Proposed Revision of The CLP Regulation on Hazard Classification, Labelling, and Packaging of Chemicals

MAY 12, 2021

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Herbert Estreicher, J.D., Ph.D.

Herbert (Herb) Estreicher is a prominent environmental lawyer who is listed in Who's Who Legal: Environment and in Marquis Who's Who in America. Herb holds a PhD in Chemistry from Harvard University (1980) in addition to his U.S. law degree (1988). He is also listed as a foreign lawyer (B List) with the Brussels legal bar. Herb is recognized as a leading expert on the Toxic Substances Control Act (TSCA) and is frequently quoted in Inside EPA, Chemical Watch, and BNA Environmental Law Reporter. He is one of the few U.S.-based lawyers that is expert on the EU REACH regulation and has successfully argued a number of cases before the European Chemicals Agency (ECHA) Board of Appeal and has briefed cases before the EU General Court and the European Court of Justice.

Herb represents leading manufacturers of chemicals, pesticides, and consumer products. His broad practice in international environmental regulatory law allows him to take an interdisciplinary approach with his clients and their needs. His extensive background in organic chemistry, risk assessment, and bioengineering is valued highly by his clients in the chemical, nanotechnology, and biotechnology industries.

Herb provides advice on product liability risk control and assists his clients with crisis management for embattled products, including wood preservatives and persistent, bioaccumulative, and toxic (PBT) chemicals. He helps his clients secure and maintain chemical approvals and pesticide registrations in Canada and Europe, advises clients on matters involving the Canadian Environmental Protection Act and on European chemical directives such as the EU Registration, Evaluation and Authorization of Chemicals (REACH) regulation, the Classification, Labelling and Packaging (CLP) regulation, and the Biocidal Products Regulation. Herb also represents clients in matters involving the Stockholm Convention on persistent organic pollutants (POPs) and has participated in the Canadian Strategic Options Process (SOP). He counsels clients on matters concerning sustainability and the circular economy.

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Ales Bartl

Ales has a broad experience in EU product regulatory law, including REACH, CLP, POPs, biocidal legislation, food law, medical devices, electronic products and product and food 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. Ales also advises on product recalls and withdrawals.

Ales primarily focuses on EU regulation of chemicals and food, including representing clients in various procedures before the European Chemicals Agency (ECHA) and European Food Safety Authority (EFSA).

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Context: Chemicals Strategy for Sustainability

- Chemicals Strategy for Sustainability (CSS) announced in October 2020: https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf
- EC webpage dedicated to CSS https://ec.europa.eu/environment/strategy/chemicals-strategy_en

Current Status of CLP Revision

- CARACAL meeting of 3–4 March 2021:
  - Roadplan for CLP revision
- Inception impact assessment published on May 4, 2021 as a first step https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12975-Revision-of-EU-legislation-on-hazard-classification-labelling-and-packaging-of-chemicals_en
- Open for feedback: 04 May 2021 – 01 June 2021
- Will be followed by full impact assessment (expected December 2021) and 12 weeks public consultation
- Indicative timing: draft CLP amendment 2022; adoption 2023

What is in Play?

- The ‘full’ impact assessment will also consider a range of non-regulatory measures to address the issues (instead of legislative measures), based on the costs and benefits – industry input needed!
- E.g., additional guidance and support measures based on existing legislation
- Provisions favorable to industry will also be considered/adopted (e.g., more flexibility in harmonized C&L procedures and more flexibility in labeling)
- Let your voice be heard during public consultations!

Main Elements of the CLP Revision

- Endocrine disruptors
- New hazard classes
- Changes in labeling
- Changes to harmonized C&L
- Other changes in classification
- Poison center notifications

Endocrine Disruptors

- Establishment of new hazard class for endocrine disruptors, based on the WHO definition, building on criteria already developed for pesticides and biocides
- Possible classification: known/presumed/suspected ED
- If classified: ban ED in consumer products (for non-essential uses) - CSS
- Recent April 2021 ANSES document identifying 16 priority ED
  https://www.anses.fr/fr/content/acc%C3%A9l%C3%A9rer-l%E2%80%99%C3%A9valuation-des-perturbateurs-endocriniens

Endocrine Disruptors (2)

- Recent European Commission fitness check of current ED rules (October 2020) https://ec.europa.eu/environment/pdf/chemicals/2020/10/Executive_summary_FC_EDC.pdf
- Identified gap: data generated by so-called 'mechanistic' tests, which can determine specific endocrine activity, are currently not required under any of the legislative instruments
- Current criteria under legislation on biocides/pesticides not workable
- Result: very few substances identified as ED so far
- But main issue: different approaches to risk management, depending on specific policy considerations (generic risk approaches, specific risk approaches or risk/impact-benefit-based approaches)

One Substance One Assessment for ED

- Possible outcome: adoption of 'one substance-one assessment' process for ED
- This would mean: risk that the assessment will be based on hazard assessment rather than on risk assessment (that is used in sector specific legislation (e.g., biocides, food contact etc.)

Changes in Labeling

- Review of CLP classification and labelling derogations for some products (cosmetics mentioned specifically, medical devices (?), waste (?))
- Clear roles and responsibilities for actors in online sales (+ digital labelling already in the process of adoption)
- Allow multilingual fold-out labels
- Introduce tailored labelling rules where there is not enough space on packaging

New Hazard Classes: PBT, vPvB, PMT, vPvM

- PBT and vPvB currently addressed by REACH, but not a hazard class as yet
- Future classification will be based on Annex XIII REACH criteria
- New classes: Persistent, Mobile and Toxic (PMT) and Very Persistent and Very Mobile Substances (vPvM)
  - Already a category of substances of very high concern (SVHC)
  - But: new hazard class for environmental toxicity?

Changes to Harmonized C&L

- Introduce a mandate for Commission to request ECHA to develop new harmonised classification and labelling dossiers
- Introduce a prioritisation mechanism for harmonising the classification of certain chemicals (now: only CMR + biocides/pesticides)
- Additional opportunity for interested parties to comment in the HCL procedure (repeat public consultation?/introduce possibility for companies to initiate a change of HCL?)

Changes in Classification

- Harmonization of human health and environment safety values (PNEC, DNEL)
- Assessment of the need for specific criteria for immunotoxicity and neurotoxicity currently covered under STOT and Reprotox categories
- Clarifications on how to apply bridging principles for classification

Poison Center Notifications

- The notification obligation should be also for distributors, and
- for substances (now only for mixtures)

Final Thoughts

The Next REACH 30/30:
Wednesday, July 14, 2021

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Thank You

Any Questions?

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