

EUROPEAN COMMISSION ROADMAPS

Key changes to European Legislation are on the horizon. Elaine Campling looks at the latest requirements for hazard classification, labelling and packaging of chemicals



Elaine Campling is Chair of ESMA's Health, Safety & Environmental Protection Committee

The European Commission has launched a further Inception Impact Assessment, IIA (Roadmap) outlining ideas to improve the effectiveness of 'essential information on chemicals, including safety and product use-instructions'.

This builds on an earlier Roadmap setting out plans to revise the European Union (EU) CLP Regulation (EC) No 1272/2008. CLP regulates the classification, labelling and packaging of substances and mixtures, implementing the international Globally Harmonised System (GHS) of the United Nations (UN) in the EU.

The CLP Roadmap released for comment earlier in the year produced some contentious points, particularly in suggesting classification options that would result in divergence from the UN GHS, such as introducing new hazard classes e.g. for endocrine disruptors.

However, some of the planned measures should result in positive impacts if

implemented, for example introducing "tailored labelling rules where there is not enough space on packaging".

REVISION OF EU LEGISLATION

There has been a revision of EU legislation on hazard classification, labelling and packaging of chemicals. This latest IIA has a wider legislative remit covering the Detergents Regulation and the Fertilising Products Regulation, as well as CLP. The Commission point to regulatory 'fitness checks of the most relevant chemicals legislation (excluding REACH), along with an evaluation of the Detergents Regulation' that found chemical labels to be 'overloaded' with information, such that consumers found it difficult to make sense of the information displayed.

"Given that labels are the primary means to communicate essential product information to users, including hazard and safety information and product use-instructions, clear communication is vital for the effectiveness of chemicals legislation in protecting human health and the environment." (europa.eu)

"Significant changes to key regulatory instruments are in the pipeline"

There is an apparent regulatory drive to simplify and streamline information, as well as introducing digital tools for some label elements. The Commission believes that digitisation of labelling elements will avoid market fragmentation and increase cost-efficiency, for example by allowing rapid updates to labels when necessary.

The closing date to respond to the IIA is 20 September 2021, Midnight CET:

"The detailed policy options will be developed in the impact assessment process after collecting the relevant data on the different product user needs (including consumers and professional users) and available IT solutions."

SIMPLIFICATION AND DIGITALISATION OF LABELLING REQUIREMENTS

The Roadmap covering the planned revision to the REACH Regulation (EC) 1906/2006, on the Registration, evaluation, authorisation and restriction of chemicals (REACH) is also likely to result in some significant changes to this key piece of legislation.

One of the biggest impacts will arise from the introduction of new registration requirements for polymers. Polymers meeting the polymer definition under REACH do not currently need to be registered, though monomers and other substances used for the manufacture of the polymer may be subject to registration if certain conditions apply.

The latest European study to review the potential criteria for polymer registration was undertaken by Wood E&S GmbH (Wood) and Peter Fisk Associates (PFA), who were contracted by the Commission to propose criteria for the identification of polymers requiring registration (PRR).

A summary of the cost-benefit analysis of the registration requirements was also delivered:

"The quantified estimates of health and environmental benefits through registration of PRRs amount to around €30 billion over 40 years (range €14 to €52 billion), while costs are estimated at €2.5 billion (range €0.8 to €5.2 billion), though several important costs and benefits could not be quantified."

GLASSPrint2022

CONFERENCE

5-6 April 2022, Düsseldorf, Germany

Register your interest at www.glassprint.org



SAVE THE DATE

EUROPE'S ONLY GLASS DECORATION EVENT



REACH REGISTRATION OF POLYMERS

According to the 2018 report from the Commission on the review of the operations of the REACH regulation, the compliance costs associated with REACH are now estimated at 2.3–2.6 billion euros for the first two registration deadlines.

“There is an apparent regulatory drive to simplify and streamline information, as well as introducing digital tools”

The estimated benefits for human health and the environment from the REACH regulation are still reported to be in the region of 100 billion over 25–30 years, more or less equally split between health and environment

REVIEW OF ELEMENTS AND REGULATIONS

Another potential forthcoming change to the REACH regulation stems from a more targeted approach on the unknown impacts resulting from exposure to ‘cocktails of chemicals.’ The current regulatory approach does not involve evaluating the effects of combined exposure of chemicals on humans or environment. The introduction of a numerical multiplication factor to address this, termed a mixture assessment factor is

being explored by the Commission.

Other aspects for reform are being investigated are as follows:

- Simplifying communication in the supply chains
 - Improving the information in safety data sheets, for example
- Revision of the provisions for dossier

and substance evaluation

- Action to revoke registration numbers in the case of incomplete dossiers is being considered
- Reforming the authorisation process
 - The possibility of national authorisations for ‘smaller applications’ is amongst the options being considered

It is clear that significant changes to key regulatory instruments are in the pipeline. Some of the changes may bring benefits, but others will result in increased costs to the chemical industry.

It remains to be seen what adaptations will be adopted by the UK government and the extent to which the EU-UK regulatory regimes will diverge going forward.

FURTHER READING

- <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R0648&from=EN>
- https://ec.europa.eu/growth/content/review-detergents-regulation-shows-improved-consumer-and-environment-protection_en
- https://ec.europa.eu/info/publications/fitness-check-most-relevant-chemical-legislation-excluding-reach_en
- <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1009&from=EN>
- <https://www.pfagroup.eu/reach-registration-of-polymers/> ■

Elaine Campling is Director of Chemical Compliance Advisory Services and a member and Chair of ESMA's Health, Safety & Environmental Protection Committee

ESMA
Driving Print Excellence

Further information:

email: info@chemadvisory.com
web: www.chemadvisory.com / www.esma.com

MultiDX!

The All-Rounder for High Demands

The Universal Computer-to-Screen (CtS) and Computer-to-Plate (CtP) System

- Easiest handling of material
- Customized machine configuration
- Dynamic autofocus system
- Resolutions between 2'400 and 10'160dpi
- Switching of Laser source by the push of a button
- Low maintenance cost
- The only all in one system worldwide

Try us!

Lüscher Technologies AG
4665 Oftringen, Switzerland
www.luescher.com



Lüscher
Technologies