

# The National helpdesk activity in Italy: report of the first year (2010)

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**Summary.** National CLP helpdesk is a service established in every Member State providing advice to companies and other stakeholders on the obligations they may have under CLP. In Italy the national helpdesk is located into the Center of Chemical Substances (CSC) in the National Institute of Health. Helpdesks will provide with wide ranging information on the provisions of CLP. They will also advice on the responsibilities the suppliers of chemical substances have to fulfill under these Regulations. Too specific questions cannot be answered as the aim of the helpdesk is to give a general interpretation of CLP principles and requirements instead of solving tailor made problems.

*Key words:* chemicals, classification, labelling, helpdesk.

**Riassunto** (*Relazione sulle attività dell'helpdesk CLP in Italia per l'anno 2010*). L'helpdesk nazionale è un servizio stabilito presso ogni Stato Membro per fornire supporto alle ditte e agli altri soggetti interessati sugli obblighi del CLP. In Italia l'helpdesk nazionale è stabilito presso il Centro Nazionale Sostanze Chimiche (CSC) dell'Istituto Superiore di Sanità. L'helpdesk fornisce un ampio ventaglio di informazioni sui requisiti del Regolamento CLP e consiglia in merito alle responsabilità dei fornitori di prodotti chimici nel soddisfare i requisiti del CLP. Le risposte ai quesiti non risolvono le esigenze troppo specifiche dei singoli richiedenti. Lo scopo dell'helpdesk è quello di fornire interpretazioni di applicabilità generale pur riferite a casi specifici.

*Parole chiave:* sostanze chimiche, classificazione, etichette, helpdesk.

## INTRODUCTION

In the application of Article 44 of Regulation (EC) 1272/2008 [1] “regarding classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and amending the Regulation (EC) no. 1907/2006” [2], the Competent Authority has charged the National Center of Chemical Substances (CSC) of Istituto Superiore di Sanità (ISS) to set up a helpdesk as technical assistance service and as support in applying the Regulation.

The Ministry of Health has to formally delegate through an actuator Decree the Institute's CSC, which has already been providing this service.

Such activity is meant to support the manufacturers, importers, distributors downstream users and simple users in charge of applying the Regulation.

The majority of the questions concerns CLP's transitional provisions. It is in fact important to underline that the CLP Regulation has become effective on January 20, 2009. Nonetheless not all the provisions are immediately mandatory, since the transitional ones (Article 61) set two different dates as for classification, communication of danger and packaging of dangerous substances and mixtures, which are December 1, 2010 and June 1, 2017.

Although the Regulation has specified other characters to solve questions not regarding CLP (application

of the Regulation 1907/2006 REACH, firms' duties on registration, evaluation, authorization and restriction) the helpdesk provides in any case assistance in identifying the institutional referential figure.

The analogous instrument in the European perspective is helpex. It is constituted by national REACH helpdesk, CLP helpdesk and European Chemicals Agency (ECHA) and is in charge of providing consistent opinions to producers, importers, simple users and others concerned figures in order to make easier a proper and full application of both Regulations 1907/2006 and 1272/2008.

This paper is meant to identify the actors somehow involved in the application of the CLP Regulation, the typology of the most frequently asked questions, the needed interpretations for a correct application and the operational modalities to convey information to ECHA.

One of the main helpdesk's activities will be to spread the information in order to ease firms' access, with particular attention given to small and medium enterprises (SME) and “Microenterprises”, to technical or scientific innovations which might change the modality for classification and labelling of substances and mixtures, as suggested by CLP Regulation's Article 15.

The helpdesk instrument turns out to be appropriate and effective especially regarding the human

resources and the technical and scientific competences that CSC has invested in its organization.

According to CLP Article 44, a helpdesk for companies has been set at the ISS National Center for Chemical Substances (CSC) in order to provide information on CLP requirements.

The CSC has been carrying out – in the national, European and international field – technical and scientific activities on chemical substances and mixtures, supporting the Ministry of Health, which has been appointed as Competent Authority for the implementation of both REACH and CLP Regulations.

The CSC is assisted by a group of specialists to develop the activities of CLP helpdesk. The attendance at Helpnet's meetings is also guaranteed. During these meetings Member States and the Agency discuss together issues and questions that either require close examination or might be subject to different interpretations. Among the Helpnet activity's results we would like to remember the Frequently Asked Questions (FAQ) publication.

The Agency's helpdesk has the duty to coordinate the activities of all the national helpdesks and represents a second level helpdesk for major issues, or for questions which have dubious interpretation.

## DESCRIPTION OF RESULTS

During 2010, national helpdesk's activity has experienced, month after month, a raise in the requests from companies and stakeholders interested in the application of Regulation 1272/2008. In fact, December 1<sup>st</sup> 2010 has represented an important day, as it was the deadline for the application of the new classification and labeling system to substances.

In addition to that, also the new and the revised entries reported in the 1<sup>st</sup> adaptation to technical progress had to be applied at the same date.

A database has been arranged in order to better organize the helpdesk management, and then enriched with users' questions. Every question has been linked to 1 or 2 key words in order to index the topics and provide homogeneous answers to similar questions. The key words identified so far are described in *Table 1*.

The number of questions sent to the helpdesk in 2010 has increased month by month, and reached its peak in November (see *Figure 1*).

The typology of applicants is shown in *Figure 2*. They are manufacturers, importers, consultants, downstream users and "not defined" (e.g. simple users). It can be pointed out that in Italy many small enterprises are supported by consultants in order to fulfill the requirements of CLP. We can see from the diagram a great difference between the number of importers

**Table 1** | Helpdesk database: numbers and percentages of the questions for each key word

Number	%	Key words	Number	%	Key words
47	7	Notification	10	< 1.8	CMR substances
39	6.5	Safety Data Sheet	9	< 1.8	Language
39	6.5	Labeling	9	< 1.8	UVCB substances
37	6.1	Classification	9	<1.8	Annex VI and I ATP
32	5.3	Hazard pictogram	8	< 1.8	Acute toxicity test
29	4.8	Hazard statement	8	< 1.8	Criteria for STOT
29	4.8	Placing on the market	8	< 1.8	Alloys
30	4.9	Corrosion	8	< 1.8	Substances and dilution
27	4.5	Mixtures	8	< 1.8	Substances off the shelves
30	4.9	Self classification	7	< 1.8	<i>In vitro</i> medical devices
22	3.6	Precautionary statement	7	< 1.8	Polymers
21	3.4	Explosives	6	< 1.8	Viscosity
17	2.8	Medicinal products	4	< 1.8	Disposal storage
17	2.8	Variable composition	5	< 1.8	C&L Inventory
15	2.4	CAS name or IUPAC name	4	< 1.8	Importers
12	1.9	Foodstuffs	2	< 1.8	Re-packaging
11	1.8	Risk assessment at work	2	< 1.8	Liquid gas
12	1.9	REACH related	1	< 1.8	ISO Standard
10	< 1.8	Packaging			

CAS - Chemical Abstracts Service;

CMR - Carcinogenic, Mutagenic or Toxic to Reproduction;

ISO - International Standard Organization;

IUPAC - International Union of Pure and Applied Chemistry;

STOT - Specific Target Organ Toxicity;

UVCB - Substances of Unknown or Variable Composition.

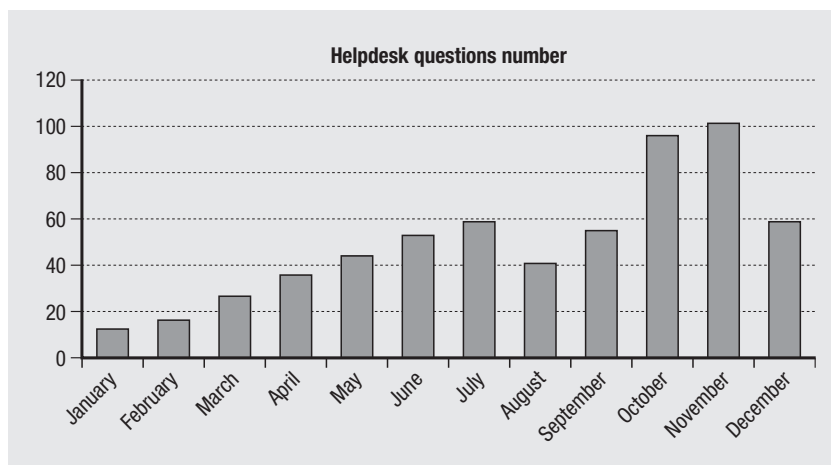


Fig. 1 | Helpdesk questions distribution by month (2010).

and manufacturers. As for Regulation 1272/2008, it is important to highlight the importer's figure, which plays a leading role in the supplying chain, since he is the one responsible for the introduction of products (substances, mixtures and items) in the European market; the importer is in fact bound to provide users with all the needed information regarding consumers and workers' safety and protection. For this reason, the CLP Regulation sees the helpdesk's start up especially as a support to SME (Article 44).

It is then understandable that the majority of the questions come from such users. Instead, downstream users – workers or employers – refer to the helpdesk for questions regarding how to fill out the Safety Data Sheets (SDS) forms or how to update the evaluations on chemical risk, as requested by Legislative Decree 81/2008 [3] on safety and health protection in work environments.

In *Figure 3* the distribution of total questions vs key words is shown and in *Figure 4* the percentage levels with relation to the key words.

In *Table 1* the key words used to group together the issues presented and considered by the helpdesk are shown. From this table we can notice that the majority of the issues concerns the fulfillment of obligations which have become compulsory since December 1<sup>st</sup>, 2010. These are the modalities of substances' notification to the database at

ECHA, labels' elements, classifications criteria for substances and mixtures, new definitions regarding the introduction of substances into the market and new indications and pictographs which replaced the old sentences and symbols of danger. Great attention has been also given to the relapse of the new Regulation concerning the legislation on safety in working environments.

This paper concerns specific questions which have appeared more frequently and which have drawn the attention of the international political scene. Some of the following questions/answers come from the helpnet platform and the final ECHA view is reported.

Otherwise other examples come from the Italian helpdesk and reflect the current view of experts in the CLP regulation issues.

#### ***Classification physical and health hazards: comparison between DSD and CLP***

A substance does not meet the classification criteria under the Dangerous Substances Directive (DSD) [4], but it could be classified under CLP; in fact for a range of hazard, the classification criteria have changed, e.g. for many physical hazards where the test methods which determine the classification criteria are often different from those of DSD. For other hazards, the applicable concentration limits for taking into account the classification of its

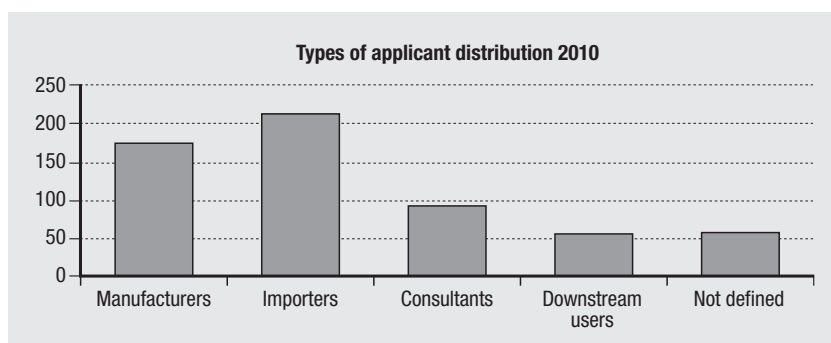


Fig. 2 | Types of applicants.

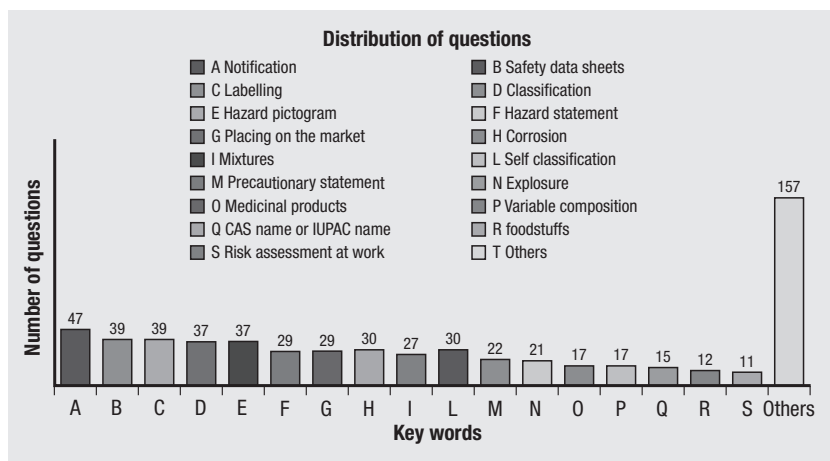


Fig. 3 | Distribution of questions vs key words.

constituents, additives and impurities contained in the substance have changed, *e.g.* for the irritation and corrosive hazards. This means that in the cases where there is no reliable test information on the substance as a whole and the bridging principles cannot be applied, the use of the calculation rules with concentration limits may lead to a classification under CLP, even though the same substance was not classified under DSD (this information is also available in *ECHA Guidelines* [5]).

***May a supplier use data which is available in open literature or for internet or in online databases for the purpose of physical hazards classification under CLP?***

He may, the data is reliable and adequate for the purpose of hazard classification.

The physical hazards of substances and mixtures should be determined through testing based on the methods of standard referred to in part 2 annex I of CLP. These methods can be found for example in the UN Manual of test, and criteria seen at website of UNECE [7]. These criteria are normally used to classify substances and mixtures for transport, however testing is not mandatory in cases where ad-

equate and reliable information from reference literature or databases is already available, and where the substance to be classified and the substance described in the reference are comparable with regard to homogeneity, impurities, particle sizes etc.

Open literature or databases often use secondary data sources. When such data is used, the original source should be cited and checked by an expert. This check should make sure that there is sufficient documentation to assess the suitability of the test used, and that the test was carried out using an acceptable level of quality assurance.

Where the criteria cannot be applied directly to available identified information, the weight of evidence determination using expert judgment shall be applied in accordance with Article 9 of CLP. For the weight of evidence determination, all available information is considered together, such as the results of suitable *in vitro* tests, relevant animal data, information from the application of the category approach, QSAR results, human experience (occupational data) etc. the quality and consistency of the data shall be given appropriate weight. For the purpose of classification for health hazards, established hazardous effects seen in appropriate animal studies

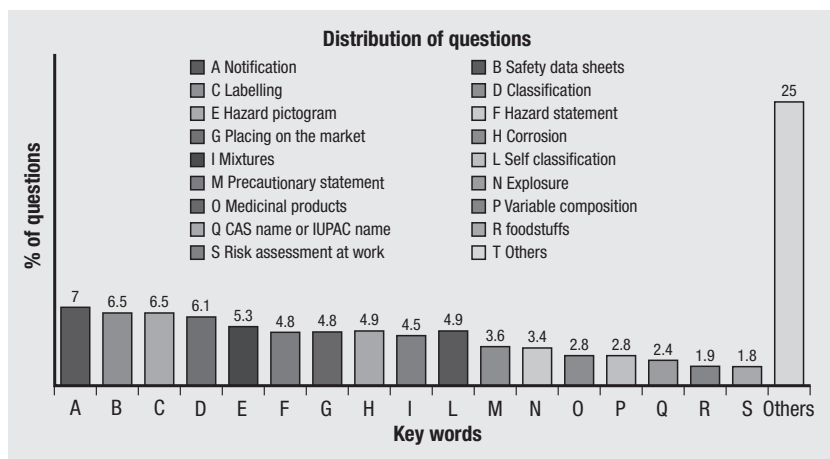


Fig. 4 | Percentage of questions vs key words. "Others" is the total of all key words % lower than 1.8.

or from human experience that are consistent with the criteria for classification shall normally justify classification. Where evidence is available from both humans and animals and there is a conflict between the findings, the quality and reliability of the evidence from both sources shall be evaluated in order to resolve the question of classification. Generally data on humans shall have precedence over other data. At this moment the helpdesk has not requested questions for environmental hazards.

#### ***The meaning of “placing on the market”***

Placing a substance or mixture on the market under CLP means supplying or making it available to third parties, whether in return for payment or free of charge within the territory of the EU Member States and those European Economic Area – European Free Trade Association (EEA-EFTA) countries which have implemented the CLP Regulation.

In addition, import, defined as the physical introduction of a substance or mixture into the customs territory of the EU and those EEA-EFTA countries which have implemented the CLP Regulation, is deemed to be placing on the market.

#### ***“Placing on the market” and notification***

In relation to notification, placing on the market is a pre-condition: substances which are referred to in CLP Article 39 have to be notified to the C&L Inventory if they are placed on the market. However, no notification is required if the information mentioned under CLP Article 40 has already been provided as part of a previous registration or notification by the same notifier.

#### ***Substances in stock on 1 December 2010 have to be notified***

Substances that are “in stock” on 1 December 2010 are not considered to be “placed on the market” on that day, and therefore will not have to be notified by 3 January 2011. However, when placed on the market, they will have to be notified within 1 month after their placing on the market by their manufacturer or importer. A distributor who takes substances off the shelves where they have been stored for a while, in order to sell them to others, will not have to notify to the C&L Inventory as this obligation affects only manufacturers and importers.

#### ***Who must do notification?***

Any manufacturer or importer, or group of manufacturers or importers (hereinafter referred to as “the notifier(s)”), who places on the market a substance referred to in Article 39, shall notify to the Agency the following information in order for it to be included in the inventory referred to in Article 42.

#### ***Deadline notification***

The notification deadline is dependent on the date on which the substance is placed on the market. When a substance is placed on the market on 1 December

2010, it must be notified to the C&L Inventory within 1 month, *i.e.* the notification deadline is 3 January 2011. If a substance is placed on the market before 1 December 2010, *e.g.* on 10 October 2010, and placing on the market is done again on 17 January 2011, the notification will be due by 17 February 2011.

In relation to import, as of 1 December 2010, the 1-month timeline is counted from the day when the substance or mixture is physically introduced into the customs territory of the EU Member States and those EEA-EFTA countries which have implemented the CLP Regulation.

#### ***Labeling and deadline***

If the substance or mixture classified, labeled and packaged in line with Directive 67/548/EEC (Dangerous Substances Directive, DSD) or, in case of mixtures, Directive 1999/45/EC (Dangerous Preparations Directive, DPD) [6], has already been placed on the market before 1 December 2010 or 1 June 2015 respectively, the substance or mixture which is still in stock does not have to be relabeled and repackaged in accordance with the CLP rules by the supplier before 1 December 2012 or 1 June 2017 respectively.

It is pointed out that under certain conditions, substances manufactured before 1 December 2010 and stored in the manufacturer’s warehouse after 1 December 2010 and mixtures prepared before 1 June 2015 and stored in a formulator’s warehouse after 1 June 2015 can benefit from the transitional arrangements provided in Article 61(4). This would normally be the case where the transfer of ownership of the substance or mixture has taken place before 1 December 2010 or 1 June 2015 respectively, although the substance or mixture does still remain in the manufacturer’s or formulator’s warehouse, *i.e.* no physical hand-over of the substance or mixture.

It is not allowed to use label elements according to Directive 67/548/EEC (DSD) or 1999/45/EC (DPD) [6] together with elements according to the CLP Regulation on the same label as this would lead to confusion on the market and hamper the transition to the CLP classification and labeling system. Only one labeling system shall be applied on any label; which one to choose will depend on the timing in relation to the transitional deadlines of 1 December 2010 and 1 June 2015. In case you decide to already classify, label and package a substance according to the CLP rules before 1 December 2010 or a mixture before 1 June 2015, you must not use any labeling elements in accordance with DSD or DPD respectively.

#### ***Safety Data Sheet (SDS)***

SDS is the most important communication tool within the supply chain of substances or mixtures. The supplier of these substances or mixtures shall provide the recipient with a safety data sheet in accordance with new Regulation (EC) 453/2010 [8] that updates Annex II of Regulation 1907/2006. Many suppliers shall know the amendments until 2015 in



the classification for substances and mixture in the SDS as shown in ECHA Guidelines [9]:

- After 1<sup>st</sup> December 2010 and until 1<sup>st</sup> June 2015 both DSD and CLP classification shall be provided in SDS for classification of substances on their own and according to DPD for mixtures containing these substances;
- Until 1<sup>st</sup> June 2015 the classification of a mixture according to DPD shall be provided in the SDS; if a mixture is classified, labeled and packaged in accordance to CLP, the CLP classification shall appear on the SDS alongside the classification based on the DPD;
- From 1<sup>st</sup> June 2015, substance and mixture classifications according to CLP shall be provided in the SDS. From this date the old legislation (DSD and DPD) will be repealed, and classifications according to DSD or DPD will no longer be allowed.
- From 1<sup>st</sup> June 2015 the SDS shall provide in accordance with annex II of Regulation (EC) 453/2010.

***Questions about the relapse of the application regarding the EC Regulation 1272/2008 on Legislative Decree 81/2008 (health safety at workplaces)***

Professional and industrial users have no obligations under CLP because they are considered to be end users of the substances and mixtures on the market. Examples of professional users are cleaning personnel, painters, or craftsmen who use paints, lime or cleaning agents in the context of their professional activity. On the contrary, formulators of mixtures are not considered as end users, but rather as downstream users of substances and mixtures.

Professional and industrial end users are required to respect the information on the label and on the SDS supplied to them. Further to this, they have to comply with the downstream users obligations set out in title V of REACH on the safe handling and use of substances and mixtures.

It is important to note that end users established within the EU who are supplied with substances or mixtures by an actor outside the EU, are considered to be importers under CLP. This means that they have the obligation to classify, label and package these substances and mixtures and to notify relevant substances information to C&L Inventory.

Especially, clarifications are required on the new prescription for the SDS's drafting, and the new criteria for the classification of dangerous substances and mixtures, given the presence of new grades of danger, which could involve changes in the risk estimation.

However, we would like to underline that when the employer, given the e-SDS, is bound to connect some exposure's scenarios with the use of chemical substances, he will have the chance to use the information given in the SDS to make the risk estimation under the Articles 223 and 236 of Legislative Decree 81/2008 as last amended. The exposure scenarios in fact, when available, represent useful sources of in-

formation that the employer has to rely to for the estimation of the risk.

Furthermore, if the employer cannot apply the uses and sceneries shown in the REACH Regulation to his workplace, he is then bound to communicate his own scenario either to the responsible for the introduction to the market (provider) or directly to the ECHA.

To cap it all we would like to remember that the provider must communicate:

- I. a SDS to the recipient of the mixture or substance (downstream users or to the employer), under REACH Article 31, as modified by UE 453/2010 Regulation, when:
  - a) the substance or the mixture meets the criteria for classification as dangerous;
  - b) the substances are persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB);
  - c) a substance is included in Annex XIV (Article 59 REACH), as substances meeting the criteria for classification as CMR Category 1 or 2, or persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII;
  - d) the substances are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII.
- II. To the recipient of articles containing a substance referable to point sub. I.c. (with a concentration higher than 0.1% weight/weight), enough information to allow a safe use of the article and, at least, the name of the substance.

In order to make a complete and correct estimation of the risk, the employer must also ask the provider a SDS for mixtures classified as non dangerous but containing dangerous substances in concentration lower than the one required for the classification duty, under REACH Article 31 paragraph 2. He will anyways have to ask for information about substances (being them actual substances or part of a mixture) concerning REACH field of application, under REACH Article 32.

The purpose of the Italian helpdesk is to propose to industry an overview of the critical documents needed for the implementation of CLP processes. A website has been recently implementing for this reason. We believe this will greatly improve the visibility and usage of information (guidance, manuals, fact sheets, etc.).

***Conflict of interest statement***

There are neither potential conflicts of interest nor financial or personal relationships with other people or organizations that could inappropriately bias the conduct and findings of this study.

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