Forum for exchange of information on enforcement

REF-11 project report on:

Safety Data Sheets (SDS)

December 2024

Disclaimer

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This report presents the results of inspections made under the Forum enforcement project. Duty holders and substances or mixtures 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.

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List of abbreviations

Word	Explanation
ATE	Acute Toxicity Estimate
ECHA	European Chemicals Agency based in Helsinki, Finland
EEA	European Economic Area
EU	European Union
MS	Member States belonging to the EEA
MSCA	Member State Competent Authority
NC	National coordinator of the REF project
NEA(s)	National enforcement authority(-ies)
PPE	Personal Protection Equipment
REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
REACH Annex II	Annex II to REACH: Requirements for the compilation of safety data sheets
REF	EEA wide harmonised enforcement project coordinated by the ECHA Forum for exchange of information on enforcement (the Forum)
SCL	Specific Concentration Limits
SDS	Safety data sheets
SME	Small and Medium Size Enterprise
SVHC	Substance of very high concern
WG	Working group of the Forum

1. Executive summary

REF-11 was conducted in 2023 following the coming into force of Regulation (EU) 2020/878 that amended regulation (EU) 1907/2006 (REACH annex II). The new Regulation introduced new subsections to some of the sections of SDS. Information on nanoforms, endocrine disrupting properties of substances, SCL/ATE/M-factors, mixtures' UFI codes are now all required to be provided in the SDS as appropriate. In addition to the elaboration on the required information in different sections of the SDS, the conditions of use of substances under authorisation are also required as relevant. These changes necessitated revision of all SDS for substances/mixtures placed in EU/EEA market. The primary objective of the project was, thus, to control the extent of compliance with these new requirements. A secondary aspect was to determine the plausibility/correctness of the information in the SDS with regard to classification, risk management measures, and content coherence.

The project was conducted in 28 MS with a total of 2528 substances/mixtures SDS controlled. 95% (2412) were actively provided with 2095 of the 2412 SDS (87%) found to be in accordance with new Regulation (EU) 2020/878. For 81% of these SDS (1956), the suppliers have procedures for proactively sending updated versions of the SDS to customers from the previous12 months. Altogether, there were 1006 SDS from Distributors, 664 from Downstream Users , 714 from Manufacturers and 144 from Importers, where 1593 SDS were from Small and Medium Sized Enterprises (SME).

The primary control of the SDS was completeness check, that is, the inspectors controlled that all the required information was provided in the SDS. A secondary control which individual inspectors were encouraged to conduct was to assess the quality of the information provided and determine if it complies with the content requirements and is correct and if there is coherence between the different subsections. Taking all that into consideration and the competence of different inspectors from different authorities, a non-compliance rate of 35% was reported. This was better than the non-compliance reported in earlier projects[1]. However, this lower non-compliance rate should be taken cautiously and be understood from the context of the project's overall primary goal.

In the new Regulation (EU) 2020/878, there are some new requirements to provide information such as nanoforms present in the substance/mixtures and endocrine disruption (ED) properties. For SDS where information on nanoforms was required, in 56 of 84 (67%) the information was not provided in the relevant subsections. For ED, out of 130 SDSs that covered substances or mixtures considered to have ED properties, 68 SDS (52%) contained the information required in the relevant subsections.

There is also a new obligation to provide other substance specific information such as specific concentration limits (SCL), acute toxicity estimate (ATE), environment multiplication factor (M-factor). Where provision of such new information was necessary, with regard to ATE, 680 (65%) of 1049 SDS in which ATE were to be included fulfilled this requirement. SCLs were present in 839 of 1029 SDSs (82%), M-factors in 693 of 876 SDSs (79%). Information on the authorisation, including conditions and monitoring arrangements relevant for downstream users, was provided in 190 (84%) of 225 SDS in subsection 15.1, whereas authorisation number required in

[1] A general overview of the compliance levels of SDS through different projects is provided in Annex II.

subsection 2.1 was provided in 73 SDS (32%).

2. Introduction

2.1. Background

Following the revision of Regulation (EU) 2015/830 (REACH Annex II) by the EU Commission and updating the regulation to correspond to the UNGHS 6th and 7th revisions, the new Regulation (EU) 2020/878 came into force in January 2020. With a two years transition period, the new Regulation (EU) 2020/878 became effective 1st January 2023.

The new regulation provided for significant change in the content of safety data sheets (SDS) with introduction of some new subsections and detailing on the information to be provided under several sections/subsections. With the new subsections and the elaborated changes in information requirements, it was necessary that suppliers update the SDS for the substances and mixtures that they place on the EU/EEA market.

Generally, all SDS had to be reviewed and updated as appropriate. There was, therefore, following the envisaged suppliers' SDS update exercise, a need to control whether the new requirements were taken on board as stipulated. Several legal requirements were considered necessary to be controlled and subsequently enforced with a harmonised approach across EU/EEA.

2.2. Objectives of the project

The main objective of the 11th REACH-En-Force (REF-11) project of the Forum for Exchange of Information on Enforcement (Forum) was, thus, to assess whether relevant dutyholders had updated the SDS according to the new requirements. The major changes in information requirements were inclusion of several new subsections, provision where relevant of information on nanomaterials, on substances with endocrine disrupting properties, UFI codes, SCL/ATE/M-factors, elaborated details of physical and chemical properties and additional transport information.

Other changes covered the provision of the conditions of use for substances of very high concern and mixtures containing such substances as provided in the authorisation decision, and a few other lesser changes in other respects.

A secondary objective was inspectors' own evaluation of the plausibility/correctness of the information provided with regard to classification, recommended risk management measures, and coherence of content.

The following project outcomes were foreseen:

- Improved quality of the information in the SDS in the supply chain.
- Increased awareness of the new Annex II requirements.
- Cooperation with related enforcement networks and authorities.
- Exchange of best enforcement practice with NEAs of the participating countries.
- Harmonised enforcement approach.
- Increased cooperation between NEAs of the countries participating in the project.

- Assessment of the size and scale of the issue of compliance with the provisions investigated in the project. A better understanding of the problematic areas will be useful for NEAs to develop and plan future enforcement activities.

2.3. Project performance

Participating MS had the prerogative to decide on the number of inspections conducted in their country as well as the number of SDS and type of substances or mixtures to be targeted. The participating inspectors followed the methodology recommended in the project manual and used the online questionnaire provided in the EU Survey tool.

The project targeted suppliers that place substances and mixtures on the market, including manufacturers, importers, formulators, online suppliers, distributors, wholesalers, and retailers, focusing especially on manufacturers, importers and the formulators of mixtures who are the main dutyholders on supply of SDS. Inspectors could also obtain SDS from professional or industrial end-users of substances or mixtures as follow-up of SDS suppliers' duty to provide updated versions when major changes in SDS content are implemented.

The operational phase of the project ran from January to December 2023. The participating countries were supported during the operational phase by the Forum working group REF-11.

3. Results

3.1. General overview

The results of the harmonised enforcement project coordinated by the Forum REF-11 on SDS are given in the following sections.

3.2. Participating countries and number of SDS inspected.

28 countries participated in the REF-11 enforcement project. MS checked 1336 SDS during an on-site inspection and 1192 SDS via desktop inspection.

Each of the participating countries investigated a varying number of SDS (Figure 1).

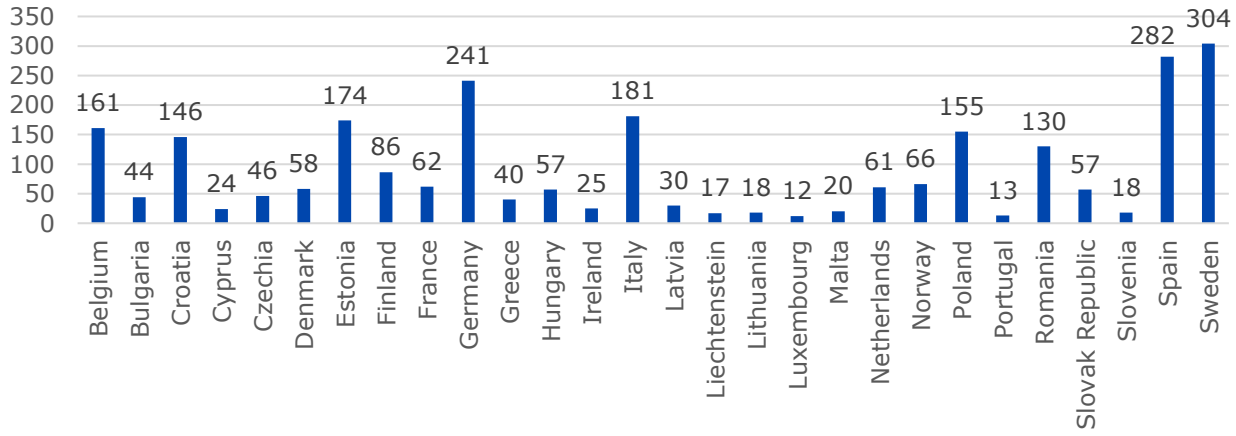

Figure 1. Number of SDS checked in participating countries.

3.3. Size and type of companies inspected.

The inspectors checked SDS in small and medium size enterprises (SME), in companies that do not correspond with the definition of SME and in companies where the size was not known as it is indicated in table 1.

Table 1. Number of SDS checked per size of company.

According to Commission Recommendation 2003/361/EC, the company qualifies as:	Total
Not SME	686
SME	1593
Unknown	249
Grand Total	**2528**

The highest proportion of SDS (63%) were checked in SME (Figure 2).

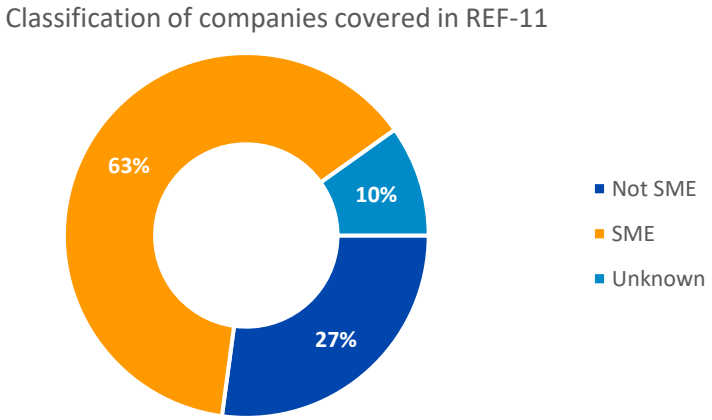

Figure 2. Percentage of SDS checked in different types of enterprises.

The project targeted the following categories of duthyholders: distributors, downstream users, importers and manufacturers. The total number of SDS checked in the different types of companies is indicated in table 2.

Table 2. Distribution of SDS checked per category of dutyholder in participating MS.

Participating country	Distributor	Downstream User	Importer	Manufacturer	Total
Belgium	76	51	17	17	161
Bulgaria	15	16	1	12	44
Croatia	49	50	8	39	146
Cyprus		24			24
Czechia	21	24	1		46
Denmark	27			31	58
Estonia	126	39	4	5	174
Finland	40	10		36	86
France	17	8		37	62
Germany	53	44	13	131	241
Greece	9	19	8	4	40
Hungary	25	7	4	21	57
Ireland	14	1	5	5	25
Italy	53	58	3	67	181
Latvia	18	7	2	3	30
Liechtenstein			2	15	17
Lithuania	14	3	1		18
Luxembourg	5		7		12
Malta			20		20
Netherlands	8	21	8	24	61
Norway	47	9	5	5	66
Poland	32	51	10	62	155
Portugal		1		12	13
Romania	38	60	15	17	130
Slovak Republic	31		2	24	57
Slovenia	16			2	18

Spain	72	81	1	128	282
Sweden	200	80	7	17	304
Grand Total	**1006**	**664**	**144**	**714**	**2528**

The company names, substance / mixture names and all the other identifiers of the non-compliant SDS were not reported for this project as they are not needed for the analysis of the aggregated results.

3.4. Analysis of the most relevant aspects of the inspected requirements

3.4.1. Does the supplier provide the recipient of chemicals with an SDS (Q.2.1)?

Every supplier of hazardous substances or mixtures is obliged to provide the recipient with a SDS according to the provisions of REACH Article 31.1. (substances and mixtures) and REACH Article 31.3 (mixtures which do not meet the criteria for classification as hazardous). Out of the 2528 SDS controlled in REF-11, 2412 SDS (95%) were provided by suppliers to recipients. The level of compliance with this requirement identified in the project are indicated in Figure 3.

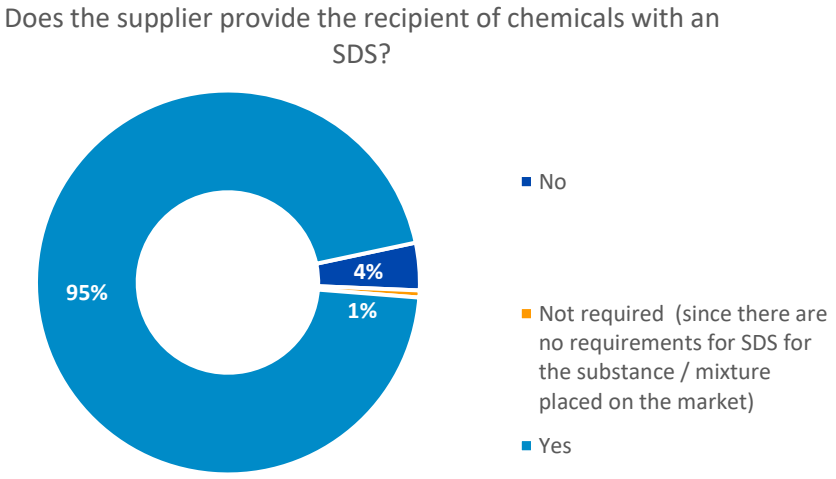

Figure 3. Level of compliance regarding the obligation to provide an SDS.

The obligation to immediately update SDS and provide them to all recipients of the last 12 months applies as soon as new information becomes available that may affect the risk management measures, new information on hazards becomes available, an authorisation has been granted or refused or a restriction has been imposed.

For the required SDS identified above, inspectors checked whether procedures are in place to

provide updated SDS to recipients of the last 12 months if Article 31.9 applies. This was fulfilled for 1956 SDS. The percentage of reviewed SDS satisfying this requirement is shown in Figure 4.

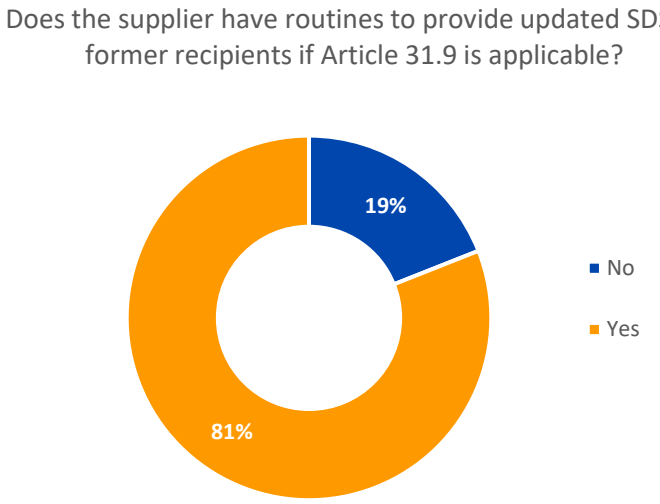

Figure 4. Percentage of SDS for which the suppliers have procedures in place to update the SDS.

3.4.2. Does the SDS checked comply with the new format required by Regulation (EU) 2020/878 (Q.2.3)?

For the SDS provided, it was checked whether the SDS complied with the new format introduced by Regulation (EU) 2020/878. 2095 of the SDS which were reviewed complied with this requirement. The remaining SDS did not comply yet with the requirements that have been mandatory since 1 January 2023. The percentage of reviewed SDS satisfying this requirement is shown in Figure 5.

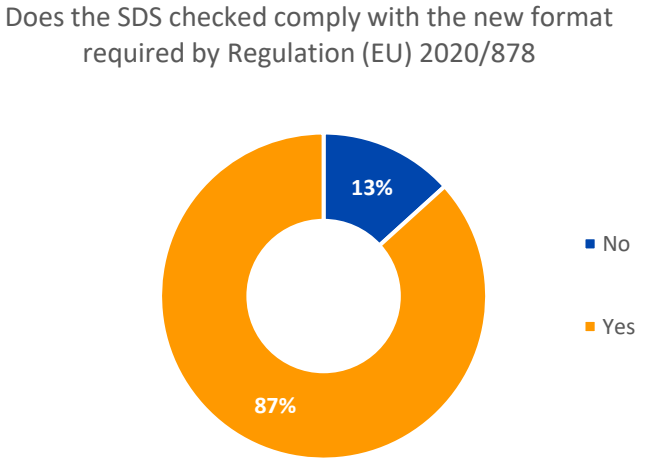

Figure 5. Percentage of SDS provided with the format required by Regulation (EU) 2020/878.

The SDS in the current format were subject to an in-depth review (see 3.4.3 to 3.5).

3.4.3. SCL, ATE, M-factors (Q.3.6)

Specific concentration limits (SCL), multiplication factors for acute and chronic aquatic hazards (M-factors) and acute toxicity estimates (ATE) according to Regulation (EC) 1272/2008 (CLP Regulation) are important for the safe use of substances and mixtures and have therefore been included in Annex II of the REACH Regulation as a new requirement for the substances to be mentioned in subsection 3.1 or 3.2 of the SDS. This information is mandatory if available (e.g. in Annex VI of the CLP Regulation or the ECHA Classification and Labelling Inventory).

2092 SDS were reviewed with regard to this new substance-specific information in section 3 of the SDS. Regarding ATE, 680 (65%) of 1049 SDS in which ATE were to be included fulfilled this requirement. SCL were present in 839 of 1029 SDS (82%), M-factors in 693 of 876 SDS (79%). Figures 6, 7 and 8 show the percentage of relevant SDS satisfying these requirements.

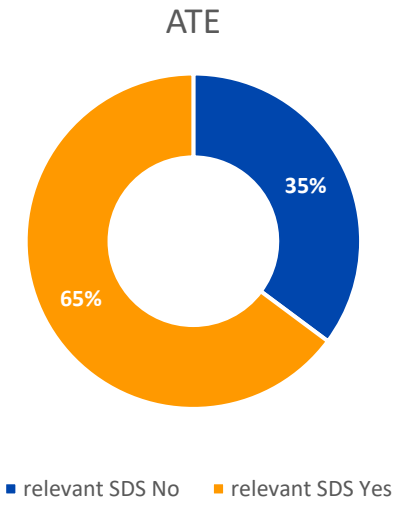

Figure 6. Percentage of SDS satisfying ATE requirement.

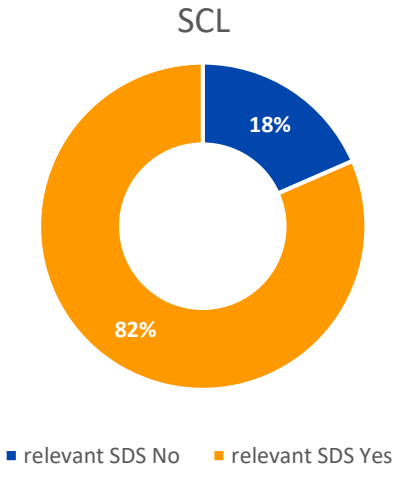

Figure 7. Percentage of SDS satisfying SCL requirement

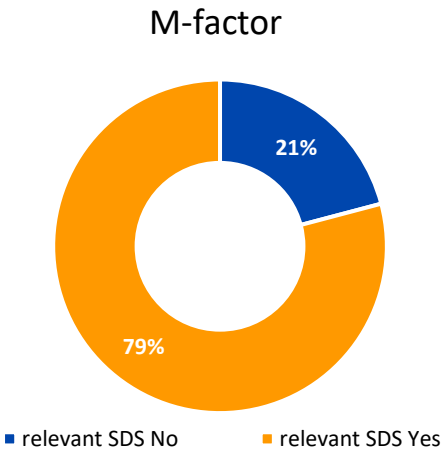

Figure 8. Percentage of SDS satisfying M-factor requirement.

3.4.4. Authorisations (Q.3.4 and Q.13)

SDS containing a substance subject to authorisation must include the authorisation numbers of the relevant authorised uses in the supply chain and information on the authorisation, including the conditions and monitoring arrangements imposed on downstream users.

225 SDS were identified as requiring relevant information on authorisation in Section 15.1. Of these, 73 SDS (32%) included the authorisation numbers in the relevant section of the SDS.

Information on the authorisation, including conditions and monitoring arrangements relevant for downstream users, was provided on 190 (84%) of 225 SDS in subsection 15.1 (Figure 9).

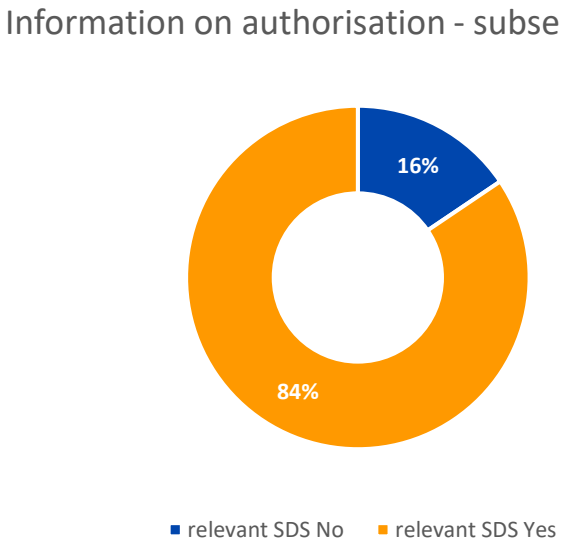

Figure 9. Percentage of SDS satisfying information requirements on authorisations in subsection 15.1 of the SDS.

3.4.5. Physical-chemical properties (Q.3.9 and Q.3.10)

According to Annex II of Commission Regulation (EU) 2020/878, SDS shall include relevant information on basic physical-chemical properties listed in section 9.1 in the annex. If a given property is not applicable or if information is not available this shall be indicated, giving the reason where possible.

In addition to the information in section 9.1, other information on physical and chemical parameters relevant for the safe use of the substance or mixture shall be indicated as described in section 9.2.

2092 SDS were inspected for relevant data provided in section 9.1 and 9.2 and the results categorised as YES or NO. Statements that a given property listed in section 9.1 was not applicable or that information on a particular property was not available was also considered "relevant data" with or without a reason for the statement.

Out of the 2092 inspected documents, 1710 SDS were considered to contain relevant information in section 9.1 whereas 382 SDS did not contain the relevant information. With regard to section 9.2, 1575 SDS were considered to include the relevant information whereas 517 SDS were considered not to include the information relevant for the safe use of the substance or mixture.

It has not been evaluated whether there is a difference in compliance between SDS for substances and mixtures.

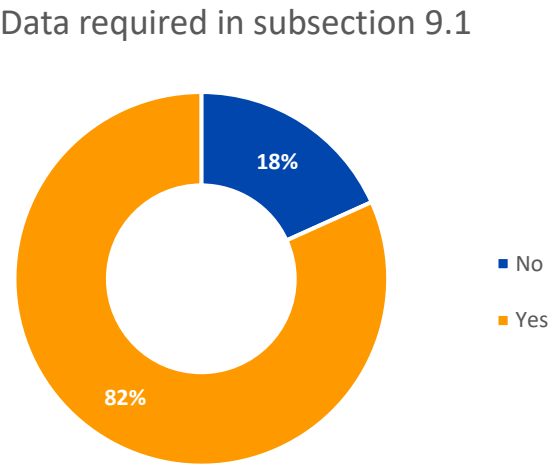

Figure 10. Percentage of SDS satisfying information requirements on subsection 9.1.

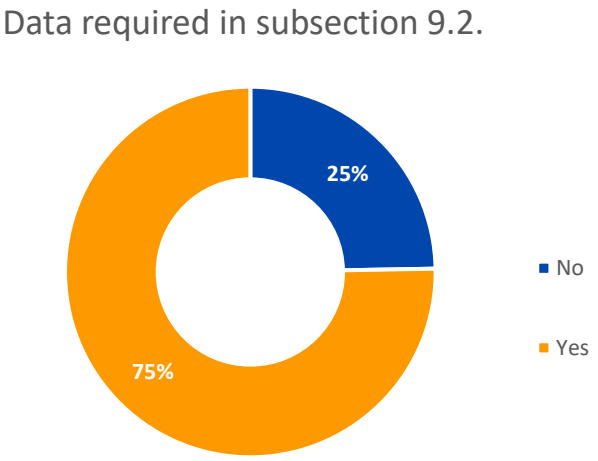

Figure 11. Percentage of SDS satisfying information requirements on subsection 9.2.

3.4.6. Nanoforms (Q.3.14)

Commission Regulation (EU) 2020/878 amended Annex II also by introducing specific requirements regarding substances in nanoform. Subsections 1.1, 3.1, 3.2 and section 9 require mentioning whether nanoforms and which different nanoforms are covered and link the relevant safety information to each of these nanoforms.

When selecting substances or mixtures to inspect in the project, nanoform was one of the suggested criteria. Substances could be found searching e.g. REACH registrations. In the project, 84 SDS for substances in nanoform or mixtures with substances in nanoform present were inspected. Out of these, 56 SDS did not contain the information required in subsections 1.1, 3.1/ 3.2 and section 9 (Figure 12).

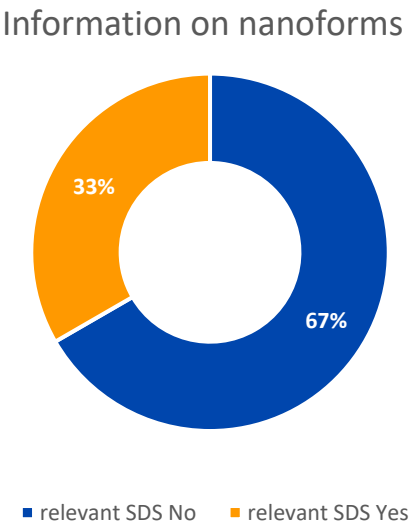

Figure 12. Percentage of SDS satisfying information requirements on nanoforms.

3.4.7. Endocrine disrupting properties (Q.3.15)

2092 SDS documents were inspected for relevant data provided on substances with endocrine disrupting properties in all the relevant subsections, i.e. 2.3, 3.2, 11.2 and 12.6.

1962 SDS were considered to cover substances or mixtures not fulfilling the criteria for having endocrine disrupting properties. 130 SDS covered substances or mixtures considered to have endocrine disrupting properties and of these, 68 SDS contained all the information required in the relevant subsections.

It has not been evaluated whether there is a difference in compliance between SDS for substances with endocrine disrupting properties and mixtures containing such substances at a concentration equal to or greater than 0.1 % by weight.

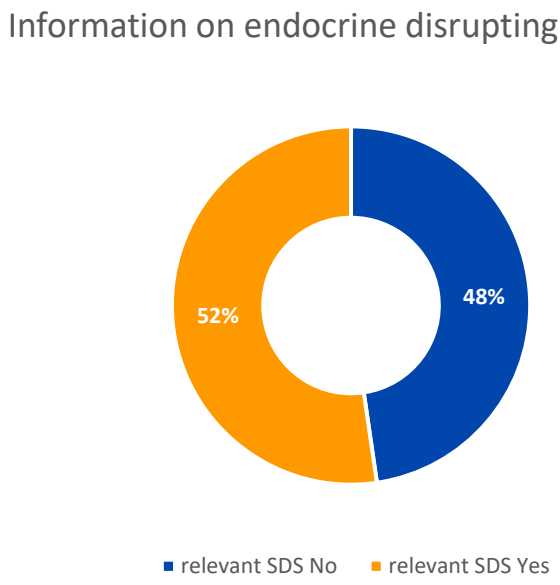

Figure 13. Percentage of SDS satisfying information requirements on endocrine disrupting properties.

3.5. Additional relevant considerations about SDS quality controls (Q.3.16)

For 1883 of 2092 SDS checked, the inspectors gave an indication of quality issues encountered in the SDS. Of these, 513 SDS were reported as having incorrect or implausible information. Table 3 indicates the number and percentage of SDS with incorrect or implausible information per section of the SDS. Quality deficiencies in sections 3, 8 and 9 were mentioned most frequently. Also, deficiencies in sections 1 and 2 were frequently found in SDS.

Table 3. Sum of sections of the SDS deemed incorrect or implausible.

Section of the SDS	Sum of SDS with incorrect information or not plausible	% of SDS with incorrect information or not plausible in SDS with quality issues (513)
1	157	31
2	122	24
3	240	47
4	27	5
5	24	5
6	28	6
7	23	5
8	249	49
9	182	36
10	21	4
11	76	15
12	47	9
13	22	4
14	25	5
15	68	13
16	43	8

In 270 of the 513 cases, where SDS information was found to be incorrect or implausible, clarification was provided. Based on this information, it is possible to show in which subsections of the SDS critical issues were encountered and identified.

Table 4. Subsections of SDS with more than 10 non-conformities found.

Subsection of the SDS	Main issues identified
1.1. Product identifier	• Wrong product identifier • UFI missing • UFI indicated in subsection 2.2 and not in subsection 1.1.
1.2 - Relevant identified uses of the substance or mixture and uses advised against	• Lacking identified uses for recipients • Wrong uses identified • Use advised against are not indicated
1.3 - Details of the supplier of the SDS	• Lacking full address and telephone number of the supplier • Lacking email address for a competent person responsible for the SDS
1.4- Emergency telephone number	• Emergency telephone number absent or incorrect • Lacking telephone number of official advisory body
2.1 - Classification of the substance or mixture	• Incorrect classification • Incomplete classification • Classification of mixture not consistent with the ingredients and their classification
2.2 - Label elements	• Missing or incorrect hazard statement • Missing or incorrect precautionary statement • Missing or incorrect pictogram
3.1 - Substances	• Lacking ATE, M-factor or SCL • Classification incorrect • For a mixture, subsection 3.1 was filled in instead of subsection 3.2.
3.2 - Mixtures	• Lacking ATE, M-factor or SCL • Classification of the ingredients of the mixture do not comply with CLP Regulation • Not all necessary substances are listed among the ingredients of the mixture

6.1 - Personal precautions, protective equipment and emergency procedures	• Lacking PPE characteristics for non-emergency personnel • Lacking advice or not clear if information is for non-emergency personnel or for emergency responders
8.1 - Control parameters	• OEL are included but their legal basis is not correctly provided • OEL missing or wrong (e.g. wrong value or from a different country)
8.2 - Exposure controls	• Lack or insufficient information on PPE • Insufficient information on gloves: Type of material, thickness, breakthrough • Lack or insufficient information on the type of respirators • Lack of information on environmental exposure controls
9.1 - Information on basic physical and chemical properties	• Absence of information requested without any justification • Absence of available information • Absence of information on the characteristics of particles
9.2 - Other information	• Lacking necessary information • Information inconsistent with the ingredients indicated in the SDS • The subsection 9.2 is missing
11.1 - Information on hazard classes as defined in Regulation (EC) No 1272/2008	• Missing toxicology data • Toxicology data in contradiction with classification
15.1 - Safety, health and environmental regulations/legislation specific for the substance or mixture	• In many cases no information or incomplete information was given on relevant national legislation • In some cases, incomplete information was given on relevant EU legislation • In some cases, no information or incorrect information was given on Restriction or Authorisation

16 - Other information	• Incomplete legend to abbreviations and acronyms used in the SDS • Lacking indication of where changes have been made to the previous version of the SDS • Missing, in the case of mixtures, an indication of which of the methods of evaluating information referred to in Article 9 of Regulation (EC) No 1272/2008 was used for the purpose of classification

3.6. Conclusions on compliance based on the analysis of subsection 4.1. in the section IV of the project questionnaire

This section of the project report reflects the opinion of the inspectors on the conformity of the SDS. Not all the sections of the SDS were checked and hence the ratios of non-compliance refer to the number of SDS where the inspector reached a conclusion on the non-conformity.

In this section, the results related to the compliance level with REACH Article 31 and 32 obligations subject to the REF-11 project are shown. The results show only the SDS supplier non-compliance with the REACH obligations. It is important to know that the inspection of each SDS document was considered as one case.

The inspectors summarised their findings in reference to the various requirements of Articles 31 and 32 REACH that were subject of the REF-11 project. It is possible that in this process other aspects were also considered by the inspectors that were not covered by the questionnaire. This may contribute to the differences in the non-compliance-levels in comparison to the outcome of the checks regarding information obligations in the supply chain and details regarding the quality of information in the SDS (section II and III of the questionnaire).

3.6.1. Compliance level of Article 31.1 and 31.3 of the REACH Regulation (provision of SDS)

The results of this part show the compliance with the relevant requirements set out in article 31.1 and 31.3 of the REACH Regulation, i.e. requirement to provide SDS.

Table 5. Results related to the compliance level with article 31.1 and 31.3.

Was the SDS concluded in compliance with the requirements?	Number of SDS
Yes	*1492*
No duties	*26*
No	*795*
Grand Total	*2313*

Figure 14 shows the total compliance rate in percentages. The SDS with no duties related to article 31.1 and article 31.3 were not integrated in the Figure 14. 65 % of the SDS where the SDS provision requirement applied were concluded to be compliant.

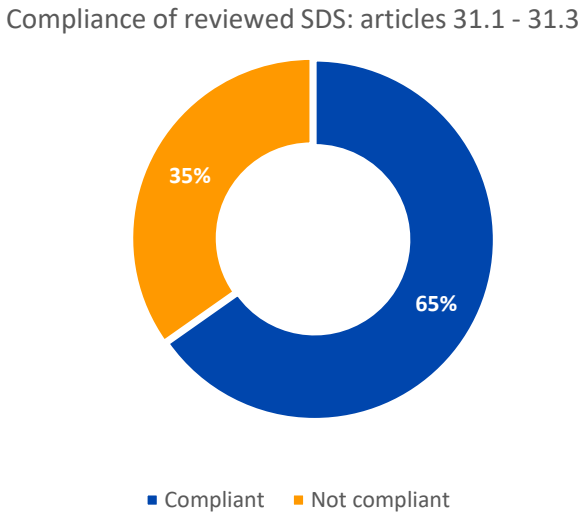

Figure 14. Compliance rate articles 31.1 and 31.3.

3.6.2. Compliance level of Article 31.5 of the REACH Regulation (language requirements)

This part describes the inspection results of the inspected SDS related to the relevant requirements set out in article 31.5 of the REACH Regulation, i.e. language requirements (Table 6).

Table 6. Results related to the compliance level with article 31.5.

Was the SDS concluded in compliance with the requirements?	Number of SDS
Yes	*1884*
No	*102*
Grand Total	*1986*

Figure 15 shows the total compliance rate of the SDS in percentages. 95 % of the SDS where the requirements applied were concluded to be compliant with the language requirements.

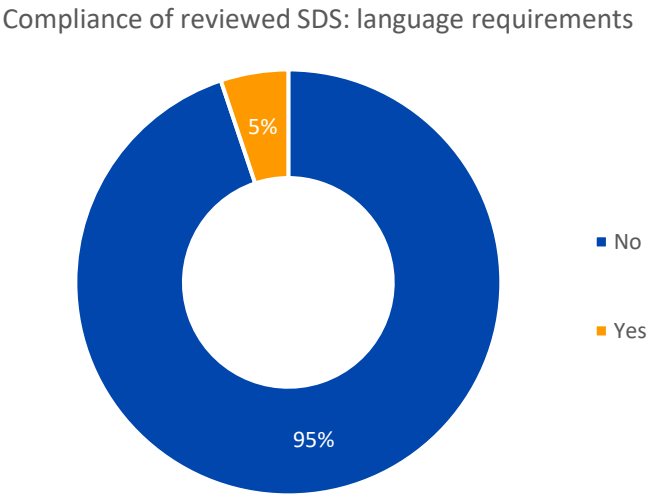

Figure 15. Compliance rate article 31.5 – language requirements.

3.6.3. Article 31.7 of the REACH Regulation (Exposure Scenarios)

This part describes the inspection results related to article 31.7 of the REACH Regulation, i.e. provision of Exposure Scenarios (ES) or incorporation of ES information in SDS.

Table 7. Results related to the compliance level with article 31.7.

Was the SDS concluded in compliance with the requirements?	Number of SDS
Yes	*685*
No duties (in cases where ES is not required)	*1152*
No	*152*
Grand Total	*1989*

Figure 16 shows the total compliance rate of the SDS in percentages. 82 % of the SDS where the requirements applied were concluded to be compliant with the ES requirements checked during the inspections.

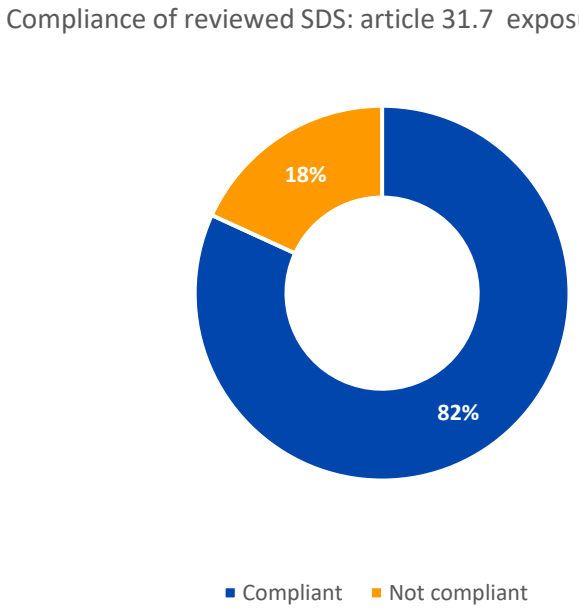

Figure 16. Compliance rate article 31.7 – Exposure Scenario annexed or incorporated.

3.6.4. Updating SDS / Provision of SDS

This part describes the inspection results related to articles 31.9 of the REACH Regulation, i.e. the update and provision of revised SDS by the supplier (Table 8).

Table 8. Results related to the compliance level with article 31.9.

Was the SDS concluded in compliance with the requirements?	Number of SDS
Yes	***1819***
No	***470***
Grand total	***2289***

Figure 17 shows the total compliance rate of the SDS in percentages. 79 % of the SDS where the requirements applied were concluded to be compliant with the requirements on updating and provision of SDS.

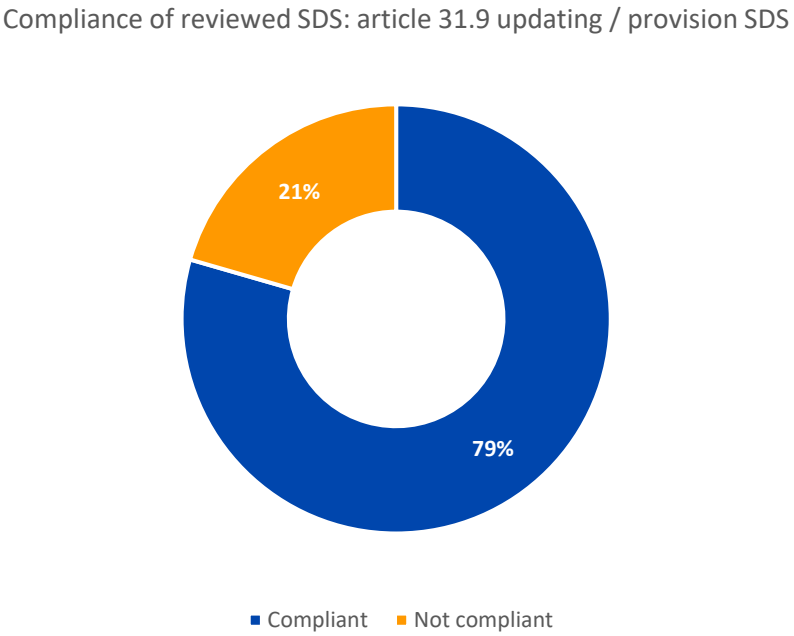

Figure 17. Compliance rate article 31.9 – Update / Provision of revised SDS.

3.6.5. Article 32 of the REACH Regulation (provision of SDS when a SDS is not required but information requirements exist)

In 14 cases, when no SDS was required, information was checked in view of verifying the conformity with article 32 of the REACH Regulation (i.e. the supplier of substances and mixtures is obliged to provide information on the registration number, authorisation, restriction or any other information on the substance that is necessary to enable the recipients to identify and apply appropriate risk management measures). Out of those, 2 cases were concluded to be non-compliant with the obligations laid down in article 32 of REACH. The total percentage of compliance related to article 32 of the REACH Regulation was 86%.

3.7. Enforcement measures

3.7.1. Enforcement action

During inspections, a total of 903 non-compliant SDS were detected for which enforcement measures were imposed by the enforcement authorities. It is important to clarify that multiple measures per case could have been taken by the enforcement authorities. Table 9 gives an overview of the enforcement measures.

The most used enforcement measure observed was the issuance of written advice (in 69 % of the cases where enforcement measures were initiated). This suggests an approach by authorities in guiding dutyholders to compliance without resorting to more severe punitive actions.

Table 9. Overview of the enforcement measures taken by inspectors (per SDS).

Enforcement measures	Number of cases
Verbal advice	12%
Written advice	69 %
Administrative order	11%
Fine	11%
Criminal complaint / handing over to public prosecutor's office	6 %
Other: (e.g. forward to other authorities)	5 %

Communication / follow-up activities

Concerning the initiated enforcement actions, there were in total 882 follow-up activities. Once the operational phase for REF-11 (1 January 2023 – 31 December 2023) was completed there were still some ongoing follow-up activities in different Member States. Table 10 shows the amount of follow up activities for the REF-11 project.

Table 10. State-of-play with the follow-up activities.

State-of-play with follow-up activity	Number of SDS
Completed	523
Ongoing	359
Grand total	882

This correlates to 59% with follow up activities being closed during the operational phase of the project.

Table 11 gives an overview of the non-compliance percentages for different REACH articles. The results show that the highest rate of non-compliance was for articles 31.1 and 31.3, which relate to the provision and compilation of the SDS. The lowest non-compliance rate came from article 31.5 which refers to the language requirements of the SDS.

Table 11. Rates of non-compliance related to specific REACH obligations.

Relevant Article	Description	% Non-compliance
Article 31.1 & 31.3	Provision of SDS according to Annex II	35
Article 31.5	Language	5
Article 31.7	Exposure scenarios	18

Article 31.9	Provision of updated SDS	21

4. Discussions, Conclusions and Recommendations

Based on the data received and its analysis, the following discussion items, conclusions and recommendations can be drawn from the project.

4.1. Discussions and Conclusions

The project discusses the following items which are categorised in different sections depending on whether they concern new requirements for SDS, quality completeness issues or enforcement actions.

4.1.1. Discussions

The discussion points turn around the main topics identified during the elaboration of the project report which are:

- Issues regarding the new requirements.
- Issues regarding the quality of the SDS and the completeness of the information in the different sections of the SDS.
- Enforcement issues.

Eight of these items are discussed in the project report.

Item 1 – Interpretation on when information on nanoform is required.

During the later part of the operational phase, there was a change in interpretation on when information on nanoform is required. FAQ ID 2015 was published at the ECHA webpage clarifying that the requirement in section 1.1. is not applicable to mixtures, and also clarifying what information is needed and when in sections 3 and 9. Updated information was sent out to the inspectors. This might have led to discrepancies in how the question was answered and uncertainties in how to interpret the result, but no conclusion can be made based on the information at hand.

Item 2 – Consistency of information on authorisation in different sections of the SDS.

84% of SDS gave information on the authorisation decision in section 15.1 when required, but only 32% indicated the corresponding authorisation number(s) under the supplemental information in section 2.2 of the SDS.

Non-compliance in relation to the authorisation number is significantly higher than in relation to the authorisation information, although the requirement to provide the authorisation number existed well before the amendment to Annex II of REACH specified the requirement in relation to the information relevant to downstream user in the authorisation decisions. It is suspected that the incorrect indication of the authorisation number in sections of the SDS other than 2.2 may have contributed to the relatively high rate of non-compliance with this requirement.

All SDS for substances or mixtures containing a substance for which an authorisation decision

has been granted should contain both elements of information, that the authorisation number corresponds to the decision in section 2.2 and the specific information of the decision that is relevant for the downstream user in the supply chain in section 15.1.

Item 3 – Compliance conclusions based on the review of limited sections of the SDS.

Several requirements including e.g. provision of information on nanoforms in substances, endocrine disrupting properties, ATE-values, SCL and M-factors are new requirements in the SDS.

The inspectors may have checked whether the information on the new requirements was provided in one or more of the subsections and made the decision on whether the SDS was compliant or not according to the outcome of subsections checked.

Item 4 – Sections of the SDS where most quality issues are identified.

Assessment of the correctness of the information in the different sections of the SDS was conducted by the inspectors as was indicated in section 3.5 above. The sections of the checked SDS that have the most quality issues are sections 1,2,3,8 and 9. The main quality issues identified in the above sections are:

- section 1: wrong product identifier, UFI absent or indicated in another section, absence or incorrect indication of identified uses and uses advised against, absence of supplier identification data, absence or incorrect indication of the emergency telephone number.
- section 2: incorrect or incomplete classification, absence or incorrect indication of H-statements or P-statements or pictograms.
- section 3: absence of the necessary ATE or M-factor(s) or SCL, incorrect classification of substances or ingredients of mixtures, the list of ingredients of the mixture is not complete as required.
- section 8: OEL missing or wrong or without legal basis, absence or insufficient information on PPE.
- section 9: absence of required data without justification, absence of available data, information inconsistent with the ingredients of the mixture, absence of subsection 9.2.

Item 5 – Interpretation of the compliance conclusion of an SDS

Article 31.1 (and Article 31.3) of REACH state that the recipient must be provided with 'an SDS drawn up in accordance with Annex II'. On the one hand, the question of non-compliance with Articles 31.1 or 31.3 may refer to the correct provision of the SDS. On the other hand, it could also be understood that any deficiency in any section of the SDS would result in it being considered non-compliant with Annex II of REACH and therefore non-compliant with Article 31.1 (or Article 31.3). As a result, the number of non-compliances identified in the SDS are reported different by the inspectors.

One uncertainty when analysing the results was when considering information required in different sections, for example, where relevant, information on nanoforms is required in sections 1, 3 and 9. However, when one finds information in one section and not in the other sections, inspectors' opinion on whether such an SDS is considered compliant or not will differ.

Item 6 – Different levels of specialisation of inspectors reviewing SDS

Concerning national competencies, it is up to each Member State to appoint the enforcement authority(-ies) in its territory. The designated enforcement authorities are responsible for different areas or may focus more explicitly on different enforcement areas. The effect of this division of responsibilities or focus may be reflected in the inspection of the SDS, where different

competencies are required to inspect the different sections. As a result, different national authorities may have checked the sections of the SDS at different levels of detail during the project, which may have affected the overall results.

Item 7 – Completeness check versus quality check of the information in SDS

The control of the SDS was primarily completeness check of the content and this was the general way to determine whether the SDS complied with the information requirement. This means that the inspectors checked how well the information was provided in the sections/subsections, that there were no empty subsections, and the extent to which the information was presented. This may have introduced some disparities in the way the inspector responded to the questions, considering the inspectors' competence based on the authority they represent.

As a secondary goal, inspectors could decide to check on the quality of the information provided in the SDS with respect to the current regulation. Where the inspector may have identified incorrect or implausible information in the SDS, or incoherence between subsections, this could also be identified as non-compliance. The results of compliance check appear to be higher than the overall number of controlled SDS. This is attributed to the different ways compliance/non-compliance was checked and counted.

Item 8 – Tools of use in certain countries facilitating sample selection

National Chemical Products registers, when available, were useful tools for selecting companies or substance/mixtures to be inspected.

4.1.2. Conclusions

General conclusion on compliance: Overall, an improvement in compliance with the distribution of SDS was observed compared to the results of previous projects. In only 4% of the cases was the obligation to provide the SDS not carried out, and just 5% of the SDS inspected were not in the appropriate language during this project. However, 13% of the SDS did not comply with the newly applicable format according to Regulation (EU) 2020/878.

Concerning further formal requirements, relatively high numbers of non-compliances were found related to the updating obligation of SDS (21%) and the absence of the necessary exposure scenarios (18%).

In addition to the formal deficiencies, issues with the content and quality of the SDS were also identified. These non-compliances concerned both the new requirements introduced by Regulation 2020/878 and the existing requirements that have been applicable for a longer period.

Opportunities for improving compliance: New information about e.g. nanoforms and endocrine disruptors in the SDS, as well as information on more physical and chemical parameters provide an improved background for safe handling of the hazardous substances and mixtures. However, the results of the inspected SDS also show that the information needs improvement with regard to quality and consistency and that more awareness on how to comply with the requirements is needed.

Sections with highest number of deficiencies: The Sections that have been identified as causing problems in the past (1,2,3,8,9) were still found to be problematic. However, some of these sections have improved in terms of completeness. In regard to sections 1, 2, 3, 8 and 9 of the SDS, the project highlighted the following main issues:

- Section 1:
  In subsection 1.1, many cases did not provide UFI codes where mandatory (or UFI was

indicated in subsection 2.2), and many cases lacked information about nanoforms (both are new requirements).

- Section 2:
  In subsection 2.2, some authorisation numbers were missing.
  In subsections 2.1 and 2.2, the classification and labelling quite often were still incorrect (checking was not mandatory).
  In subsection 2.3, many cases lacked information about endocrine-disrupting properties (new requirement).
- Section 3:
  In subsections 3.1 and 3.2, most cases did not indicate specific concentration limits (SCL, multiplication factors for acute and chronic aquatic hazards (M-factors), or acute toxicity estimates (ATE) (new requirement).
  In subsections 3.1 and 3.2, the classification quite often was still incorrect (classification of substances was not in accordance with the C&L Inventory, checking was not mandatory).
  In subsection 3.2, information about endocrine-disrupting properties was missing.
- Section 8:
  In subsection 8.1, there was a lack of information about occupational exposure limit (OEL) values or their required notations and legal basis.
  In subsection 8.2, the information regarding Personal Protective Equipment (PPE) was incomplete (e.g., missing information about glove thickness, standard, and breakthrough time).
- Section 9:
  In subsection 9.1, information about the available data is absent. Information about nanoforms was missing (new requirement).
  In subsection 9.2, there was a lack of information regarding physical hazard classes or other safety characteristics (new requirement).

4.2. Recommendations

Based on the findings of the project and the conclusions drawn, the following recommendations are addressed to the different actors with certain level of responsibility in the implementation of the legislation related to this project (dutyholders, ECHA, the European Commission, the Member State Competent Authorities, the national Helpdesks, the NEAs and the Forum).

4.2.1. Recommendations to dutyholders

- Those responsible are encouraged to ensure that the latest requirements are applied and in general that the consistency of all the information throughout the document is assured.

- It is recommended that the dutyholders have a procedure to assess that substances and mixtures which are being supplied to them will be supplied together with the latest version of the SDS and that SDS comply with the relevant requirements of article 31 of the REACH Regulation.

- It is strongly recommended that the dutyholders work to improve their understanding of the requirements related to the SDS document. This can be achieved by consulting Q&A, guidance documents and information provided by sector organisations.

- It is recommended that manufacturers, importers and formulators consider the uses of the substance and then extract the relevant information needed for downstream users. For example, they should check whether the required information on authorisation is provided.

- It is also recommended that industry associations pay attention and help raise awareness of the legal duties related to the requirements for the SDS documents included in this project.

4.2.2. Recommendations to ECHA/COM

Based on the finding of this project, ECHA is encouraged to:

- Further develop Q&A focusing on sections 1, 2, 3, 8 and 9 where issues continue to be identified (see conclusion 3).
- Raise awareness among stakeholders, in particular SME.
- Provide support to Forum for broader issues that may be open to enforcement interpretation and require a harmonised approach on the EU level, for future SDS projects, for training etc.

4.2.3. Recommendations to the National Enforcement Authorities (NEA)

- The NEA should continue to do controls on the quality of the SDS including new areas of SDS, both formal completeness check and in-depth controls of the compliance of SDS are relevant for promoting the quality of the information in the supply chain.
- Organising awareness raising measures on the new SDS requirements for improving the knowledge of all stakeholders, particularly those responsible for compilation of SDS, would result in greater compliance with the regulations. The awareness raising campaigns should be oriented to improve the quality of SDS in general, such as the coherence of content between different heading of the SDS (e.g. address the issues highlighted in conclusions 5 and 7 in chapter 4.1.1.).
- Inspectors are encouraged to utilize the EUON list of substances in nanoform as a starting point when looking for nanoforms in enforcement of substance/mixtures including nanoforms (Search for nanomaterials - European Observatory for Nanomaterials (europa.eu)) and when relevant, also make use of the list of substances undergoing an ED assessment (Endocrine disruptor assessment list - ECHA (europa.eu))
- A new REF project concerning SDS should be considered in the future, to check if the quality of the SDS is further improved in relation to the legislation.

4.2.4. Recommendations to Forum

The following recommendation is addressed to the Forum.

- Execute a follow-up project on SDS in the future to monitor the evolution of the requirements controlled in the REF-11 project.

5. Annexes

5.1. Annex I - Project questionnaire

Please fill in **one questionnaire per inspected SDS**

The questionnaire is divided into six sections:

- **Section 0** – General information about the inspection.
- **Section I** – General information about the company responsible for SDS checked (supplier)
- **Section II** - Details regarding information obligations in the Supply Chain
- **Section III** - Details regarding the quality of the information in the SDS (Annex II REACH Regulation (EU) 2020/878)
  - **Section IIIa** – Nanoforms
  - **Section IIIb** – Endocrine disrupting properties
  - **Section IIIc** – Quality issues encountered
- **Section IV** - Summary/Enforcement actions/Follow-up Action
- **Section V** - Informal comments (free text)

The questionnaire is intended only for use by enforcement authorities and **shall not be distributed to companies inspected.**

The information requested in questions 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 1.1, 1.2, 1.3, 1.4 is only for internal use in the NEA or MS (e.g., in case you need to forward the questionnaire to another NEA for assistance). In case this information is not removed from the online version of the questionnaire (EU Survey tool) before the electronic submission of the form, these data will be available to the ECHA Focal point in the HET and later on to the NC. Therefore, please verify internally within your authority in advance if you are authorised to send any information requested in these questions and remove it from the questionnaire before sending it to the ECHA Focal point if you do not want this information to be available to other parties.

Forum REF 11
Safety Data Sheets
QUESTIONNAIRE

Section 0: General information about the inspection

0.1 Participating country:	
0.2 Name of the authority: **0.3** Inspector: **0.4** Telephone (inspector): **0.5** E-mail address (inspector): **0.6** Date of inspection: **0.7** File reference	This data is only for internal use
0.8 Type of inspection The SDS or Article 32 information has been obtained ◯ during an on-site inspection ◯ via desktop inspection only	

Section I – General information about the company responsible for SDS checked (supplier)

1.1 Name of company: **1.2** Name of contact person: **1.3** Telephone of contact person: **1.4** Contact person's role:	This data is only for internal use
1.5 Company NACE code:	
1.6 According to Commission Recommendation 2003/361/EC, the company qualifies as: ◯ SME ◯ Not SME ◯ Unknown SME: <250 employees and ≤50 million euro annual turnover	
1.7 Role of the company responsible for the SDS or Article 32 information checked: ◯ Downstream User ◯ Distributor ◯ Manufacturer	Note: Specify role in connection with SDS or article 32-information checked.

◯ Importer	

Section II – Details regarding information obligations in the Supply Chain

2.1 Does the supplier provide the recipient of chemicals with an SDS? ◯ Yes (go to 2.3) ◯ No (go to section IV) ◯ Not required (go to 2.2) (since there are no requirements for SDS for the substance / mixture placed on the market) If the answer to 2.1 is yes, does the supplier have routines to provide updated SDS to former recipients if Article 31.9 is applicable? ◯ Yes ◯ No	Note: If an SDS is required and not actively provided, the answer to this question is NO. This is a non-compliance.
2.2 If an SDS is not required, does the supplier provide the information required in Article 32? ◯ Yes ◯ No	Note: Mandatory only if SDS is not required. After answering this question, please proceed with section IV of the Questionnaire.
2.3 Does the SDS checked comply with the new format required by Regulation (EU) 2020/878? ◯ Yes ◯ No	Note: If the answer to this question is NO, please proceed with section IV of the Questionnaire. Please note, only SDS in the new format or provided to recipients of the substance/mixture after 31.12.2022 are within the scope of the project.
2.4 Are exposure scenarios annexed to the SDS/incorporated in the SDS? ◯ Yes ◯ No ◯ Not required (since there is no requirement for ES to be placed in annex/incorporated to SDS)	
2.5 Does the SDS and, if required, exposure scenarios, fulfil the requirements of Article 31 paragraph 5 regarding the language? ◯ Yes	Note: The exposure scenarios (if required) shall also be supplied in an official language of the

◯ No	Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide otherwise.

Section III – Details regarding the quality of the information in the SDS (Annex II REACH as amended by Regulation (EU) 2020/878) obligations in the Supply Chain

SDS SECTION 1	
3.1 For mixtures: If the Unique Formula Identifier (UFI) is indicated in the SDS, is it provided in the subsection 1.1? ◯ Yes ◯ No ◯ UFI not provided in SDS	Note: If an UFI is provided in the SDS, it must be indicated in section 1.1. The inspector can choose to check the requirement of an UFI according to Annex VIII CLP, though CLP is not part of the project.
3.2 Are the contact details of the supplier of the SDS specified in the subsection 1.3? Supplier here is referring to the last supplier supplying to the user. ◯ Yes ◯ No	Note: Mandatory. It may be necessary to indicate more than one supplier. A distributor is also a supplier and needs to add its contact details.
SDS SECTION 2	
3.3 Is the classification of the substance or mixture, which results from the application of the classification criteria in CLP, provided in subsection 2.1? ◯ Yes ◯ No	Note: Required here is to check if the overall substance/mixture classification is provided, e.g., Acute Toxicity – Inhalation cat. 3; Skin corrosion cat. 1B (including H-Statements) The inspector can choose to check the correctness of the classification. CLP is not part of the project.
3.4 Does the supplemental information in subsection 2.2 indicate the authorisation number(s) of the relevant authorisation decision? ◯ Yes	

◯ No ◯ Not required (no substance subject to authorisation present or authorisation process on-going)	
SDS SECTION 3	
3.5 For mixtures, is the CLP classification of each ingredient substance given in subsection in 3.2 as required in regulation 2020/878 (Annex II to REACH) ◯ Yes ◯ No	Note: Required here is to check if classification (abbreviated) and H-statements for the substances are provided, e.g., Acute Tox. 1; H301, Skin Irrit. 2; H319, Aq. Chronic 1; H410. The inspector can choose to check the correctness of the classification of the substances. CLP is not part of the project.
3.6 Are following parameter provided for the respective substances in section 3? ATE: ◯ Yes ◯ No ◯ Not required (not available) SCL: ◯ Yes ◯ No ◯ Not required (not available) M-factor: ◯ Yes ◯ No ◯ Not required (not available)	ATE: Required for Acute Tox. SCL: Mostly for acids/bases and their salts M-Factors: For Aquatic Acute and Aquatic Chronic.
SDS SECTION 8	
3.7 Are relevant Occupational Exposure Limit (OEL) values including any notations and their legal basis provided in subsection 8.1? OEL values: ◯ Yes ◯ No ◯ Not required (substances have no OEL established)	Experiences show that in most cases, OEL values are provided but not the notations and the legal basis.

Notations and legal basis: ◯ Yes ◯ No ◯ Not required (substances have no OEL established)	
3.8 Does the information on Personal Protective Equipment in subsection 8.2 indicate full detailed specifications of equipment that provides adequate and suitable protection? ◯ Yes ◯ No	Note: If the information is not fully provided according to the requirements in regulation 2020/878 (amended annex II), the answer is "NO"
SDS SECTION 9	
3.9 Is all relevant data required for subsection 9.1 provided? ◯ Yes ◯ No	The inspector should refer to the Regulation 2020/878 to determine what is required in this subsection
3.10 Is information in subsection 9.2 with regard to physical hazard classes or other safety characteristics provided? ◯ Yes ◯ No	The inspector should refer to the Regulation 2020/878 to determine what is required in this subsection.
SDS SECTION 10	
3.11 Is the information on desensitised explosives in subsections 10.2 and 10.4 provided? ◯ Yes ◯ No ◯ Not required (Not relevant)	The inspector should refer to the Regulation 2020/878 to determine what is required in these subsections with reference to desensitised explosives.
SDS SECTION 14	
3.12 Is the transport information in subsections 14.2 and 14.7 provided as required in regulation 2020/878? ◯ Yes ◯ No ◯ Not required (Not relevant)	The inspector should refer to the Regulation 2020/878 to determine what is required in these subsections
SDS SECTION 15	
3.13 Is the information on authorisation including conditions and	

monitoring arrangements imposed by the respective decisions provided in subsection 15.1? ◯ Yes ◯ No ◯ Not required (no substance subject to authorisation)	

Section IIIa: Nanoforms

3.14 If a substance in nanoform is present in the substance or mixture, does the SDS contain the information required in sections 1.1, 3.1/3.2 and 9? ◯ Yes ◯ No ◯ Not required (no substance in nanoform present) If the answer to 3.14 is yes, please provide the substance identity (CAS Nr, EC Nr) for the nanoform present.	The inspector should refer to the Regulation 2020/878 to determine what is required in these subsections. The answer is "NO" if information is not provided in all relevant subsections. Note: The inspector should inquire to determine if the substance/mixture contains any nanoform material Note: – Subsection 1.1 - word "nanoform" – Subsection 3.1/3.2 – particle characteristics – Subsection 9.1 – particle characteristics

Section IIIb: Endocrine disrupting properties

3.15 If a substance with endocrine disrupting properties is present in the substance or mixture, does the SDS contain the information required in all the relevant subsections, i.e., 2.3, 3.2, 11.2 and 12.6? ◯ Yes ◯ No ◯ Not required (no substance with endocrine disrupting properties present)	The inspector should refer to the Regulation 2020/878 to determine what is required in these particular subsections. The answer is "No" if information is not provided in all relevant subsections. Note: Since ED properties are not yet included as CLP classification, it may not be obvious that ED substances are present

	and need to be indicated in the SDS. The inspector therefore may need to determine if any of the substances given in 3.2 are reported to have ED properties. Note: – Subsection 2.3 – substance(s) identified as having endocrine disrupting properties – Subsection 3.2 – substances identified as having endocrine disrupting properties – Subsection 11.2 – adverse health effects caused by endocrine disrupting properties – Subsection 12.6 – adverse effects on the environment caused by ED properties

Section IIIc: quality issues encountered

3.16 From your general consideration of the content of the SDS, did you find any information that you considered to be incorrect or not plausible? ◯ Yes ◯ No ◯ Not considered If yes, please list the section(s) of the SDS in which you found wrong or not plausible information:	Required here is to provide a general consideration on the quality of the information, and whether you find some of the information in the SDS to be incorrect (e.g., can be incorrect classification, labelling, wrong national OEL-values, etc) or not plausible based on the nature of the chemical (e.g., water-based mixture given as to give explosive vapours, or respiratory protection not necessary despite having a mixture that contains VOCs)

Section IV: Summary/Enforcement actions/Follow-up Action

4.1 Have non-compliances with REACH obligations subject to this project been detected? Please specify:	Note: Only the SDS supplier non-compliance with REACH obligations shall be filled out.
Articles 31.1 and 31.3 of REACH on provision and compilation of SDS ◯ Yes ◯ No ◯ No duties	Please consider the results of Q2.1 and Q2.3.
Article 31.5 of REACH on language requirements ◯ Yes ◯ No	This article is connected to Q2.5.
Article 31.7 of REACH on provision of ES annexed to / incorporated in SDS ◯ Yes ◯ No ◯ No duties (in cases where ES is not required)	This article is connected to Q2.4.
Article 31.9 of REACH on updating and provision of the revised SDS ◯ Yes ◯ No	This article is connected to the sub-question in Q2.1.
Article 32 of REACH on information, when an SDS is not required ◯ Yes ◯ No	This article is connected to Q2.2.
4.2 Has an enforcement action been initiated against the supplier? ◯ Yes ☐ Verbal advice ☐ Written advice ☐ Administrative order	

□ Fine □ Criminal complaint / handing over to public prosecutor's office □ Other: ◯ No	
4.3 The follow-up activities are: ◯ Completed ◯ On-going	

Section V: Informal comments (free text)

Please fill this section if you would like to inform on obstacles overcome, lessons learned, need for clarification/harmonisation
.....

5.2. Annex II – Evolution of compliance of SDS in different projects.

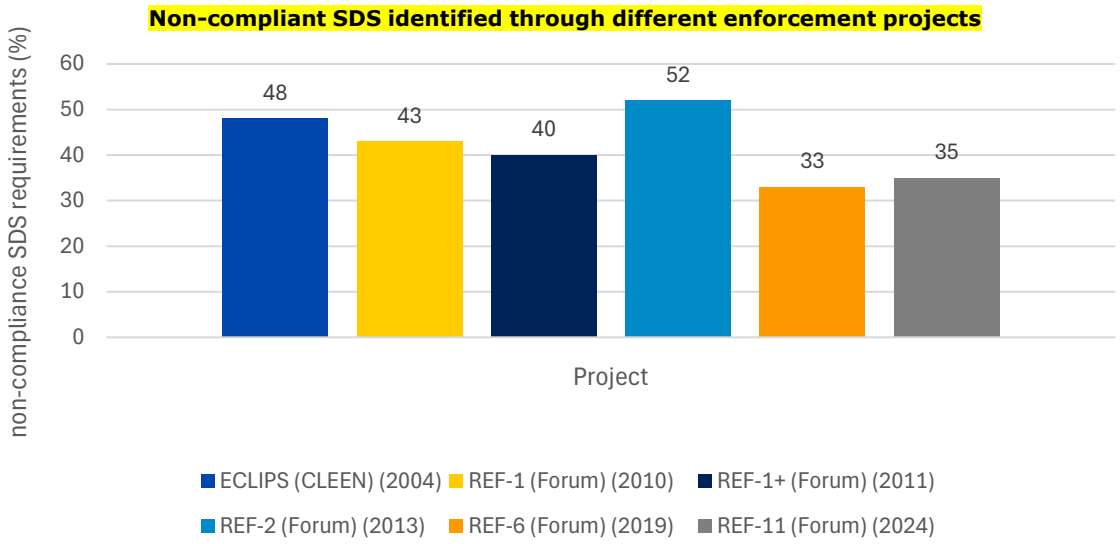

Figure 18. Non-compliant SDS identified through different enforcement projects.

Figure 18. shows that the number of SDS identified as non-compliant for any of the requirements applicable to SDS has decreased in relation to the projects carried out from CLEEN (ECLIPS) based on pre-REACH legislation. In comparison to the projects carried out after the application of REACH, the results show that there is a net improvement from the previous projects REF-1 and especially REF-2 enforcement projects. REF-2 was a quite detailed project on SDS applicable to formulation of mixtures and therefore a good starting point for a comparison of REF projects after REACH entry into force.

REF-6 which addressed both CLP and SDS and remains almost at the same level than REF-11 although REF-11 yields slightly higher non-compliance values. REF-11 is however a more detailed project on SDS and has targeted new requirements, so it is not always possible to carry out the intercomparability of the results between different enforcement projects and hence it is hard to conclude on the trends with the observed levels of compliance although generally speaking a certain improvement has been found since the first projects carried out by CLEEN in 2004.

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