Mark 'partially' if the obligation is not fulfilled for all the substances, and/or when only some of the RMM are fulfilled (e.g. gloves are specified but eye protection is not).
C1.3 Is the information on workers' protection in section 7 and section 8 of the extended SDS consistent with that given in the ES for communication, which is annexed to the extended SDS? ◯ Yes ◯ No (Infringement of provisions in Section 0.1.2 of Annex II and Article 31(2) REACH) ◯ Not checked ◯ Partially *a) If partially, number of substances controlled for which section 8 of the extended SDS is not consistent with the ES (optional):*	RMM and OC in the extended SDS should align with what is required according to the ES.
C1.4 Is the information on workers' protection given in the ES consistent with the corresponding chemical safety reports for the substances?	

◯ Yes ◯ No ◯ Not checked, because: ☐ Have no access to CSR ☐ Requested for CSR, but not received, by time of the inspection. ◯ Partially a) *If answered partially, the number of substances controlled for which the information is not consistent (optional):*	
Environmental protection	
C1.5 Where OCs are provided (cf. C1.1), are conditions with relevance to protection of the environment given? ◯ Yes ◯ No (Infringement of provision 5.1.1, annex I in Reg. 1907/2006 REACH) ◯ Not required ◯ Not checked ◯ Partially a) *If partially, number of substances controlled for which the OC does not reflect on environmental protection (optional):*	
C1.6 Are there risk management measures to ensure that the releases to the environment are adequately controlled? ◯ Yes ◯ No (Infringement of provision 5.1.1, annex I in Reg. 1907/2006 REACH) ◯ Not required ◯ Not checked ◯ Partially a) *If partially, number of substances controlled for which there are not measures in place (optional):*	
C1.7 Is the information about environmental protection in section 8 of the extended SDS consistent with that given in the ES for communication which is annexed to the extended SDS? ◯ Yes ◯ No (Infringement of provisions in Section 0.1.2 of Annex II and Article 31(2) REACH) ◯ Not checked ◯ Partially a) *If answered partially, the number of substances controlled for which there is an inconsistency (optional):*	
C1.8 Is the information about environmental protection in the ES consistent with the corresponding chemical safety report for the substance? ◯ Yes ◯ No ◯ Not checked ◯ Partially a) *If answered partially, number of substances controlled for which there is an inconsistency (optional):*	
Consumer protection	

C1.9 Are the conditions of use in the exposure scenario(s) related to consumer uses/products clearly described? ◯ Yes ◯ No (Infringement of provision 5.1.1, annex I in Reg. 1907/2006 REACH) ◯ Not required ◯ Not checked ◯ Partially *a) If answered partially, the number of substances controlled for which it is not clear it is aimed for consumer use (optional):*	For consumer use RMM is not an effective tool for risk control.

QUESTIONNAIRE – CLUSTER 2 Suppliers	
C2.1 The company is a supplier of: ◯ Substances only ◯ Mixtures only ◯ Both substances and mixture	
Incoming extended SDS and use	
C2.2 Has the company inspected received extended SDS from the supplier for all the inspected substances/mixtures? ◯ Yes ◯ No **If No,** C2.2.a) Did the company demand them from their supplier? ◯ Yes ◯ No	
C2.3 Does the company check if the registration numbers are given in the received extended SDS of the substances? ◯ Yes ◯ No **If Yes**, C.2.3.a) Where the registration numbers are **not** given, does the company ask the reason for this from their supplier? ◯ Yes ◯ No	
C2.4 Does the company check if exposure scenarios are attached to the received extended SDS of the substances for the identified uses? ◯ Yes ◯ No **If Yes,** C2.4.a) Where exposure scenarios/safe use information are **not** attached/included, does the company ask for them from the supplier? ◯ Yes ◯ No	
C2.5 Does the company consider the information in the EXTENDED SDS received when compiling the extended SDS for its own products? ◯ Yes ◯ No (Infringement of provision Article 37(5) Reg. 1907/2006, REACH) ◯ Not applicable	
C2.6 Has the company identified any inappropriate RMM recommended in the ES or any case where not all necessary RMM are mentioned? ◯ Yes ◯ No **If Yes,** **C2.6 a)** Does the company inform their supplier?	

◯ Yes ◯ No (Infringement of Art. 34 in Reg. 1907/2006, REACH) **C2.6 b)** Does the supplier respond? ◯ Yes ◯ No **C2.6.c)** Is the company provided with an updated extended SDS? ◯ Yes ◯ No	If no updated extended SDS is provided, the supplier has infringed Art. 31(9) (a) of Reg. 1907/2006, REACH). The company can be informed on this.
Outgoing extended SDS	
C2.7 Does the company make changes / additions to the extended SDS or translate the extended SDS of the substances they receive and then supply downstream? ◯ Yes ◯ No ◯ Not applicable (*where no substances supplied*) **If Yes,** **C2.7 a)** Are all extended SDS changes recorded and traceable? ◯ Yes ◯ No (Infringement of Art. 31(1) Reg. 1907/2006, REACH) **C2.7 b)** Are the changes based on information provided by their customers? ◯ Yes ◯ No	REACH Art. 34 and 37(2)
C2.8 Does the company compile extended SDS for the mixtures that they prepare and supply downstream? ◯ Yes (Go to C2.9) ◯ No (Infringement of Art. 31(1) in Reg. 1907/2006, REACH) (Go to C2.18) ◯ Not applicable (*where no mixtures are supplied*) (Go to C2.18) ◯ Not required (Go to C2.18)	
C2.9 The extended SDS are compiled using/by: ☐ extended SDS software. ☐ External consultant ☐ Company's in-house personnel	
C2.10 How is the mixture classification determined? ☐ Using classification software/tools ☐ Manually according to CLP Annex I	
C2.11 How are the relevant RMMs for the mixture identified? ☐ Expert opinion of company's risk assessors ☐ Expert opinion of external consultant ☐ Applying sectors' guideline	

☐ Using CSR/ES Roadmap products such as the LCID ☐ Other	
C2.12 Does the company make use of the relevant ES for the identified uses when preparing extended SDS for the mixture? ◯ Yes ◯ No (Infringement of Art. 31(2) Reg. 1907/2006, REACH)	
C2.13 How is this safe use information (OC/RMMs) communicated? ☐ Integrated into the respective sections of the main body of the extended SDS ☐ As an attachment to the extended SDS in a consolidated form. In this case, for the attachment, does the company consider the language of the customers in other Member State? ◯ Yes ◯ No ☐ Using Safe Use of Mixtures Information (SUMI) and other industry/sector developed templates ☐ Mixture ES (not SUMI/developed by sector)	
C2.14 Are the available registration numbers from the incoming substance extended SDSs indicated in the mixture extended SDS (Section 3.2)? ◯ Yes ◯ No (Infringement of provision 3.2.4 in annex of Reg. 2015/830)	
C2.15 Are the relevant DNELs/PNEC and OELs or other relevant national parameters from the incoming substance extended SDS included in the mixture extended SDS (Section 8)? ◯ Yes ◯ No (Infringement of provision 8.1 in annex of Reg. 2015/830)	
C2.16 (Only for those RMM that are mentioned in ES or extended SDS): are RMM for worker protection (technical measures and PPE) sufficiently specified and given in a consistent form in the exposure scenario and/or the body of the extended SDS? ◯ Yes ◯ No (Infringement of provision 8 in annex of Reg. 2015/830) ◯ Not checked ◯ No Partially	Mark 'partially' if the obligation is not fulfilled for all mixtures and/or when only some of the RMM are fulfilled (e.g. gloves are specified but eye protection is not).
C2.17 Can the company document that there is control of the content and consistency between different sections of the extended SDS for mixtures supplied? ◯ Yes ◯ No	The documentation does not need to be elaborate; an inclusion in the internal routines to this effect should suffice.
Downstream / Upstream communication (Information from downstream users up the supply chain and other relevant items)	
C2.18 Does the company possess additional information that should be included in the extended SDS they received? ◯ Yes ◯ No	

If Yes: C2.18a) Did it inform the supplier? ◯ Yes ◯ No (Infringement of Art. 34 in Reg. 1907/2006, REACH)	
C2.19 Has the company informed the supplier of a use that is not covered in the identified uses? ◯ Yes ◯ No ◯ Not applicable	
C2.20 Does the company keep records of the information handled or passed up the supply chain? ◯ Yes ◯ No ◯ Not applicable	

QUESTIONNAIRE – CLUSTER 3 Users	
General Information about the inspection	
C3.1 Inspection performed by or in cooperation with inspector from: ☐ Labour Inspectorate ☐ Environmental Inspectorate ☐ Other	
Details of the user company inspected	
C3.2 Has the company received any extended extended SDS from the supplier of substances used? ◯ Yes (If Yes, answer questions **C3.3-C.14**) ◯ No (If No, go to **C3.15**)	Where the answer is "Yes" *i.e.* one/several extended extended SDS are received. Questions C3.3- C3.14 must be answered. C3.15 –C3.20 become redundant and there is no need to fill them. In cases where the answer is "No", it will not be possible to answer C3.3 – C3.14. Instead, questions C3.15 – C3.20 shall be answered as an alternative.
C3.3 Does the company have procedures and routines in place for the receipt and assessment of extended extended SDS, use of information in their workplace assessment and implementation of RMM? ◯ Yes ◯ No	Relevant to REACH and other regulations
C3.4 Does the company keep records on substances that are used and the (extended) extended SDSs that are received (for example, in form of a substance inventory)? ◯ Yes ◯ No **If Yes (Optional):** **C.3.4.a)** What information is recorded in this inventory? ☐ Product commercial name ☐ Substance name ☐ Mixture name with the substances identified ☐ CAS number ☐ EC number ☐ Registration number ☐ Supplier identification (country in case of imported product) ☐ Extended SDS version/issue date ☐ The date the extended SDS is received ☐ Substance use (in the company) ☐ Workplace where the substance is used ☐ Classification and labelling (pictograms) ☐ ES (use descriptors, RMM and OC) ☐ Quantities of the substance consumed (in the last 3 years) ☐ Others (not listed above)	
C3.5 Has the 12 month deadline for the implementation of the RMMs passed for those substances for which an ES was provided?	Relevant to REACH and other regulations (*e.g.* OSH)

◯ Yes ◯ No ◯ Partially ◯ Not possible to determine (No records kept)	"Partially" to be used when the inspector controls more than one substance, and for some, the 12 month deadline is exceed and not for others.
C3.6 Is the DU's use of the selected substance an identified use given in the extended extended SDS received? ◯ Yes (Go to C3.7) ◯ No (Go to C3.13)	Art. 37(4) Relevant to REACH and other regulations
C3.7 Is an exposure scenario for the DU's identified use included in the ES which are annexed to the extended SDS? ◯ Yes (Go to C3.8) ◯ No (Go to C3.13)	Art. 37 (4) REACH requirement relevant for other regulations
If answer to C3.7 is YES:	
C3.8 Does the ES applicable to the company's identified use: ☐ Describes specific RMM for workers' exposure control ☐ Describes specific RMM for environmental control	Art. 37(4) REACH requirement relevant for other regulations
C3.9 Does the DU use the substance within the OC/RMM indicated in the ES? ◯ Yes ◯ No **If No**, C3.9 a) Has the company done its own DU CSR or other solutions from REACH Art. 37(4)? ◯ Yes ◯ No ◯ No, but RMM were selected based on other legislation or user's workplace assessment	Art. 37(4) REACH requirement relevant for other regulations
C3.10 How are the OC/RMM given in the ES implemented in the company? ☐ Implemented as provided without any change ☐ Scaled up/down based on supplier instructions to fit with the condition of the workplace.	Art. 37(4) (d) REACH requirement relevant for other regulations
C3.11 Has the company applied additional measures other than those provided in ES in order to improve safety? ◯ Yes ☐ for workers' exposure control ☐ for environmental control ◯ No **If Yes**, **C3.11.a)** Do these measures complement those given in the ES and are not completely different? ◯ Yes ◯ No	Art. 37 (5) REACH requirement relevant for other regulations
C3.12 Does the DU keep records to demonstrate that his implementation of conditions conform with the OC and RMM provided in the relevant ES? ◯ Yes ◯ No	Art. 36 (1) REACH requirement relevant for other regulations

(Go to C3.14*)*	
If answer to C.3.6 or C3.7 is No:	
C3.13 Where the use(s) and/or conditions of use are not covered by the ES received, identify which of the following options apply: ☐ Uses < 1 tonne ☐ Substance is diluted below concentrations indicated in Article 14(2) ☐ The DU made his use known to the supplier ☐ The DU decided to search for a supplier with ES covering his use ☐ The DU prepared a DU CSR and implements those conditions of use (Answer questions C3.13.a) and b) ☐ User can demonstrate safe use by other means (*e.g.* workplace assessment or regulatory prescription of specific RMM's) ☐ None of the above	Art. 37 (4) Art. 37 (4) Art. 37 (2) (3) Art. 37 (4) (d) Art. 37 (4)
(only reply if you ticked the box "The DU prepared a DU CSR"**)** **C3.13.a)** If the DU prepared a DU CSR or if he uses below 1 tonne per year or PPORD, did he report to the Agency the information specified in Art. 38 (2)? ◯ Yes ◯ No (Infringement of Art. 38(1) in Reg. 1907/2006, REACH) ◯ Art. 38 (2) is not applicable **C3.13.b)** If the DU prepared a DU CSR, was this up to date and available? ◯ Yes ◯ No (Infringement of Art. 37(7) in Reg. 1907/2006, REACH)	
C3.14 Do the workers and their representatives have access to the information provided in accordance with Art. 31 and 32? ◯ Yes ◯ No (Infringement of Art. 35 in Reg. 1907/2006, REACH) *(Go to Section 3)*	REACH requirement relevant for other regulations
The following questions must only be answered if answer to C3.2 is No	
C3.15 Has the company asked why their suppliers have not provided the ES for the substances they use? ◯ Yes ◯ No	General requirements relevant for REACH and other regulations
C3.16 Has the company received "normal"extended SDSs from their suppliers for the substances used? ◯ Yes ◯ No	"Normal" *i.e.* not extended, no annexed ES. General requirements relevant for REACH and other regulations
C3.17 Does the company have routines and procedures in place to ensure the keeping of records of information received from the suppliers? ◯ Yes ◯ No	General requirements relevant for REACH and other regulations

C3.18 Does the company have routines and procedures in place to ensure compliance with other chemical regulatory requirements such as the work and environment regulations? ◯ Yes ◯ No	General requirements relevant for REACH and other regulations
C3.19 Does the company have a system to document the implementation of the safe use information in the extended SDS which the company has received? ◯ Yes ◯ No	General requirements relevant for REACH and other regulations
C3.20 Does the company make the information received from the supplier available to the workers? ◯ Yes ◯ No (Infringement of Art. 35 in Reg. 1907/2006, REACH)	General requirements relevant for REACH and other regulations
C3.21 Does the company actively inform their workers on the available information received from the suppliers? ◯ Yes ☐ the information is explained orally ☐ the information is available on documental support ◯ No	General requirements relevant for REACH and other regulations

Section 3: Summary / Follow-up Action	
3.1 Measures imposed due to non-compliance with REACH obligations subject to this project (table 1 of the manual)? (multiple responses possible) ☐ No measures ☐ Verbal advice ☐ Written advice ☐ Administrative order ☐ Fine ☐ Criminal complaint / Handing over to public prosecutor's office ☐ Others	
3.2 Are the follow-up activities ◯ completed ◯ on going	
3.3 Have any cases been forwarded to other Member States? ◯ Yes**, to**: ☐ National Competent/Enforcement Authority ☐ Forum Member ☐ National coordinator ◯ No	

Annex 2: Supplementary figures and tables

TABLE A1: EXAMPLES OF CRITERIA USED BY INSPECTORS FOR ASSESSING NON-COMPLIANCES

Cluster 1	
Question	**Guideline**
Do the exposure scenarios recommend the operational conditions (OCs) for the identified uses of the substance(s)? *Legal reference: REACH Art.14(6)*	**As a minimum**, the operational conditions for a hazardous substance in each communicated identified use should cover: • Physical **form**: gas/liquid/solid • Limitation(s) in terms of **concentration** e.g. limit the substance content in the product to 5%. • Limitation(s) in terms of the **duration** and **frequency** of a particular task e.g. daily exposure upto 8 hours. The maximum amount per site in tonnes per day or tonnes per year which are applicable for uses **at industrial sites**. Release rates (kg/d) to air and water alone are not sufficient. **Note**: Not applicable to professional and consumer uses, hence no comparable information may be described in the corresponding environmental contributing scenario(s).
Cluster 2	
(Only for those RMM that are mentioned in ES or SDS): are RMM for worker protection (technical measures and PPE) sufficiently specified and given in a consistent form in the exposure scenario and/or the body of the SDS?	RMM given in the SDS or in annexed ES should be sufficient to give RCR<1. Exposure assessment parameters should be stated; PPE sufficiently specified, including: - Ventilation and parameters describing it, e.g. efficiency - Eye/face protection - Gloves material type, thickness and breakthrough - Mask and filter type for respiratory protection. For this project, the correctness of the control measures given is not assessed.
Cluster 3	
Is an exposure scenario for the DU's identified use included in the ES which are annexed to the SDS? Legal references:	Uses of a substance should be described in the ES by the use descriptor system (ECHA Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system). See from the company's documentation that the company has find / identified their own uses. Take into consideration that differences between the description of conditions of use in the ES and company's own practice do not always mean that the use is not covered. Some cases process understanding is needed to evaluate this. Make also sure that the company understand their role (e.g. as a downstream user, manufacture) correctly. The inspector can also consult chapter „4.2 Checking if the use and conditions of use are covered by the exposure scenario" from the

Article 37 (4)	„Guidance for downstream users" (Version 2.1 October 2014) or Chapter «2.2 What to do when you receive an exposure scenario» from the „Practical Guide 13 - How downstream users can handle exposure scenarios". Search Q&A's available in ECHA's website in order to find some Q&A that might be applicable to your questions.
	Inspectors were encouraged to refer to an example of an exposure scenario, based upon an ECHA annotated exposure scenario template: https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats

TABLE A2: NUMBER OF INSPECTIONS AND NON-COMPLIANCES FOUND IN ALL NACE DIVISIONS INSPECTED UNDER REF-5

NACE unit	NACE Divisions covered during inspections in REF-5	Number of inspected companies	Number of non-compliances
A	*C 10 Manufacture of food products*	24	-
A	*C 11 Manufacture of beverages*	19	-
A	*C 13 Manufacture of textiles*	9	1
A	*C 14 Manufacture of wearing apparel*	5	2
A	*C 15 Manufacture of leather and related products*	6	-
A	*C 16 Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials*	7	-
A	*C 17 Manufacture of paper and paper products*	16	1
A	*C 19 Manufacture of coke and refined petroleum products*	23	8
A	*C 20 Manufacture of chemicals and chemical products*	339	80
A	*C 21 Manufacture of basic pharmaceutical products and pharmaceutical preparations*	14	1
A	*C 22 Manufacture of rubber and plastic products*	24	2
B	*C 23 Manufacture of other non-metallic mineral products*	37	2
B	*C 24 Manufacture of basic metals*	27	5
B	*C 25 Manufacture of fabricated metal products, except machinery and equipment*	43	1
B	*C 26 Manufacture of computer, electronic and optical products*	8	1
B	*C 27 Manufacture of electrical equipment*	15	1
B	*C 28 Manufacture of machinery and equipment n.e.c.*	8	-
B	*C 29 Manufacture of motor vehicles, trailers and semi-trailers*	11	1
B	*C 30 Manufacture of other transport equipment*	9	3
B	*C 31 Manufacture of furniture*	4	-
B	*C 32 Other manufacture*	7	-
C	*G 45 Wholesale and retail trade and repair of motor vehicles and motorcycles*	14	2
C	*G 46 Wholesale trade (except of motor vehicles and motorcycles)*	117	40
C	*G 47 Retail trade (except of motor vehicles and motorcycles)*	8	1
D	*A 1 Crop and animal production, hunting and related service activities*	6	1
D	*B 7 Mining of metal ores*	4	-
D	*B 8 Other mining and quarrying*	1	-
D	*C 18 Printing and reproduction of recorded media*	4	4

D	*C 33 Repair and installation of machinery and equipment*	2	-
D	*D 35 Electricity, gas, steam and air conditioning supply*	7	-
D	*E 36 Water collection, treatment and supply*	11	1
D	*E 38 Waste collection, treatment and disposal activities; materials recovery*	4	1
D	*E 39 Remediation activities and other waste management services*	1	-
D	*F 43 Specialised constructions activities*	3	-
D	*H 50 Water transport*	5	-
D	*H 52 Warehousing and support activities for transportation*	1	-
D	*I 55 Accommodation*	2	-
D	*L 68 Real estate activities*	1	-
D	*M 71 Architectural and engineering activities, technical testing and analysis*	2	1
D	*M 72 Scientific research and development*	5	-
D	*M 74 Other professional, scientific and technical activities*	2	-
D	*M 75 Veterinary activities*	2	-
D	*N 81 Services to building and landscape activities*	5	-
D	*N 82 Office administrative, office support and other business support activities*	4	1
D	*O 84 Public administration and defence; compulsory social security*	1	-
D	*O 85 Education*	1	1
D	*Q 86 Human health activities*	6	-
D	*R 90 Creative, art and entertainment activities*	1	-
D	*R 93 Support activities and amusement and recreation activities*	4	-
D	*S 96 Other personal service activities*	13	1

FIGURE A1: DISTRIBUTION OF THE NUMBER OF INSPECTIONS AND NON-COMPLIANCES BY THE NACE DIVISIONS

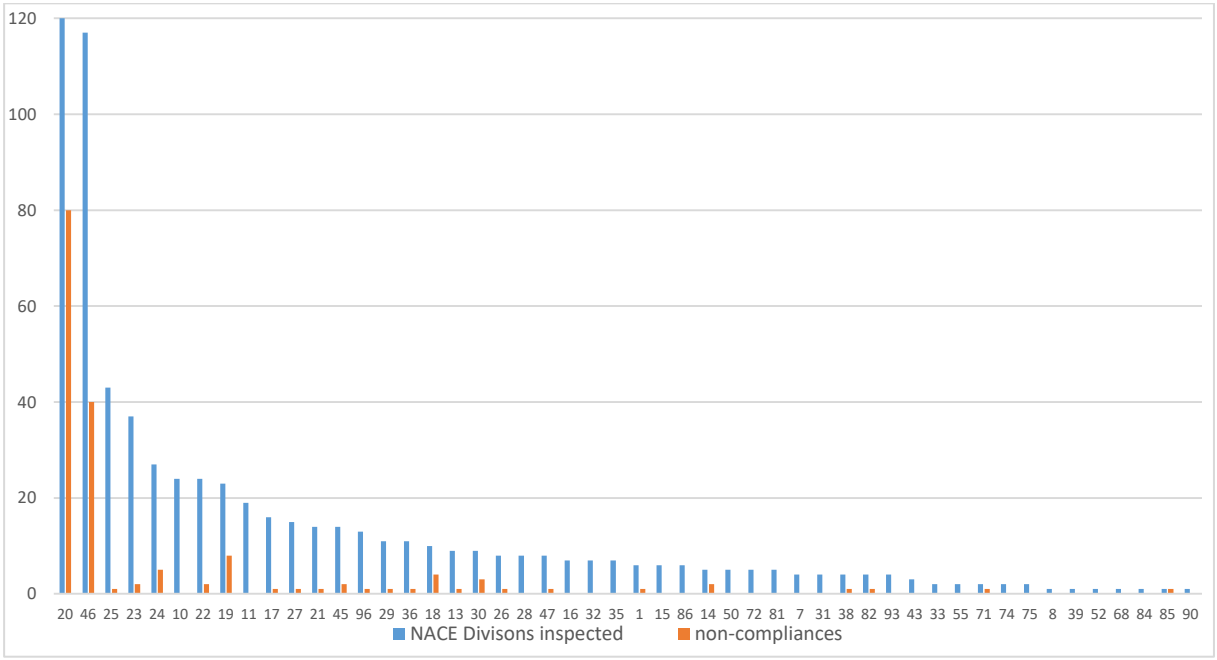


TABLE A3: FREQUENCY OF THE INVESTIGATIONS (HIGH TO LOW) AND THE CORRESPONDENT NON-COMPLIANCES FOUND FOR THE SUBSTANCES CHECKED IN THE PROJECT

Substance	No. of investigations	No. of non-compliances
Sodium hydroxide	77	4
Ethanol	68	10
Sulphuric acid	62	7
Hydrogen chloride	49	5
Toluene	48	4
Acetone	39	8
Ammonia	38	1
Formaldehyde	38	7
Styrene	36	16
Nitric acid	32	3
Sodium hypochlorite	32	2
Xylene	30	7
2-Propanol	28	2
Calcium dihydroxide	25	2
Methanol	24	8
Ammonium nitrate	23	1
Hydrogen peroxide	22	4
Phosphoric acid	21	3
Aluminium sulphate	19	7
Fuels, diesel	15	1
Chromium trioxide	13	
Sodium carbonate	13	2
Acetic Acid	12	2
Lead	12	3
Calcium oxide	11	
Ethan-1,2-diol	11	2
Ethyl acetate	11	1
Hydrocarbons C10-C13	11	2
Zinc oxide	11	5
Hydrocarbons C9-C12	10	2
Boric acid	9	1
Lead monoxide	9	1
Rosin	9	5
n-Butyl acetate	8	1
Acetylen	7	1
Chlorine	7	1
Ethyl methyl ketone	7	2
Oil shale, thermal processing waste	7	1
Gasoline	6	
Potassium hydroxide	6	1
4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane	5	
Cyclohexane	5	1
Formic acid	5	
Hydrogen fluoride	5	1
Iron trichloride	5	1
Methyl methacrylate	5	1
Suphur	5	
1-Methyl-2-pyrrolidon	4	
2-aminoethanol	4	
Amides, C8-18 (even)	4	
Ammonium chloride	4	1
Calcium diformate	4	
Citric acid	4	1
Dichloromethane	4	3

Substance	No. of investigations	No. of non-compliances
Ethylene glycol butyl ether	4	
Flue dust, portland cement	4	
Naphtha (petroleum), hydrotreated light	4	
Nickel(II) chloride hexahydrate	4	
Potassium dichromate	4	1
Propan-1-ol	4	
Sodium hydrogensulfite	4	
Sodium silicate	4	
Sodium Tetraborate	4	
Strontium chromate	4	2
Tetrahydrofurane	4	
1-methoxy-2-propanol		
monopropylene glycol methyl ether	3	
Acetonitrile	3	1
Aluminium sodium dioxide	3	1
Aluminum chloride hydroxide sulfate	3	1
Benzyl alcohol	3	1
Bisphenol A	3	2
Butan-1-ol	3	
Calcium chloride	3	2
Chloroform	3	1
Diethylene glycol	3	
Diphenylmethane 4,4'-diisocyanate	3	
Distillates (petroleum), hydrotreated light naphthenic	3	2
Ethylene oxide	3	1
Fuel oil, residual	3	
Lead Chromate Molybdate Sulphate	3	2
Lead Sulphochromate Yellow	3	2
N-N-Dimethylformamide	3	
Oxybis(methyl-2,1-ethanediyl) diacrylate	3	
Potassium permanganate	3	
Residues (petroleum), atmospheric	3	2
Shale oils, middle fraction	3	1
Sodium peroxydisulphate	3	2
Tetrachloroethylene	3	
1,4-butandiol	2	
1-Methoxy-2-propyl acetate	2	1
1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-C8-18(even numbered) acyl derivs., hydroxides, inner salts	2	
2-(2-butoxyethoxy)ethanol	2	
2,6-Di-tert-butyl-4-methylphenol	2	
2-Phenoxy-ethanol	2	1
4-Methyl-m-phenylene diisocyanate	2	
4-Methylpentan-2-on	2	
Acrylic acid	2	
Alcohols, C12-14, ethoxylated, sulfates, sodium salts	2	1
Alcohols-C12-C14-ethoxyated(1.-2,5SED sulfates sodium salts	2	1
Aluminium	2	
Amidosulfuric acid	2	
Ammonium hydrogendifluoride	2	1
Bis(2-ethylhexyl) phthalate	2	
Butyl glycollate	2	

Substance	No. of investigations	No. of non-compliances
Calcium sulfate	2	
Dibenzoyl peroxide	2	
Diiron tris(sulphate)	2	
Distillates (petroleum), hydrotreated middle Gasoil - unspecified	2	2
Fuel oil, n 4	2	1
Heptane	2	2
Hydrocarbons C11-C14	2	1
Hydrocarbons, C10-C13	2	
hydrocarbons, C7-C9	2	
Iron sulphate	2	
Magnesium	2	1
Methylcyclohexane	2	
N-(1,3-Dimethylbutyl)-N'-phenyldiamine	2	
Naphtha (petroleum)	2	1
Natriummetasilicat	2	
Nickel	2	
Nickel sulfate	2	1
Oksygen	2	
Oxalic acid	2	
Pentalead tetraoxide sulphate	2	
Phenol	2	1
Phenolphthalein	2	
Polyetheramide	2	1
Polymethylene polyphenyl isocyanate	2	
Shale Oil Bitumen	2	1
Shale oils, light fraction	2	1
Sodium chlorate	2	
Sodium disulfite	2	
Sodium floride	2	1
Sodium hydrogen sulphate	2	1
Sodium metasilicate	2	
Sodium nitrate	2	
Solvent naphtha (petroleum), heavy arom.	2	1
Tert-Butyl methyl ether	2	1
Tetralead trioxide sulphate	2	
Toluene-4-sulphonic acid	2	1
Trisodium hexafluoroaluminate	2	1
Zinc chloride	2	
Zinc selenit	2	1
Zincdihydrogenphosphate	2	
Other substances inspected only once	231	50
TOTAL	**1 435**	**243**

TABLE A4: RESULTS FOR THE NUMBER OF ENQUIRIES FROM THE DOWNSTREAM USERS/CUSTOMERS THE COMPANY RECEIVED PER YEAR

Inquiries	0	1-10	11-50	>50	N
Uses in ES annex	231	69	14	3	86
Hazard information	226	54	13	11	78
Operational conditions in exposure scenarios	253	43	7	3	53
Risk management measures in the exposure scenario(s)	250	42	10	2	54

Please note that it was not mandatory for the inspectors to report this information (Question 2.7a) of the questionnaire – Annex 1).

TABLE A5: RESULTS FOR THE TYPES OF RECORDS KEPT BY THE "USER" COMPANIES FOR SUBSTANCES THAT ARE USED AND EXTENDED SDS ARE RECEIVED

Information recorded	Frequency reported
Substance name	268
Product commercial name	264
Classification and labelling (pictograms)	213
CAS number	209
Supplier identification (country in case of imported product)	184
Workplace where the substance is used	181
Substance use (in the company)	168
SDS version/issue date	166
EC number	154
Registration number	150
Quantities of the substance consumed (in the last 3 years)	135
Mixture name with the substances identified	127
Exposure Scenarios (use descriptors, RMM and OC)	116
The date the SDS is received	114
Others (not listed above)	85

Please note that it was not mandatory for the inspectors to report this information (Question C3.4a) of the questionnaire – Annex 1). Moreover, more than one option could be selected.

TABLE A6: MOST COMMON ISSUES IDENTIFIED IN THE CHEMICAL SAFETY REPORTS

Main issue	What's the issue/shortcoming
Creation, maintenance and update of chemical safety report within the joint submission	• Coexistence of multiple versions of the same chemical safety report within a joint submission. • Desynchronisation of updates between the IUCLID dossiers and the chemical safety report.
Completeness of the registration dossiers and the chemical safety reports	• Missing, empty or partial chemical safety reports (section 9 and 10 not provided, for example) • Missing exposure scenarios in the chemical safety report • Inconsistent information between the chemical safety reports and IUCLID (section 3 on uses)
Quality of the chemical safety reports	• chemical safety report not updated after a change in classification (e.g. harmonised classification according to CLP annex VI). • Missing, or partial exposure assessment. • Operating conditions and risk management measures are not concrete/specific/detailed enough. • Inconsistent information on operating conditions and risk management in the chemical safety report. • Systematic use of some exposure estimation models outside of their applicability domain. Questionable exposure estimates (linear exposure reduction applied for the Targeted Risk Assessment method (by ECETOC), assumptions not justified).
Relevance and extraction of information in the chemical safety reports to be transmitted via the exposure scenarios for communication	• Name and identification of the ES and contributing activity (CA) are not sector/use specific enough to be easily recognised by the downstream users. Operating conditions and risk management measures are not sufficiently concrete and use-specific. • The members of a joint submission are likely to generate different ES for communication for the same uses because the chemical safety reports all look different. • Time consuming to find and extract the information in a chemical safety reports to be used to generate an exposure scenario for communication.

Annex 3: Available tools and methods for safe use information: a summary

Improving the quality of "safe use" information.

In recent years, ECHA has collaborated with industry stakeholders and Member States to develop and publish a series of products to support registrants and downstream users to communicate safe use information along the supply chain. They consist of harmonised templates, IT tools, guidance on methodologies etc. with the aim of structuring the information required by a REACH actor to minimise the variability in the formats in circulation i.e. that the information is presented in a more consistent and clear manner, and that it can be retrieved more easily. By so doing, the flow of realistic and meaningful information on use and exposure in the supply chain should improve over time. These tools are sometimes referred to as "ENES tools".

Most of these ENES tools became available by the end of 2016[22]. REF-5 was taken as an opportunity to gauge the level of awareness of these products amongst the "first level supplier" and "supplier" companies, and the extent to which these businesses were utilising them.

The inspectors reported that 64 % (n=464) of the inspected companies utilised one or more tools/methods to facilitate the **generation** of extended SDSs in accordance with the REACH Regulation. The use of a template for the exposure scenario predominated (42 %), with awareness and implementation of use maps and two mixture methodologies at a lower level, 20 % and 13%, respectively.

TABLE A7: RESULTS FOR THE TOOLS/METHODS USED BY THE "FIRST LEVEL SUPPLIER" AND "SUPPLIER" COMPANIES TO FACILITATE THE GENERATION OF EXTENDED SDS (MULTIPLE OPTIONS WERE POSSIBLE)

Tools/methods	Frequency reported	Percentage (n=464)
Exposure scenario template given in guidance document	101	22 %
Exposure scenario generation from CSA via Chesar (template)	91	20 %
ESCom standard phrases	54	12 %
Use Map information from (downstream) companies	48	10 %
Use Map information from (downstream) sectors	45	10 %
For mixtures: Safe Use of Mixtures Information (SUMI)	30	6 %
For mixtures: Lead Component IDentification (LCID) methodology	29	7 %
Others (For example - top 5): *Information/Assistance from consortiums* *External consultants* *Own software tools* *ChemGes software* *Chemeter software*	106	23 %

The levels of template usage for the exposure scenario was 33 % (n=459) when it came to companies **communicating** safe use information in the extended SDS for their

[22] Improving safe use information in the supply chain – infographic: https://echa.europa.eu/documents/10162/15669641/safe_use_chemicals_en.pdf/789d0235-5872-4527-baad-db681edefdb0

substances, whereas for two mixture methodologies, the application of the methodology was less, 19 % (Table A8).

TABLE A8: RESULTS FOR THE TOOLS/METHODS USED BY THE "FIRST LEVEL SUPPLIER" AND "SUPPLIER" COMPANIES TO FACILITATE THE COMMUNICATION OF THE EXTENDED SDS (MULTIPLE OPTIONS WERE POSSIBLE)

Tools/methods	Frequency reported	Percentage (n=459)
For substances: exposure scenario template given in guidance document	152	33 %
For mixtures: Safe Use of Mixtures Information (SUMI)	53	12 %
For mixtures: Lead Component IDentification (LCID) methodology	34	7 %
Others (For example - top 5): *Own software tools* *Communication by email* *External consultants* *SAP* *Use of consortiums*	80	17 %

In the "suppliers" companies that prepare their own mixtures, 23 % (n=188) made use of a tool developed by industry in cooperation with ECHA, like Cefic's/industry's *Lead Component Identification Methodology* to identify the relevant risk management measures for their mixtures.

In terms of how the safe use information (operational conditions and risk management measures) are then communicated with the mixture SDS supplied, the majority of the suppliers (78 %) integrate the safe use information in the respective sections of the main body of the SDSs. 7 % made use of the mixture's exposure scenario template not developed by any industry/sector, whilst 6 % used the safe use of mixtures information (SUMI) prepared by industry/sector.

The results show that awareness and knowledge of the tools/methods available to support registrants and downstream users exists albeit at a low level. This is not surprising as the tools are still relatively novel. The utilisation of harmonised templates, e.g. the exposure scenario template, is a positive finding, as consistency in the presentation of the "safe use" information builds confidence and helps recipients to locate the information they need. Regarding the communication of "safe use" information for mixtures, the inspection findings reveal that the practice of integrating the "safe use" information into the main body of the safety data sheet is commonly applied. It is possible that companies' authoring systems for mixture SDSs have yet to adapt to other ways of providing the information e.g. as a consolidated attachment. This is important as downstream recipients need to recognise the component "exposure scenario-based" information within their mixture SDSs to apply, to meet their REACH obligations as a downstream user.

EUROPEAN CHEMICALS AGENCY
ANNANKATU 18, P.O. BOX 400,
FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU