CLP Regulation Revision: Release of the Compromise Agreement

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Ales Bartl

- Ales Bartl has a broad experience EU product regulatory law, including Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) regulation, the Classification, Labelling, and Packaging (CLP) regulation, Biocidal Products Regulation (BPR), medical devices, electronic products, and general product compliance and product safety. He advises on regulatory compliance of a broad range of products marketed in the EU and represents clients before EU and national competent authorities on compliance and enforcement issues, including product withdrawals and recalls.
- Ales also represents clients before the Court of Justice of the European Union and the Board of Appeal of European Chemicals Agency.

Marie Escornebouеu

- Marie Escornebouеu counsels clients on regulatory and compliance matters related to food and drug law, with an emphasis on food and drug packaging, cosmetics, chemical control, and environmental issues.
- She assists companies in obtaining regulatory clearances for food-contact materials at the European Union (EU) and Member State level and advises clients with respect to mutual recognition. She also advises companies on sustainability initiatives; REACH matters; the Classification, Labelling, and Packaging (CLP) Regulation; and Biocidal Products Regulation (BPR).

Background

Commission Proposal

- **Proposal for a revision of Regulation (EC) No 1272/2008 on classification, labelling and packaging of chemicals ('CLP Amendment')**
  - Scheduled in the CSS, most important amendment since 2008
  - Current status:
    - Compromise EP/Council text with a view to agreement adopted on 19 December 2023
    - If approved by the EP and the Council (likely), will constitute the final version of the amendment

Hazard Classification – New Hazard Classes

Incorporation of the New Hazard Classes

- **New hazard classes introduced via Regulation (EU) No 2023/707**
  - Incorporation of the classes ED, PBT, vPvB, PMT, and vPvM into the body of the CLP
    - Prioritized for harmonized classification and labelling
- **Coordination under other regulatory regimes**
  - COM empowered to adopt delegated acts with a new classification where:
    1) A substance has been integrated in the REACH Candidate list due to its ED, PBT, or vPvB properties
    2) it has been found to have such properties by competent authorities in the context of an assessment under the PPPR or the BPR

Background – One Substance One Assessment

- On 7 December 2023, the European Commission issued three regulation proposals implementing the objectives of the ‘One substance, one assessment’ (‘OSOA’) initiative
- They address the creation of a common data platform and the re-attribution of tasks among EU agencies – shift of assessment to ECHA
- Cooperation with other agencies in risk assessment reinforced, with priority given to ECHA in case of disagreement (e.g., in case of disagreement with EFSA)

OSOA - Impact

- **Likely outcome:** The CLP Regulation would become the central piece for hazard classification, with a centralized hazard assessment (and limit value setting?) performed by ECHA
  - = hazard may prevail over risk (e.g.: PBT/vPvB: no safe threshold under REACH)
- **Likely:** classification of a substance as CMR and ED (likely also PBT and PMT, possibly neurotox/immunotox) would become an automatic showstopper before risk assessment is carried out
  - = risk assessment limited to substances that pass the REACH/CLP test
  - Key role of the ‘essential use’ concept/definition!

Classification Procedure

Initiation of Harmonized C&L Procedure

- **COM empowered to initiate the CLH procedure**
  - Before: exclusively triggered by companies and Member States
  - COM to mandate ECHA or EFSA to prepare a classification proposal
  - Potential for a substantive increase in hazard classification procedures
  - ECHA and EFSA can in turn advise COM and MS that a classification of a substance or a group would be approriate

Obligations Related to Classification and Labelling Inventory

- **Obligations related to Classification and Labelling Inventory**
  - Obligation to provide reasons in case of divergence from existing entries
  - In case of a change of classification of a substance, obligation for notifiers to update their notification within 6 months
  - Identity of notifiers public unless risk of harm to commercial interests
- **Introduction of a new delay in the classification process**
  - COM to adopt classification decision "*without undue delay*" and "*preferably before the end of the calendar year*" following the issuance of the RAC opinion

Introduction of the NAMs into the CLP

- **Inclusion of direct references to the use of New Approach Methodologies ('NAMs')**
  - Alternatives to animal testing, combining in silico, in chemico, and in vitro assays as well as conventional methodologies
  - Development of NAMs re ED, immunotoxicity and neurotoxicity set as priority by ECHA
  - In the CLP Amendment:
    - Data obtained from NAMs may be taken into consideration during hazard classification
    - COM to regularly update Annex I of the CLP to reflect technical progress re NAMs
    - COM to adapt Annex I within 18 months in case of inclusion of NAMs for classification at UN GH level

- **Inclusion paving the way for increased focus on NAMs under REACH**
  - Currently: not specifically considered as adaptations
  - COM considering inclusion in REACH Amendment proposal

Hazard Classification & Grouping

- **Emphasis on grouped hazard assessment**
  - Grouping prioritized "*whenever considered scientifically justified and possible*" by a CA or the COM
  - Possibility for ECHA and EFSA, on their own motion, to inform COM or a CA that grouping would be appropriate
  - Consistent with COM approach re restrictions under REACH

- **Criteria used in the definition of a group**
  - Substances grouped together based on "clear scientific reasoning," taking into account how the available information:
    1) Supports the grouping of substances
    2) Allows the property(ies) of the substance(s) to be reliably predicted from other substances in the group

Consideration of a Substance's Physical State

- **Principle**
  - Classification applicable to substance in all its physical states or forms
- **Exception**
  - If scientifically justified, classification may target a specific form or physical state (e.g., particle state)
  - Ex: case of TiO2 Carc. classification

Classification of Multi-Constituent Substances (1)

- **New provisions on the classification of multi-constituent substances**
  - So far only addressed via ECHA Guidance on Identification and naming of substances : 'Multi-constituent'= where more than one constituent is present in a concentration between 10% and 80% (w/w)
  - **Under CLP Amendment**:
    - By default, hazard evaluated in light of **both** data on their known constituents, as well as data on the substance itself
    - Specific case of CMR, ED, PBT, vPvB, PMT, and vPvM hazards:
      1) Assessment primarly based on the hazard classification of the constituents;
      2) Data on the multi-constituent substance itself taken into account only if it supports the conclusion made on the basis of the individual constituents

Classification of Multi-Constituent Substances (2)

- **Exemptions**
  - Not applicable to substances which are extracted from plants or plant parts and which are not chemically modified
  - COM may exempt a substance on an ad hoc basis following evaluation by ECHA

Labelling

Fold-Out Labels & Formatting

- **Expansion of the use of fold-out labels**
  - Current ECHA guidance document: precludes their use for the purpose of accommodating multilingual labels
  - Now permitted, with formatting requirements:
    - **Front**: Hazard pictograms, abbreviation of the language covered, manufacturer's identity
    - **Inner part**: other labelling elements under Article 17(1) in all languages covered
- **New formatting requirements**
  - Minimum font size (min. 1.2 mm x-height), pictograms dimension & font colour

Digital Labels

- **Possibility to rely on a digital label to complement the physical one**
  - **Mandatory elements** of Article 17 to remain on the physical label (supplier information, quantity, pictograms, signal words, statements)
  - Digital label to include **elements which are not instrumental** to the protection of health, safety, and the environment & which are not mandatory under UN GHS
    - Supplier to provide physical version upon request
- **Formatting requirements**
  - Use of a data carrier affixed on the label or close by on the packaging
  - Indication "*more hazard information available online*"
  - Information readily accessible to all EU users for at least 10 years, free of charge (no download, no registration, max 2 clicks, no tracking)

Packaging

Refill & Bulk

- **Introduction of specific requirements re supply via refill stations**
  - Possibility to supply via refill stations extended from cement to other substances and mixtures
    - Goal to follow consumers' increased demand for products in bulk (e.g., detergents)
  - Conditionned upon respect of condition set out under Annex II:
    - Presence of the mandatory labels on the station
    - Application of risk mitigation measures to prevent use by children
    - Presence and control of refill station by staff

Our Intake

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- **Timeline**
  - Scheduled for a vote in EP Plenary of 11 March 2024 (ENVI Committee WIP)
  - Adoption before the elections?

- **Impact of the revisions**
  - OSOA
  - Extension of generic approach to risk management under REACH review & sectoral legislation
    - (harmonized) classification could trigger automatic restrictions
  - Acceleration of hazard classification procedure
  - In parallel, simplified requirements re labelling and packaging

Thank You

Any questions?

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