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CTPA UK Chemicals and Cosmetic Ingredients Management Webinar 29 June 2022

Questions and Answers

Classification, Labelling, Packaging (CLP) Regulation

Question (Q). If finished cosmetic products are exempt from CLP, how shall those classed as hazardous (e.g. nail polish remover is flammable) be treated?
Answer (A). Finished cosmetic products are exempt from the requirements of the CLP Regulation and, therefore, do not need to be labelled with the CLP hazard symbols and warnings.

If a finished cosmetic product is flammable, the flammability labelling is voluntary by the Responsible Person. There is an industry recommendation published by Cosmetics Europe (CE, the European personal care association) where voluntary labelling is described without specific details about logo and writing characteristics, therefore it is a company decision whether to apply voluntary labelling.

Q. Why is there a mandatory classification process under CLP, rather than just leaving industry to classify chemicals?
A. Substances or mixtures can be self-classified by manufacturers or importers. All relevant hazard classes must be assessed by the manufacturer or importer and the self-classification must be applied to all hazard classes for which the classification criteria are fulfilled. The self-classification is not legally binding and different manufacturers may provide different self-classifications for the same substance.

Some substances may also have one or more harmonised/mandatory classifications under Annex VI to the EU or GB CLP Regulation. The harmonised/mandatory classifications are legally binding, as they have been identified by the regulator following a thorough assessment and regulatory process. This is to ensure that certain substances of concern are classified under the same hazard.

Within the EU, any new harmonised classification is added to Annex VI of CLP through a process called Adaptation to Technical Progress (ATP). Within GB, the legal process to amend the Annexes to GB CLP is not currently clear.

For further information about harmonised classifications under CLP in the EU, see the European Chemicals Agency (ECHA) website. In GB, see the Health and Safety Executive (HSE) website.

Q. What is the timeframe that applies to the harmonised classification process under GB CLP?
A. The timeline for the harmonised classification process under GB CLP is not yet fully defined. According to the HSE website, the process involves the following steps; however a timeline is not given for all of them.

- GB Mandatory Classification List (MCL) proposal, by businesses, competent authorities, or HSE.
- Public consultation, to gather information on the scientific and technical aspects of proposed classifications, the policy and socio-economic aspects of such proposal.
- Technical report, which involves the independent evaluation of the information submitted under the stand-alone GB mandatory classification and labelling process or as part of the EU process.

- A final opinion forms the basis of the recommendation made to Ministers for new or revised GB MCL.
- The HSE issues a recommendation and decision to introduce or revise a new GB MCL. This must be done within 12 months of the publication of the GB MCL Agency Opinion (previous step).
- Where the decision is to support the recommendation, the GB MCL is updated without undue delay including the entry into force date from which the new or revised entry should be complied with.

Q. Does CLP apply only to cosmetic ingredients, but not finished products?
A. CLP applies to ALL substances and mixtures irrespective of the volume supplied.

Finished cosmetic products (ready for sale to the consumer) are exempt from the requirements of the CLP Regulation. However, cosmetic ingredients as raw materials or cosmetic mixtures (such as bulk cosmetic formulation that is not in the finished state) fall under the remit of the CLP Regulation.

Q. What are the criteria used by the HSE to prioritise chemical assessment under GB CLP?
A. Information on the criteria used by the HSE to prioritise chemical assessment under GB CLP can be found on this page of the HSE website.

Q. Does every substance placed on the GB market have to be classified, either through self-classification or harmonized classification?
A. No. Chemicals are classified based on their hazard properties, which are identified by their physico-chemical characteristics. All chemicals have specific properties, some of which are hazardous. The Globally Harmonised System (GHS) of Classification and Labelling of Chemicals was Adopted by the United Nations in 2002 with a view to facilitate worldwide trade while protecting human health and the environment. It is a single worldwide system for classifying and communicating the hazardous properties of industrial and consumer chemicals. It is a non-legally binding international agreement which provides the basis for harmonising regulations on chemicals at national and regional level.

There is an important difference to be aware between self-classification of hazards under CLP and mandatory, or harmonised, classification of hazards. Self-classification is determined by manufacturers and importers of hazardous substances, whereas a mandatory classification is legally binding and has been agreed by the Government authority responsible for CLP. In GB CLP, they are listed in the GB MCL list, available on the HSE website.

Q. Should every substance supplied have a Safety Data Sheet (SDS)?
A. SDSs are documents that describe the physico-chemical characteristics of a substances, as well as how it should be used, and any risk management measures that shall be implemented to safely use the substances. SDSs are mandatory if a chemical is hazardous and is being supplied for use at work. SDS are also needed if your chemical is not classified as hazardous but contains small amounts of a hazardous substance. More information can be found on the HSE website.

Cosmetics Regulation

Q. Is the Scientific Advisory Group on Chemical Safety in Consumer Products (SAG-SC) planning to do a full review of the current cosmetic ingredients in the future, or will they carry out reviews based on specific concerns?
A. The SAG-CS is not expected to carry out a review of all cosmetic ingredients, in particular if referring to ingredients that have already been assessed and are already regulated under the Annexes of the UK

Cosmetics Regulation. SAG-CS would review those cosmetic ingredients that may raise concerns from a safety point of view, if mandated by the Office for Product Safety and Standards (OPSS).

Q. How does the Scientific Committee on Consumer Safety (SCCS) for the EU compare to SAG-CS? Does SAG-CS have access to the same amount of data to make a decision for an ingredient?
A. The remit of the SCCS in the EU and SAG-CS in the UK is very similar: both are an independent scientific panel objectively reviewing scientific data, to assess the safety of chemicals used in consumer products (e.g. in cosmetic products). The mode of operating is also similar; more information can be found online for the SCCS and SAG-CS.

Industry is responsible for compiling the safety dossier to be submitted for review by the SCCS and/or SAG-CS. Therefore, industry chooses the amount of data to provide to these entities to ultimately make a decision on the safety of an ingredient.

CTPA promotes full and transparent data sharing where possible to ensure that a scientific decision can be taken on the best available evidence.

Q. The EU has a documented process with timelines for newly classified CMR substances used as cosmetic ingredients. Having a clear process allows industry and regulators to decide whether to defend or not a substance and plan work accordingly. Will there be a similar clear process for managing CMR substances under the UK Cosmetics Regulation?
A. CTPA is advocating for a clear process to be implemented under the UK Cosmetics Regulation to manage CMR ingredients. CTPA is advocating for sufficient time for preparation and submission of the dossier by industry before Annex amendments are drafted and clear transition periods, suitable for each ingredient and established as early as possible in the process, for newly classified CMR ingredients.

Q. How can a company contribute to defend an ingredient?
A. When a concern with a cosmetic ingredient is raised, a call for data will be announced. Individual companies may submit data, or defence may be coordinated across the wider industry through a legally-established Consortium. Calls to join a consortium established by trade associations such as CTPA will be widely publicised across the whole industry, both members and non-members of the association, to ensure all companies have a chance to participate. This is very important to ensure compliance with Competition Law.

Q. If something is not covered by the Cosmetic Products Enforcement Regulations, does it have to meet the requirements of the General Product Safety Regulations? For example, would the Responsible Person need to have a justification to use a substance that has been restricted in EU but not yet in GB.
A. The General Product Safety Regulations only apply to general products. Cosmetic products must meet the requirements of the Cosmetics Regulation.

If an ingredient has already been banned in the EU and not in GB, cosmetic and personal care products containing this ingredient can legally continue to be placed on the market and sold in GB until a regulation implementing the ban in GB as well is in place.

However, cosmetic products sold in GB must meet the safety requirements of the UK Cosmetics Regulation, having undergone a rigorous safety assessment by an expert safety assessor to ensure their safe use.

It is important to bear in mind that a ban may have been introduced in the EU for reasons other than safety. For example, if industry did not defend the ingredient, it would have been banned without its safety being assessed.

Q. What is the difference between the CMR Omnibus and a CMR amendment?
A. The CMR Omnibus is a regulatory process occurring in the EU, which implements the ban or restriction (when the exemption criteria of Article 15 of the EU Cosmetics Regulation have been met) in cosmetic products of substances classified as CMR under the EU CLP Regulation.

If a substance obtains a harmonised classification as a CMR under CLP, then the CLP Regulation is amended accordingly to make such classification legally binding.

Please check the below infographics for more information.
https://www.ctpa.org.uk/file.php?fileid=4211
https://www.ctpa.org.uk/file.php?fileid=4212

CTPA members can also access more resources explaining these processes in more detail.
https://www.ctpa.org.uk/reference-zone/classification-labelling-and-packaging-eu
https://www.ctpa.org.uk/reference-zone/cmr-substances

Registration, Evaluation, Authorisation of Chemicals (REACH) Regulation

Q. As a brand owner, what are the responsibilities for ensuring ingredient manufacturers have conducted due diligence with regards to REACH?
A. REACH applies to substances on their own or within mixtures (e.g. finished goods), therefore REACH also applies to cosmetic ingredients that make up a cosmetic product and not only to cosmetic ingredients as raw materials on their own. If a company imports products, bulk or ingredients from outside of GB, the company needs to check which substances and their quantities are being imported. And the company also needs to check with the suppliers of the ingredients, on their own or within the bulk/product to understand their compliance with UK REACH.

If the company was a downstream user (before 1 January 2021 when the transition period for the UK leaving the EU ended) and is now classed as an importer, the company needs to submit Downstream User Import Notifications (DUINs) to comply with UK REACH. The company's future obligations will depend on the compliance plans that suppliers of the relevant ingredients will have in regard to UK REACH.

Companies are advised to check the below resources, to understand why and how REACH applies to cosmetic ingredients and what are the obligations under UK REACH.

CTPA REACH Infographics (public)
CTPA UK REACH Reference Zone page (members only)
Comply with UK REACH information (members only)
CTPA webinar: Know UK REACH for Cosmetics (public)
CTPA webinar: UK REACH (members only)
CTPA webinar: role and obligations under REACH (second part of the webinar – members only)
HSE website on UK REACH (public)

The registration provisions are currently going through a review by the Department for the Environment, Food and Rural Affairs (Defra), to make UK REACH a more workable framework. However, until the new model is in place and new legislation takes it into effect, the current requirements apply.

CTPA also has a partnership with the Chemical Industries Association (CIA), which have a REACHReady consultancy programme that helps companies and downstream users comply with REACH. Only CTPA members can benefit from this partnership with the CIA and access the REACHReady services at a discounted price.

Q. If a substance has no safety data, can it still be used if under 1 tonne?
A. The 1 tonne/year threshold only applies to the remit of REACH. If a substance is manufactured or imported below 1 tonne/year, then REACH obligations do not apply.

However, independent of the quantities, the CLP Regulation and the Cosmetics Regulation still apply to substances and cosmetic ingredients.

It is important to have safety information on all substances manufactured, imported or used: this is vital to ensure substances are handled/stored/used safely.

Q. With respect to UK REACH, it was stated that CTPA is working with Defra on the review of UK REACH. Are individual companies also present in this working group, or only associations?
A. CTPA and other trade associations are working closely with Defra to review UK REACH and create a new, more workable model. CTPA and other associations' input into this work is informed by members of the associations. This can be through CTPA's Committees and Working Groups or direct requests published on the members' website.

CTPA does not have visibility of the full range of stakeholders working with Defra on UK REACH. It is however understood that Defra and HSE are seeking technical input from companies with experience in working within the REACH framework.

Q. How is it possible to identify whether a chemical on the Rolling Action Plan (RAP) or other REACH regulatory processes is a cosmetic ingredient?
A. When checking the ingredients going through the RAP process or other REACH regulatory processes, you may want to identify the CAS number of the chemical. The CosIng database is publicly available and links CAS numbers to INCI names.

If a CAS number has an INCI name, then it has the possibility to be used as a cosmetic ingredient (subject to any legislative restrictions).

Divergence

Q. Is industry concerned that ingredients banned or regulated in the EU, which are then implemented in GB with a delay, may create the opportunity for potentially unsafe cosmetic products to be dumped on the GB market? Could this have a reputational impact on the GB cosmetics industry?
A. If an ingredient has already been banned in the EU and not in GB, cosmetic and personal care products containing such ingredient can legally continue to be placed on the market and sold in GB until a regulation implementing the ban in GB as well is in place.

However, cosmetic products sold in GB must meet the safety requirements of the UK Cosmetics Regulation, having undergone a rigorous safety assessment by an expert safety assessor to ensure their safe use.

Q. Are there any ingredients that are banned in UK but not the EU?
A. No, there is no cosmetic ingredients that are currently banned in the UK but not in the EU. However, this possibility cannot be excluded in the future.

Q. Will the Health and Safety Executive (HSE – UK chemical agency) and the European Chemicals Agency (ECHA) work together or align around the Chemical Strategy for Sustainability (CSS)?
A. The CSS is an EU initiative which sets the long-term direction for EU chemicals policy and it is a key part of the EU Green Deal. The goals of the CSS are to support innovation for safe and sustainable chemicals, strengthen the protection for human health and the environment, simplify and strengthen the legal framework for chemicals.

The UK is currently developing a UK Chemicals Strategy. A public consultation is expected within the coming months.

Under the UK/EU Withdrawal Agreement, there is a legal basis for the HSE and ECHA to work together on matters concerning chemical management. However, to this date, this collaboration has not yet been implemented in practice.

Q. Will GB adopt the proposed EU changes to Cosmetics Regulation Annexes currently ongoing?
A. Following the UK's exit from the EU, independent frameworks to manage chemicals, including cosmetic ingredients, have been established in the UK. The UK adopted the EU Annexes of the Cosmetics Regulation up until 31 December 2020; from this date cosmetic ingredients must undergo independent scientific assessment in the UK prior to management under the UK Cosmetics Regulation, which may lead to different outcomes from the EU.