

REPORT

Forum Pilot Project on Child-resistant fastenings

Adopted at 16-06-2016 Forum-24



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Report - Forum Pilot Project on Child-resistant fastenings

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1. Executive summary for the overall project

1.1 Content of the project

At the Forum-19 plenary meeting, the Forum agreed to conduct a pilot project on the requirements for safe packaging with special attention to child resistant fastenings (CRF) for hazardous substances and mixtures supplied to the general public. This was the first Forum project on enforcement of specific packaging requirements. The project was implemented in the second half of 2015.

Ultimately aiming at a safer environment for children, the main objective of the project was to help to identify and reduce incidences of non-compliance with CRF requirements across Member States and establish a harmonised approach for enforcement of the provisions with regard to safe packaging under the CLP Regulation ((EC) No. 1272/2008). Awareness raising on the importance of safe packaging, specifically on CRFs, as well as promoting cooperation and information exchange among authorities were also key aspects of the project.

The provisions on safe packaging and child-resistant fastenings are integral parts of the CLP Regulation, included in Article 35 (2). Under this provision it is required that packaging of hazardous substances and mixtures which are for supply to the general public do not mislead the consumer, attract or arouse the active curiosity of children and that those classified for specific human health endpoints are fitted with child-resistant fastenings and tactile warnings of danger (TWD) for safe use as relevant.

The Forum decided that the project should focus only on those products that require child resistant fastenings. The Forum also considered that the provisions of Article 35 (2) complement each other and support the aim of ensuring safety for children in their totality. Therefore, in order to have a comprehensive picture for products requiring a CRF, compliance with all the above requirements of Article 35 (2) with regard to packaging, as well as the classification and labelling leading to the requirement for CRFs, and TWD had to be inspected and reported in the course of this pilot project.

It has to be emphasized that this project focused on product compliance as opposed to compliance of an actor within the supply chain, which also determines the extent to which company-related statistical data can be used to draw further conclusions.

The Forum set up a Working Group (Forum WG Pilot Project on Child Resistant Fastenings) that was responsible for project management of the pilot project, including establishment of scope and methodology for the project, the provision of relevant documentation, in particular the project manual and a questionnaire, the training of national coordinators appointed for this project and also preparation of the final report on results. Its work was supported by the ECHA Forum Secretariat. The inspections were conducted by inspectors of National Enforcement Authorities in participating Member States and EEA countries. The inspectors performed inspections according to the project manual and were required to fill in the corresponding questionnaire, which they submitted to their national coordinators.

The first step of an inspection was to establish whether a substance or a mixture supplied to the general public fell under the scope of the provision requiring a CRF. In theory, children may come into contact with any product supplied to the general public. Consequently, there was no limitation on which consumer products inspectors focused on, but the selection criteria depended on whether such consumer products required CRF in line with the relevant legislation. Although implementation of this pilot project took place after the 1st of June 2015 deadline for mixtures to comply with CLP, which had to be considered when assessing compliance, the aim was to get a general picture of the enforceability of child resistant fastenings and related obligations, regardless of whether

the obligation is based on Directive 99/45/EC (Dangerous Preparations Directive, (DPD)) or the CLP Regulation.

1.2 Main results and conclusions

Fifteen (15) Member States and EEA countries participated in the implementation of the project, and all together 797 products were inspected.

Within the scope of the project, *i.e.* hazardous products intended for the general public, for which a child-resistant fastening is required, a wide variety of types of products were inspected. The majority of products were drain cleaners, oven/window/surface cleaners, toilet cleaners, solvents, motor vehicle products (e.g. oils, degreaser), as well as disinfectants, bleaches, lamp oils or diluents. Mixtures represented 86% of all inspected products.

Most of the inspected products that required CRF to be fitted were classified as Skin Corrosion Category 1 or Aspiration Hazard Category 1, which reflects the classification of the broadest categories of products aimed at the general public. The classification was mainly verified by checking the label and the safety data sheet, as well as the documented exact formulation.

Out of the 797 products inspected, in the case of 230 products non-compliance was identified in relation to either the obligations under Article 35 (2) of CLP or the related classification and labeling requirements. This resulted in an overall non-compliance rate of 29%. While it was possible that the same product had various deficiencies, it was concluded that 136 products did not comply with the CRF provisions, mainly the certificate of conformity was either not available or was issued by a non-accredited laboratory. Seventy-seven (77) products did not meet the requirements for TWD, in particular the warning symbol was missing, was wrongly placed or was not prominent on the packaging. The classification and labeling was incorrect in 66 cases which may have resulted in hazardous products not being fitted with the required CRF. There were 32 reported cases where inspectors judged the CRF on the packaging to be inadequately secure.

With regard to the non-compliant cases, 411 legal actions and enforcement measures were taken by inspectors. Again, several actions might have been taken in relation to the same non-compliant product. Most of the actions were verbal or written advice, administrative orders, as well as, in cases where the security of packaging was compromised, prohibition of placing on or withdrawal from the market. In a number of cases companies were also willing to take voluntary actions to remedy the situation.

The Forum considers that this pilot project met its objectives with regard to promoting cooperation amongst NEAs with the 15 EEA countries participating. Cross-border cooperation was initiated in 18 cases.

One of the main conclusions of this project is that the level of non-compliance with safe packaging requirements is high, and the awareness of actors concerning their obligations was considered low. Clearly, the responsible actors must be made aware of the requirements set out in Part 3 of Annex II of CLP relating to CRFs. During the project inspectors also recorded issues and challenges faced. The observations include whether the certificates corresponded to inspected packaging, trustworthiness of certificates and the lack of knowledge of requirements in supply chain both with regard to CRF and TWD. It has to be noted that the existence of a certificate for CRF does not guarantee compliance of the product. Inspectors also indicated issues of interpretation, such as discrepancy in terminology of CLP and relevant standards, and a lack of detailed guidance on requirements.

1.3 Main recommendations resulting from the project

Recommendations are based on the experience of the members of the Working Group as well as on the results of the pilot project and the feedback in the questionnaire from the inspectors/national coordinators. Recommendations are addressed to the Forum, ECHA, national authorities, concerned industry, as well as the European Commission. The most important recommendations are also highlighted here in the executive summary.

Considering the high non-compliance rate, it is recommended that the Forum addresses the requirements of safe packaging in future REF projects on CLP where a wider number of national enforcement authorities could examine and enforce compliance with these provisions. It is also necessary to initiate awareness raising activities and highlight the problem to stakeholders.

The project clearly showed that there are issues which are challenging to actors within the supply chain, therefore, useful guidance by ECHA on how to comply with the requirements of, in particular CRF and TWD, is considered much needed. Guidance to inspectors, especially regarding the interpretation of relevant standards and the provision within 3.1.4.2 of Annex II concerning waiving of testing, is also considered necessary. Other problematic points are the acceptance of certificates issued by a non-EU testing laboratory and identification of when a product is for "Professional use only". Guidance and clarification of these issues are also needed. ECHA is also invited to promote awareness of concerned industry as well as consumers.

National authorities are also recommended by the Forum to promote awareness at the national level on the requirements of CRF and TWD, as well as on the certificate of conformity. NEAs are encouraged to include checks of safe packaging in their national programmes of work and train their inspectors especially on the necessary technical specifications of the standards and their certification. Inspectors should be aware that the presence of a CRF certificate does not ensure that a product is compliant with the requirement to be child resistant. Where products are found to be non-compliant with the requirements of Article 35 (2) of CLP, NEAs should also issue a RAPEX alert as relevant.

The relatively high non-compliance rate with the requirements of Article 35(2) of CLP relating to CRF and TWD warrants attention by concerned industry, particularly those who package the product. Awareness of relevant requirements amongst retailers and distributors was clearly low, therefore, it is necessary to improve their knowledge on the importance of safe packaging and especially on CRF and TWD and the need for certification of conformity. Sufficient guidance and support particularly for SMEs by stakeholder organisations are essential.

The Forum considers that the Commission also has room for facilitating improvement of compliance levels. Especially it is considered that more detailed information is needed in the Annex of CLP (or in a form of guidance) on the TWD requirements as often the relevant standard is not available to companies. The Commission is also invited to explore if the information requirements for certification of standards could be extended so that the information in the certificate ensures better traceability. Also some discrepancies in terminology used in the legal text of CLP and the relevant standard need to be addressed.

2. Detailed results of the project

2.1 General overview

At the Forum-19 plenary meeting in 2014, Forum members agreed to conduct a pilot project on the requirement for safe packaging with special attention to child resistant fastenings (CRF) for hazardous substances/mixtures supplied to the general public. The project was set up in the first half of 2015 with inspections taking place in the second half of that year. Reporting and evaluation of national feedback took place in spring 2016. This was the first Forum co-ordinated project where the focus was on enforcement of specific packaging requirements.

The provisions on safe packaging and child-resistant fastenings have been integral parts of the Dangerous Preparations Directive 1999/45/EC (DPD) legislation, and now they are also important parts of the CLP Regulation ((EC) No. 1272/2008), included in Article 35 (2), with a wider range of substances/mixtures falling under the scope due to the new classification requirements. The provisions require that packaging of hazardous substances and mixtures which are for supply to the general public do not mislead the consumer and that those classified for specific human health endpoints are fitted with child-resistant fastenings and tactile warnings of danger for safe use as relevant.

According to the European Commission, several hundreds of incidents occur yearly where children are harmed, and which may be avoided by using adequate child-resistant fastenings¹. In some EEA countries, e.g. Sweden, Norway and Germany, national enforcement projects were implemented reporting 10 to 20% of inspected products as deficient with regard to child-resistant fastenings. Also, information from the CLEEN network (Chemicals Legislation European Enforcements Network) indicated a high non-compliance rate observed with regard to this precautionary measure during a recent project conducted on detergent products (EuroDETER²).

Information from some national poison centres also supports that accidents do happen relatively frequently with household products containing substances/mixtures that require child-resistant fastenings. While it does not necessarily mean that all these products have deficient packaging, it showed the need to pay more attention to the requirements of Article 35 (2) of CLP. Also, relevant awareness-raising about the obligation to apply safe packaging and child-resistant fastenings seemed justified.

It was expected that this Forum coordinated pilot project would help to reduce the incidences of non-compliance with CRF requirements across Member States and establish a harmonised approach for enforcement of the provisions with regard to safe packaging under Article 35(2) of the CLP Regulation for national enforcement authorities (NEAs).

Ultimately aiming at a safer environment for children, the objectives of the project were to:

assess the level of compliance with the specific provisions under Article 35(2) and
 Part 3 of Annex II of the CLP Regulation and, where relevant, with Article 9 of the

¹ Reference is made to an international conference held in Brussels in 2013 organised at the North Rhine-Westphalia Representative Office to the European Union.

² Details of the CLEEN EuroDETER project including the final report may be found at the following link: http://www.cleen-europe.eu/projects/eurodeter.html

- Dangerous Preparations Directive (DPD) focusing on the packaging containing hazardous substances/mixtures requiring child-resistant fastenings (CRFs)
- verify whether CRFs used on re-closable or non-re-closable packages comply with the relevant EN standards as specified in Part 3 of Annex II of CLP
- establish a practical way of enforcing the provisions of Article 35 (2) for packaging requiring CRF and develop a harmonised enforcement approach for EEA countries
- where required, exercise enforcement in cases of non-compliance with regard to the requirements of Article 35 (2) for packaging requiring CRF, thereby, reducing the incidences of non-compliant packaging in EEA countries
- raise awareness amongst inspectorates, duty holders and the general public on the importance of safe packaging, specifically on CRF closures
- promote cooperation among national enforcement authorities and foster information exchange between all enforcement inspectorates at regional and national levels and throughout EEA countries.

The project focused on consumer products containing hazardous substances/mixtures requiring CRF and the fulfilment of requirements of Article 35 (2) of the CLP Regulation by such products. Inspection of compliance with the new provisions of Article 35 (2) relating to the outer packaging of liquid laundry detergent capsules did not fall under the scope of this project as it was too premature to check those requirements.

The first step of an inspection was to establish whether a substance or a mixture supplied to the general public fell under the scope of the provision requiring a CRF. In theory, children may come into contact with any product supplied to the general public. Consequently, there was no limitation on which consumer products inspectors focused on, but the selection criteria depended on whether such consumer products require CRF in line with the relevant legislation. Although implementation of this pilot project took place after the 1 June 2015 deadline for mixtures to comply with CLP, which had to be considered when assessing compliance, the aim was to get a general picture of the enforceability of child resistant fastenings and related obligations, regardless of whether the obligation is based on the old (DPD) or the new (CLP) legislation.

Further to this, it should be pointed out that the requirements of Article 35 (2) of CLP on child resistant fastening, tactile warning of danger (TWD) and safe packaging complement each other and support the aim of ensuring safety for children in their totality. Therefore compliance with all these requirements was addressed during inspection and reported accordingly in order to have a comprehensive picture.

Consequently, this pilot project focused on the inspection of products supplied to the general public:

- All consumer products that fall under the scope of the second subparagraph of Article 35 (2) of CLP *i.e.* those products which require CRF:
 - o consumer products containing substances/mixtures that shall be classified as Skin corrosion Category 1, 1A, 1B, 1C; Acute toxicity Cat. 1 to 3; Single target organ toxicity (STOT) Single exposure (SE) Cat. 1; STOT Repeated exposure (RE) Cat. 1; Aspiration hazard cat. 1 (except aerosols or if in container with sealed spray attachment);
 - o consumer products containing methanol or dichloromethane in a concentration equal to or greater than 3% or 1% respectively;

- In the case of these products, all requirements of Article 35 (2) with regard to packaging, i.e. shape or design likely to attract or arouse the active curiosity of children or possibly misleading due to similarity of packaging to foodstuff or animal feeding stuff or medicinal or cosmetic products, CRF and TWD, were checked:
 - o inspecting the TWD focused on its availability, placement on the package and whether the sign was prominent, and
 - o inspecting the CRF involved checking the closure on the packaging visually and manually and, where relevant, checking certification for the relevant standards.

In order to verify whether a substance or mixture falls under the scope of the second subparagraph of Article 35 (2) the classification and the consistency of labelling with the classification was examined as well, confirming it by inspecting all relevant documents in the frame of the pilot project (e.g. label, safety data sheet).

It has to be emphasized that – in line with the above scope – this project focused on product compliance as opposed to compliance of an actor within the supply chain. Inspectors were not requested to record the number of companies inspected or the number of products inspected per company. Instead the number of products was recorded. Therefore, no data of statistical relevance on the level of non-compliance by companies (size, role or NACE division) can be extracted from this project.

2.2 Coordination of the project

The preparation, implementation and reporting of the project were supported by several actors.

The Forum set up a Working Group (Forum WG Pilot Project on Child Resistant Fastenings) that was responsible for (project) management of the pilot project. The Working Group (WG) was composed of Forum Members and invited experts from National Enforcement Authorities (NEAs) and Helpdesks from Member States. The WG was responsible for the establishment of the scope and methodology for the project, the provision of relevant document, in particular the development of a project manual including a questionnaire, the training of National Co-ordinators (NC), as well as for the collation and evaluation of the inspection findings and compilation of the final report on the project.

The project manual took into account experience gained from previous Forum pilot and REACH-EN-FORCE projects, as well as the knowledge gained by EEA countries during similar projects.

The manual had two purposes:

- to assist Forum members and NEA inspectorates involved in carrying out the project in the EEA and
- to contribute to harmonised enforcement of CLP provisions for safe packaging with special emphasis on child resistant fastenings.

The WG was supported by the Forum Secretariat, as per Forum's previous enforcement projects. In particular, the Secretariat contributed to the preparation of the project

manual and report, supported the collection, and analysis of national results, and provided all the necessary administrative, logistic and technical support to the WG.

Participating NEAs with responsibility for enforcing the CLP Regulation each appointed a NC who was responsible for organisation, coordination and implementation of the project in their country. They also supported the work of inspectors by providing information, training and a language check for translation of manuals, facilitated communication between inspectors and the WG (if necessary), and finally, they collected and checked the completed questionnaires at national level. The work of NCs was supported by the WG, whenever necessary.

The inspections in the frame of this pilot project were conducted by NEA inspectors in participating Member States and EEA countries. The inspectors performed inspections according to the project manual and were required to fill in the corresponding questionnaire provided (see Annex 1), which they submitted to their NC.

2.3 Participation, number of inspections and types of products inspected

Fifteen (15) Member States and EEA countries participated in the implementation of the project, and all together 797 products were inspected, as shown in Table 1.

| Country | Number of products inspected |
|----------------|------------------------------|
| Austria | 8 |
| Belgium | 58 |
| Bulgaria | 25 |
| Czech Republic | 24 |
| Estonia | 30 |
| Germany | 136 |
| Greece | 58 |
| Hungary | 227 |
| Ireland | 27 |
| Latvia | 13 |
| Liechtenstein | 17 |
| Luxembourg | 26 |
| Malta | 10 |
| Norway | 71 |
| Spain | 67 |
| Total number | 797 |

 Table 1: Number of products inspected per country participating in the pilot project.

Eighty-six (86%) of all inspected products were mixtures (684 mixtures and 113 substances inspected).

Within the scope of the project, *i.e.* hazardous products intended for the general public, for which a child-resistant fastening is required, a wide variety of types of products were inspected, the majority being drain cleaners, oven/window/surface cleaners, toilet cleaners, solvents, motor vehicle products (e.g. oils, degreaser), as well as disinfectants, bleaches, lamp oils or diluents.

The exact distribution of inspected products is indicated in Table 2 (please note that in

some cases more than one option was chosen).

Table 2: Distribution of inspected products

| Type of product | Number of products inspected |
|---|------------------------------|
| Other: e.g. disinfectants, bleach, lamp oil, diluent, metal/surface strippers | 233 |
| Drain cleaner | 173 |
| Oven/window/surface cleaner | 134 |
| Toilet cleaner | 94 |
| Solvent | 64 |
| Motor vehicle product | 41 |
| White spirits | 40 |
| Grill/lighter fluid | 28 |
| Windshield washing fluid | 13 |
| Paint product | 13 |
| Laundry detergent (powder or liquid) | 11 |
| Washing up liquid | 3 |
| Adhesive/glue | 3 |

The majority of the inspected products that required CRF to be fitted were classified as Skin Corrosion Category 1 or Aspiration Hazard Category 1, which reflects the classification of the broadest categories of products aimed at the general public. The classification was mainly verified by checking the label (in 724 cases), the safety data sheet (in 652 cases), and/or the documented exact formulation (in 77 cases).

It must be noted that all mixtures have to be classified in line with CLP after 1 June 2015, but where a mixture was placed on the market before that date it is possible that it is still classified, labelled and packaged according the DPD. Such compliant products can "stay on the shelves" until 1 June 2017 at the latest without relabeling and repackaging. Inspectors collected information on whether mixtures were classified according to CLP, and it turned out that only 52 of the products inspected were classified according to DPD. The exact distribution according to the classification of the inspected products is indicated in Table 3 (please note that more than one classification may have been relevant for certain products).

| Classification | Number of products inspected |
|---|------------------------------------|
| Skin corrosion Cat. 1, 1A,1B,1C (H314) | 519 |
| Aspiration hazard Cat. 1 (H304) | 213 |
| Acute toxicity Cat. 3 (H301, H311, H331) | 30 |
| Single Target Organ Toxicity (STOT) Single Exposure (SE) Cat. 1 (H370) | 13 |
| STOT Repeated Exposure (RE) Cat. 1 (H372) | 8 |
| Acute toxicity Cat. 2 (H300, H310, H330) | 3 |

Acute toxicity Cat. 1 (H300, H310, H330)

Table 3: Distribution according to the classification of the inspected products

120 of the inspected products (mixtures) contained either methanol or dichloromethane, but only 32 contained these substances in a concentration of at least 3% and 1%, respectively, requiring CRF. Only 6 of these 120 products were tested to confirm the documentary evidence of the presence of these substances.

2.4 Types of companies where the products were inspected

All manufacturers, importers, downstream users and distributors, who supply hazardous substances and mixtures to be used by the general public, fell under the scope of this project.

The main target companies were those with ultimate responsibility for ensuring that hazardous mixtures for supply to the general public comply with Article 35(2) of CLP, primarily downstream users, *i.e.* formulators and re-fillers and re-importers, repackagers, and importers. Distributors, including retailers, were also targets as they are the main source of supply of mixtures to the general public.

Where necessary, follow up regarding compliance was carried out with the relevant actors up the supply chain. Manufacturers of substances were also inspected for compliance where there was evidence that they sold substances intended for the general public, for example, white spirits.

As it has been highlighted before, this project focused on product compliance and therefore the number of products inspected was recorded and not the number of companies. As a result, Table 4 below shows the number of products per company role and not the number of companies inspected. As can be noted from the table, the majority of products were inspected at distributors sites, and particularly retailers, which correlates with the aim of the project *i.e.* to target those products aimed at the general public.

Table 4: Distribution of companies where products were sampled according to their role in the supply chain

| Company role | Number of products inspected |
|-----------------------|------------------------------|
| Distributor | 646 |
| Retailer | 496 |
| Wholesaler | 184 |
| Other | 6 |
| Downstream user | 218 |
| Formulator | 162 |
| Re-filler/Re-packager | 70 |
| Re-importer | 1 |
| Manufacturer | 56 |
| Importer | 16 |

Note that companies could fulfill multiple roles.

According to the statistical classification of their economic activities (NACE-codes)³, the vast majority of companies where the products were inspected belong to three main categories as indicated in Table 5.

Table 5: Main NACE divisions of the companies inspected in the project

| NACE divisions | Definitions | Number of products investigated |
|----------------|---|---------------------------------|
| 47 | Retail trade, except of motor vehicles and motorcycles | 382 |
| 20 | Manufacture of chemicals and chemical products | 190 |
| 46 | Wholesale trade, except of motor vehicles and motorcycles | 160 |
| Others | - | 65 |

The distribution of inspected companies by size shows clearly that the majority of companies were SMEs or even micro sized (Figure 1). Again, as this project focused on product compliance, inspectors were not requested to record the number of inspections carried out per company. Therefore, Figure 1 is indicative only of the size of companies where products were inspected during the project, but no further statistical information or conclusion can be drawn based on this data

³ NACE, the Statistical Classification of Economic Activities in the European Community, is a European industry standard classification system for economic activities, Regulation (EC) No 1893/2006.

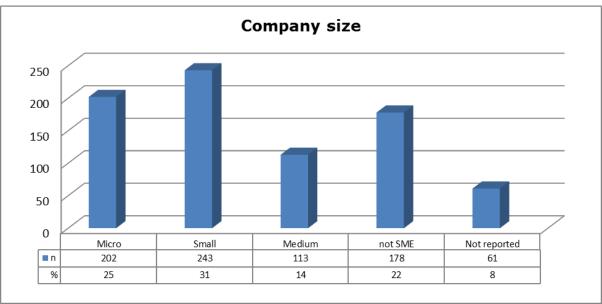


Figure 1: Distribution of company sizes where the products were inspected (n=797)

2.5 Legal obligations

The legal obligation to be verified within the scope of the project was the compliance with Article 35 (2) and Part of Annex II of the CLP Regulation.

However, in the case of hazardous mixtures placed on the market before 1 June 2015 and classified, labelled and packaged according to the old legislation (DPD), inspectors first assessed whether the relevant national provisions implementing Article 9, paragraphs 1.2 and 1.3 of Directive 1999/45/EC were met. With reference to the transitional provisions of Article 61 paragraph 4 of CLP, if the mixture was compliant with the packaging/CRF requirements, it could remain on the market until 1 June 2017. If the mixture did not meet these requirements, then classification, labelling and packaging according to CLP had to be enforced, again, in line with the same transitional provisions.

When assessing the child resistant fastenings, inspectors made reference to the EN ISO standard 8317 on re-closable packages and CEN standard EN 862 on non-re-closable packages. In addition, when assessing the TWD, the inspectors took into consideration its conformity with EN ISO standard 11683.

2.6 Infringements

During the inspection procedure of a product, when the need for a packaging fitted with a CRF was established, inspectors checked the product both visually (examining the shape and design of the packaging) and manually (the closure itself being child-resistant or not and placement and prominence of tactile warning of danger). Inspectors normally

requested the certificate⁴ stating that the packaging conformed to standards EN ISO 8317 or EN 862. The laboratory issuing the certificate should be accredited according to ISO/IEC 17025. Inspectors were advised to allow a 30-day period for the supplier to provide the certificate.

The focus of the project was on product related requirements. Therefore no conclusions can be drawn from statistics related to the non-compliance of companies.

All the infringements resulting from the inspection as well as the enforcement actions that followed were recorded by the inspectors in the questionnaire.

In the course of the operational phase of the pilot project a total of 797 products were inspected in the 15 participating countries.

2.6.1 Non-compliances

A total of 230 products (29%) were found to be non-compliant with the obligations on packaging of Article 35 (2) of CLP and the requirements for classification and labelling necessary to establish the need for CRF. In many cases, products were non-compliant for more than one reason.

The following graph presents the reasons for non-compliance recorded for the products inspected (Figure 2).

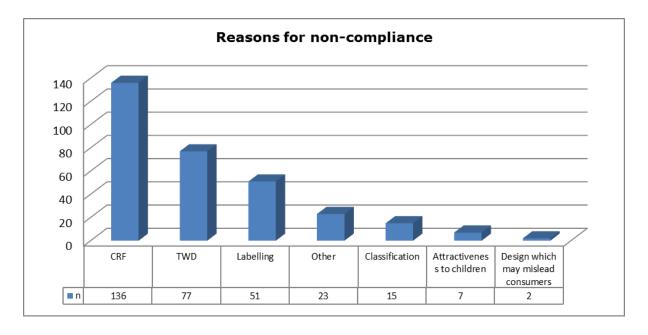


Figure 2: Non-compliances reported for the products inspected.

⁴ For 70 products, the inspectors reported that a certificate was not requested when they considered the CRF was manually secured.

The two most frequently reported non-compliances related to the requirements of Article 35 (2) on child-resistant fastenings and tactile warnings of danger (136 for CRF and 77 for TWD, respectively). Also a total of 66 non-compliances reported concerned issues related to classification and labelling of the product. In 15 cases the classification and in 51 cases the labelling was non-compliant.

Only in 7 cases inspectors reported that the product was deemed to be attractive to children and in 2 additional cases that the design might be misleading consumers. Also 23 infringements against other legal obligations were detected by the inspectors.

2.6.1.1 Non-compliances related to CRF requirements

The non-compliances concerning the child-resistant fastening can be further subdivided as follows:

2.6.1.1.1 Provision of certificates

With regard to re-closable packages, 288 cases were reported where the certificate of conformity of the packaging to EN ISO 8317 standard was available on site. For another 206 cases, the certificate of conformity was made available within the timeframe given by the inspectors (30 calendar days recommended).

As far as non-re-closable packages are concerned, 22 cases were reported where the certificate of conformity to EN 862 standard was available on site. In 3 cases the certificate of conformity was made available within the timeframe given by the inspectors.

There was a total of 85 cases of products (83 products with re-closable packaging and 2 products with non re-closable packaging), for which a certificate was requested but not provided within the timeframe of the project.

2.6.1.1.2 Certifying laboratory not accredited according to EN ISO/IEC 17025

In the course of the project the inspectors received a total of 519certificates⁵ for reclosable and non-re-closable packages. 63 of these certificates were issued by laboratories which were not accredited according to EN ISO/IEC 17025.

2.6.1.1.3 CRF present but found to be not secure after manual inspection

One of the first steps of the inspection procedure was the manual inspection of the fastening of the product. In 32 cases inspectors reported that the product was fitted with a closure that was not child-resistant even though one was required.

It is also important to note that there were two cases of products with re-closable packages reported where, even though a certificate of conformity with the ISO 8317 standard was available and issued by an EN ISO/IEC 17025 accredited laboratory, the manual inspection performed by the inspector proved that the products were not secure. For example, inspectors noted that the correct torque was not applied on the filling line when certified caps were being fitted to the containers and, therefore, caps and containers were not aligned correctly. In-house quality control checks at the point of filling had not been carried out to ensure child resistance of the packaging.

519 is the total number of certificates provided, regardless of when the certificate was provided by the supplier (in the timeframe given by the inspector or later).

⁵ Note that a certificate was not requested for all inspected products.

In Annex II, Part 3 of CLP (paragraph 3.1.4.2) reference is made to specific cases regarding child-resistant fastenings where the need for a test of conformity with packaging standards can be waived, because it seems obvious that packaging is sufficiently safe for children as they cannot gain access to the contents without the help of a tool. For 70 products, certificates were not requested due to the national approach, and based upon the data we can conclude that in other 113 cases the certificate was not requested. Although the reason for not requesting the certificate was not provided by inspectors in each case, it appears that it was not requested due to the interpretation by the inspectors of paragraph 3.1.4.2 Part 3, Annex II of CLP or simply because the inspector found the packaging secure and did not wish to have a more detailed examination.

2.6.1.2 Non-compliances regarding tactile warnings of danger (TWD)

The second-highest number of non-compliances reported was related to the requirements for the tactile warning of danger. A total of 77 non-compliances were reported.

Of these, 69 products were not fitted with a TWD and in 8 cases even though the TWD existed, it was not prominent on the surface of the packaging. For some cases, the inspectors also considered whether the TWD was appropriately placed on the packaging as per the requirements of the standard. According to the legislation (Annex II, Part 3 of CLP, paragraph 3.2.2.2), the technical specifications for TWD shall conform to EN ISO standard 11683, however there is no legal requirement for a certificate.

2.6.1.3 Non-compliances regarding classification and labelling

A total of 66 cases of non-compliance regarding classification and labelling – within the scope of the project *i.e.* in relation to the requirements for a CRF - were reported. In most cases the non-compliance was related to the lack of consistency between classification and labelling of the product.

2.6.1.4 Non-compliances regarding general packaging requirements other than those relating to CRF or TWD

Less common non-compliances (only 9 cases reported) were related to the design of the product being misleading to consumers or attractive to children. Nonetheless, it needs to be noted that it can be a matter of subjective judgement or interpretation on the part the inspector.

2.6.1.5 Other non-compliances

Other infringements were reported in 23 cases. These cases of non-compliance were *inter alia* related to Safety Data Sheet requirements, general labelling requirements (e.g. pictogram size) as well as special labelling requirements for entries of Annex XVII of Regulation (EC) number 1907/2006 (REACH), or labelling obligations according to national law.

2.6.2 Legal actions initiated in the frame of the project

The total number of legal actions initiated against the offender in the frame of the project was 411.

More than one type of legal action may have been initiated against the offender, such as written advice and administrative order or withdrawal from the market. Multiple actions were documented for certain non-compliant products.

For 24 non-compliant products a prohibition from placing on the market was ordered and in addition, 24 non-compliant products were withdrawn from the market. 31 administrative orders were given. In 5 cases the inspectors issued a fine and for 2 cases, a criminal complaint.

In 42 cases companies took voluntary actions to remedy the non-compliance. In only 2 of these 42 cases there was no other reported legal action issued for product non-compliance.

Written advice was given in 103 cases and in 50 cases verbal advice was issued. No "Name and shame" action was reported, however, only a few Member States have the power to issue such an action against an offender.

Follow-up activities were still on-going for 101 cases at the end of the operational phase. In most cases, the follow-up was preceded by other actions, like written or verbal advice. But in 32 of these cases no other action was initiated at the time of reporting. For 12 cases non-compliances were documented but no legal action reported.

Two cases of legal actions were documented, even though there were no non-compliances reported related to the requirements of Article 35 (2). In these cases, non-compliances were related to other legal requirements.

Figure 3 presents the actions initiated against the offenders. In many cases, more than one enforcement action was taken at the same time.

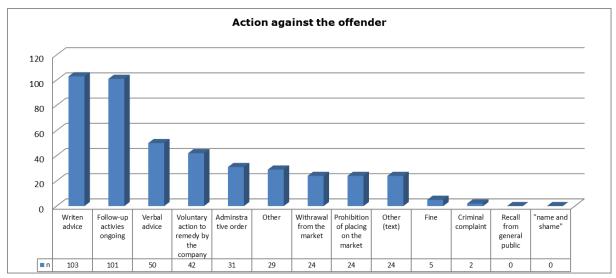


Figure 3: Enforcement actions taken against offenders.

18 cases have been forwarded to other Member States for follow up by the responsible actor and feedback was already available for 3 products at the end of the operational phase.

Actions initiated by inspectorates not participating directly in this pilot project but involved in follow-up actions up the supply chain were not documented in the results.

2.7 Observations by inspectors

There were a number of issues and challenges recorded by inspectors while carrying out inspections and investigations as part of this pilot project. The WG has summarised the reported observations below.

- It was difficult to prove that certificates of conformity with the relevant standards for child resistant packaging (standards EN ISO 8317 or EN 862 for re-closable or non-re-closable packaging, respectively) corresponded to the actual packaging which was inspected. Certificates were in some cases generic without unambiguous reference to the identification (e.g. batch number) of the packaging. While the standards require that unambiguous identification (e.g. specification number, drawing numbers and a complete description) of the package tested must be included in the test report this was often not available in an appropriate way on certificates provided to inspectors. In the absence of batch numbers for the packaging or similar information, inspectors found it difficult to establish compliance.
- Certificates were deemed in some instances to be untrustworthy. For example, they
 did not reference the correct standard number or their origins were either
 untraceable or doubtful.
- It was observed that there is a discrepancy in the terminology used in the legal text of Article 35(2) and the associated Annex II text of CLP which refers to packaging fitted with "child-resistant fastenings" and in the relevant standards EN ISO 8317 and EN 862 which refer to "child-resistant packaging". Inspectors found it difficult to distinguish whether certificates of conformity with EN ISO 8317 would be acceptable in the case where a manufacturer of a container buys the child-resistant closure (e.g. cap) from a supplier with an EN ISO 8317 certificate separately to the package e.g. bottle.
- It was recorded that formulators refused to send certificates of compliance of CRF requirements to retailers, indicating a lack of knowledge of the national legal requirements to provide information to inspectors upon request.
- Inspectors noted that provision of certification does not ensure that a product is compliant with the requirement to be child resistant. This project showed incidents where, although a certificate of conformity with EN ISO standard 8317 had been issued, the packaging was non-compliant with child resistance requirements. It was found in some cases that the correct torque was not applied on the filling line when caps were being fitted to the containers and therefore not aligned correctly. In-house quality control checks of packaging had not been carried out.
- Inspectors recorded cases where certificates of compliance had expired. In some Member States certain laboratories issue certificates that are valid only for a specific period of time, therefore, where applicable, inspectors did not accept out of date certificates.
- With regard to the tactile warning of danger, it was noted that the TWD was not in the correct position on the packaging. The EN ISO standard 11683 on tactile warnings of danger stipulates where on the packaging the TWD must be located. Inspectors noted that the TWD was placed on the lids/caps of packaging, on the bottom of containers and either too high on packaging and not necessarily on the handling surface as required (see examples in <u>Annex 2</u>).

- In some cases, retailers confused the recycling symbol for the TWD showing a lack of awareness of this requirement.
- Inspectors reported difficulties in establishing whether products were for professional use only (and thereby would not require a CRF). Although the companies inspected stated that the products were for professional use only, the distribution channels which are used indicate that it may be possible for the products to be sold to the general public. It could not be guaranteed that products without compliant CRFs would not reach consumers.
- There were few reported cases of attractiveness of the product to children. However, in the absence of guidance on this requirement, it is difficult for NEAs to establish whether a product may be attractive to children and enforce accordingly.

3. Conclusions and recommendations

3.1 Conclusions

During the course of the project, a total of 797 products established as being for consumer use were assessed throughout fifteen EEA countries. This large number of product inspections and the substantial amount of data gathered constitute a representative sample of the level of compliance with the provisions of Article 35(2) of CLP.

The overall non-compliance rate with Article 35(2) and related classification and labelling requirements for products under the scope of this project is 29% (230/797), which represents, in total, 298 reported non-compliances for 230 products. 136 cases relate to non-compliance with the requirements for child resistant fastenings (CRF) and 77 cases relate to non-compliance with tactile warning of danger (TWD) requirements. The remaining non-compliances deal with classification, labelling and packaging design issues.

Overall, the findings from the project show that there is a general lack of compliance with the requirements of Article 35(2). There were 32 reported cases where inspectors judged the CRF on the packaging to be inadequately secure. In addition, awareness of the requirement to have a certificate of conformity with the relevant standards for child resistant packaging (standards EN ISO 8317 or EN 862 for re-closable or non-re-closable packaging, respectively) is low. In 63 out of 519 cases where a certificate was provided, it failed to meet CLP legal obligations as it was not issued by an accredited laboratory.

Although the requirement for the presence of a compliant CRF conforming to the relevant international standards was already obligatory under the DPD, the certificate should be issued by a laboratory accredited according to EN ISO/IEC 17025 as per CLP Annex II, Part 3. Previously under DPD, a different standard was relevant for accreditation of testing laboratories.

A relatively high number of non-compliances (77 cases) were reported related to the requirements for the presence of a tactile warning of danger on hazardous chemicals classified for specific human health endpoints. In the majority of these cases (69) the package was not fitted with a TWD. In other cases (8), the package had the required TWD but it was not prominent on the surface of the packaging as specified in EN ISO standard 11683 (please see examples in Annex 2).

As the hazard classification dictates the obligation for the presence of a CRF on packaging of hazardous substances and mixtures, inspectors checked classification and labelling as part of the assessment of products. 66 cases relate to classification and labelling issues for products requiring CRF. This indicates that there is a need for manufacturers/importers/downstream users to apply the correct classification as failure to do so could result in a hazardous product not being fitted with the required CRF.

There were a minimal number of cases of breaches of Article 35(2) with regard to misleading design of packaging and attractiveness of the product to children. It should be noted, however, that assessment of these provisions is subjective and based on the individual judgement of inspectors. In the absence of guidance on these requirements, it

is difficult for NEAs to establish whether a product may be attractive to children and enforce accordingly.

Where non-compliance with CRF requirements was found, inspectors generally initiated enforcement action in the form of verbal/written advice. In the majority of cases where the security of the CRF was compromised, enforcement action involved prohibition from placing the product on the market or withdrawal of the product from the market.

It was demonstrated during this project that companies are willing to work with NEAs as a number of companies voluntarily remedied identified non-compliance(s).

This pilot project met its objectives with regard to promoting cooperation amongst NEAs with 15 EEA countries participating. In 18 cases, participating countries referred cases of non-compliance to the NEA where the supplier of the product was located, demonstrating efficient information exchange between EEA countries.

A relatively high number of actors have been reached by this project and were made aware of the need for safe packaging. However, from the reported findings it is also clear that all those who are responsible for placing consumer products on the market must be made aware of the requirements set out in Article 35(2) of CLP and in particular the CRF and TWD requirements.

3.2 Recommendations

Recommendations are based on the experience of the members of the Working Group as well as on the results of the pilot project and the feedback in the questionnaire from the inspectors/national coordinators.

3.2.1 Recommendations to National Enforcement Authorities, Inspectorates and Member State Competent Authorities

- Where products are found to be non-compliant with the requirements of Article 35(2) of CLP, NEAs should use the Rapid Alert System for dangerous non-food products (RAPEX) as relevant.
- Awareness raising at a national level on the requirements to provide child resistant
 fastenings and tactile warnings of danger on relevant hazardous products particularly
 amongst formulators, retailers and distributors and their trade/sector organisations
 would be beneficial to raise levels of compliance.
- To raise awareness that only a laboratory conforming to EN ISO/IEC 17025 may certify evidence of conformity with the standards EN ISO 8317 and EN 862 for reclosable and non-re-closable packaging, respectively, and that only those products which are certified for compliance with the relevant standards may be placed on the market for the general public.
- NEAs are encouraged to include checks for the provisions of Article 35(2) of CLP, namely those on child resistant fastenings and tactile warnings of danger, in their national programmes of work.
- Train inspectors nationally on the provisions of Article 35(2), specifically on the certification for standards for CRF and TWD and the technical specifications for TWD (may be coordinated with a Train the Trainers event as suggested above).
- Inspectors should be aware that the presence of a CRF certification does not ensure that a product is compliant with the requirement to be child resistant. Quality control

- of packaging is essential to ensure that child resistance is adequate and secure even where certification is available for the packaging.
- Raise awareness at consumer level (perhaps in conjunction with national Poison Centres and other relevant stakeholders (NGOs)) regarding the need for adequate child resistant packaging and tactile warnings of danger.

3.2.2 Recommendations to the Forum

- The WG recommends that the provisions of Article 35(2) should be included in a future REF project on CLP where a wider number of national enforcement authorities (NEAs) could examine and enforce compliance as necessary and raise awareness further.
- The Forum is invited to consider raising the issues regarding the high rate of non-compliance with child resistant fastenings and tactile warnings of danger requirements and the lack of knowledge on the relevant standards and certification at the next Accredited Stakeholder Organisations Open Day at the Forum 25 plenary meeting.
- The Forum should give consideration to include training on the provisions of Article 35(2) at a future Train the Trainers event for inspectors.

3.2.3 Recommendations to the Commission

- The WG invites the Commission to examine the possibility of updating the relevant Annex of CLP with regard to the requirements on tactile warning of danger which companies are required to comply with. Alternatively, we recommend the provision of relevant guidance for Industry who may not have access to the EN ISO standard 11683 on tactile warnings of danger specifically in relation to the position of the TWD on the package.
- For ensuring consistency between packaging and certification, the WG would like to request that the Commission explore the possibility of
 - a) addressing terminology discrepancies between the CLP Regulation legal text and the standards referred to in paragraphs 3.1.2 and 3.1.3 of Part 3 of Annex II of the Regulation

and

- b) including at least the following information in the certification for relevant standards, *i.e.* EN ISO 8317 for re-closable and EN 862 for non-re-closable packaging:
 - o batch number of the packaging, and
 - o product identification or identification of bottles/caps in order to make it easier to match the product and certificate.
- If necessary, COM is invited to liaise with the relevant certification/accreditation bodies.
- The WG recommends to the Commission to initiate a public consultation on and assess SMEs knowledge and understanding of the requirements of Article 35(2) of CLP relating to CRF and TWD, as well as Part 3 of Annex II.
- Provide guidelines on attractiveness to children/misleading packaging design for clarity on this provision under Article 35(2) for all actors and inspectors.

3.2.4 Recommendations to ECHA

- The Guidance on Labelling and Packaging should include useful guidance to the user
 on ensuring that child resistant fastenings and tactile warnings of danger comply with
 the standards set out in Part 3 of Annex II of CLP. Also, more guidance on when the
 specific provisions in 3.1.4.2 of Annex II can be evoked may be useful for industry as
 well.
- Include information for consumers on the ECHA "Chemicals for Life" webpage on the need for child resistant packages and tactile warnings of danger as well as on the rules on the design of packaging and attractiveness to children.
- Include requirements of Article 35(2) on their SME/downstream user presentations/webpage section.
- Consider sector-specific guidance for distributors and/or ECHA WebEx for labelling and packaging requirements aimed at small formulators/distributors/retailers.
- Provide guidance to relevant actors (manufacturers/downstream users) on how to source a reputable laboratory.

3.2.5 Recommendations to Industry

- The relatively high non-compliance rate with the requirements of Article 35(2) of CLP relating to child resistant fastenings and tactile warnings of danger warrants attention by those actors responsible for ensuring compliance *i.e.* manufacturers, importers, downstream users including formulators, re-fillers and re-packagers.
- Awareness of the requirements of Article 35(2) should be increased amongst retailers and distributors. Improving the knowledge of these sectors on the importance of child resistant packaging and the need for tactile warnings of danger should be a focus for the relevant industry sectors.
- To raise awareness that standards EN ISO 8317 for re-closable and EN 862 for non-re-closable packaging must be certified by a laboratory conforming to EN ISO/IEC 17025 and that only those products which are fully in compliance with the relevant standards may be placed on the market for the general public.
- Advise actors that compliant certificates of conformity with standards EN ISO 8317 and EN 862 must be made available to requesting national enforcement authorities at any stage of the supply chain.
- Stakeholder organisations should ensure sufficient support and guidance on the labelling and packaging of hazardous chemicals focusing on small and micro businesses.
- Advise relevant actors (formulators and/or bottlers/packagers), that when filling the
 bottles/containers, attention is given to the fill line ensuring that the correct torque is
 applied to the caps. It is important that the cap aligns correctly with the bottle
 otherwise the child resistance is lost despite the fact that certified child resistant caps
 are used. This requires in-house quality checks.

4. Annexes

Annex 1: Questionnaire

OUESTIONNAIRE COMPANY DETAILS (fill out one Section 0 and I per company visited) If checking more than one product per company, fill out Section I in full for the first product, thereafter, fill out Q1.1 only for each subsequent product checked at that company. Fill out Section 0 for each product checked. Section 0 - General Information about the inspection (questions 0.2 to 0.5 will not be recorded) 0.1.Participating country: 0.2. Authority: Only for internal use do not submit data 0.3. Inspector name: Telephone: Fax. F-mail: 0.4. Date of inspection: 0.5. File reference: Section I - General information about the inspected company and product (questions 1.1. to 1.7. will not be recorded) 1.1. Name of company inspected: Only for internal use do not submit data 1.2. Address of the company inspected: 1.3. Name of the contact person: 1.4. Telephone of the contact person: 1.5. Function of the contact person: 1.6.Other discussion participants (if relevant): Name and function: Name and function: Name and function: 1.7. Product name: CAS number (if relevant) 1.8. Name of product formulator/manufacturer/importer if different to inspected company: 1.9. Address and tel. no. of product formulator/ manufacturer/importer if different to inspected company: 1.10. Comments: 1.11. Company's NACE-Code(s): Source for NACE Code - see Annex 3A of this Manual.

| 2. Role(s) of the company under CLP (multiple responses possible): | Note: | |
|--|--|--|
| □ Downstream user If downstream user, please indicate whether: □ Formulator □ Re-filler/Re-packager □ Re-importer | Art. 2(19) of CLP | |
| ☐ Distributor If distributor, please indicate whether: ☐ Retailer ☐ Wholesaler ☐ Other | Art. 2(20) of CLP | |
| ☐ Manufacturer ☐ Importer | Art. 2(15) of CLP Art. 2(17) of CLP | |
| 3. According to Commission Recommendation 2003/361/EC, does the company qualify as: | | |
| ○ Micro ○ Small ○ Medium ○ not SME ○ unknown | | |
| Micro: <10 employees and ≤2 million euro annual turnover Small: <50 employees and ≤10 million euro annual turnover Medium: <250 employees and ≤50 million euro annual turnover Not SME: >250 employees and > 50 million euro annual turnover | | |

| PRODUCT DETAILS | | |
|--|---|--|
| (fill out one per product) | | |
| Section II – Details of the product inspected | | |
| 4. Is the product intended for the general public <i>i.e.</i> consumer use? Yes No Substance Mixture | Note: Article 35(2) of CLP/Annex. If product not for consumer use, it does not fall under the scope of the pilot project so there is no requirement to fill out questionnaire | |
| 6. Is the product checked: a substance manufactured on site a mixture formulated on site an imported substance an imported mixture a mixture refilled on site a mixture repackaged on site a mixture re-imported by company a mixture for distribution only a substance for distribution only other, please specify | | |
| 7. Please specify product type: Laundry detergent (powder or liquid) Washing up liquid Oven/window/surface cleaner Drain cleaner Toilet cleaner Adhesive/glue Paint product Grill/lighter fluid Solvent Motor vehicle product e.g. oil, degreaser Windshield washing fluid White spirits Other Please specify: | Note: Cosmetics, medicinal and veterinary products are not within the scope of this project | |

| Section III - Requirement to be fitted with CRF | | | |
|---|--|--|--|
| 8. Is the product classified and labelled as hazardous? Yes No If Yes and if the product is a mixture, it was classified according to: CLP DPD | If the product doesn't need a CRF it does not fall under the scope of the pilot project so there is no requirement to fill out questionnaire | | |
| 9. Does the classification on the label of the product require that the packaging is fitted with a CRF? Yes No If Yes, please provide details of the classification requiring | Reference: CLP Annex II Part 3 3.1.1.1 and 3.1.1.2 Also see Annex 3D in this manual for details on labelling elements related to the classification for CRF requirements | | |
| CRF: Skin corrosion Cat. 1, 1A,1B,1C (H314) Acute toxicity Cat. 1 (H300, H310, H330) Acute toxicity Cat. 2 (H300, H310, H330) Acute toxicity Cat. 3 (H301, H311, H331) STOT SE Cat. 1 (H370) STOT RE Cat. 1 (H372) Aspiration hazard Cat. 1 (H304) | Note: more than one classification may be ticked | | |
| 10. How was the classification of the product checked? (Multiple responses are possible) Label Safety Data Sheet Exact Formulation Other Please specify if by other means: | | | |
| REMARK: If only the label was checked or classification was not checked, please tick N/A for Q11 and Q12 | | | |
| 11. Was the classification correct? Yes No N/A | Where the classification is incorrect or needs to be confirmed, an assessment to confirm the classification should be conducted. Where it is not possible to confirm the correct | | |
| 12. Was the labelling consistent with the classification? Yes No N/A | classification within the timeframe of the project, then the questionnaire should stop here. Where the classification is determined, continue through with the questionnaire. | | |

| Section IV - Compliance with general packaging requirements | | | |
|--|--|--|--|
| 13. Is the design of the packaging misleading to consumers? Yes Please specify why: No Too difficult to identify Please specify why: | According to Article 35(2) of CLP packaging containing a hazardous substance or a mixture supplied to the general public must not mislead consumers, or have a similar presentation or a design used for foodstuff or animal feeding stuff or medicinal or cosmetic products. | | |
| 14. Is the design of the packaging attractive to children? Yes Please specify why: No Too difficult to identify Please specify why: | According to Article 35(2) of CLP packaging containing a hazardous substance or a mixture supplied to the general public must not have either a shape or design likely to attract or arouse the active curiosity of children. If possible, please send relevant photos of the noncompliant or difficult cases to your National Coordinators | | |
| | | | |
| SECTION V: Compliance with CRF requirements | | | |
| 15. Was testing carried out to determine the presence of methanol or dichloromethane in the mixture? Yes No N/A | Reference: Annex II Part 3 3.1.1.3 of CLP For Q15, 16 and 17: -No should be ticked where | | |
| 16. If the presence of methanol is ≥3% in the mixture, was the packaging fitted with CRF? O Yes O No O N/A | methanol or dichloromethane were present according to the information provided, but testing was not carried out to verify this. | | |
| 17. If the presence of dichloromethane is ≥1% in the mixture, was the packaging fitted with CRF? ○ Yes ○ No ○ N/A | -N/A should be ticked where not relevant to the product examined <i>i.e.</i> neither methanol or dichloromethane were not present in the product. | | |
| 18. Is the CRF visually and manually sufficiently secure? Yes No N/A | | | |

| 19. Was a certificate available issued by a certified laboratory stating that the re-closable package has been tested and found to conform to EN ISO standard 8317 ? Yes | Reference: Annex II Part 3 3.1.2 of CLP |
|---|---|
| O Yes O No O N/A | For Q 19 and 20, tick N/A, if the specific provisions of section 3.1.4.2. in Annex II |
| If No , indicate how many calendar days it took to get the certificate: days | of CLP apply. |
| Tick the box if the certificate was not provided within the timeframe given to the company to provide it | |
| 20. Was a certificate available issued by a certified laboratory stating that the non-reclosable package has been tested and found to conform to EN standard 862 ? Yes | Reference: Annex II Part 3 3.1.3 of CLP |
| O Yes O No O N/A | Note: If the CRF is not adequate even though a Certificate states that it |
| If No , indicate how many calendar days it took to get the certificate: days Tick the box if the certificate was not provided within the timeframe given to the company to provide it | conforms to EN ISO standard 8317 or EN ISO standard 862 is available, please indicate this in Section VIII. |
| 21. Was evidence of conformity with standards EN ISO 8317 or EN 862 issued by a certified laboratory which conforms with standard EN ISO/IEC 17025? Yes No Not checked | Reference: Annex II Part 3 3.1.4.1 of CLP |
| | |

| Section VI - Compliance with tactile warning of danger requirements for products requiring CRF | | | |
|---|---|--|--|
| 22. Was the product fitted with a tactile warning of danger? Yes No | Reference: Annex II Part 3 3.2.1 of CLP | | |
| 23. Is the tactile warning of danger prominent on the surface of the package? Yes No Further investigation required N/A | | | |

| Section VII - Summary /Enforcement action |
|---|
| 24. Has non-compliance with CLP obligations of Article 35(2) of CLP regarding packaging requirements been detected? |
| ○ Yes ○ No |
| If YES, did the non-compliance relate to (more than one may be ticked): Classification Labelling CRF Design which may mislead consumers Attractiveness to children Tactile warning of danger Other. Please specify: |
| 25. Which actions were initiated against the offender? |
| □ Verbal advice □ Written advice □ "Name and shame" □ Administrative order □ Fine □ Prohibition from placing on the market of the non-compliant product □ Withdrawal from the market the non-compliant product □ Recall from the general public □ Criminal complaint / handing over to public prosecutor's office □ Other. Please, specify □ Follow up activities still on-going □ Voluntary action by the company to remedy the situation ○ None |
| 26. Has this case been forwarded to any other Member States? O Yes No |
| 27. Is feedback from the other Member State approached already available? O Yes No N/A |
| Section VIII – Informal comments ⁶ (not obligatory) |
| |
| |
| |
| |

 $^{^{6}}$ Please fill this section if you would like to inform on obstacles overcome, lessons learned, need for clarification/harmonization.

Annex 2: Examples of non-compliances

This annex includes photographs of products inspected during the course of the project, presenting cases of non-compliances regarding the tactile warning of danger (TWD), child resistant fastenings and labelling.



Product 1

Each entire symbol for tactile warning of danger shall be located on the upright handling surface near the edge within the range indicated in figure 3 of EN 11683 standard, such that top of the triangle is not more than 50 mm from the bottom of the packaging (see section 7.2.1 of EN ISO 11683 standard).

For small packaging the TWD may be located on the handling surface at the discretion of the manufacturer (7.4 of standard). In this example, the TWD is placed on the top of the bottle cap which was not considered to be the handling surface of this packaging.



Product 2

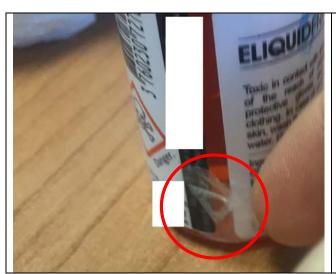
Example of a product that was considered by the inspector to be attractive to children.



Product 3

Example of product with TWD not placed correctly according to EN ISO 11683 standard, furthermore, its attractiveness is debatable, too.

Only in specific cases set out in section 7.2.2. of the EN ISO 11683 standard the tactile warning shall be located on the handling surface as near as possible to the opening.



Product 4

Example of product with TWD in the form of deficient sticker.

The warning shall remain tactile during the expected period of use of the package under normal handling conditions (see section 8 of EN ISO 11683 standard).





Product 5

Example of a drain cleaner without a child resistant fastening, on sale in a hardware/home ware store for general public.

Also non-compliance with labelling requirement was established as both hazard pictogram and hazard symbol are included.

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