

# CLP activities and control in Ireland

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**Summary.** The 10<sup>th</sup> December 2010 marked a new beginning for Regulation (EC) no. 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP) in Ireland with the start of its *operational phase*. It was on this date that the administrative and enforcement provisions for CLP were encompassed in the new Chemicals Amendment Act, 2010. In this Act, the Health and Safety Authority, known as the “the Authority” is named as Competent Authority (CA) for CLP, along with the Minister for Agriculture, Fisheries and Food, in respect of pesticides and plant protection products and the Beaumont Hospital Board with responsibility for receiving information relating to emergency health response. In practice, the Authority has been *de facto* CA for CLP since its publication on the 31<sup>st</sup> December 2008, given its role in existing classification and labelling regimes. This article focuses on the work undertaken by the Authority on CLP at a National, European and International level including its implementation, training, helpdesk, guidance, enforcement and awareness raising activities.

*Key words:* CLP, GHS, enforcement, implementation, Ireland.

**Riassunto** (*Attività e controllo del CLP in Irlanda*). Il 10 dicembre 2010 rappresenta in Irlanda un nuovo punto di partenza per il Regolamento 1272/2008 (CLP) con l’inizio della sua “fase operativa”. Infatti, a partire da questa data, le disposizioni amministrative e attuative del CLP sono rientrate nel nuovo *Chemicals Amendment Act*, 2010. In questa legge, l’*Health and Safety Authority*, nota come Autorità, viene nominata Autorità Competente per il CLP (CA) insieme con il Ministro per l’agricoltura, la pesca e l’alimentazione (*Minister for Agriculture, Fisheries and Food*), per quanto attiene ai pesticidi e ai prodotti per la protezione delle piante, e il *Beaumont Hospital Board* organismo incaricato di ricevere le informazioni relative a risposte di emergenza sanitaria. In pratica, a partire dalla pubblicazione della legge il 31 dicembre 2008 l’Autorità, in considerazione del suo ruolo nell’attuale sistema di classificazione ed etichettatura, è diventata *de facto* CA per il CLP. Questo articolo presenta le attività intraprese dall’Autorità, relativamente al CLP, a livello nazionale, europeo e internazionale incluse attività di controllo, formazione, *helpdesk*, orientamento, attuazione e sensibilizzazione all’uso.

*Parole chiave:* CLP, GHS, attuazione, controllo, Irlanda.

## INTRODUCTION

It seems appropriate to say that “Rome wasn’t built in a day” when it comes to describing the work undertaken by the Health and Safety Authority in Ireland in preparing for Regulation (EC) no. 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP).

Although a small island on the periphery of Europe, Ireland has a large chemical industry with eight of the top ten pharmaceutical companies based here. This generates over 50 percent of the country’s exports, making Ireland the largest net exporter of medicines in the world. It is also an important source of employment having grown from 5200 in 1988 to over 24 000 by 2009 ([\[mchemicalireland.ie/Sectors/PCI/PCI.nsf/vPages/About\\\_us~industry-profile?\]\(http://mchemicalireland.ie/Sectors/PCI/PCI.nsf/vPages/About\_us~industry-profile?\)\). Aside from this large chemical sector, Ireland’s chemicals industry is made up of thousands of small and medium enterprises who mostly use or formulate chemicals. Both of these groups are impacted by the changes introduced by Regulation \(EC\) no. 1272/2008 on the Classification, Labelling and Packaging of substances and mixtures \(CLP\) on how they classify, label and package their chemical products. These changes are there for companies whether they are manufacturers, importers or users of chemicals. CLP also brings challenges to the Authority and the other Irish CA’s with responsibility for regulating it. However, regardless of all the challenges,](http://www.phar-</a></p></div><div data-bbox=)



Fig. 1 | CLP warning sign logo for helpdesk.

there are also plenty of opportunities and benefits for companies and Authorities too with the introduction of CLP.

#### THE HEALTH AND SAFETY AUTHORITY

This Agency was established in Ireland in 1989 and employees 186 staff, most of whom are inspectors. In addition to CLP, the Authority has responsibility for the enforcement of occupational safety and health law, promoting and encouraging accident prevention and providing information and advice to all companies, organisations and individuals. It is also the Competent Authority for Regulation (EC) no. 1907/2008 on the registration, evaluation, authorization and restriction of chemicals (REACH) along with other chemicals legislation, dealing with every size of workplace, in every economic sector in Ireland ([www.hsa.ie/eng/About\\_Us](http://www.hsa.ie/eng/About_Us)). Although the Authority always had a remit for chemicals legislation, its focus for many years was on occupational health and safety law. This changed with the introduction of REACH, which brought the importance of chemicals management in the workplace and its impact on consumers and the environment sharply into focus. This ultimately led to the establishment of a new Chemicals Division within the Authority in 2006, the first Chemicals Act in 2008, and a new strategic focus from 2010. This sent a clear message that chemicals were now clearly within the remit of Authority, as reflected in one of its strategic goals “To promote the safe and sustainable management of chemicals” [1]. The implementation of CLP in Ireland and indeed throughout Europe followed closely the legislative format and processes already developed and established by REACH. For the most part, this made the CLP implementation process in Ireland run more smoothly. However the aligned first registration deadline under REACH and classification and notification deadline under CLP at the end of 2010 did lead to some confusion for Irish stakeholders.

#### CLP IMPLEMENTATION

The Authority CLP implementation process commenced in January 2006, when its first Globally Harmonized System for the Classification and Labelling of Chemicals (GHS) implementation plan was drafted. This plan outlined who would be affected and the steps the Authority would take towards its implementation. This led to the first of many successful seminars in May of that year, where invited speakers from the European Commission, the European Chemical Industry Council (CEFIC) and the United Kingdom Health and Safety Executive (HSE) gave a flavour of what could be expected to change in Europe as a result of the GHS. In August of 2006, the much anticipated draft GHS regulation and public consultation process commenced. In early 2007, the GHS implementation work activities began in earnest, having already been identified in the national implementation plan. The Authority incorporated the GHS work activities into its “REACH implementation plan”, which then became the “REACH and GHS implementation plan”. This was to ensure that the Authority was equally prepared for both REACH and CLP.

The GHS stream within this implementation plan included activities such as the European Council negotiations, guidance development and United Nations work, along with awareness raising activities. The GHS activities remained within this implementation plan until June 2008, when REACH became operational, which also coincided with the end of the CLP negotiations. The Authority’s resources were focused towards raising awareness on REACH as this regulation was the priority for Irish Industry. As CLP had not entered into force in 2008, it was deemed too early to commence a full awareness raising effort on CLP. However, 2008 it was still a busy year for the Authority regarding CLP/GHS activities in terms of supporting the development of European Chemicals Agency (ECHA) guidance and finalising the CLP Regulation itself.

It was only when CLP entered into force on the 20<sup>th</sup> January 2009, that the Authority’s activities to provide the necessary support to its Irish Stakeholders increased. It was also clear from the publication of CLP as an official journal, that the Authority had an impending role under CLP and therefore work was required. At a National level, this included training the Authority’s chemicals inspectorate, establishing a dedicated Helpdesk, raising awareness and implementing the necessary administrative and enforcement provisions. At European level, CLP was being managed by ECHA and was included in the remit of the REACH CA meetings, renamed as Competent Authorities for REACH and CLP (CARACAL), and the work by both ECHA and European Commission began in earnest to incorporate CLP into their programmes of work.

#### CLP COMPETENCY AND TRAINING

While the Commission and ECHA were busy preparing for CLP during 2007/2008, the Authority too

was making plans; part of this was ensuring that our own expertise on classification and labelling was kept up to date. This was mostly achieved by engaging in the United Nations Sub-Committee of Experts on GHS (UNSCEGHS) sessions and its informal working groups, participating in the European Commission's REACH implementation projects and the European Councils Negotiations on CLP. The Authority staff engaged in this work, while small in number, were already classification and labelling experts, but the knowledge gained on GHS and subsequently CLP was to be a significant advantage when it came to passing this knowledge to their inspectorate colleagues at home.

Once the work on the CLP negotiations were completed in the latter half of 2008, along with the finalisation of the CLP guidance, the Authority's classification and labelling experts commenced training the chemicals inspectorate in 2009. For the CLP training, the REACH precedence again proved to be useful, as the training model developed by the Authority for CLP was based on one previously developed for REACH. The CLP training was of modular design, with seven modules delivered over six months. It was designed to slowly build up the CLP expertise of those who were not directly involved with the existing classification and labelling regime or CLP but who would become our CLP experts of the future.

This training plan developed into what we recognized as a *phased and tiered approach* to CLP competency. This took into consideration the different types of inspectors within the Authority and what their focus would be during an inspection. These training plans were developed in conjunction with the Authority enforcement strategy for CLP. In addition, ECHA's forum for exchange of information on enforcement, known as the "FORUM" is now actively engaged in CLP, having hosted its first "CLP train the trainer" event in January 2011 and incorporating CLP within its processes. The Authority anticipates that at a National level, enforcement of CLP will also be driven by the FORUM's projects on CLP in the future.

### CLP HELPDESK

The CLP helpdesk within the Authority was formally established in January 2009, following the entry into force of CLP. It had in fact been running informally since June 2007 as the GHS helpdesk [2]. The only change internally was the change in its name from GHS to CLP (*Figure 1*). The main advantage of its formal establishment was its inclusion in the support already established in ECHA via the network of national helpdesks for REACH and CLP, known as HelpNet. These tools have proven to be an invaluable resource to the national CLP helpdesk team both in giving and receiving information. During its first year of operation, CLP helpdesk queries were low in number. However, during 2010, over two hundred queries were processed, with more than one hundred

in the last quarter of 2010 running up to the CLP classification and notification deadlines.

The Authority attended the first HelpNet meeting in February 2010. This twice yearly meeting is a good opportunity to meet ECHA staff and other Member State CLP helpdesk members, with whom the Authority's CLP helpdesk team have regular correspondence with via a tool known as the HelpEx. This online tool is used to post difficult CLP related questions and also to formulate ECHA's frequently asked questions (FAQs). Following similar processes already established for the REACH helpdesks, this system is a significant step forward in the interpretation of CLP and agreeing an approach on questions and answers. In addition to national helpdesk activities, the Authority's CLP helpdesk team participated extensively in the development of the ECHA CLP FAQ's during 2009 and 2010. This provided an excellent opportunity for improving and maintaining competency in CLP and also in assisting the attainment of a greater practical understanding of CLP.

### EUROPEAN CHEMICALS AGENCY (ECHA) ENGAGEMENT

The Authority was involved in the development of the ECHA CLP introductory and classification criteria guidance from 2007, whose development at that time was part of the REACH implementation projects (RIPs). This proved to be a great opportunity for the Authority's classification and labelling experts to demonstrate and maintain their competency in CLP while gaining further practical experience. The Authority was involved in three of the four working groups and on a specialist experts group during what was known as the RIP 3.6 project. In more recent times, the Authority has participated in the development of the ECHA CLP labelling and packaging guidance and in updating the CLP criteria guidance, to take account of the proposed changes with the 2<sup>nd</sup> adaptation to technical progress (ATP) to CLP, most notably for the environmental hazards. Both sets of guidance are due to be published in 2011. In addition, the Authority also provides comments, as part of its ECHA Member State Competent Authority role, on Harmonized Classification and Labelling (CLH) proposals as they go through the consultation process.

### EUROPEAN COUNCIL AND COMMISSION ENGAGEMENT

During 2007/2008, the Authority participated in the CLP Negotiations at Council, the legislative reviews of the 1<sup>st</sup> ATP and more recently, the 2<sup>nd</sup> ATP to CLP. The Authority participates at CARACAL and the Article 133 meetings ensuring that CLP is kept up to date with technical progress and scientific developments. It would appear that this "biennium cycle" of updating CLP will continue and this adds to the challenge of regulators and industry to keep up to date with CLP.

## IRISH GOVERNMENT ENGAGEMENT

At a national level, the Authority was involved in the development of the Chemicals (Amendment) Act, 2010 (no. 32 of 2010) which was lead by the Irish Government's Department of Enterprise, Jobs and Innovation (DEJI). The Chemicals (Amendment) Act, 2010 put the necessary administrative and enforcement provisions for CLP in place in Ireland. This amendment was an update to the existing Chemicals Act 2008 (no.13 of 2008), which incorporated REACH. The 2008 Act was modelled on the Safety, Health and Welfare at Work Act, 2005 (no. 10 of 2005) to include consistency in the enforcement of the new direct acting chemical regulation and the existing Occupational Safety and Health (OSH) Directives. The Acts includes the appointment & powers of Inspectors and the level of fines and penalties. A summary conviction may result in a max of 5000 € fine or 12 months in prison, whereas a conviction on Indictment gives a fine of 3 000 000 € or 2 years in prison. There is also an option for a summary conviction to use a "fixed payment notice" of 2000 € which negates the requirement to go to court. In addition to the Chemicals Amendment Act, the Irish Government also recently published a Regulation under the Act to allow the use of English only on labels as required by Article 17.2 of the CLP Regulation. It is known as the Chemicals Act (CLP Regulation) Regulations 2011 (S.I no 102 of 2011) and came into effect on the 2<sup>nd</sup> March 2011.

## AUTHORITY ENFORCEMENT AND CONTROLS

The Authority sees its primary role in CLP to provide information and advice to all companies, organisations and individuals. However, there are of course the necessary enforcement activities. The first national enforcement strategy for CLP was drawn up in 2010 following the first round of training completed at the end of 2009. CLP was incorporated into the existing REACH enforcement strategy within the Authority, which had been running since 2007. This programme included 1200 inspections during 2010. At the beginning of 2010, the Authority was not officially appointed as enforcement Authority for CLP, therefore the primary focus of the inspections undertaken during 2010 was to raise awareness

and information gathering about CLP. In view of this, two specific questions were prepared that our inspectors asked on site.

The questions and the results are set out in *Table 1*.

Given our experience from the existing labelling and Safety Data Sheet (SDS) regime, the results for question 1 were as expected. At the face of it, the results for question 2 were initially surprising; however as the majority of Irish industry fall into the small and medium enterprise sector, the results would be in line with expectations. However, Irish industry did submit a significant amount of classification and labelling (C&L) notifications by the first deadline amounting to 3% of the total received by ECHA. Therefore, if Irish industry is taken as a small cohort to the rest of Europe, the statistics from our inspections hold up really well with the reality of what notifications were submitted by Irish industry.

For 2011, the Authority CLP strategy will be similar to its 2010 activities except that the number of inspections has increased to 1500. Again the proposed CLP questions will focus on the hazard labels and their consistency with the SDS and Classification and Labelling Notification requirements. In addition, the Authority intends to participate in the FORUM enforcement project on downstream users, including formulators. This is expected to include both REACH and CLP elements. It is also anticipated, now that the Authority is formally appointed as the enforcement Authority for CLP, it will move from awareness raising activities on CLP only, to include enforcement action, where required. The chemicals inspectorate responsible for enforcing CLP is located in eight different locations throughout Ireland. The Authority has a centralized database system for recording all inspection data regardless of location, known as GeoSmart. This makes collating the information from the inspections relatively easy.

## CLP AWARENESS RAISING

The Authority started raising awareness on GHS in 2006, creating a GHS logo, running seminars, presentations, creating a website [www.ghs.ie](http://www.ghs.ie) and a GHS helpdesk [ghs@hsa.ie](mailto:ghs@hsa.ie). Stakeholders were becoming familiar with the GHS term when the new acronym "CLP" emerged near the end of the negotiations

**Table 1** | *Programme of Work 2010*

Question 1: Is hazard labelling information consistent with that provided in the SDS?	No action	Verbal advice	Written advice	Improvement notice	Prohibition notice
Result in %	44%	42%	13%	0%	0%
Question 2: Is company required to notify the Classification & Labelling of substances(s) which they manufacture or import in accordance with Article 40 of the Classification, Labelling & Packaging Regulations?				No	
Result in %	3%			97%	

2008. So although two years were spent promoting the term GHS, the Authority made a decision in January 2009 to switch from GHS to CLP for national awareness raising activities in order to distinguish the now “*direct acting European Regulation*” CLP from the “*United Nations International Convention*” that was GHS. This created its own difficulties when referring to CLP and GHS at the same time as it created confusion due to a misunderstanding of the relationship between the Regulation and UN convention. A similar situation had occurred in 2007, when confusion would occur on mention of both REACH and CLP. Today however, the fog of confusion appears to be lifting. Just like what happened with REACH and CLP by 2009, Industry now understand the links between CLP and GHS.

Awareness raising activities during 2009 focused on making industry familiar with the new terminology, classification criteria and labelling rules. In 2010 the focus was on the first CLP deadlines regarding classification and notification requirements. Four seminars and two webinars were hosted during this period, as well as taking every opportunity to be guest speakers at events lead by other stakeholder organisations. In terms of our seminars and webinars in 2010, we incorporated the changes to the label and the SDS together, as in practical terms, the label and SDS have to be considered and planned for as one. This approach proved to be very successful especially given the CLP influence on the new SDS regulation ([www.hsa.ie/clp](http://www.hsa.ie/clp)).

In 2009 the Authority published a successful CLP Brochure, which gave a broad overview of the CLP requirements. Then in 2010, in the run up to the classification and notification deadlines, the Authority circulated postcards and posters on CLP, placed advertisements in the national newspapers, published articles in trade magazines and the Authority newsletter. In addition, quarterly e-bulletins, stakeholder emails and website formed part of our CLP communications strategy. For 2011 creativity on communicating the CLP message against a backdrop of diminishing resources and budget constraints will be important.

#### UNITED NATIONS GHS

From 1998 to 2001, Dr Iona Pratt, ([www.milieu.be/iona\\_pratt.html](http://www.milieu.be/iona_pratt.html)) working for the Authority at that time, chaired the International Labour Organization Working Group of Hazard Communication, within the framework of GHS. This subsequently developed into the UNSCEGHS, which the Authority has participated in since 2005. Our involvement since the beginning of GHS has certainly proven to be a great advantage when it came to the introduction of the GHS criteria into Europe, especially during the CLP negotiations for a number of reasons. Firstly, because we knew what was coming down the tracks and secondly, because we were directly involved from the beginning when the classification criteria and la-

bellling rules were being decided so this ultimately helped to shape our own future. Although, a lot of the hard work in agreeing the classification criteria and labelling rules is complete at the UNSCEGHS forum, now that we have introduced this GHS criteria into Europe via CLP, our continued involvement at the UN GHS, either as individual national experts or collectively as a European Union, is crucially important to ensure that GHS is implemented around the world in a consistent manner. This is especially true as Europe, being one of the largest trading blocks to implement GHS first, so the world is watching to see how we get along. This is to insure that we attain the ultimate aim of having one global chemical hazard communication scheme. As an Authority, we remain committed to this work.

#### CONCLUSION

After more than five years of working behind the scenes, the Health and Safety Authority is ready as one of the Competent and Enforcement Authorities for CLP in Ireland. The publication of the Chemicals Amendment Act 2010 may have marked the Authority's official appointment, *i.e.* the beginning for CLP, but it also marked the end of the first implementation process for the Authority and the inclusion of CLP into its programme of work. CLP is now part of the Authority's remit, along with a long list of other chemical and occupational safety and health legislation administered and enforced by the Authority. The CLP implementation process, having closely followed that of REACH, certainly brought with it advantages in its implementation both within the Authority and within Europe generally, especially in following the processes already established by REACH. The disadvantage of CLP and REACH being implemented together was that it brought certain challenges to the Authority, in particular issues around resources, training and awareness raising initiatives. As it transpired, it took time to prepare for CLP, time to absorb what CLP was about and time to disseminate the CLP message.

Given the added complexity of the phased transitional period of CLP, there are obvious challenges with having a dual classification and labelling system for a number of years and having part of CLP operational and part still to be implemented fully. In addition, the international dimension that is GHS will bring with it an ever changing regime, with updates to CLP very two years. This process is familiar to colleagues responsible for implementing changes in ADR policy, but new for those responsible for CLP policy. In time, the changes to GHS and therefore CLP will reduce considerably as the rest of the globe follow the European lead, *i.e.* focus more on implementing GHS rather than changing its content leading to the ultimate goal of having one global hazard communication system. Another challenge faced by the Authority relates to the work generated by CLP from the European Commission, ECHA and the United Nations, *i.e.* how will we attain a

balance with these outside obligations alongside our own national responsibilities and workloads?

Looking ahead, CLP is now operational and incorporated into the Authority's strategy whose goal is to promote the safe and sustainable management of chemicals. To support this, 1500 inspections will be undertaken in 2011, focusing on both hazard labels and notification obligations. The Authority will continue to develop the CLP enforcement strategy, work on FORUM projects incorporating CLP, increase the number of inspections looking at chemicals, focus on high risk sectors and high risk chemicals and continue to improve our inspectorate knowledge on CLP. In addition, the classification and labelling experts within the Authority will prepare for the next transitional

phase regarding classification of mixtures under CLP, keep up to date with UNGHS activities, implement future ATP's to CLP and disseminate that message outwards among our inspectorate and industry. In essence, a lot done and a lot more to do!

#### ***Conflict of interest statement***

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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