ECHA
EUROPEAN CHEMICALS AGENCY

Forum

REF-6 PROJECT REPORT
Classification and labelling of mixtures

Adopted on 11.12.2019

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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.

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1. Executive summary

1.1 Content of the project

The main scope of this sixth Forum REACH-EN-FORCE (REF) project was classification and labelling of mixtures. The project also included additional optional modules for Classification, labelling, and packaging (CLP) Regulation exemptions from labelling and packaging requirements, harmonised classification and labelling of substances, specific rules applicable to Liquid Laundry Detergent Capsules (LLDC) and the enforcement of biocides.

The aim of the project was to check compliance and to raise awareness, by investigating and enforcing a variety of legal provisions in CLP, the most relevant stipulated in Articles 4, 37 17, 29 and 35 of CLP, Article 31 of REACH and Articles 17 and 69 of Biocidal Products Regulation (BPR), with a special focus on classification and labelling of mixtures.

The 'main module' on classification and labelling of mixtures was obligatory but it was for each participating country to decide whether they wanted to check any of the four optional modules. Any mixture classified as hazardous could be chosen to be checked and reported. Classification of mixtures using bridging principles for the classification, or mixtures where test data are not available for the complete mixture, and cases related to extreme pH were outside the scope of the project. The companies inspected for the project were manufacturers, importers, downstream users or distributors of mixtures.

In the project for the classification and labelling of mixtures, 28 countries reported on 1620 inspected companies in which 3391 mixtures where checked. The results from these inspections as well as from inspections regarding the optional modules are given in this report.

The working group who developed the manual and report of the project consisted of members and experts from both the Forum and the Forum Subgroup for Biocides (BPRS). This was the first joint project between the Forum and its BPRS subgroup.

1.2 Main results and conclusions

The results from REF-6 show that 17 % of the reported mixtures had incorrect classification which may also lead to incorrect labelling.

In the reported cases, the classification of the substances in the mixture given in Section 3.2 of the safety data sheets (SDS) corresponded either to the harmonized classification in Annex VI Table 3 in CLP (93 %), or to a notification in the Classification and labelling of chemical substances and mixtures (C&L) Inventory (92 %). Most frequently the inspectors used the SDSs to check the classification.

Although the quality of the SDSs is improving compared to the results of other Forum projects, such as the REF-2 project and a joint project with Accreditated Stakeholders on SDS[1], 33 % of the SDSs still contain various issues and/or shortcomings.

[1] In REF-2, 52 % of SDS had deficinecies (https://www.echa.europa.eu/documents/10162/13577/forum_report_ref2_en.pdf/6ae12cf0-a24d-4263-a30f-3dabf9928aed). For Joint project, the 50 % of the checked SDSs had defects in the information provided.

The project also examined more in depth the consistency between information on the product label and Section 2.2 in the SDS (REACH Annex II) of 3139 of the checked mixtures. The information was consistent in 81 % (2546) of the cases and non-compliances were found for 17 % of the mixures. In 2 % of the cases the information on the label and Section 2.2 in the SDS did not correspond due to exemptions from labelling and packaging requirements (CLP Article 29). The Member States National enforcement authority (MS NEA) interpret article 29 differently which constitutes a challenge for the harmonisation of enforcement.

A total of 45 % of the inspected companies had at least one non-compliance and 44 % of the mixtures checked were found to be non-compliant. These data show a substantial non-compliance rate.

The project showed that for 22 % of the checked LLDCs, the closure of the outer packaging did not maintain its functionality when repeatedly opened and closed during the life span of the packaging.

For the checked biocides, 7,1 % are illegally on the market as they lack either valid authorisations according to BPR or to national legislation during the transitional period. Regarding the labelling, the label was different when compared to the summary of product characteristics (SPC) or to Article 69(2) of BPR for 5,8 % and 11,6 % of the checked biocides, respectively.

Written advice and administrative orders were the measures imposed by the NEAs most frequently.

1.3 Main recommendations resulting from the project

Manufacturers, importers and downstream users should put more effort in deriving the right hazard classification of the mixtures and communicating it down the supply chain. This will prevent dissemination of incorrect information in the SDS and on the label.

Industry should do more to improve the quality of the SDSs which will, in turn, improve the quality of the information in the supply chain. This can be achieved with better and more active communication and cooperation in the supply chain, by including the recommendations from the Forum SDS working group, and by providing information campaigns and traning to improve industry knowledge on the topic.

Forum should consider repeating the project in a few years in order to monitor the compliance with the requirements for classification and labelling of mixtures according to CLP Regulation and the quality of the information in the supply chain including the SDS.

2. Detailed results of the project

2.1 General overview

REF-6 was the sixth REACH-EN-FORCE project of the Forum for Exchange of Information on Enforcement (Forum)[2]. As decided at the 27th plenary meeting of the Forum in June 2017[3], the aim of the project was to control classification and labelling of mixtures according to CLP Regulation criteria and rules, and the enforcement of REACH provisions regarding the content of Sections 2 (hazard identification), 3 (composition/ information on ingredients), 9 (physical and chemical properties), 11 (toxicological information), 12 (ecological information) and 16 (other information) of the SDS. In addition to this main module, the project also comprised of four optional modules, which focused on the enforcement of exemptions from labelling and packaging requirements, to check for any deviations to the harmonised classification and labelling of substances, specific rules applicable to Liquid Laundry Detergent Capsules and specific rules applicable to the Biocidal Product Regulation.

The operational phase of REF-6 was during 2018, which means that the legal provisions on classification and labelling of CLP Regulation were completely applicable to mixtures (Article 61(4) and the second paragraph of Article 62 of CLP Regulation).

2.2 Coordination of the project

The project was prepared by a Working Group of the Forum and BPRS and steered by the Forum. A National Coordinator was nominated to the project by each participating country. The task of the national coordinator was to first nationally provide information and guidance on the project methodology, timing and targeting and then collect information on the national results and report it to the Forum Working Group for the reporting provided in this report. The report has been prepared by the Working Group, and consulted with and approved by the Forum and BPRS.

2.3 Participation and number of inspections

In the project, 28 countries reported on 1620 inspected companies in which 3391 products where checked (Tables 1 and 2). In the number of inspections and products checked for the module D on biocides, the Switzerland (CH) inspections on BPR are included. 70 % of controls included on-site inspection. It was possible for the participating inspectors to inspect more than one mixture per company, and a maximum of five mixtures per inspected company.

Each participating country decided for itself which module 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. The main part was obligatory for all inspections except for CH, as Switzerland does not apply the CLP Regulation directly but

[2] https://echa.europa.eu/forum

[3] https://echa.europa.eu/documents/10162/23408787/forum-27_agenda_en.pdf/97c024ff-0090-f658-c9bc-78d38a1de7f5

via harmonising their own legislation (the Swiss Chemicals Ordinance) with the CLP Regulation.

Table 1. Reported inspections per country and module

Country	Main Part	Module A on small packagings	Module B on harmonised classification	Module C on LLDC	Module D on BPR
BE	56	20		10	
BG	56			1	13
CY	10	2		1	2
CZ	35	12		2	8
DE	195	21	3	10	42
DK	12				12
EE	50				11
EL	35	17			
ES	190	22	19	6	61
FI	17				3
FR	79	2	3	14	14
HR	106			5	53
HU	105				50
IE	28		1		6
IT	110	2	14	11	1
LI	7	2			1
LT	18				15
LU	10			5	2
LV	24	13			12
NL	55	13			14
NO	33	1			5
PL	135	31			74
PT	93	11	33	5	
RO	91	9			20
SE	14	7	2		4
SI	11			11	
SK	38	9	6	4	18
UK	7				
CH					22
Grand Total	**1620**	**194**	**81**	**85**	**463**

Table 2. Number of checked products per module and participating countries

Module	Main	A on small packagings	B on harmonised classification	C on LLDC	D on BPR
Mixtures / Substances / LLDCs / Biocides	3391	355	151	111	760
Countries	28	17	8	13	24

It should be noted that as the questions were not mandatory, the response rate varied. Therefore, the total number of reported mixtures were not consistent between different questions.

2.4 Type of companies and products inspected / targeted by the project

The target groups for this project were all actors in the supply chain that place hazardous mixtures on the market and who classify, label and package them in accordance with the CLP Regulation provisions.

The most controlled types of companies, based on individual NACE (The Statistical Classification of Economic Activities in the European Community) codes, were:

- manufactures of chemicals and chemical products – 32 %;
- wholesale trade – 29 %; and
- retail trade – 21 % (Tables 3 and 4).

The majority, 76 %, of the controlled companies where small and medium sized enterprises (SMEs).

Table 3. The aggregated NACE codes of the inspected companies

	NACE Code	Amount of inspected companies
No NACE code indicated		5
Agriculture, forestry and fishing	0-3.99	3
Mining and quarrying	5.00-9.99	1
Manufacturing	10.00-33.99	**684**
Electricity, gas, steam and air conditioning supply	35.00-35.99	1
Water supply; sewage, waste management and remediation activities	36.00-39.99	2
Construction	41.00-43.99	**13**
Wholesale and retail trade; repair of motor vehicles and motorcycles	45.00-47.99	**844**
Transportation and storage	49.00-53.99	**17**
Accommodation and food service activities	55.00-56.99	3
Information and communication	58.00-63.99	4

Financial and insurance activities	64.00-66.99	1
Professional, scientific and technical activities	69.00-75.99	**21**
Administrative and support service activities	77.00-82.99	**15**
Human health and social work activities	86.00-88.99	2
Arts, entertainment and recreation	90.00-93.99	1
Other service activities	94.00-96.99	3
	Grand Total	**1620**

Table 4. The roles of the companies checked

Role(s) of the company under CLP (multiple choices possible for each company)		
Downstream user		**665**
a	Formulator	564
b	Re-filler/Re-packager	140
c	Re-importer	4
Distributor		**1015**
a	Retailer	532
b	Wholesaler	569
c	Other	35
Manufacturer		**199**
Importer		**164**
	Total	**2043**

It was up to each participating country to decide which product category to control during the operational phase of the project. The most controlled product categories were:

- washing and cleaning products – 26 %;
- biocidal products – 22 %; and
- coatings and paints, thinners, paint removers – 15 % (Table 5).

Table 5. The product categories checked

Most common product categories	**Sum**
PC35 Washing and cleaning products (including solvent based products)	808
PC8 Biocidal products (e.g. Disinfectants, pest control)	690
PC9a Coatings and paints, thinners, paint removers	471
PC0 Other	223
PC1 Adhesives, sealants	175
PC28 Perfumes, fragrances	114
PC3 Air care products	96
PC9b Fillers, putties, plasters, modelling clay	71
PC24 Lubricants, greases, release products	55

PC14 Metal surface treatment products, including galvanic and electroplating products	51

2.5 Legal obligations

Table 6. The legal obligations subject to REF-6 inspections

Reg.	Legal provisions (Article and Annexes)	Summary
Main module		
CLP	Article 4 (1), (3) and (4)	General obligation to classify, label and package mixtures before placing them on the market.
CLP	Article 6	Identification and examination of available information on the mixture itself or the substances contained in it for the purposes of determining whether the mixture entails a physical, health or environmental hazard as set out in Annex I.
CLP	Article 9	Evaluation of hazard information for substances and mixtures.
CLP	Article 10 and 11	Concentration limits and M-factors for classification of substances and mixtures and cut-off values.
CLP	Article 13	Decision to classify substances and mixtures, by assigning one or more hazard categories for each relevant hazard class or differentiation and, subject to Article 21, one or more hazard statements corresponding to each hazard category assigned.
CLP	Article 14	Specific rules for the classification of mixtures.
CLP	Article 15	Review of classification for substances and mixtures.
CLP	Articles 17, 18, 19, 20, 21, 22,23, 25, 26, 27, 28	Content and language of the label.
CLP	Article 31	General rules for the application of labels.
CLP	Article 49	Obligation to keep available all the information used by that supplier for the purposes of classification and labelling under CLP for a period of at least 10 years after the

Reg.	Legal provisions (Article and Annexes)	Summary
		substance or the mixture was last supplied by that supplier.
CLP	Annex I, Part 1, Section 1.2.1.4.	Minimum dimensions of labels and pictograms.
REACH	Article 31 (1) (2) (5) (6) (9)	Requirements for safety data sheets.
REACH	Annex II	Requirements for the compilation of Safety Data Sheets .
Optional Module A		
CLP	Article 29 (1) (2)	29(1) Derogations from Article 31 requirements when packaging is too small or in such form or shape that makes full labelling information impossible to be displayed. 29(2) Omission of certain label elements.
CLP	Annex I, Part 1, Section 1.5.1.	Exemptions from Article 31 – Situations where Article 29(1) applies.
CLP	Annex I, Part 1, Section 1.5.2.1.	Exemptions from Article 17 - Situations where Article 29(2) applies: Labelling of packages where the contents do not exceed 125 ml.
CLP	Annex I, Part 1, Section 1.5.2.4.	Exemptions from Article 17 - Situations where Article 29(2) applies: Labelling of inner packaging where the contents do not exceed 10 ml.
Optional Module B		
CLP	Articles 4 (3) and (4) and 16 (2)	Obligation to classify and label substances subject to harmonised classification and labelling in accordance with the corresponding entry in Part 3 of Annex VI.
CLP	Article 40 (1) (2) (3) See also Article 39 See also Article 16	Obligation to notify the Agency - substances referred in Article 39 and placed on the market.
REACH	Annex VI part 2.3.2, 2.3.3, 2.3.4 and 4.1.	Obligation to include classification and labelling in the registration dossier, in line with Title I and II of the CLP Regulation,

Reg.	Legal provisions (Article and Annexes)	Summary
		including information on impurities, additives or individual constituents.
Optional Module C		
CLP	Article 35 (2)	Duty to apply additional requirements of Section 3.3 of Annex II where a liquid consumer laundry detergent is contained in a soluble packaging for single use.
CLP	Annex II, Part 3, Section 3.3	Special rules for packaging LLDC.
CLP	Annex I, Part 1, Section 1.5.2.2.	Exemptions from Article 17 - Labelling of soluble packaging for single use.
Optional Module D		
BPR	Article 17 Article 17 (1) Article 52 Article 53 Article 55 Article 89 (2) Article 95 (2)	Obligation to only make authorized products available on the market.
BPR	Article 69 (2) Article 22 (2)	Obligation to label biocides with complementary information.

2.6 Results

Main module: Classification and labelling of mixtures

The main module of the REF-6 questionnaire focused on assessment of the compliance levels with the CLP Regulation regarding classification and labelling of hazardous mixtures, as well as the compliance with the requirements of REACH Regulation to include the classification and labelling details in Sections 2 and 3 of the SDS, and the coherence of the information included in Sections 9, 11, 12 and 16 with the classification of the mixtures checked.

The scope of the project included all mixtures classified as hazardous with the exception of mixtures classified using bridging principles where test data are not available for the complete mixture and cases related to extreme pH, due to the potentially increased complexity of these cases.

Details of the mixtures checked

The total number of checked mixtures was 3391.

For 1591 (50 %) of the reported mixtures, the inspected companies had derived the classification. The rest of the companies take over the classification for a mixture derived already by another actor in the supply chain, provided that they do not change the composition of this mixture (in accordance with Article 4(5) and (6) of CLP).

In 340 (43 %) of the cases where the classification was derived by the inspected company, they used an IT-tool.

For 3045 (90%) of the mixtures the inspectors used the composition in the SDS to check the classification of the mixtures. For 2041 (60%) of the mixtures this was done using table 3 of Annex VI of CLP, for 1385 (41%) of the mixtures – the C& L inventory, for 948 (28%) of the mixtures – information provided by the company (e.g. the exact composition) and in 157 (10%) of the cases – an IT tool.

For 2570 (83 %) of the mixtures the classification of the mixtures was correct, while for 539 (17 %) it was not. It was reported that in 71 (13 %) of the latter the company used an IT tool.

Overall, for 131 checked mixtures the classification could not be concluded by the inspectors by the time of the reporting.

In 2873 (91 %) of the cases the labelling in Section 2.2 in the SDS(s) corresponded to the classification of the mixture in Section 2.1 of the SDS(s), while in 277 (9 %) it did not correspond.

In 2483 (93 %), the classification of the substances with a harmonised classification in the mixture in Section 3.2.1 of the SDS(s) corresponded to the harmonised classification in Annex VI Table 3 in CLP, while in 188 (7 %) it did not correspond.

For 506 of the checked mixtures there was no substance with harmonised classification.

In 2103 (92 %), the classification of the substances in the mixtures in Section 3.2 of the SDSs correspond to a notification in the C&L Inventory, while in 171 (8 %) it did not correspond.

In 357 inspections this provision was not checked.

Overview of the SDSs checked

Within the project 3134 SDSs were checked.

In 2108 cases the inspected relevant section in the SDS conform to REACH Article 31 and Annex II (Commission Regulation (EU) 2015/830).

In 1026 cases the checked SDSs contained errors/deficiencies in the content of sections 2 (hazard identification), 3 (composition/information on ingredients), 9 (physical and chemical properties), 11 (toxicological information), 12 (ecological information) and 16 (other information) (Figure 1).

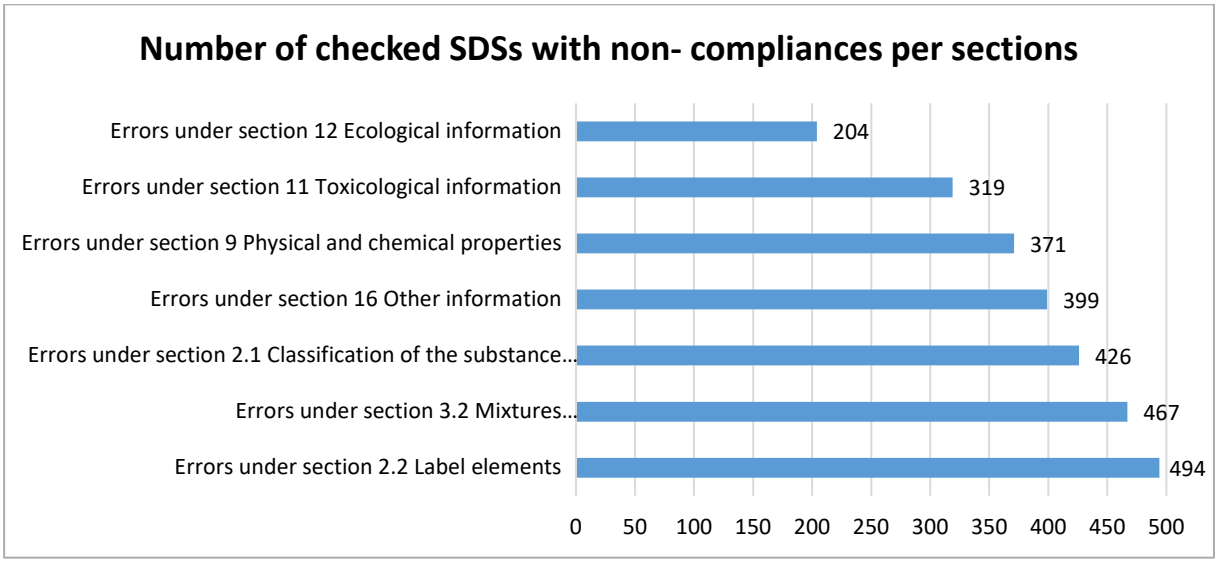

Figure 1. The sections of SDSs that were checked and the related number of non-compliances

Most of the errors or deficiencies, 920 – were in Section 2, followed by 467 in Section 3 and 399 in Section 16.

These results show that although the quality of the SDSs is improving compared to previous Forum projects (REF-2 project and a joint project with Accreditated Stakeholders on SDS), 1026 of the 3134 checked SDSs still contained issues and/or shortcomings. This makes a 33 % rate of non-compliance of the SDSs checked in this project compared to 52 % in REF-2.[4] These results show that the percentage of non-compliance has decreased and the quality of the SDSs seems to be improving.

The availability in the SDS of the M-factors for substances classified as "Aquatic Acute 1" or "Aquatic Chronic 1" was checked. In 619 checked SDSs the corresponding M-factors were available and in 482 SDSs they were missing. 736 of the inspections checked mixtures with substances not requiring M-factors.

The project examined more in depth the consistency between information on the hazard label and Section 2.2 in the SDS (REACH Annex II) of 3139 of the checked mixtures. The information was consistent in 81 % (2546) of the cases and non-compliances were found for 17 % (521) of the mixures. In 2 % (72) of the cases the information on the hazard label and Section 2.2 in the SDS did not correspond due to exemptions from labelling and packaging requirements (CLP Article 29) (Figure 2).

[4] https://www.echa.europa.eu/documents/10162/13577/forum_report_ref2_en.pdf/6ae12cf0-a24d-4263-a30f-3dabf9928aed

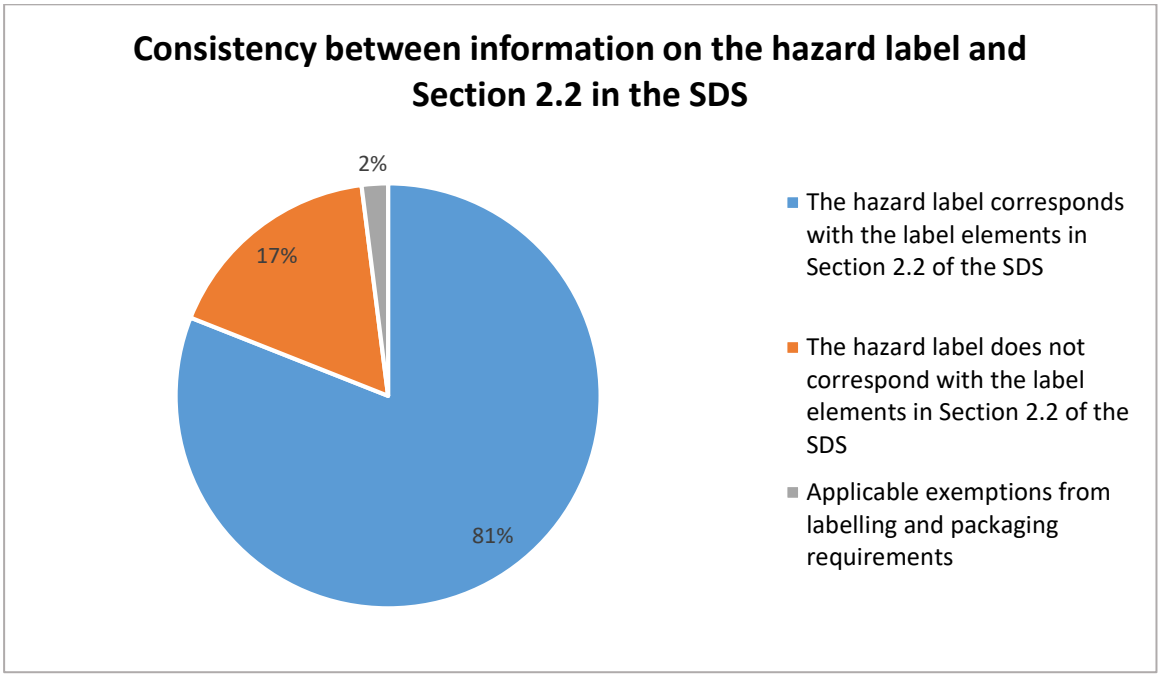

Figure 2. Consistency of information between the hazard label and SDS

Examples of the inconsistencies are SDSs with classification according to Directive 67/548/EEC[5] and Directive 1999/45/EC[6]; missing labelling elements either on the label or in Section 2.2 of the SDS; and differences in the information on the label and in Section 2.2 of the SDS.

Information on the label

The REF-6 project checked the hazard label of mixtures for compliance with Article 17 of CLP. In total, 1732 inspections were done and 3189 mixture labels were checked.

In 63 % (2001) of cases the labeling elements of the checked mixtures were in accordance with Article 17 of CLP. However, in 33,5 % (1067) of the labelling elements of the checked mixtures, labelling information was missing and/or had errors or deficiencies. In 4 % (121) of the labels of the checked mixtures, labeling elements were missing due to the application of exemptions from labelling and packaging requirements (CLP Article 29) (Figure 3) (**Optional Module A: Exemptions from labelling and packaging requirements**).

Labelling of the mixtures in accordance with Article 17 of CLP		
Correct labelling	2001	63 %
Incorrect labelling of the mixtures due to errors/deficiencies	1067	33 %

[5] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

[6] Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

Reduced labelling of the mixtures due to the application of exemptions (Article 29) (**Optional Module A: Exemptions from labelling and packaging requirements**)	121	4 %

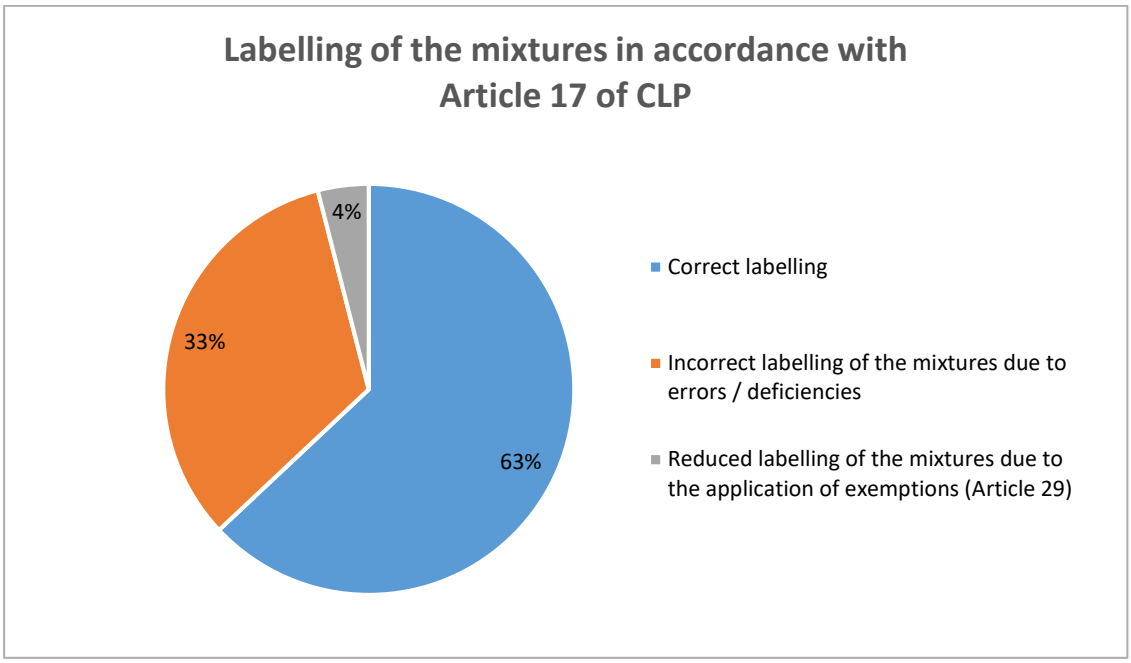

Figure 3. Results of the labelling of checked mixtures

Missing labelling information due to errors and/or deficiencies in the label was mostly related to hazard statements (22 %), precautionary statements (15 %), hazard pictograms (14 %), signal word (12 %) and product identifier (11 %) (Figure 4). As mentioned, missing labelling information could be much related to the wrong classification of mixtures.

Table 7. Errors/deficiencies identified in the labels

	Error / deficiency	**No of mixtures**
1	Hazard statements	468
2	Precautionary statements	336
3	Hazard pictogram	310
4	Signal word	265
5	Product identifier	246
6	Contact information	149
7	Not in official language	130
8	Other, please specify	88
9	Supplemental information	69
10	General rules for the application of labels	44
11	Label size	42
12	Nominal quantity	38

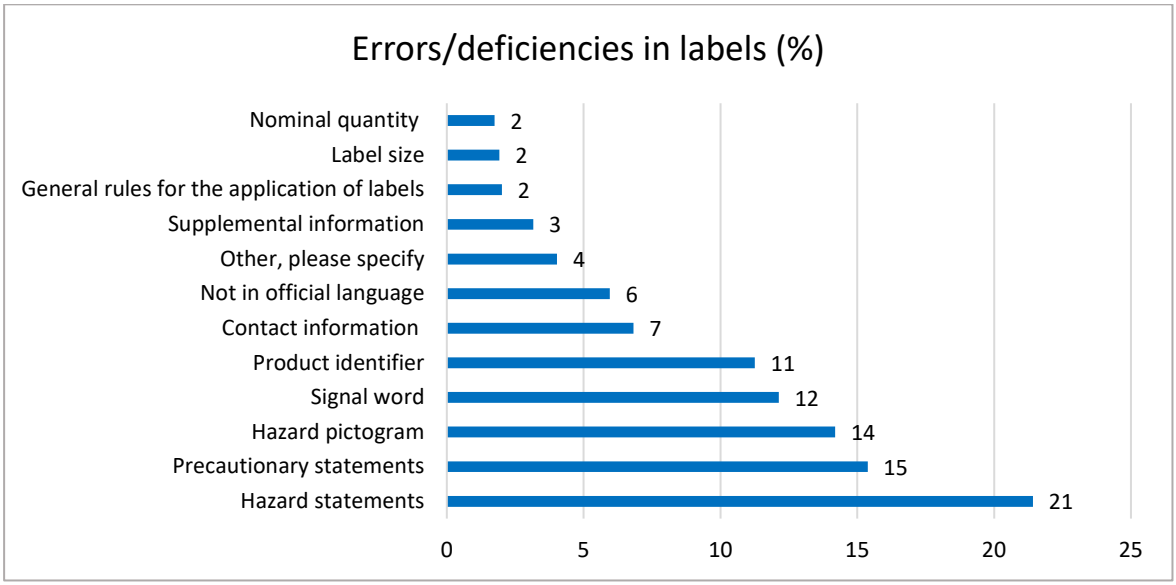

Figure 4. Distribution of labelling errors/deficiencies identified

In 77 % of the cases the errors and/or deficiencies in the product identifier were related to the missing listing of substances and in 23 % of the cases to missing or incorrect product name. In addition, according to the errors/deficiencies on hazard pictograms, in most cases they were missing (47 %) or wrong (38 %). Another issue was wrong or missing hazard or precautionary statements (22 and 15 %, respectively) (Figure 4). Again in most of the cases it could be related to the wrong classification.

Optional Module A: Exemptions from labelling and packaging requirements

I. Introduction

Out of the 28 countries that reported on results of the REF-6 project 17 also participated in the Optional Module A concerning exemptions from labelling and packaging requirements.

A total number of 194 inspections were carried out, in the context of Optional Module A, during which a total number of 355 mixtures were checked.
For the above mentioned products, the labelling check was performed using the mixture classification from:

- Section 2.1 of mixture SDS only - for 233 of the checked mixtures, and
- mixture classification was performed by the inspector for 150 of the checked mixtures.

From the figures above, it is noted that in some of the checked mixtures, the inspectors used both labelling check methods.

II. Compliance with general rules for labelling (CLP Article 31)

For 172 checked mixtures in module A, the general rules for labels according to Article 31 were reported not to apply.

For 43 of these mixtures, there was no reason for exemption according to Article 29(1), therefore there was an infringement of Article 31.

The justifications for exemption of Article 31 requirements reported in the questionnaires are shown in the following figure:

Figure 5. Reasons for exemption of Article 31 requirements (according to Article 29(1))

In the figure above, the total number of checked mixtures exempt from Article 31 requirements is higher than 172, because in some cases both reasons for exemption according to Article 29(1) apply.

III. Label elements provided in fold-out labels or on tie-on tags or on an outer packaging (CLP Article 29(1), CLP Annex I, 1.5.1. - Exemptions from Article 31)

Full labelling (according to Article 31) was provided in the following ways, as described to Article29(1), for a total of 148 checked mixtures:

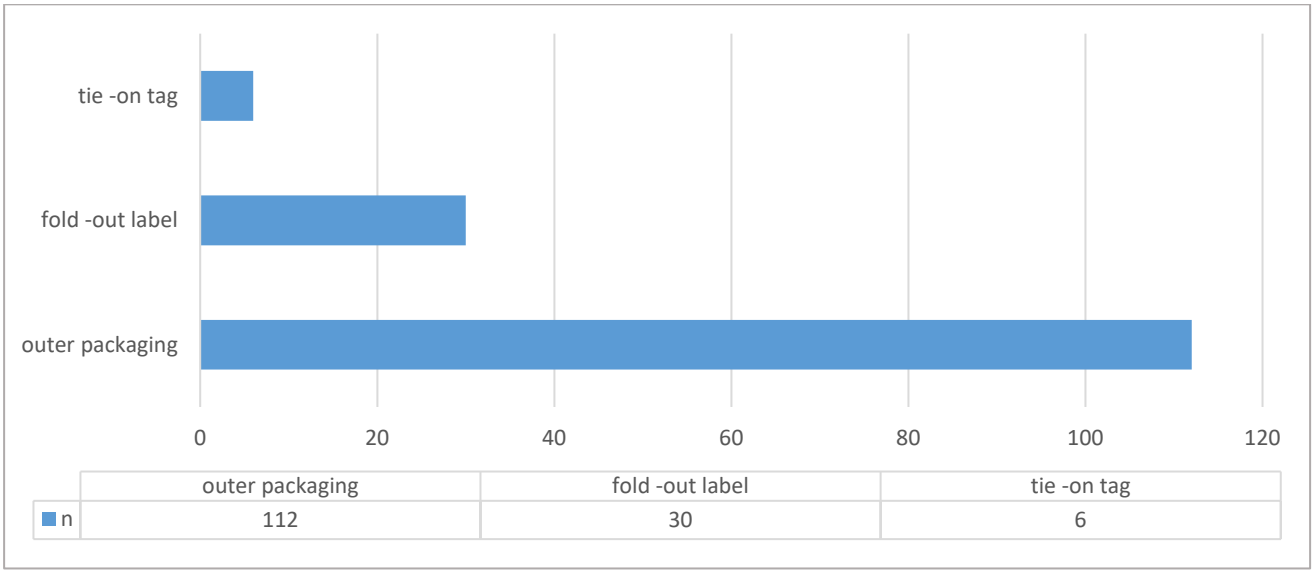

Figure 6. Options of providing full labelling according to Article 29(1)

In the above figure, in some cases more than one way of providing labelling according to Article 29(1) apply.

Despite using fold-out labels or tie-on tags or an outer packaging, in 32,1 % of the checked mixtures the full labeling information was not provided according to Article 17(1), whereas only 8,6 % of the cases the labelling elements were not written in the official language of the Member State where the mixture is placed on the market, which is an infringement of Article 17(2).

For the mixtures checked, a relatively small rate of non compliance was observed regarding the general rules for the application of labels (Article 31(2), (3), (4)) and the location of information on the label (Article 32), 14,5 % and 11,8 % respectively.

Regarding the mandatory information on the label of the inner packaging (hazard pictograms, mixture identifier, name and telephone number of supplier), compliance was as presented in the following figure.

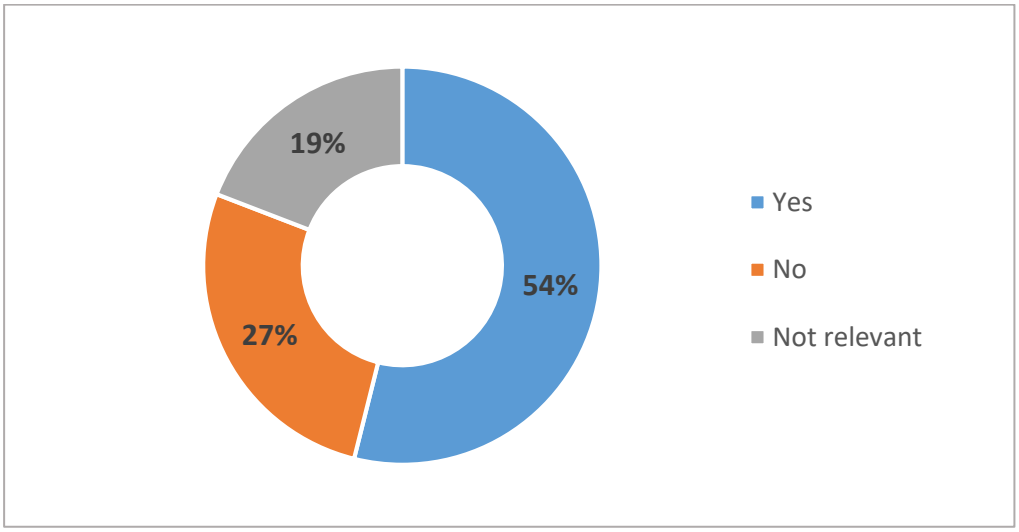

Figure 7. Compliance of inner packaging with the provisions of Article 29(1) and Annex I Section 1.5.1.2

IV. Exemptions from Article 17 (CLP Article 29(2), Annex I, 1.5.2.)

A total number of 108 cases fell under the provisions of Article 29(2), as shown in Figure 8.

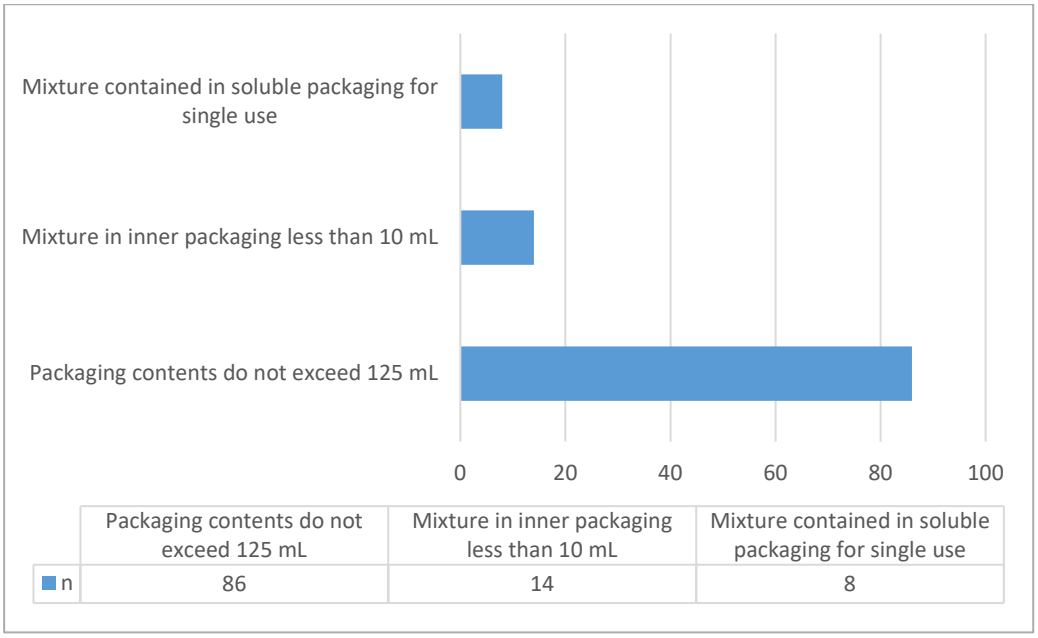

Figure 8. Distribution of checked mixtures according to the options of Article 29(2)

IV(A). Labelling of packages where the contents do no exceed 125 mL (CLP Annex I, 1.5.2.1)

For the above-mentioned 86 checked mixtures for which the contents did not exceed 125 mL, inspectors found that 74 of them were classified in hazard categories that permitted the omission of hazard and precautionary statements (Annex I, 1.5.2.1). These hazard categories are presented in Figure 9, below.

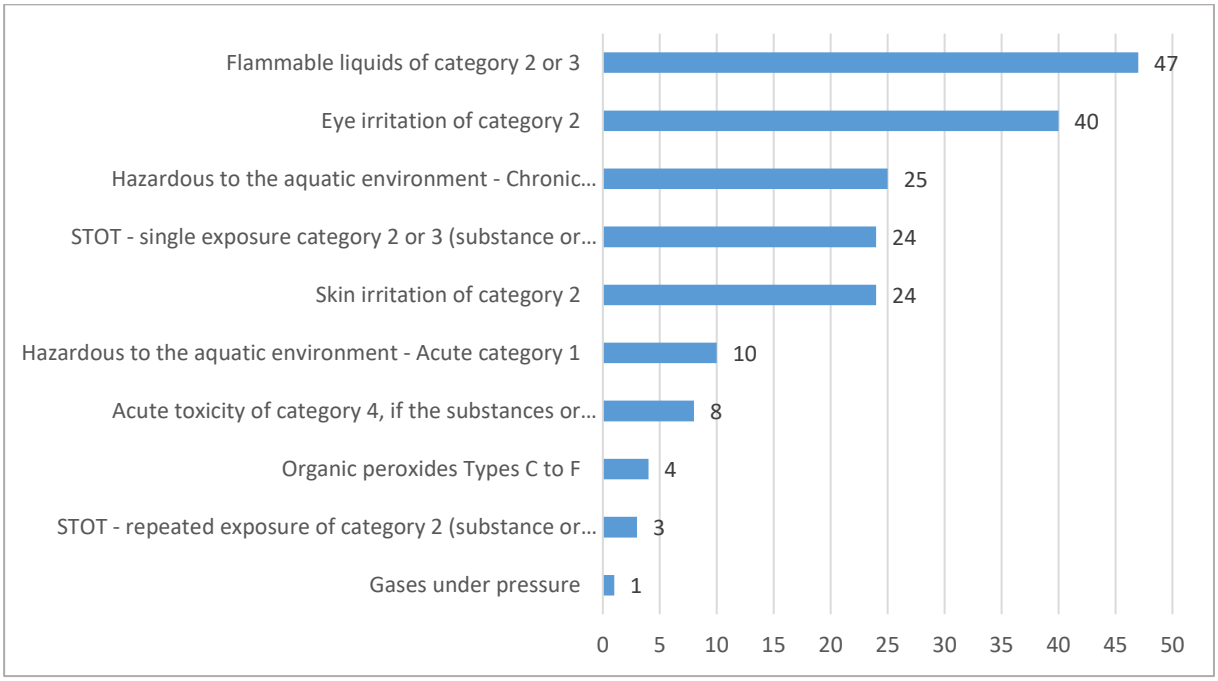

Figure 9. Distribution of hazard categories for the mixtures checked, which led to the omission of H-statements and P-statements

For the mixtures which had a classification that permitted the omission of H-statements and P-statements, inspectors checked whether the rest of the obligatory information (hazard pictogram(s) and signal word) were present on their label. The vast majority of the checked mixtures was found to be compliant with the above requirements.

Seven mixtures were classified as "Hazardous to the aquatic environment - Chronic category 3 or 4" which permitted the omission of P-statements. Only for five out of these seven mixtures the rest of the obligatory information (signal word and hazard statement(s)) was present on their label.

Five mixtures were classified in hazard categories other than those mentioned in paragraphs 1.5.2.1.1., 1.5.2.1.2. and 1.5.2.1.3. of Annex I and all of them were found to be compliant with the label requirements of Article 17.

Finally, in one out of the three checked mixtures that were fitted with an aerosol dispenser, the provisions regarding the exemptions that apply for small packages of aerosols classified as flammable (according to Directive 75/324/EEC[7]) were fulfilled.

IV(B). Labelling of soluble packaging for single use (CLP Annex I, 1.5.2.2)

Out of the eight checked products where the mixture was contained in soluble packaging for single use, none fell within the scope of Regulation (EC) No 1107/2009[8] (Plant Protection Products regulation) or (EU) No 528/2012 (Biocide Products regulation).

[7] Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers

[8] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

All the abovementioned eight checked mixtures were contained in soluble packaging for single use, the content of which did not exceed a volume of 25 ml. These mixtures were classified in hazard categories that permitted the omission of the label elements required by Article 17 (Annex I, 1.5.2.2). These hazard categories are presented in Figure 10, below.

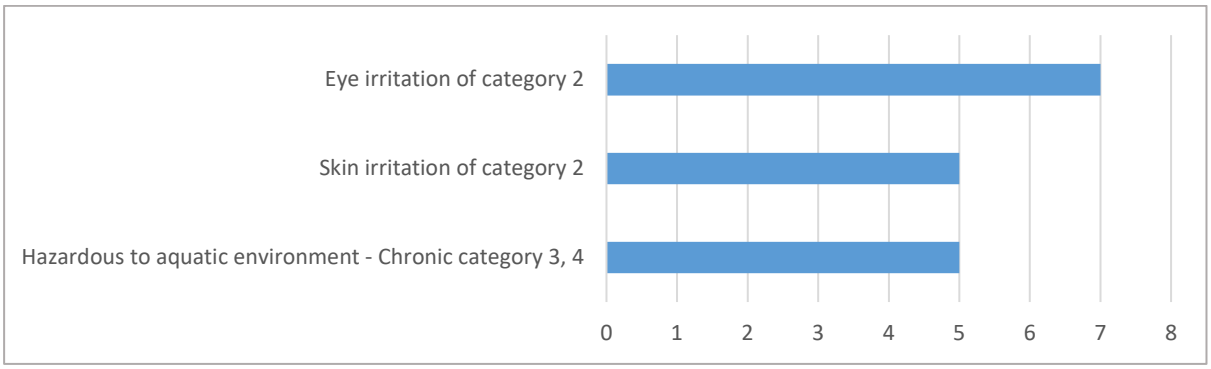

Figure 10. Distribution of hazard categories for the mixtures checked, which led to the omission of the label elements required by Article 17

For all of the eight checked products, the soluble packaging was contained within outer packaging that fully met the requirements of Article 17.

In the questionnaire, inspectors were advised that if the soluble packaging for single use contained liquid consumer laundry detergent, then additional labelling and packaging requirements applied and the Optional Module C (LLDC) of the questionnaire should be filled in as well. This recommendation was not always taken into account and therefore the Optional Module A questionnaire was not filled in for all relevant cases of LLDC products checked in Optional Module C.

IV(C). Labelling of inner packaging where the contents do not exceed 10 mL (CLP Annex I, 1.5.2.4)

From the 14 checked mixtures, for which the contents of inner packaging did not exceed 10 ml, one mixture fell within the scope of Regulation (EC) No 1107/2009 (Plant Protection Products regulation) or (EU) No 528/2012 (Biocide Products regulation), but was not labelled according to CLP Article 17.

For the remaining mixtures, the following infringements of CLP Article 17 were observed:

- six checked mixtures were placed on the market for supply to a distributor or downstream user for reasons other than scientific research and development or quality control analysis;
- one checked mixture had an outer packaging that did not fully meet the requirements of Article 17; and
- two checked mixtures had a label on the inner packaging which contained the product identifier but not the appropriate hazard pictogram(s), according to paragraph 1.5.2.4.2. of Annex I.

V. Other results of Optional Module A inspections

There were also the following qualitative findings which arose during the inspections.

The first issue concerned fold-out labels. Specifically, the obligation to include certain information, including the pictograms (as required in point 1.5 of Annex I to CLP), to the

part firmly attached to the bottle. The inspectors questioned whether this is mandatory, or if these elements can be on other pages of the fold-out label. There are different viewpoints concerning the enforceability of this obligation and the issue has also been discussed during the 14th HelpNet Steering Group meeting[9] and addressed by ECHA in the Guidance on labelling and packaging[10].

Another issue concerned whether it was mandatory to have the hazard statement EUH202, on the immediate inner packaging. The question is important because it concerns a great number of widely used consumer products (e.g. certain types of glues etc). For reasons of consumer protection, the prevailing view is that the EUH202 hazard statement should appear on the inner/immediate packaging, even though it is not clearly mentioned in the legislation.

Optional Module B: Harmonised classification

The Optional Module B focused on compliance of substances (as such or in mixtures) with harmonized classification (Annex VI of CLP). In the module, NEAs of the MSs investigated whether substances brought to their attention were classified and labelled in accordance with the provisions of Article 4(3) of CLP Regulation, respecting harmonised classification. Differing from other modules, for Optional Module B, manufacturers of substances and importers of substances and mixtures fell within the scope.

In total, 81 inspections were carried out and 151 substances were checked with respect to compliance with Annex VI of CLP. The information on target substances and companies to be checked was provided to each participating MS either by ECHA, other MSs, or by national origin (Figure 11).

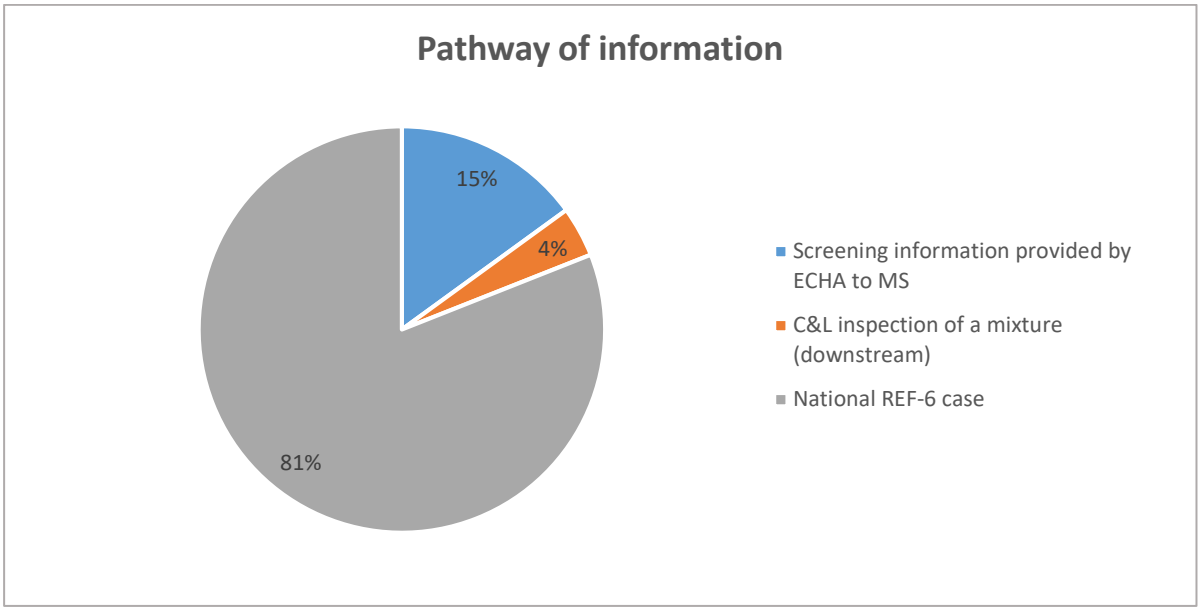

Figure 11. The source of information for the inspected cases

[9] https://echa.europa.eu/documents/10162/21971153/helpnet-14_minutes.pdf/1657f51a-5c0b-c860-4b0e-939636e336bc

[10] https://www.echa.europa.eu/documents/10162/23036412/clp_labelling_en.pdf/89628d94-573a-4024-86cc-0b4052a74d65

Mostly MSs chose to select the inspected substance and company based on its own REF-6 mixture C&L inspection or other means of screening or assessment (81 %). The screening information provided by ECHA to NEA about suspected non-compliances constituted 15 % of the cases. Out of the 22 cases ECHA sent to the NEAs, 11 were inspected (50 %). Of the checked cases provided by ECHA the non-compliance rate was 50 %.

In most of the cases, actual non-compliances with substance classifications were not detected (90 % of the checked substances). Regarding the detected non-compliances, in 9 % (14) of the cases, the classifications derived by manufacturers and importers were not in compliance with the Harmonised classification and labelling of chemical substances and mixtures (CLH) provisions, whereas 1 % (2) of the cases was still under investigation at the time of reporting (Figure 12).

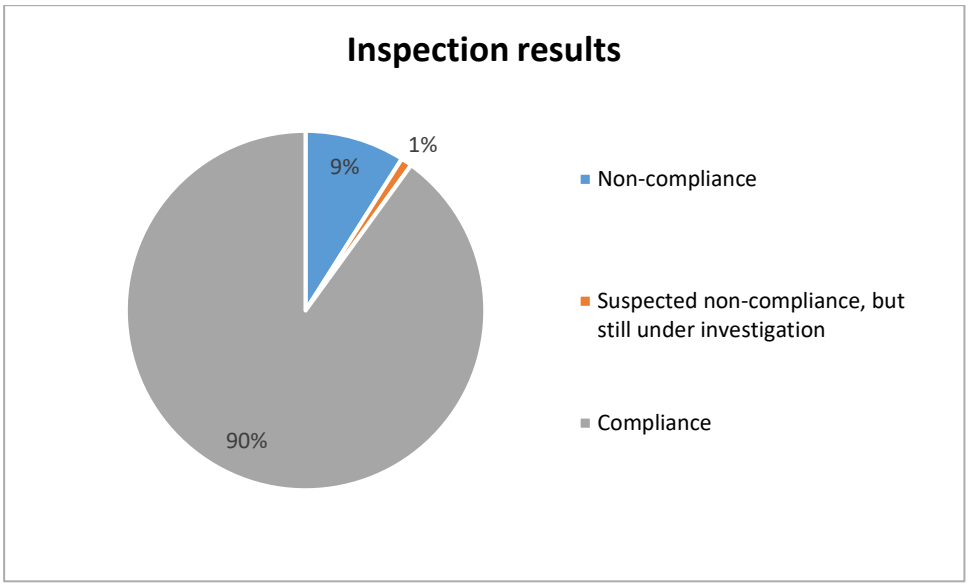

Figure 12. The results of the inspections

Most common non-compliances (47 % of 14 detected non-compliances) concerned CMR-endpoints (categories 1A, 1B and 2), respiratory sensitisation, skin sensitisation and specific target organ toxicity in repeated exposure (categories 1 and 2). In addition, 29 % were related to the other endpoints (e.g. environmental, skin or eye damage and/or irritation etc.) (Figure 13).

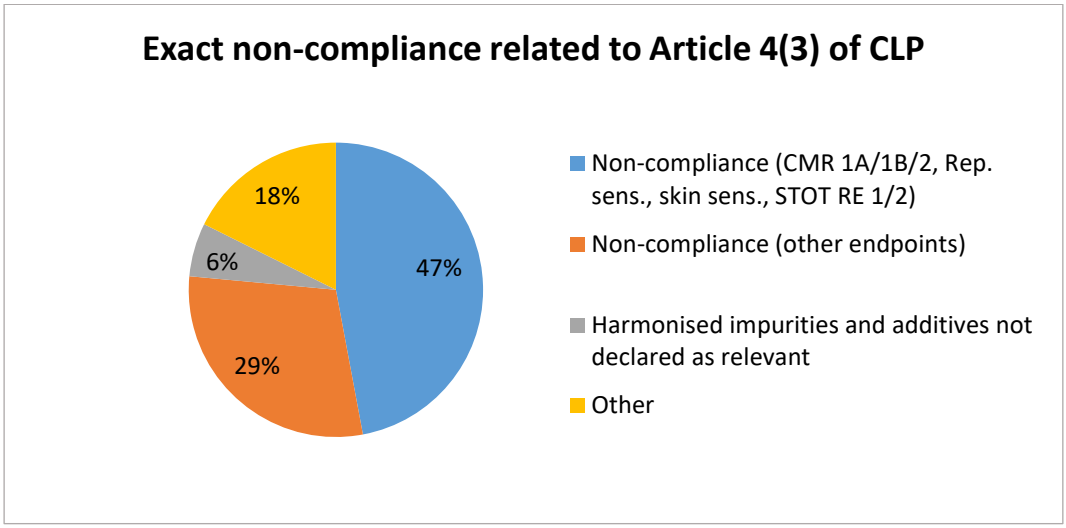

Figure 13. The found non-compliances related to Article 4(3) of CLP

Optional Module C: LLDC

The aim of the Module C was to determine the level of compliance with the new requirements introduced in Article 35(2) and Annex II, Part 3, Sections 3.2 and 3.3 of the CLP Regulation. The classification of the products and compliance with the general CLP labelling requirements were checked before inspection of specific labelling and packaging provisions and were reported in the main obligatory module of the questionnaire.

Altogether 13 countries participated in the Optional Module C. A total number of 85 inspections were carried out, during which a total number of 111 mixtures (LLDC) were checked.

In total, 91 % of the LLDCs were classified correctly, 9 % were classified incorrectly and the labelling of the outer packaging was consistent with the classification (97 %).

A total 31 out of 98 (32 %) of the individual capsules were labelled. 67 (67 %) capsules were not labelled. But in 64 cases of the 67 (96 %) non-labelled capsules the criteria for exemptions in Annex I, Section 1.5.2.2 of the CLP regulation were met. That means that just 4 % of the non-labelled capsules should have been labelled.

The unit doses contained several product forms. From the reported 91 LLDCs, the following types were found:

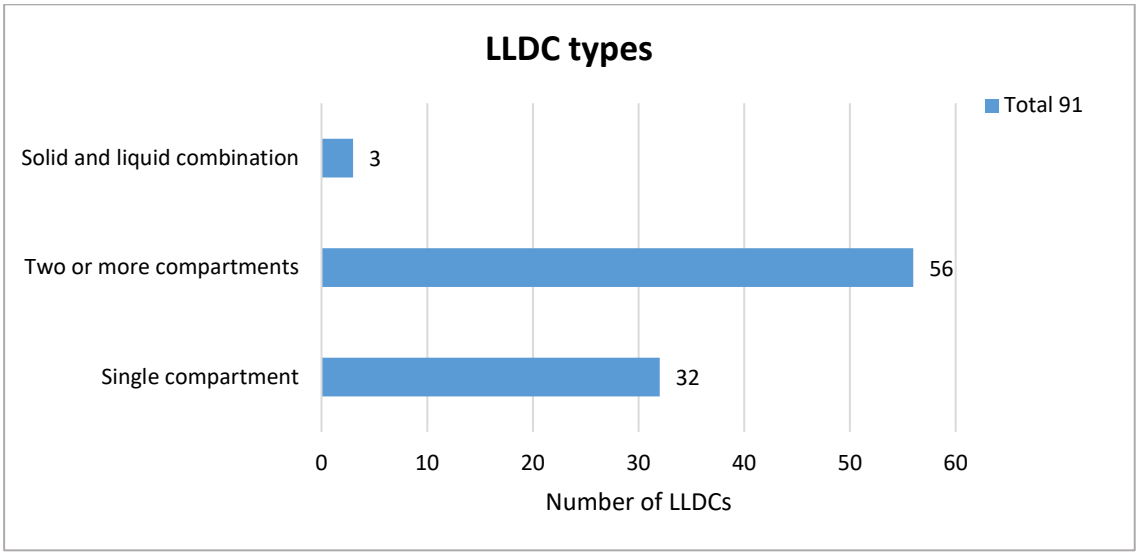

Figure 14. LLDC types checked

The 111 inspected hazardous LLDCs were classified as indicated in Figure 15:

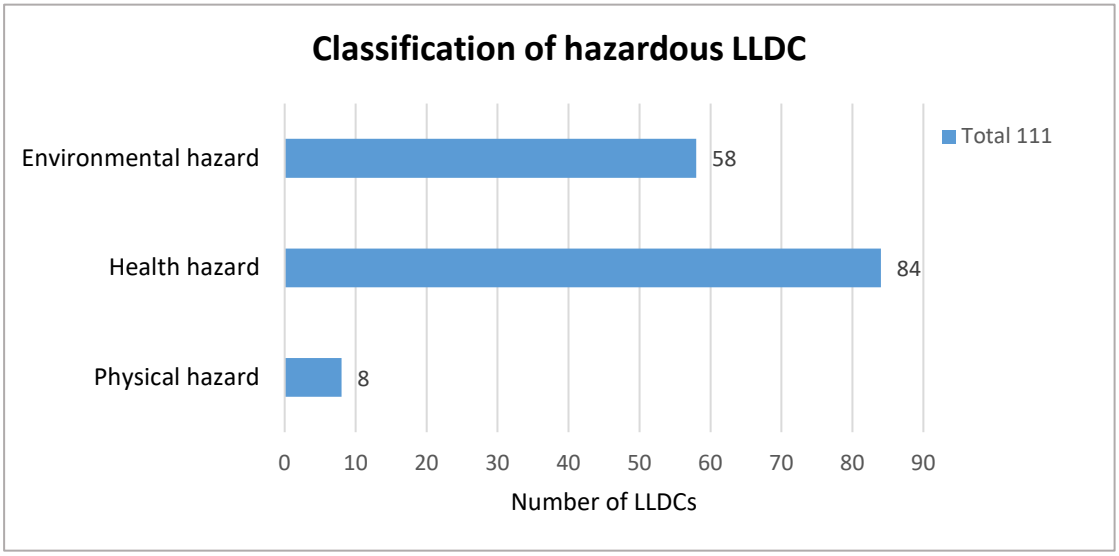

Figure 15. Classification of hazardous LLDCs

In all cases, the classification of the LLDCs was checked by checking the SDS. Additionally, the labelling of 87 LLDCs and the exact formulation of 12 LLDCs were checked (Figure 16).

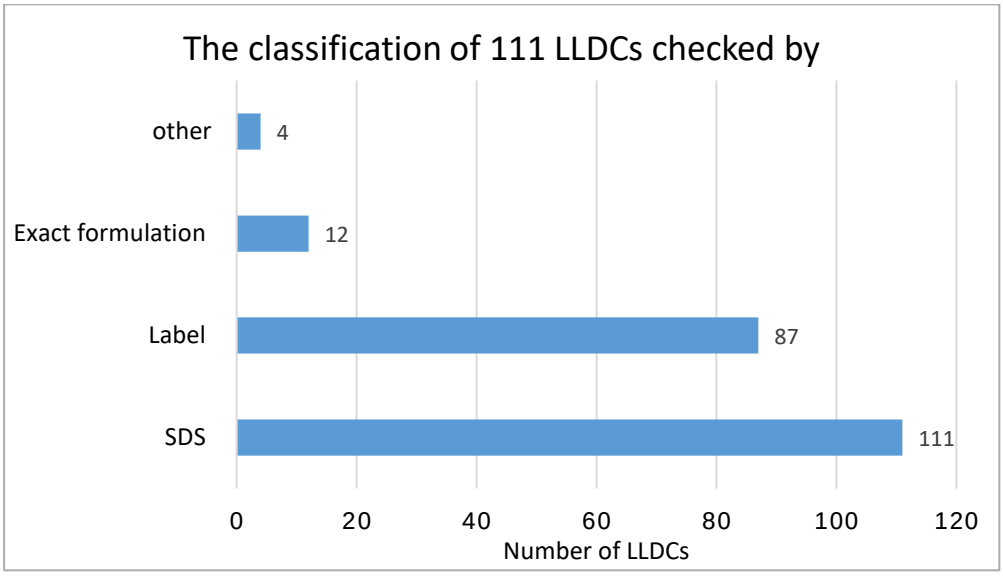

Figure 16. The data source where classification was checked from

All LLDCs inspected were contained in an outer packaging. Out of 111 checked packages only 87 (78 %) met the criteria of a closure that maintains its functionality under conditions of repeated opening and closing for the entire life span of the outer packaging. For the rest of the provisions in Section 3.3.2 of Annex II to CLP, at least 93 % of the outer packages were in compliance (Figure 17).

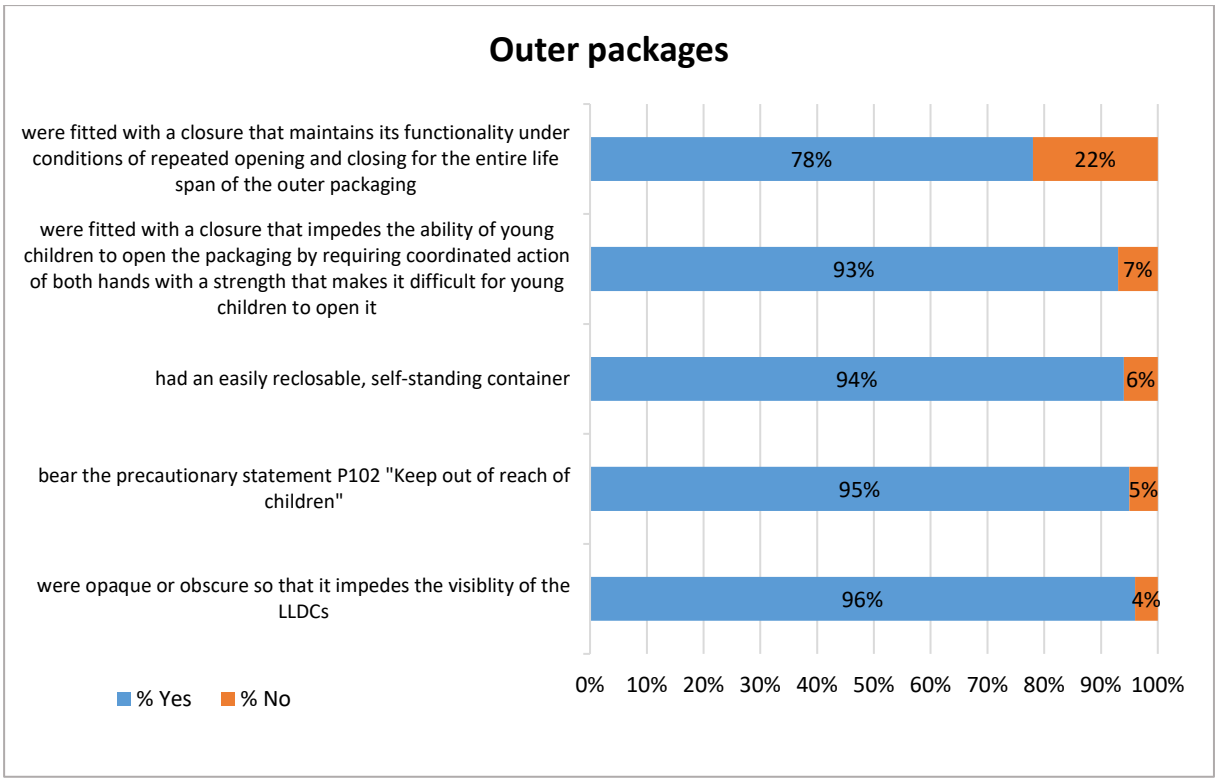

Figure 17. Outer packages conformity with Section 3.3.2 of Annex II to CLP

Mostly, the LLDCs where contained in a box (69 %) rather than in a pouch (14 %) or other packaging type (17 %). Other packaging types for example, could be a two- or three-latch closure box.

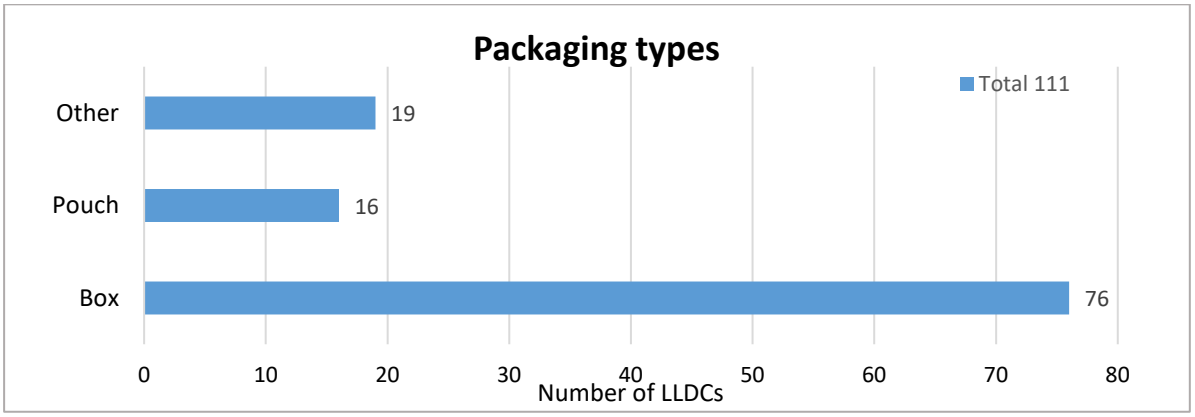

Figure 18. The number of LLDCs checked per packaging types

With regard to the soluble packaging, no standard(s) are available for measuring water solubility or mechanical resistance; however, a laboratory certificate was requested from the supplier. The companies could not provide sufficient justification that the soluble packaging (Figure 19):

a) resists mechanical compressive strength of at least 300 N under standard test conditions for three out of 67 reported LLDCs; and
b) retains its liquid content for at least 30 seconds when the soluble packaging is placed in water at 20 °C for three out of 68 reported LLDCs; and
c) contains an aversive agent in a concentration which is safe and elicits oral repulsive behaviour within a maximum of six seconds for three out of 71 reported LLDCs.

There is an additional level of uncertainty for the level of non-compliance due to the high number of LLDCs that were reported as not being checked (see Figure 19).

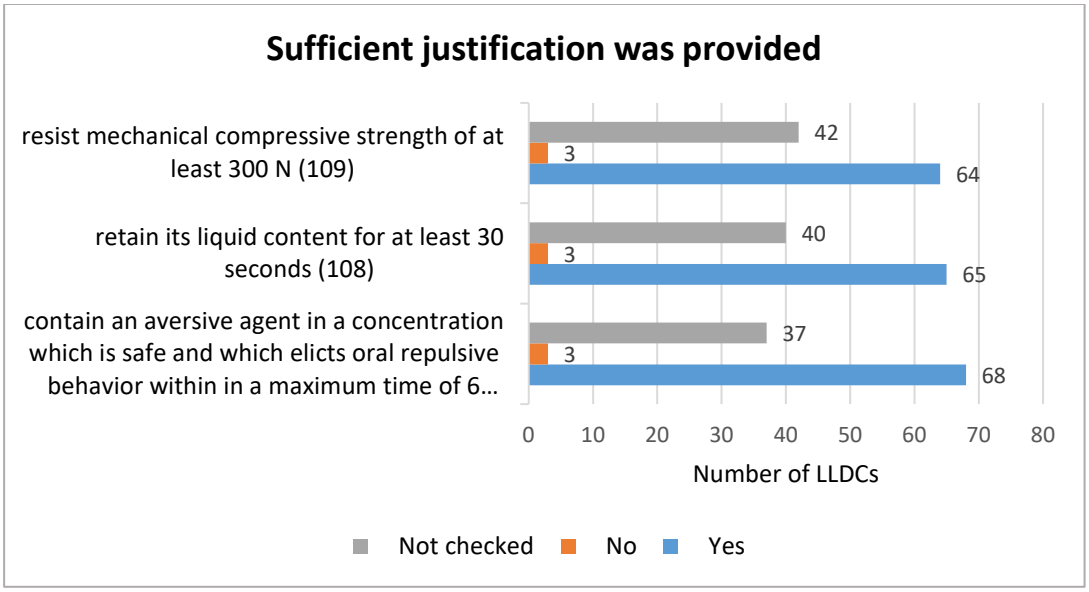

Figure 19. Sufficient justifications concerning requirements for soluble packaging

In addition to checking the documentation, NEAs in Germany (in the scope of REF-6) tested 10 products (eight capsules per product) in an accredited laboratory. Altogether three out

of 10 products did not resist mechanical compressive strength of at least 300 N. That means that 30 % of the tested products failed. NEAs in Germany used test specifications for safety of toys (DIN EN 71-1; February 2015).

Optional Module D: Biocides

Optional Module D focused on compliance of biocides with Regulation (EU) 528/2012 (BPR). In the module, NEAs of the MSs investigated whether biocides brought to their attention had been authorized and properly labelled in accordance with the provisions of Regulation (EU) 528/2012 (BPR) before being placed on the market. Another important task of the module was to check the consistency between information on the hazard label and the granted authorisation for the biocides.

The target groups for Optional Module D of the project were all the actors in the supply chain who place biocidal products on the market and who must classify, label and package them in accordance with the CLP Regulation provisions.

Altogether 24 countries participated in the Optional Module D on BPR. The number of biocides that were checked was 760.

Detailed information about the results of the reported inspections are presented in the tables and figures below.

Table 8. The legality of the reported biocides in the market based on BPR and national legislation

Requirement for authorization	
Biocide products placed legally on the market according to BPR	380
Biocide products placed on the market according to national legislation during the transitional period	301
Biocide products placed on the market with lack of a valid authorisation according to Articles 17 (1) in BPR	19
Biocide products that do not fulfil Article 95 in BPR	2
Biocide products placed on the market with lack of a valid authorisation according to national legislation during the transitional period	35

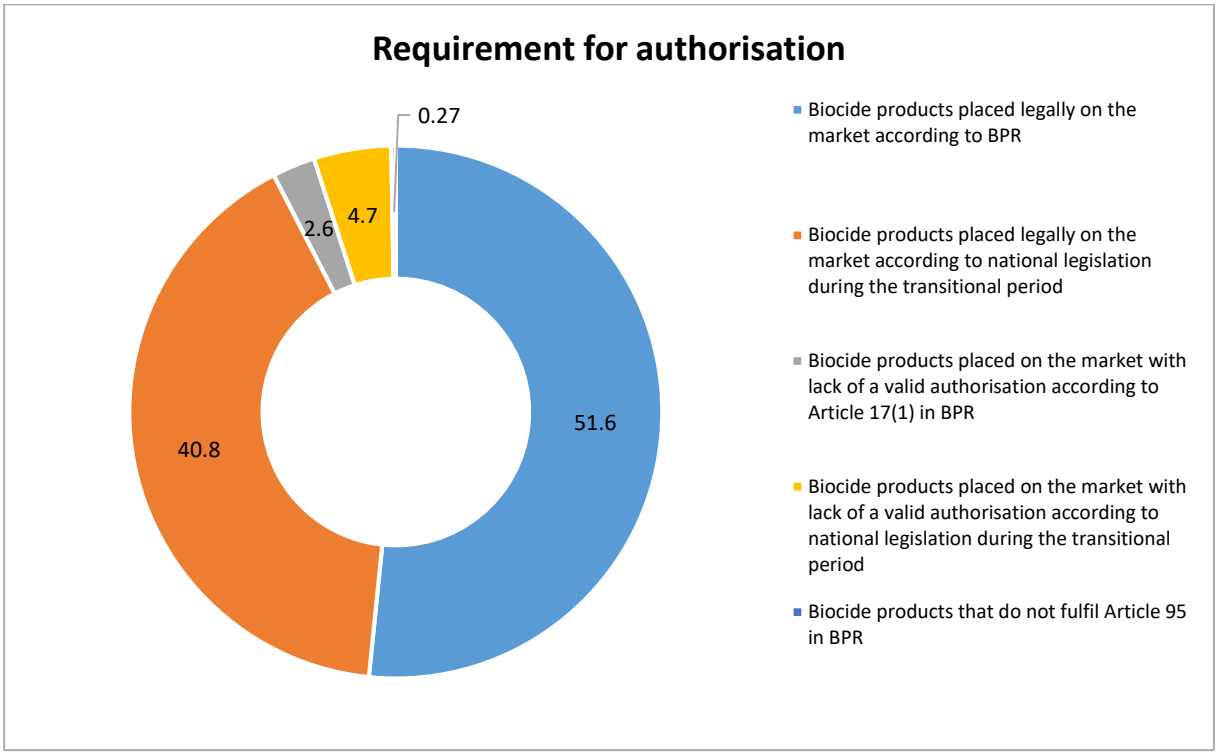

Figure 20. The percentages of the legality of biocides on the market

Table 9. Consistency of information on the hazard label of the reported biocides

Consistency between information on the hazard label and the granted authorisation for the biocides (SPC)	
Biocide labels that correspond with the hazard and precautionary statements in the granted authorisation (SPC) for it	427
Biocide labels that have a different hazard labelling compared to the granted authorisation (SPC)	40
Not applicable	223
Consistency between information on the hazard label and Article 69(2) of BPR	
Biocide labels that correspond with Article 69(2) of BPR	410
Biocide labels that do not correspond with Article 69(2) of BPR	80
Not applicable	200

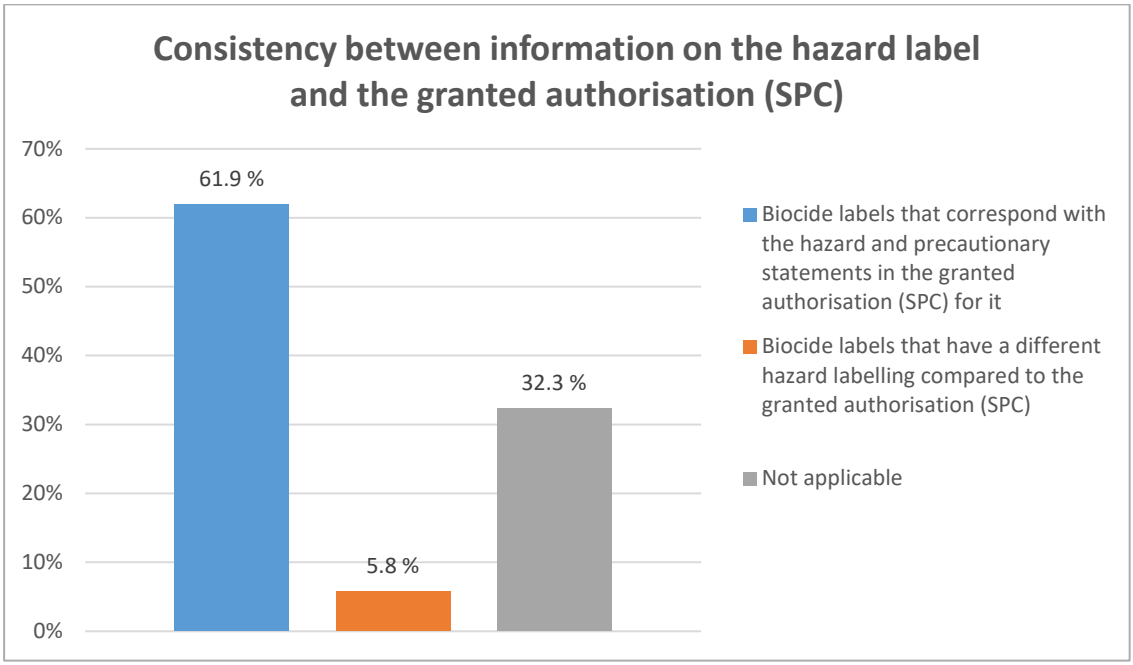

Figure 21. Consistency of information between the hazard label and the granted authorisation.

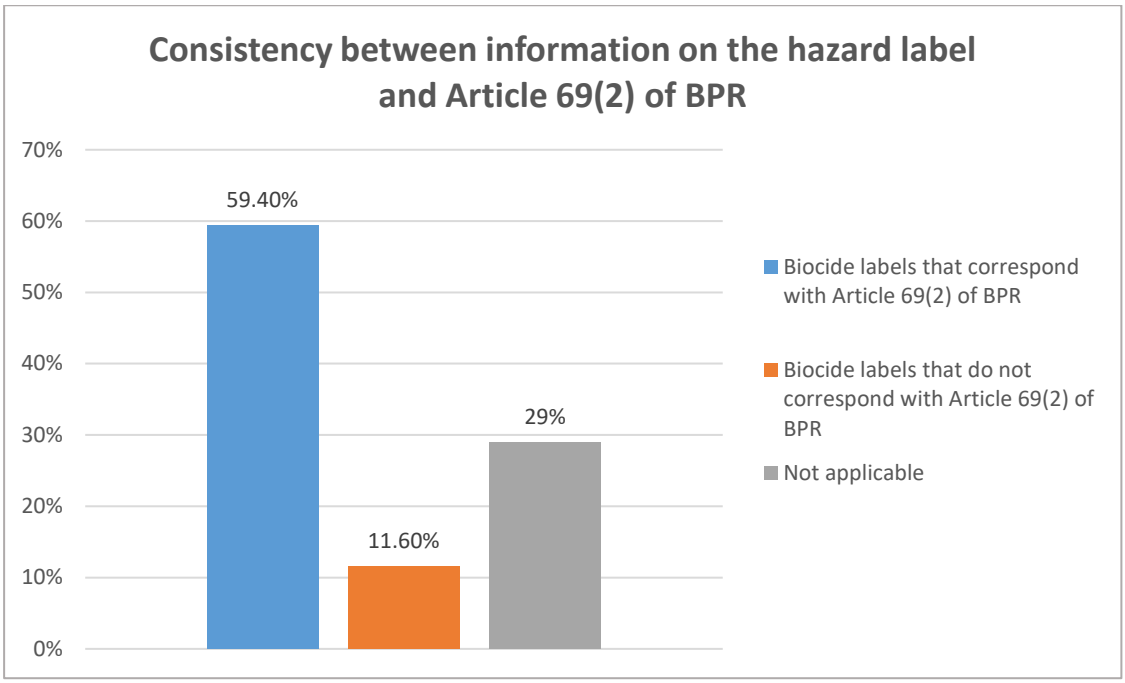

Figure 22. The consistency of information between the hazard label and Article 69(2) of BPR.

The above presented 32 % (223) of the reported biocide labels not fulfilling the requirements regarding consistency between information on the hazard label and the granted authorization (SPC) (Figure 21), and 29 % (200) of the reported biocide labels not fulfilling requirements regarding consistency between information on the hazard label and Article 69(2) of BPR (Figure 22), are non-applicable since both these groups of biocides are under transitional measures.

The inspections revealed at least one non-compliance with BPR obligations subject to this project for 29 % of the companies and 23 % of the products (see Table 6).

2.7 Infringements

In total, non-compliances related to at least one mixture were found in 734 (45 %) inspections out of 1620 inspections conducted during REF-6. The total number of mixtures with non-compliances was 1398 (44 %) while the total number of mixtures reported was 3204 (Table 10).

Table 10. The found non-compliances of REF-6 project

Inspections in which non-compliances were found	734
Mixtures with non-compliances	1398
Inspections in which no non-compliances were found	886
Mixtures without non-compliances	1806

It is to be noted that the information for (non-)compliance was not reported for all the mixtures inspected during the project.

Regarding the companies, 45% (556) of the checked SMEs (1226) and 44 % (174) of the checked non-SMEs (394) had non-compliant mixtures.

The companies with non-compliant mixtures are presented according to their role in Table 11.

Table 11. Rate of non-compliance per company role

Role(s) of the company under CLP:	Number of companies with non-compliant mixtures	% of companies with non-compliant mixtures compared to the total number of companies with each role
Downstream user:	**317**	**48%**
Formulator	274	49%
Re-filler/Re-packager	73	52%
Re-importer	2	50%
Distributor:	**483**	**48%**
Retailer	231	43%
Wholesaler	291	51%

Other	17	49%
Manufacturer	**85**	**43%**
Importer	**77**	**47%**

As a result of the non-compliances, different measures have been imposed by the NEAs. Often more than one measure could be imposed for each non-compliance, depending on the national procedures of each Member State. In total, 945 measures were reported to have been imposed due to non-compliances with the obligations for classification and labelling of mixtures according to CLP Regulation criteria and rules and on the enforcement of REACH provisions regarding the content of Sections 2, 3, 9, 11, 12 and 16 of the SDS in the scope of this project. The measures are given in Figure 23.

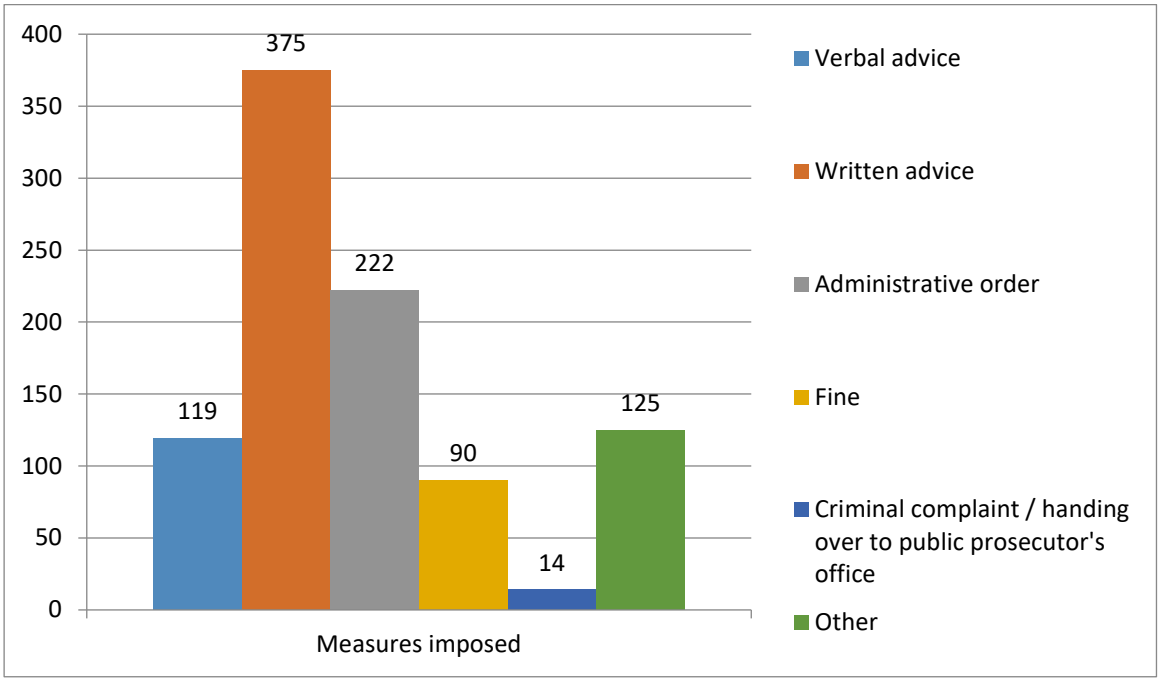

Figure 23. Measured imposed for the found non-compliances

Written advice and administrative orders were used most frequently. In some cases the company undertook voluntary measures to restore compliance.

Approximately two-thirds (almost 1100) of the follow up activities for the 1620 inspected companies were completed by the inspectors by the time the data was submitted by the National Coordinators to the Working Group.

3. Conclusions and Recommendations

Based on the data received on the five different modules and the analyses that could be conducted on them, the following conclusions and recommendations could be drawn from the project.

3.1 Conclusions

The most frequent way of checking the classification of the mixtures by the inspectors was via the SDS for 90 % (3045) of the checked mixtures, followed by CLP annex VI Table 3 for 60 % (2041) of the checked mixtures and C&L Inventory for 41 % (1385) of the checked mixtures.

Altogether 17 % of the reported mixtures had wrong classification. The classification was correct in 79 % and inconclusive in 4 % of the reported mixtures. For the reported substances with harmonized classification, 93 % of the checked mixtures the classification of the substances in Section 3.2 of the SDS(s) corresponded to the harmonized classification in Annex VI Table 3 in CLP. In addition, for 92 % of the checked mixtures the classification of the substances in the mixture in Section 3.2 of the SDS corresponded to a notification in the C&L Inventory.

In 43 % of the cases where the classification of the mixtures was derived by the inspected company it was done using an IT-tool. The IT-providers and quality of their IT-tools are therefore of great importance to have mixtures with correct classification on the EU market.

The results of the project show that although the quality of the SDSs is improving compared to previous Forum projects (the REF-2 project and a joint project with Accredited Stakeholders on SDS), 33 % of the SDSs still contain various issues and/or shortcomings.

In 15 % of the checked SDSs, the M-factors for substances classified as "Aquatic Acute 1" or "Aquatic Chronic 1" were missing without proper justification.

From the results it can be concluded that in most cases the information on the hazard label was consistent with CLP regulation, nevertheless, more than one third of checked mixtures had incorrect labels. However, that did not indicate that labels themselves were wrong because correctness of the label much depends on correctness of classification. In most cases, the information on the hazard label was consistent with that in Section 2.2 in the SDS. Therefore, if the classification of the mixture in the SDS is wrong, it is most likely that it would be wrong on the label as well.

The most frequent errors and/or deficiencies in the label were:

- wrong or missing hazard statement – in 468 of the cases;
- followed by missing precautionary statements – in 336 of the cases; and
- errors and/or deficiencies related to the hazard pictogram - in 310 of the cases.

A total of 45 % of the inspections in the scope of REF-6 detected at least one non-compliance and 44 % of the total number of mixtures checked were found to be non-compliant. According to the company size, similar percentage of non-compliances was found in SMEs and non-SMEs.

Written advice and administrative orders were the measures imposed by the NEAs most frequently. In some cases the company undertook voluntary measures to restore compliance.

Conclusions from Optional Module A inspections

From the findings from Optional Module A inspections, one of the most significant conclusions was relevant to the interpretation of Article 29. The REF-6 questionnaire was constructed following the CLP legal text, which is written in a way that it requires the conditions of Article 29(1) to be fulfilled before Article 29(2) can be considered.

However, the interpretation from some Member States of the legal text and consequently of the way inspectors filled in the relevant REF-6 questionnaire suggested a different approach. More specifically, the results of Optional Module A inspections showed that inspectors considered that the conditions of Article 29(1) and Article 29(2) applied simultaneously.

The issue of the interpretation of CLP Article 29, paragraphs 1 and 2, has also been discussed during a CLP workshop that took place during the 14th HelpNet Steering Group meeting. Moreover, the usefulness of Article 29(2) was questioned, as there seemed to be an understanding that paragraph 1 would always apply. These concerns of HelpNet members were confirmed by the real examples from the findings from Optional Module A inspections.

The different interpretations of Article 29 described above, constitute a challenge for the harmonisation of enforcement.

Conclusions from Optional Module B inspections

In the great majority of the cases the deviations that led to inspections on substances did not originate from the original classifications made by manufacturers and importers, indicating problems concerning the forwarding of information in the downstream supply chain regarding the cases.

The high rate of non-compliance from the screening cases provided by ECHA indicates that this method is a good way of finding non-compliances with harmonised classification of substances.

Conclusions from Optional Module C inspections

The project showed that for 22 % of the checked LLDCs, the closure of the outer packaging did not maintain its functionality when repeatedly opened and closed during the life span of the packaging. In addition, when NEAs in Germany were testing the LLDCs, inspectors found that there was a discrepancy between laboratory certificates from the manufacturer of the LLDCs and the test results from the accredited laboratories. One reason for this could be that the test conditions are not standardised yet.

Conclusions from Optional Module D inspections

The results of the checks carried out show that about 50 % of the biocidal products checked were placed on the market in accordance with European or relevant national legislation and only a small proportion of the biocidal products checked were found to have been placed on the market without authorization.

The inspections show that only 0.27 % of biocidal products that were checked do not fulfil Article 95 in BPR.

3.2 Recommendations

To industry

33 % of the SDSs checked in the scope of REF-6 had issues and/or shortcomings. Therefore, industry should strive to improve the quality of the SDSs which will lead to better quality of information in the supply chain. This is in line with Action 3 “Improving the workability and quality of extended safety data sheets” in the Commission’s REACH review and the recommendations in the Report on Improvement of Quality of SDS.

Manufacturers, importers and downstream users have to put more effort in deriving the right classification of the mixtures and communicating it down the supply chain. This will prevent dissemination of incorrect information in the SDS and on the label.

The actors in the supply chain have to cooperate more actively to enhance the communication and cooperation between them. This will ensure that the information will reach the distributors and downstream users and at the same time, the feedback provided by the latter will improve the quality of the information.

There are still companies with poor internal knowledge on REACH and CLP. The employers have to ensure that their personnel receives the necessary training.

As noted in the report, 22 % of the outer packages of LLDCs were fitted with a closure that did not maintain its functionality. The packages should be improved in order for the closure mechanisms to retain their functionality throughout the life span of the packages.

Regarding BPR Regulation, the industry has to put more effort to ensure that their personnel is highly qualified in this field. This would improve the understanding of the different procedures and minimise breaches caused by a lack of knowledge of BPR legislation.

To the Member States

To provide training and information campaigns for the industry aiming to improve the knowledge about the criteria and the rules for classification and labelling of mixtures according to CLP and the quality of the SDSs.

As the NEAs have gained valuable knowledge during the project, they have to strive to maintain it.

To the European Commission

It is recommended that a request for clarification of the different interpretations of Article 29 described above in the “Conclusions from Optional Module A inspections” section would be made, as these constitute a challenge for the harmonisation of enforcement.

It is recommended to define or initiate a development of testing standards for technical requirements of the LLDCs in order to get a high and harmonized standard of safe liquid laundry detergents in soluble packaging for single use in all European Member States.

To the Forum

Forum should consider repeating such a project either as a REF or as pilot in a few years in order to monitor the compliance with the requirements for classification and labelling of mixtures according to CLP Regulation and the quality of the information in the supply chain

including the SDS. Similarly, the compliance with requirements of BPR Regulation should also be monitored.

As different MSs have different interpretations of Article 29 to CLP, i.e. exemptions from labelling and packaging requirements, the Forum should address this (as a practical issue) and try to reach a common understanding.

To ECHA

Continue and develop the screening method for possible non-compliance with harmonised classification based on the information available in the registration dossiers.

Annex 1: Questionnaires

Forum Project REF-6 **QUESTIONNAIRE** Fill out one questionnaire for each company inspected. Please note that the **Main Module is obligatory and Modules A - D are optional**.	
Section 0 - General Information about the inspection	
0.1.Participating country:	
0.2. Inspector: 0.3. Date of inspection: 0.4. File reference:	This data will be deleted by NC – this data are only for internal use e.g. in the case you need to forward this case to other NEAs for assistance.
0.5 The inspection is: ☐ On-site inspection ☐ Desktop inspection	
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:	This data will be deleted by NC – this data are only for internal use e.g. in the case you need to forward this case to other NEAs for assistance.
1.4. Company's NACE-Code(s):	See Annex 6 for guidelines.
1.5. According to Commission Recommendation 2003/361/EC the company qualifies as: (☐) SME (☐) not SME SME: <250 employees and ≤50 million euro annual turnover	
1.6. Role(s) of the company under CLP: ☐ Downstream user	See Annex 6 for guidelines. Art. 2(19) of CLP
If downstream user, please indicate whether: ☐ Formulator ☐ Re-filler/Re-packager ☐ Re-importer	
☐ Distributor	Art. 2(20) of CLP

If distributor, please indicate whether: ☐ Retailer ☐ Wholesaler ☐ Other	
☐ Manufacturer ☐ Importer	Art. 2(15) of CLP Art. 2(17) of CLP

Section 2 - Details of the mixtures checked					
Note: The inspector decides on the number of hazardous mixtures requiring classification and labelling to be checked, maximum 5					
2.0	Mixture name (Checked)	Product category (See Annex 8)	Product supplied to general public	For BPR Product type (PT) number according to Annex V to BPR (See Annex 9 of the Manual for PT numbers)	
1			◯ Yes ◯ No		
2			◯ Yes ◯ No		
3			◯ Yes ◯ No		
4			◯ Yes ◯ No		
5			◯ Yes ◯ No		
2.1 Classification of mixtures				CLP Article 4(1) CLP Articles 6-16	

2.1. Was the classification of the mixtures derived by the inspected company? ☐ Yes, for __ of the checked mixtures ☐ No, for __ of the checked mixtures If yes, did the company use an IT tool to calculate the classification? ☐ Yes The tool that was used, if known: _____ ☐ No	According to CLP Article 4(5) and (6) the downstream user and the distributor may take over the classification for a substance or mixture derived in accordance with Title II of CLP already by another actor in the supply chain, provided that they do not change the composition of this substance or mixture. See Annex 6 for guidelines.
2.2. The classification of all the mixtures was checked by the inspector using: ☐ The SDS for __ of the checked mixtures ☐ Table 3.1 of Annex VI of CLP (harmonised classification) for __ of the checked mixtures ☐ The C&L Inventory (non-harmonised) for __ of the checked mixtures ☐ Information provided by the company for __ of the checked mixtures: ☐ the exact composition of the mixture ☐ reliable scientific information of the mixtures ☐ the substances in the mixture (SDS of the components) ☐ the CMR substances in the mixture ☐ An IT tool The tool that was used:_____ ☐ By other means (not specified above) for __ of the checked mixtures	CLP Article 4(3) and article 6 See Annex 6 for guidelines. In Annex 7 (supporting material) some commercially available tools are listed.

2.3. Was the classification of the mixtures correct? ☐ Yes, for __ of the checked mixtures ☐ No, for __ of the checked mixtures Was an IT tool used by the company? ☐ Yes ☐ No ☐ Cannot conclude, for __ of the checked mixtures If no, please state the reasons for wrong/inconclusive classification: _____	Parts 2-5 of Annex I of CLP REACH Article 31 and CLP Article 18
2.4. Does the labelling in Section 2.2 in SDS correspond with the classification of the mixture in Section 2.1 of the SDSs? ☐ Yes, for __ of the checked mixtures ☐ No, for __ of the checked mixtures	REACH Article 31, Annex II section 2 NOTE: Missing labelling information may be due to exemptions. See optional module A. See Annex 6 for guidelines.
2.5. Does the classification of the substances in the mixtures in section 3.2.1 of the SDS(s) correspond to the harmonized classification in Annex VI table 3.1 in CLP? ☐ Yes, for __ of the checked mixtures ☐ No, for __ of the checked mixtures If no please forward the information to NEA responsible for the supplier of the mixture/substance ☐ Not relevant. __ of the checked mixtures have not harmonised classification for any of the substances in the mixture. Go to Q2.6	REACH Article 31 and CLP Article 18 See Annex 6 for guidelines.
2.6. Does the classification of the substances in the mixtures in section 3.2 of the SDS(s) correspond to a notification in the C&L Inventory ☐ Yes, for __ of the checked mixtures ☐ No, for __ of the checked mixtures ☐ Not checked.	See Annex 6 for guidance.

<table>
<tr><td>3. Check of the safety data sheet (SDS)
Note to inspectors: in this project it is only relevant to check the information in sections 2 (Hazards identification), 3 (Composition/information on ingredients), and if necessary sections 9 (Physical and Chemical Properties), 11 (Toxicological information), 12 (Ecological information)) and 16 (Other information: an indication of which of the methods of evaluating information was used for the purpose of classification)</td><td>See Annex 6 for guidelines.</td></tr>
<tr><td>3.1. Do the inspected relevant section in the SDS conform to REACH Article 31 and Annex II (Commission Regulation (EU) 2015/830)

☐ Yes; __ of the checked SDSs. If ‘yes’, go to question 3.2.

☐ No,__ of the checked SDSs contain errors/ deficiencies. If “no”, go to question 3.1.1.</td><td>The transitional period in 2015/830 art. 2 ended 31 May 2017.</td></tr>
<tr><td>3.1.1. Please specify the errors/deficiencies and the corresponding number of mixtures in the table below:

<table>
<tr><th>Errors/ deficiencies in the SDS</th><th>Number of checked SDSs with non-compliances in these sections</th></tr>
<tr><td>☐ Errors under section 2.1</td><td></td></tr>
<tr><td>☐ Errors under section 2.2</td><td></td></tr>
<tr><td>☐ Errors under section 3.2</td><td></td></tr>
<tr><td>☐ Errors under section 9 (information is missing or does not correspond with the classification)</td><td></td></tr>
<tr><td>☐ Errors under section 11 (information is missing or does not correspond with the classification)</td><td></td></tr>
<tr><td>☐ Errors under section 12 (information is missing or does not correspond with the classification)</td><td></td></tr>
<tr><td>☐ Errors under section 16 (information is missing or does not correspond with the classification)</td><td></td></tr>
</table>
</td><td>REACH Annex II</td></tr>
</table>

<table>
<tr><td>3.2. Are the M-factors given in the SDS for those substances that are classified "Aquatic Acute 1" or "Aquatic Chronic 1"?

☐ Yes, in __ of the checked SDSs
☐ No, in __ of the checked SDSs
☐ Not checked
☐ Substances do not have this classification or do not have M-factors</td><td>This is not a requirement, but it is recommended because it is an important aspect in the classification of the mixture</td></tr>
<tr><td>4. Check of the Hazard label</td><td></td></tr>
<tr><td>Information on the hazard label

4.1. Are the mixtures labelled in accordance with CLP?

☐ Yes, __ of the checked mixtures

☐ No, __ of the checked mixtures
If “no”, go to question 4.1.1.

☐ No, __ of the checked mixtures
Missing labelling information, due to exemptions from labelling and packaging requirements (CLP Article 29). Please fill out Optional Module A.

NOTE: In case there are additional deficiencies other than those due to exemptions (CLP Article 29), question 4.1.1 should be also filled in.</td><td>Obligatory information on the label is specified in CLP Article 17.</td></tr>
<tr><td>4.1.1 Please specify the errors and/or deficiencies and the corresponding number of mixtures in the table below:
<table>
<tr><th>Errors/ deficiencies on the labels</th><th>Number of checkeded labels with non-compliances</th></tr>
<tr><td>A. ☐ Incorrect label size</td><td></td></tr>
<tr><td>B. ☐ Missing or wrong contact information (name, address and/or telephone number)</td><td></td></tr>
<tr><td>C. ☐ Missing nominal quantity (only if made available for the general public and not specified elsewhere on the package)</td><td></td></tr>
<tr><td>D. ☐ Not in official language</td><td></td></tr>
<tr><td>E. ☐ Product identifier, (trade name/designation and identity of all substances in the mixture that contribute to the classification of the mixture. List of hazard classes is mentioned in the Article)</td><td></td></tr>
<tr><td>E.1. ☐ Product name missing</td><td></td></tr>
</table></td><td>See Annex 6 for guidelines.

CLP Article 31 (4) and Annex I, Table 1.3

CLP Article 17 (1)(a)

CLP Article 17 (1)(b)

CLP Article 17 (2)

CLP Article 18 (3)</td></tr>
</table>

E.2. ☐ Listing of substances missing		
F. ☐ Hazard pictogram		CLP Articles 19 and 26 Section 1.2.1 in Annex I Annex I, table 1.3
F.1. ☐ Missing		
F.2. ☐ The pictogram differs from the requirements for shape or color as set out		
F.3. ☐ Incorrect size		
F.4. ☐ Other, please specify:		
G. ☐ Signal word wrong or missing		CLP Article 20
H. ☐ Hazard statements wrong or missing		CLP Articles 21 and 27
I. ☐ Precautionary statements missing I.1. ☐ Not checked		CLP Articles 22 and 28
J. ☐ Supplemental information		CLP Article 25. See Annex 6 for guidance.
K. ☐ General rules for the application of labels		
K.1 ☐ The label is not firmly affixed to one or more surfaces of the packaging immediately containing the mixture		CLP Article 31(1)
K.2. ☐ The label is not readable horizontally when the package is set down normally		CLP Article 31(1)
K.3. ☐ The hazard pictogram does not stand out clearly on the label		CLP Article 31(2)
K.4. ☐ The label elements from Article 17 are not clearly and indelibly marked		
K.5. ☐ The label elements do not stand out clearly from the background and is not easily read		CLP Article 31(3)
L. ☐ Other, please specify:		For instance Articles 32 and 33
5. Consistency between information on the hazard label and section 2.2 in the SDS (REACH Annex II)		

5.1. Does the hazard label of the checked mixture(s) correspond with the label elements in section 2.2 of the SDS? ☐ Yes, __ of the checked mixtures ☐ No, __ of the checked mixtures have a different hazard labelling compared to the corresponding SDS ☐ No, __ of the checked mixtures. Differencies in labelling information, due to exemptions from labelling and packaging requirements (CLP Article 29). The Optional Module A should be also filled in.	NOTE: Differencies in labelling information may be due to exemptions. See optional module A. See Annex 6 for guidelines.
6. Follow-up Actions	
6.0 Has the inspection of CLP and REACH obligations subject to this project revealed any non-compliance with CLP ☐ Yes, __ of the checked mixtures ☐ No, __ of the checked mixtures	
6.1 Measures imposed due to non-compliance with CLP and REACH obligations subject to this project ☐ No measures ☐ Verbal advice ☐ Written advice ☐ Administrative order ☐ Fine ☐ Criminal complaint / Handing over to public prosecutor's office ☐ Others. Please specify: _____	
6.2. Are the follow-up activities ◯ completed ◯ ongoing	
7. Cooperation with other Member States	
7.1. Have any cases been forwarded to other Member States? ◯ Yes, to ☐ Focal point ☐ Forum Member ☐ National coordinator REF-6 ◯ No	

7.2. The cases have been forwarded via: ☐ PD-NEA (Portal Dashboard for National Enforcement Authorities) ☐ Article 11 notification (General Product Safety Directive 2001/95/EC) ☐ Article 12 notification (RAPEX, General Product Safety Directive 2001/95/EC) ☐ ICSMS ☐ Informal (e.g. via e-mail) ☐ Other: please specify _____	
8. Additional Information (optional):	If you have additional information regarding the inspection performed

Questionnaire for Optional Module A: Exemptions from labelling and packaging requirements

REF-6 **QUESTIONNAIRE** **Optional Module A: Exemptions from the labelling and packaging requirements** (a substance or mixture is contained in awkwardly shaped or small packaging, CLP Art.29)	
A 0.1 Checked mixture ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	Mixture number should correlate to numbering in Q 2.0 of the Main Module.
A1.1 The labelling check was performed using the mixture classification from: ☐ section 2.1 of mixture SDS only for __ of the checked mixtures ☐ mixture classification after inspector check for __ of the checked mixtures	
A1.2 Do the general rules for labels (CLP Art.31) apply for the mixture label? ☐ Yes, for __ of the checked mixtures [End of Optional Module A.] ☐ No, for __ of the checked mixtures [Go to A1.3]	CLP Art. 31 See Annex 6 for guidelines
A1.3 Does any of the following reasons for exemption of labelling requirements of Article 31 apply? ☐ Yes (if "Yes", please tick appropriate boxes and go to question A1.4) ☐ Packaging is difficult to label because of its shape or form, so that full labelling information cannot be displayed for __ of the checked mixtures ☐ Packaging is too small, so that full labelling information cannot be displayed for __ of the checked mixtures ☐ No, for __ of the checked mixtures (infringement of Article 31) [End of Optional Module A. Go to Section "Follow-up actions"]	CLP Art. 29(1) See Annex 6 for guidelines
A1.4 Is the label information provided in one of the following ways? ☐ Yes (if "Yes", please tick appropriate box, and go to question A1.5) ☐ in fold–out label for __ of the checked mixtures ☐ on tie–on tag for __ of the checked mixtures ☐ on outer packaging for __ of the checked mixtures ☐ No, for __ of the checked mixtures (go to question A1.11)	CLP Art. 29(1) See Annex 6 for guidelines
Label elements provided in fold-out labels or on tie-on tags or on an outer packaging CLP Art. 29(1), CLP Annex I, 1.5.1. – Exemptions from Art.31	
A1.5 Is the full labelling information according to Article 17(1) displayed on the fold–out label/tie-on tag/outer packaging of the mixture?	CLP Art. 29(1) CLP Annex I, 1.5.1

☐ Yes, for __ of the checked mixtures ☐ No, for __ of the checked mixtures (infringement of Article 17(1))	See Annex 6 for guidelines
A1.6 Are the labelling elements in the fold–out label/tie-on tag/outer packaging written in the official language(s) of the Member State(s) where the mixture is placed on the market? ☐ Yes, for __ of the checked mixtures ☐ No, for __ of the checked mixtures (infringement of Article 17(2))	CLP Art. 29(1) CLP Annex I, 1.5.1 See Annex 6 for guidelines
A1.7 Do the label elements displayed on the fold–out label/tie-on tag/outer packaging of the mixture comply with the general rules for the application of labels provided in Article 31(2), (3),(4)? ☐ Yes, for __ of the checked mixtures ☐ No, for __ of the checked mixtures (infringement of Article 31)	CLP Art. 29(1) CLP Annex I, 1.5.1
A1.8 Do the label elements displayed on the fold–out label/tie-on tag/outer packaging of the mixture comply with the provisions of Article 32 concerning the location of information on the label? ☐ Yes, for __ of the checked mixtures ☐ No, for __ of the checked mixtures (infringement of Article 32)	CLP Art. 29(1) CLP Annex I, 1.5.1 See Annex 6 for guidelines
A1.9 Does the label on the inner packaging of the mixture comply with the provisions of section 1.5.1.2 of Annex I (hazard pictograms, mixture identifier, name and telephone number of supplier)? ☐ Yes, for __ of the checked mixtures ☐ No, for __ of the checked mixtures (infringement of Article 29(1)) ☐ Not relevant for __ of the checked mixtures	CLP Art. 29(1) CLP Annex I, 1.5.1.2
A1.10 Is the fold–out label/tie-on tag/label on outer packaging of the mixture securely attached/affixed to the packaging? ☐ Yes, for __ of the checked mixtures ☐ No, for __ of the checked mixtures ☐ Not relevant for __ of the checked mixtures	See Annex 6 for guidelines
A1.11 Can the full labelling information be provided in fold–out label or tie-on tag or on the outer packaging of the mixture? ☐ Yes, for __ of the checked mixtures (infringement of Article 31) [End of Optional Module A. Go to Section "Follow-up actions"] ☐ No (tick the appropriate box) ☐ Contents of packaging do not exceed 125 mL __ of the checked mixtures (go to question A1.12) ☐ Mixture is contained in soluble packaging for single use for __ of the checked mixtures (go to question A1.19) ☐ Mixture is contained in inner packaging where contents do not exceed 10 mL for __ of the checked mixtures (go to question A 1.23)	

Omission of certain label elements
CLP Art. 29(2), CLP Annex I, 1.5.2. – Exemptions from Art.17

Labelling of packages where the contents do no exceed 125 mL
CLP Annex I, 1.5.2.1

A1.12 Are the mixtures classified in one or more of the following hazard categories?
☐ Yes (If "Yes" please fill in the following table and go to question A1.13)

Hazard categories	Number of checked mixtures
☐ Oxidising gases of category 1	
☐ Gases under pressure	
☐ Flammable liquids of category 2 or 3	
☐ Flammable solids of category 1 or 2	
☐ Self-reactive substances or mixtures Types C to F	
☐ Self-heating substances or mixtures of category 2	
☐ Substances and mixtures which, in contact with water, emit flammable gases of categories 1, 2 or 3	
☐ Oxidising liquids of category 2 or 3	
☐ Oxidising solids of category 2 or 3	
☐ Organic peroxides Types C to F	
☐ Acute toxicity of category 4, if the substances or mixtures are not supplied to the general public	
☐ Skin irritation of category 2	
☐ Eye irritation of category 2	
☐ Specific target organ toxicity — single exposure of category 2 or 3, if the substance or mixture is not supplied to the general public	
☐ Specific target organ toxicity — repeated exposure of category 2, if the substance or mixture is not supplied to the general public	
☐ Hazardous to the aquatic environment — Acute of category 1	
☐ Hazardous to the aquatic environment — Chronic of category 1 or 2	

☐ No , for __ of the checked mixtures (If "No" go to question A1.14)

CLP Art. 29(2)
CLP Annex I, 1.5.2.1.1

The classification of the mixture can be either obtained from section 2.1. of the SDS, or it can be the result of the inspectors check of the mixture classification correctness.

A1.13 Are the hazard pictogram(s) and signal word required for the hazard categories ticked in question A1.12, provided on the mixture label?
☐ Yes, for __ of the checked mixtures

CLP Art. 29(2)
CLP Annex I, 1.5.2.1.1

See Annex 6 for guidelines

<table>
<tr><td>☐ No, for __ of the checked mixtures (infringement of Article 17) [End of Optional Module A. Go to Section “Follow-up actions”]</td><td></td></tr>
<tr><td>A1.14 Are the mixtures classified in one or more of the following hazard categories?
☐ Yes (If “Yes” please fill in the following table and go to question A1.15)

<table><tr><th>Hazard categories</th><th>Number of checked mixtures</th></tr><tr><td>☐ Flammable gases of category 2</td><td></td></tr><tr><td>☐ Reproductive toxicity: effects on or via lactation</td><td></td></tr><tr><td>☐ Hazardous to the aquatic environment — Chronic category 3 or 4</td><td></td></tr></table>
☐ No, for __ of the checked mixtures (If “No” go to question A1.16)</td><td>CLP Art. 29(2)
CLP Annex I, 1.5.2.1.2

The classification of the mixture can be either obtained from section 2.1. of the SDS, or it can be the result of the inspectors check of the mixture classification correctness.</td></tr>
<tr><td>A1.15 Are the hazard statement(s) and signal word required for the hazard categories ticked in question A1.14 displayed on the mixture labels?
☐ Yes, for __ of the checked mixtures
☐ No, for __ of the checked mixtures (infringement of Article 17, Article 29(2) and section 1.5.2.1.2 of Annex I)</td><td>CLP Art. 29(2)
CLP Annex I, 1.5.2.1.2

See Annex 6 for guidelines</td></tr>
<tr><td>A1.16 Are the mixtures classified in one or more hazard categories other than: a) those hazard categories mentioned in questions 1.12 and 1.14 or b) Corrosive to metals (H290)?
☐ Yes, for __ of the checked mixtures (got to question A1.17)
☐ No, for __ of the checked mixtures (go to question A1.18)</td><td></td></tr>
<tr><td>A1.17 Are the label elements related to hazard categories other than a) those hazard categories mentioned in questions A1.12 and A1.14 and b) Corrosive to metals (H290) included on the labels according to Article 17?
☐ Yes, for __ of the checked mixtures (go to question A1.18)
☐ No, for __ of the checked mixtures (infringement of Article 17 and go to question A1.18)</td><td>CLP Art. 29(2)
CLP Annex I, 1.5.2.1</td></tr>
<tr><td>A1.18 If the mixtures are fitted with an aerosol dispenser, are the provisions fulfilled regarding the exemptions that apply for the labelling of small packages of aerosols classified as flammable (according to Directive 75/324/EEC)?
☐ Yes, for __ of the checked mixtures
☐ No, for __ of the checked mixtures (infringement of Article 17)
☐ Not applicable (mixtures not fitted with aerosol dispenser), for __ of the checked mixtures</td><td>CLP Art. 29(2)
CLP Annex I, 1.5.2.1

See Annex 6 for guidelines</td></tr>
<tr><td colspan="2">Labelling of soluble packaging for single use
CLP Annex I, 1.5.2.2</td></tr>
</table>

IMPORTANT NOTE: If the soluble packaging for single use contains liquid consumer laundry detergent, then additional labelling and packaging requirements apply and the optional module C (LLDC) of the questionnaire should be filled in as well.

A1.19 Does the mixture fall within the scope of regulation (EC) No 1107/2009 (Plant Protection Products regulation) or (EU) No 528/2012 (Biocide Products regulation)?

☐ Yes

If "Yes", is the mixture labelled according to CLP Art 17?

☐ Yes, for __ of the checked mixtures [End of Optional Module A. Go to Section "Follow-up actions"]

☐ No, for __ of the checked mixtures (infringement of Article 17) [End of Optional Module A. Go to Section "Follow-up actions"]

☐ No, for __ of the checked mixtures (go to question A1.20)

CLP Annex I, section 1.5.2.3

See Annex 6 for guidelines

A1.20 Is the content of the soluble packaging for single use ≤ 25 mL?

☐ Yes, for __ of the checked mixtures (go to question A1.21)

☐ No, for __ of the checked mixtures (infringement of Article 17) [End of Optional Module A. Go to Section "Follow-up actions"]

CLP Art. 29(2)
CLP Annex I, 1.5.2.2

A1.21 Is the classification of the contents of the soluble packaging for single use exclusively one or more of the categories listed below?

☐ Yes (please fill in the following table and go to question A1.22)

CLP Art. 29(2)
CLP Annex I, 1.5.2.2

Hazard categories	Number of checked mixtures
☐ Oxidising gases of category 1	
☐ Gases under pressure	
☐ Flammable liquids of category 2 or 3	
☐ Flammable solids of category 1 or 2	
☐ Self-reactive substances or mixtures Types C to F	
☐ Self-heating substances or mixtures of category 2	
☐ Substances and mixtures which, in contact with water, emit flammable gases of categories 1, 2 or 3	
☐ Oxidising liquids of category 2 or 3	
☐ Oxidising solids of category 2 or 3	
☐ Organic peroxides Types C to F	
☐ Acute toxicity of category 4, if the substances or mixtures are not supplied to the general public	
☐ Skin irritation of category 2	
☐ Eye irritation of category 2	
☐ Specific target organ toxicity — single exposure of category 2 or 3, if the	

substance or mixture is not supplied to the general public	
☐ Specific target organ toxicity — repeated exposure of category 2, if the substance or mixture is not supplied to the general public	
☐ Hazardous to the aquatic environment — Acute of category 1	
☐ Hazardous to the aquatic environment — Chronic of category 1 or 2	
☐ Flammable gases of category 2	
☐ Reproductive toxicity: effects on or via lactation	
☐ Hazardous to the aquatic environment — Chronic of category 3 or 4	
☐ Corrosive to metals	

☐ No, for __ of the checked mixtures (infringement of Article 17) [End of Optional Module A. Go to Section "Follow-up actions"]

A1.22 Do the outer packagings containing the soluble packaging for single use fully meet the requirements of Article 17? ☐ Yes, for __ of the checked mixtures ☐ No, for __ of the checked mixtures (infringement of Article 17)	CLP Art. 29(2) CLP Annex I, 1.5.2.2
Labelling of inner packaging where the contents do not exceed 10 mL CLP Annex I, 1.5.2.4	
A1.23 Does the mixture fall within the scope of regulation (EC) No 1107/2009 (Plant Protection Products regulation) or (EU) No 528/2012 (Biocide Products regulation)? ☐ Yes If "Yes", is the mixture labelled according to CLP Art 17? ☐ Yes, for __ of the checked mixtures [End of Optional Module A. Go to Section "Follow-up actions"] ☐ No, for __ of the checked mixtures (infringement of Article 17) [End of Optional Module A. Go to Section "Follow-up actions"] ☐ No, for __ of the checked mixtures (go to question A1.24)	CLP Art. 29(2) CLP Annex I, section 1.5.2.5 See Annex 6 for guidelines
A1.24 Are the contents of the inner packaging ≤ 10 mL? ☐ Yes, for __ of the checked mixtures (go to question A1.25) ☐ No, for __ of the checked mixtures (infringement of Article 17) [End of Optional Module A. Go to Section "Follow-up actions"]	CLP Art. 29(2) CLP Annex I, section 1.5.2.4.1 See Annex 6 for guidelines
A1.25 Are the mixtures placed on the market for supply to a distributor or downstream user for scientific research and development? ☐ Yes, for __ of the checked mixtures (go to question A1.26)	CLP Art. 29(2) CLP Annex I, section 1.5.2.4.1 See Annex 6 for guidelines

☐ No, for __ of the checked mixtures (infringement of Article 17) [End of Optional Module A. Go to Section "Follow-up actions"]	
A1.26 Are there an outer packagings (containing the inner packaging) that fully meets the requirements of Article 17? ☐ Yes, for __ of the checked mixtures (go to question A1.27) ☐ No, for __ of the checked mixtures (infringement of Article 17) [End of Optional Module A. Go to Section "Follow-up actions"]	CLP Art. 29(2) CLP Annex I, section 1.5.2.4.1 See Annex 6 for guidelines
A1.27 Does the label on the inner packaging contain the mixture identifier? ☐ Yes, for __ of the checked mixtures (go to question A1.28) ☐ No, for __ of the checked mixtures (infringement of Article 17) [End of Optional Module A. Go to Section "Follow-up actions"]	CLP Art. 29(2) CLP Annex I, section 1.5.2.4.2
A1.28 If according to the product classification, the hazard pictograms "GHS01", "GHS05" "GHS06" and/or "GHS08" are required, do the labels on the inner packagings contain the appropriate hazard pictogram(s)? ☐ Yes, for __ of the checked mixtures ☐ No, for __ of the checked mixtures (infringement of Article 17)	CLP Art. 29(2) CLP Annex I, section 1.5.2.4.2 When more than two pictograms are assigned, "GHS06" and "GHS08" may take precedence over "GHS01", "GHS05"

Questionnaire for Optional Module B: Harmonised classification

Forum Project REF-6
Optional Module B - Harmonised classification
QUESTIONNAIRE

Fill out one questionnaire per company inspected.

Section B1 – Information on the case and inspected substance

B1.1

	Substance name (Checked)	EC number
1		
2		
3		
4		
5		

Provide substance information according given data and corresponding entry of Annex VI of CLP.

Give the answer below according to the numbers listed here

B1.2. Case origin:

☐ Screening information provided by ECHA to MS:

Self-classification not consistent with harmonised classification (CMR 1A/1B/2, respiratory sensitisation, skin sensitisation, STOT RE 1/2)
1 2 3 4 5
☐ ☐ ☐ ☐ ☐

Harmonised impurities and additives not declared as relevant for classification and labelling.
1 2 3 4 5
☐ ☐ ☐ ☐ ☐

☐ C&L inspection of a mixture (downstream):

A case forwarded by other MS, REF-6 file reference (if applicable):
1 2 3 4 5
☐ ☐ ☐ ☐ ☐

☐ National case, REF-6 file reference (if applicable):
1 2 3 4 5
☐ ☐ ☐ ☐ ☐

Section B2 – Non-compliances identified in the inspection

B2.1. For the inspected substance, has non-compliance with obligations of the inspected company related to Article 4(3) of CLP Regulation been detected? 1 2 3 4 5 ☐ ☐ ☐ ☐ ☐ Yes ☐ ☐ ☐ ☐ ☐ Suspected, but still under investigation ☐ ☐ ☐ ☐ ☐ No (End of questionnaire.)	CLP Article 4(3) See Annex 6 for guidelines.
B2.2 What was exactly the non-compliance related to Art 4(3) of CLP? Self-classification of the substance itself not consistent with harmonised classification (CMR 1A/1B/2, respiratory sensitisation, skin sensitisation, STOT RE 1/2) 1 2 3 4 5 ☐ ☐ ☐ ☐ ☐ Self-classification of the substance itself not consistent with harmonised classification (other endpoints) 1 2 3 4 5 ☐ ☐ ☐ ☐ ☐ Harmonised impurities and additives not declared as relevant for classification and labelling. 1 2 3 4 5 ☐ ☐ ☐ ☐ ☐ Other, please specify: 1 2 3 4 5 ☐ ☐ ☐ ☐ ☐	CLP Article 4(3) The violations of harmonised classification vary in terms of severity and complexity different endpoints and hazard categories violations for the substance itself or for constituents, impurities or additives explicitly listed in Annex VI of CLP or falling within group entries See Annex 6 for guidelines.

Questionnaire for Optional Module C: LLDC

Forum Project REF-6
Optional module C - LLDC

QUESTIONNAIRE

PRODUCT DETAILS (fill out one **per company**)	
Section C1 – Details of the LLDC inspected	
C 1.1 Checked LLDC ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 C1.2. Please specify LLDC type (multiple options may apply): ☐ Liquid laundry detergent in a soluble packaging (single compartment) ☐ Liquid laundry detergent in a soluble packaging (two or more compartment, liquids only) ☐ Liquid laundry detergent in a soluble packaging (two or more compartment, solid and liquid combination) ☐ Other Please specify:	Numbering of the LLDC should correlate to numbering in Q 2.0 of the Main Module. See Annex 6 for guidelines.

Section C2 – Compliance with special labeling and packaging requirements	
C2.1.Were LLDCs classified according to (multiple responses possible): ☐ physical hazard(s) for __ of LLDCs checked ☐ health hazard(s) for __of LLDCs checked ☐ environmental hazard(s) for __ of LLDCs checked C2.2. Was the classification correct? ☐ Yes for __ of LLDCs checked ☐ No for __ of LLDCs checked C2.3. How was the classification of the LLDC checked? (multiple responses possible) ☐ Label for __ of LLDCs checked ☐ Safety Data Sheet for __ of LDCs checked ☐ Exact Formulation for __ of LLDCs checked ☐ Other Please specify:	Art 35(2) of CLP See Annex 6 for guidelines.

C2.4. Was the labelling of the outer packaging consistent with the classification? ☐ Yes for __ of LLDCs checked ☐ No for __ of LLDCs checked	
C2.5. Were the individual capsules labelled? ☐ Yes for __ of LLDCs ☐ No for __ of LLDCs If No, was the exemption in Annex I, Section 1.5.2.2. applied properly? ☐ Yes for __ of LLDCs checked ☐ No for __ of LLDCs checked	See Annex 6 for guidelines. Art. 31, Art. 29, Annex I, Part 1, Section 1.5.
C2.6. Is the LLDC contained in an outer packaging? ☐ Yes for __ of LLDCs checked If Yes, the outer packaging (multiple responses possible): ☐ is opaque or obscure so that it impedes the visibility of the LLDC or individual doses for __ of LLDCs checked ☐ bears the precautionary statement P102 “Keep out of reach of children” at a visible place and in a format that attracts attention for __ of LLDCs checked ☐ an easily reclosable, self-standing container for __ of LLDCs checked ☐ for __ of LLDCs checked is fitted with a closure that impedes the ability of young children to open the packaging by requiring coordinated action of both hands with a strength that makes it difficult for young children to open it; ☐ for __ of LLDCs checked is fitted with a closure that maintains its functionality under conditions of repeated opening and closing for the entire life span of the outer packaging ☐ No for __ of LLDCs checked (Go to Q C2.9)	See Annex 6 for guidelines. CLP Annex II, Part 3, Section 3.3.
C2.7. Please specify outer packaging type: ☐ Box for __ of LLDCs checked ☐ Pouch for __ of LLDCs checked ☐ Other Please specify:	
C2.8. The company has provided sufficient justification that the soluble packaging (multiple responses possible): - contain an aversive agent in a concentration which is safe, and which elicits oral repulsive behaviour within a maximum time of 6 seconds ☐ yes for __ of LLDCs checked	CLP Annex II, Part 3, Section 3.3.

☐ no for __ of LLDCs checked ☐ not checked for __ of LLDCs checked - retain its liquid content for at least 30 seconds when the soluble packaging is placed in water at 20 °C ☐ yes for __ of LLDCs checked ☐ no for __ of LLDCs checked ☐ not checked for __ of LLDCs checked - resist mechanical compressive strength of at least 300 N under standard test conditions ☐ yes for __ of LLDCs checked ☐ no for __ of LLDCs checked ☐ not checked for __ of LLDCs checked	See Annex 6 for guidelines.

Section C3 – Informal comments[11] (not obligatory)
…… …… …… …… …… …… ……

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

Questionnaire for Optional Module D: BPR

Forum Project REF-6 **QUESTIONNAIRE** **Optional module D - Questions regarding Regulation (EU) no 528/2012 (BPR)** Fill out one questionnaire for each company inspected.

Section D1 - Details of the biocide(s) checked	
Note: The inspector decides on the number of biocide(s) to be checked, maximum 5	
Checked Biocide(s) ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5	Biocide number should correlate to the numbering in Q 2.0 of the Main Module.
Section D2. Requirement for authorisation	Relevant articles in BPR
D2.1 Are the biocide(s) legally on the market? ☐ Yes, for _ of the checked biocide(s) according to BPR ☐ Yes, for _ of the checked biocide(s) according to national legislation during the transitional period ☐ No, _ of the checked biocide(s) lack a valid authorisation according to articles 17 (1), 52 in BPR ☐ No, _ of the checked biocide(s) do not fulfil article 95 in BPR ☐ No, _ of the checked biocide(s) lack a valid authorisation according to national legislation during the transitional period	Article 17 (1) Article 52 Article 53 Article 55 Article 89 (2) Article 95 (2) See Annex 6 for guidelines.
Section D3. Consistency between information on the hazard label and the granted authorisation for the biocide(s) /article 69 (2) of BPR	

D3.1. Does the hazard label of the checked biocide(s) correspond with the hazard and precautionary statements in the granted authorisation (SPC) for it? ☐ Yes, __ of the checked biocide(s) ☐ No, __ of the checked biocide(s) have a different hazard labelling compared to the granted authorisation (SPC) ☐ Not applicable, _ of the checked biocide(s) are not/still does not have to be authorised	Article 22 (2) See Annex 6 for guidelines.
D3.2. Does the label of the checked biocide(s) correspond with article 69 (2) of BPR? ☐ Yes, __ of the checked biocide(s) ☐ No, __ of the checked biocide(s) have a different labelling compared to art. 69 (2) of BPR ☐ Not applicable, _ of the checked biocide(s) are covered by national legislation	Article 69 (2) See Annex 6 for guidelines.
4. Follow-up Actions	
4.1 Measures imposed due to non-compliance with obligations according to BPR. ☐ No measures since there were no non-compliance ☐ Verbal advice ☐ Written advice ☐ Administrative order ☐ Fine ☐ Criminal complaint / Handing over to public prosecutor's office ☐ Others. Please specify:	
4.2. Are the follow-up activities ◯ completed ◯ on going	
5. Cooperation with other Member States	

5.1. Have any cases been forwarded to other Member States? ◯ Yes, to ☐ Focal point ☐ BPRS Member ☐ National coordinator REF-6 ◯ No	

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