
Richard Elsmore

RICHARD ELSMORE
JSC International Limited, The Exchange, Station Parade, Harrogate HG1 1TS, United Kingdom
Member of Chimica Oggi / Chemistry Today Scientific Advisory Board

2015 A new year and new regulatory challenges

Dear Readers,

With 2015 ahead of us and Christmas and New Year celebrations a distant memory, it is worth looking forward, possibly with apprehension, to some of the regulatory challenges that 2015 has to offer.

While 2014 saw several new pieces of legislation and reinterpretation and revision of existing legislation, 2015 will see a number of regulatory deadlines that will impact many areas and these changes will be visible to the man (or woman) on the street. I have included summaries of some of the legislation below (several of these have been considered in more detail in recent editions of Chemistry Today).

The scope of the European version of GHS (1), CLP (2) will now cover mixtures (i.e. formulated products) from 01 June 2015. The initial phase of CLP captured chemical substances and from June it will also be required for formulated products. These changes should be clearly visible to consumers, as products such as cleaners and detergents on the supermarket shelves will start to appear bearing the new diamond shaped pictogram rather than the old DPD (3) orange square hazard symbols. New pictograms ('exclamation mark' and 'silhouette' [sometimes referred to as the 'exploding man']), signal words ("Danger" or "Warning"), precautionary statements (a phrase that describes recommended measures to minimise or prevent adverse effects e.g. "Wear eye protection") and hazard statements (e.g. "Toxic if swallowed") will also appear on common household products.

CLP also introduces new classification thresholds, which means that some products will appear to be more highly classified, or may have to carry a hazard pictogram where they did not have to under DPD. There are options for companies facing higher classification requirements to undertake new in-vitro studies or use bridging principles to studies on similar formulations where actual data shows that particular hazard criteria do not apply.
It is important to note that changes in classification will impact on other pieces of legislation, for example the need to have child resistant closures or braille labelling on packs. It may impact on transport legislation and also may result in products triggering the higher tier Seveso III Directive (4) (COMAH in the UK) for manufacturing and warehousing sites or trigger these requirements for the first time.

While there is a two-year period of grace for mixtures that are already 'on the shelves' and labelled to DPD, for goods being first placed on the market, on or after 01 June 2015, CLP must be applied.

Other significant regulatory changes in 2015 will affect biocidal products. These are products such as disinfectants, preservatives and insecticides. With entry into application of the BPR (5) on 01 September 2013 and its subsequent amendment in 2014 (6), the BPR will start to bite for many companies in 2015. As of 01 September 2015 all biocidal products must be based on active substances that are included in an approved supplier list published by ECHA (7). There is no phase-in for this requirement and it will affect all biocidal products that are made available on the European market. Active substance manufacturers who have historically been involved in supporting their active substances through the EU biocides review programme, or who have already submitted complete dossiers for new active substances, will automatically appear on this list. Alternative suppliers of active substances who have not been involved with this process previously will need to join with existing applicants, submit a new dossier or exit the market.

The BPR also introduces the concept of treated articles within the scope of the legislation. A treated article is any substance, mixture or article which has

been treated with, or intentionally incorporates, one or more biocidal products. Treated articles can be biocidal products in themselves and require authorisation, they may require special labelling or, in the case of products that are simply preserved with a biocidal product, the active substance it contains must be supported under the EU biocides legislation. There are some transitional measures affecting treated articles but the section affecting labelling takes immediate effect. Because of this we are already seeing treated articles being labelled on supermarket shelves.

As more active substances complete their evaluation under the BPR it triggers the requirement for more biocidal products to seek BPR product approvals. Historically, national approvals for biocidal products have varied considerably from country to country within the EU. This requirement means that many products that were only very lightly regulated in some countries previously will now need to be supported with technical dossiers that are able to show the product is both safe and effective. This can represent a significant challenge for companies but a successful product approval should permit a more harmonised and easier route for products to be sold in other member states.

EU legislation is both complex and broad and in the examples above, relating only to two pieces of legislation (CLP and BPR), the effect will be apparent to the general public through products they buy on the high street. Many other pieces of legislation exist impacting general chemicals (such as REACH), agricultural pesticides, cosmetics, medicines (animal and human), medical devices and product safety to name but a few. While some of these pieces of legislation may be less visible to the general public, they can touch or even overlap with each other and it is important to be aware that changes happening in one area may have knock-on effects that will affect your business as changes in one piece of legislation may impact others.

The strategic importance of legislation for companies should be seen as an opportunity and not necessarily as a threat to business. Companies who are able to recognise this fact and react rapidly to changes in legislation will see benefits in 2015 and in the longer term.

REFERENCES AND NOTES

1. United Nations Economic Commission for Europe: http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html
2. The European Parliament and The Council, Regulation (EC) No 1272/2008, Off. J. Eur. Union, **L353**, 1-1355 (2008)
3. The European Parliament and The Council, Directive 1999/45/EEC, Off. J. Eur. Union, **L200**, 1-68 (1999)
4. The European Parliament and The Council, Directive **2012/18/EU,** Off. J. Eur. Union, **L197**, 1-37 (2012)
5. The European Parliament and The Council, Regulation (EU) 528/2012, Off. J. Eur. Union, **L167**, 1-123 (2012)
6. The European Parliament and The Council, Regulation (EU) **334/2014,** Off. J. Eur. Union, **L103**, 22- 32 (2014)
7. See: http://echa.europa.eu/web/guest/information-on-chemicals/active-substance-suppliers