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Q1 2011 / Harmonizing the global language of safety – a monumental but necessary undertaking

The convergence of several chemical reclassification and labeling initiatives being implemented in the global business arena to boost health, safety and environmental protection to an unprecedented level is poised to have a monumental impact on the world's industrial sector, Stephen Harrison explains.



Together with chemical sectors that use raw materials and which introduce new formulae, other process industries are being required to make rapid and sweeping changes to comply with a whole new level of regulatory requirements. The new legislation impacts on product registration, classification and labeling, packaging and transportation, storage, product information and product disposal.

Launched in 2005, the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS) affects more than sixty countries and, since December 1, 2010, directly impacts all chemical substances in European Union (EU) countries. The GHS aims to achieve uniform worldwide criteria for classifying chemicals according to their health, environmental and physical hazards. This uniformity will also apply to hazard communication requirements for labeling and Safety Data Sheets. The GHS is not a formal treaty, but is rather a non-legally binding international agreement. In addition to improving health and safety in this arena, a key UN objective with this initiative is to make it easier for companies to conduct international trade.

The GHS addresses the classification of chemicals by types of hazard and proposes harmonized hazard communication elements, including labels and safety data sheets. It aims to ensure that information on chemical hazards is made available to enhance the protection of human health and the environment during the handling, transportation and use of these chemicals. The GHS also provides a basis for harmonization of rules and regulations on chemicals at national, regional and worldwide level - an important factor for trade facilitation.



REACH and CLP

The European Union has already taken the lead in the harmonization quest with its REACH regulation on chemicals and their safe use, which applies to substances manufactured or imported into the EU in quantities of one metric ton or more per year. Implemented in June 2007, REACH deals with the Registration, Evaluation, Authorization and Restriction of Chemical substances. The purpose of this regulation is to ensure a high level of protection for human health and the environment. This includes the promotion of alternative methods for assessment of hazards of chemicals, as well as the free movement of substances on the market of the EU. REACH makes industry responsible for assessing and managing the risks posed by chemicals and providing appropriate safety information to their users. Substances in volumes over one ton per year that are either manufactured or imported into the EU (even in preparations/mixtures and articles), now have to be registered.

The CLP regulation, a more recent EU initiative implemented in January 2009 has the dual objectives of facilitating international trade in chemicals and improving protection of human health and the environment. CLP aligns the EU system of Classification, Labeling and Packaging of substances and mixtures to the GHS. It is expected to facilitate the harmonized communication of hazard information of chemicals and to promote regulatory efficiency. It complements REACH and replaces the current system contained in the Dangerous Substances Directive and the Dangerous Preparations Directive. CLP introduces new classification criteria, hazard symbols (pictograms), signal words and labeling phrases (hazard and precautionary statements), while taking account of elements which are part of the current EU legislation.

CLP provides a transitional period to allow a gradual migration from the existing system to the new regime. These arrangements cover a transitional period of up to seven and a half years from implementation.

ISO 10156: 2010

Although less formidable in implication, another critical technical standard coming into play is ISO 10156: 2010, superseding ISO 10156: 1996. This norm impacts on how mixtures of two or more products are classified and where and how they should be labeled, transported, used and stored. Once this revision comes into effect, the impact on affected products could include a new identification label, a new cylinder shoulder color to indicate the change from either a non-flammable to a flammable mixture, or from a flammable to a non-flammable mixture, updated safety data sheets to include the changes for cylinder safety and transportation and a different cylinder valve outlet.

In terms of the end user, storage conditions may now need to be reviewed, including permits for storage of dangerous substances. Transport conditions will need to be revisited, as will risk assessment to update operational procedures according to the new risk assessment outcome. Gas control equipment and supply system compatibility may also need to be checked, as changes may be required for both cylinder connections and supply line labeling.

Linde Gases' Stephen Harrison, head of Specialty Gases and Specialty Equipment, explains it this way: "Although the physical properties of gases do not change, our understanding of the physics of these gases has certainly changed and this impacts on whether or not they represent a safety hazard. The implication is that even though a product someone may have purchased in the past may have been labeled as non-flammable, in the future it might be labeled as flammable.

"And there's knock-on effect associated with this. The implication to customers is how they will train their personnel to handle these gases in the future. If the product is now labeled as flammable, they'll need to look at factors such as fire safety procedures, transport measures and storage configurations. Previously used regulators may not do the trick anymore, because the outlet valve has changed to comply with a new classification."

REACH, the forerunner of the global harmonization initiative, is now moving beyond Europe. There are moves to implement it in the USA within the next two years and a similar system has already been implemented in China. Dubbed "China REACH", it draws on many elements of REACH – particularly those concerning risk assessment, risk management and data submission.

The timelines for the EU are as follows: To comply with REACH, all substances imported or produced in quantities greater than 1000 metric tons per annum had to be registered by December 1, 2010. By the same date, all (pure) substances had to be classified and labeled to comply with CLP. By June 1, 2013 all substances imported or produced in quantities between 100 and 1000 metric tons per annum must be registered to comply with REACH and by June 1, 2015, all mixtures must be classified and labeled according to CLP. The final deadline for REACH is June 1, 2018, by which time all substances imported or produced in a range between more than one metric ton and less than 100 metric tons per annum must be registered. ISO 10156: 2010 came into effect in April 2010.

Tsunami of new regulations

Dr Fridtjof Schucht, Linde Gases' head of REACH and CLP Implementation Europe, has this to say about the rapidly changing regulatory climate: "This veritable tsunami of new regulations will have a monumental impact on industry - it's the biggest shake-up we've experienced in the last 100 years. It can be compared to the introduction of regulations in the pharmaceutical industry in the 1960s following the Thalidomide issue, which was called one of the biggest medical tragedies of modern times. Fortunately, the new regulations we're now dealing with are not following in the wake of a large scale tragedy - on the contrary, these are proactive initiatives being driven to prevent major incidents like this."

Schucht says while the argument in favor of harmonization is sound, the practical implementation is costly and complex.

"The implementation of REACH and CLP will have a profound affect on all process companies, and will change all applications within that industry tremendously. All products - pure substances as well as mixtures - have to comply with the requirements of these regulations. Within the legally required implementation phases, labeling must be adapted to the new standards, all products must be reclassified and safety data sheets accordingly amended.

"For the companies concerned, this therefore calls for adjustments to the IT systems which generate the labels and requires a considerable additional amount of work and expense," he says." In our case, for example, Linde Gas Germany had to submit 600,000 new safety data sheets to our customers and re-label about 1.5 million gas cylinders before December 1, 2010."

"There are tight deadlines attached to the new regulations. For example, the so-called revision of REACH Annex II came into force on May 20, 2010 and applied from December 1, 2010. This gave industry only six months to completely update its safety data sheets and involved intensive work."

Tremendous success and admirable progress

While most countries have systems for the classification of hazardous chemicals to ensure safe transportation, storage, use and disposal, up until now various national or regional systems have not always been compatible. This incompatibility has often

meant re-labeling or use of multiple labels on a product, increasing the handling risks involved. For organizations operating at an international level, the need to comply with multiple regulations on hazard classification and labeling has created the risk of end users misinterpreting label warnings.

Harrison says despite the rapid convergence of these regulations, there has been "tremendous success and admirable progress."

"Using different icons and words to describe hazards and risks is okay if the products remain in that particular country, but once you start to export, confusion can enter into the equation and compromise safety," he comments. "At some point in the not-too-distant future, there will be harmonization of all chemical labels. So we will all see only one label for a particular product. New Zealand and Japan implemented GHS three years ago. Now all eyes are on Europe, before the focus shifts onto other major economic blocks such as the USA."

"Industrial regulations will converge around the middle of this decade and we expect that harmonization of chemical labeling will be achieved to a level of about 80 percent. I doubt we will ever perfect this process, because there are many local regulations which cannot simply be completely removed and the manufacturers and authorities will have to work around these.

"As an international industrial gases company, Linde is being confronted by the same legislation, processes and timelines as the chemicals sector and we are well placed to transfer our experience and knowledge to this industry. The agility with which Linde is implementing GHS is testament to our unwavering commitment to customers to partner in their success through safety and compliance. Linde is being very proactive in helping gas customers understand and adopt the multiple changes that will impact the way gases are transported, stored and handled across their supply chains. Customers are invited to engage with our EU classification experts to understand how these changes can actually benefit them."

With producers of chemicals hard at work to meet harmonization compliance deadlines, the onus of responsibility now extends to suppliers who are required to cascade this updated information not only down their complex supply chains, but ultimately to an immense world market.

Stephen Harrison concludes, "And here we mustn't forget product use at the most elementary end of the supply chain - the home user. Take the use of butane and propane for patio barbecues, for instance. Ultimately, this is a common product coming out of the petrochemical sector. But it's a product the man in the street would buy at his local garden center or gas station. The label on that cylinder will change to become much more detailed. It's now the responsibility of the company selling this cylinder of gas to the local outlets to label it in the new format. This is a big change implication for such companies and is going to require a huge amount of effort to push the safety data sheet right down the distribution line to the end user."

About the Author

Stephen Harrison is Linde Gases' head of Specialty Gases and Specialty Equipment.

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