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Draft Commission Regulation to Amend CLP with New Hazard Classes

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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).

Marie Escornebouleu

- Marie Escornebouleu 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).

Context of the Initiative

- Draft Commission Delegated Regulation published on September 20, 2022 for public consultation, until October 18, 2022
  - Amending Annex I CLP with five new hazard classes viewed as “most critical”: Endocrine Disruptors (ED), PBT/vPvB, PMT/vPvM
- In addition to ongoing CLP revision
  - Incl COM capacity to initiate classification dossiers, multilingual fold-out labels
  - Legislative proposal scheduled for 26 October, 2022 (tentative)

I. Presentation of the Draft Delegated Act

Objectives

- Current situation for those hazards
  - PBT, vPvB: assessment in CSA under Annex XIII REACH (10+ t) (only 98 so far!), SVHC
  - ED: SVHC + excluded under pesticides (PPPR) and biocides (BPR) regulations
  - PMT/vPvM: only SVHC (2019)
  - Therefore, currently no obligations under CLP, while some MS take actions to identify these hazards

Endocrine Disruptors (1)

- Scope
  - Based on WHO definition & building on criteria from PPPR and BPR
  - Def: "*a substance or a mixture that alters one or more functions of the endocrine system and consequently causes adverse effects in an intact organism, its progeny, populations or subpopulations*"
  - Level of evidence "may be of different scientific strength":
    - Therefore, division into two categories: "presumed" (Cat. 1) and "suspected" (Cat. 2), both for HH ED and ENV ED

Endocrine Disruptors (2)

- <u>Cat. 1, « known or presumed » ED</u>
  - (a) endocrine activity;
  - (b) an adverse effect on an intact organism or its offspring and future generations;
  - (c) a biologically plausible link between the endocrine activity and the adverse effect.
    - If information raises doubt about relevance of the biologically plausible link → Cat.2
- <u>Case of overlaps</u>
  - If ED effects appear combined with other toxic effects, ED effects considered to be present where they are *"not **conclusively demonstrated to be a solely non-specific consequence of the other toxic effects**"*
  - Limited usability in practice

Endocrine Disruptors (3)

- Testing impact
  - Classification based on a WOE determination
  - Abundant in vitro data, uncertain impact on in vivo data generation
  - Impact of new REACH data req for ED endpoint

PBT, vPvB (1)

- Reasons for inclusion
  - 1) do not easily break down in the environment, 2) tend to accumulate in living organisms, 3) accumulation is difficult to reverse, 4) effects of accumulation hard to predict in the long term
- Scope
  - No category for “suspected”
  - PBT & vPvB gathered
    - Common rules for scientific assessment of properties related to persistency and bioaccumulation
    - Relying on existing criteria under REACH, without adding to them

PBT, vPvB (2)

- Testing impact
  - Classification based on WOE
  - Currently limited identification under REACH, could substantially increase

PMT, vPvM

- Reasons for inclusion
  - High persistence, low absorption, high mobility lead to spread across water cycle
- Scope
  - Two classes: PMT and vPvM, diverging re toxicity, but no “suspected” category
  - Persistence & toxicity: same as PBT
  - Mobility:
    - based on the logarithm of the water to organic carbon partition coefficient (logKoc)
    - Using results of absorption/desorption testing …
    - … or other info incl QSAR
  - Testing impact
    - WOE
    - Mobility data typically not available

Way Forward and Entry Into Force

- Next steps:
  - Consultation until 18 October
  - COM to submit text for approval in CARACAL
  - If approved, COM adopts the act
  - Parliament and Council to scrutinize (usually 6-8 weeks)
- COM goal to adopt by year end
  - New classes would only become effective 18 months after entry into force
  - Supplementary transition periods for substances already on the market

II. Impact of the New Classes

A Substantial Increase in Testing Burden

- Obligation to gather data
  - For all manufacturers and importers, need to collect data for self classification (new data?)
  - New classification under CLP entails notification to ECHA and update of REACH dossier
  - COM estimations: 1650 substances to be classified in these categories
- UN GHS discrepancies
  - Disadvantage for companies selling on the EU market

Impact Beyond the Scope of the CLP

- REACH
  - New classes to serve as basis for consideration of the new hazards in the safety assessment
  - Can be used for prioritization of certain substances for phase-out
- FCMs: Revision of FCM Framework Regulation (EC) 1935/2004 (public consultation ongoing until January 11, 2023)
  - COM envisages tired prioritization approach:
    - Precedence given to certain hazard classes incl CMR, EDs, PBTs, vPvBs
  - CLP classification would therefore have **direct impact** on the safety assessment relating to its use in food contact materials, leading potentially to their phase-out

III. A Contestable Procedural Choice

COM Choice of a Delegated Act (1)

- COM chose to rely on a "delegated act"
  - Non-legislative act, no active involvement of European Parliament and Council
  - Used to amend "non-essential" elements of a legislative instrument to adapt it to technical and scientific progress
  - Consequence: closed door process, accelerate, little to no room for stakeholder input beyond the consultation

COM Choice of a Delegated Act (2)

- How COM justifies its choice
  - Amendment does not aim to introduce major changes & does not affect essential elements of CLP
  - Only an adaptation to scientific and technical progress and not a political choice
  - COM is in the scope of its mandate under Art 53 CLP
  - BPR/PPPP argument
- We consider Commission's justification not convincing, contradicted by legislative text and history

Final Considerations

- Only a draft for now
  - Expected to pass through REACH committee phase as already discussed in CARACAL
  - This will have a very substantive impact:
    - Affecting whole industry with testing req, and impact on other pieces of legislation under review (Cosmetics, FCMs, REACH…)
- How you may act
  - Participation in consultation running until 18 October
  - Once act is in OJ, opened to a legal challenge:
    - Possibility of an action for annulment, but no suspensive effect
    - To be filed within 2 months (+10 days) of the date of OJ publication

Please join us at 1:00 PM Eastern U.S.

Wednesday, October 19, 2022

www.khlaw.com/OSHA3030

Please join us at 10:00 AM Eastern U.S.

Wednesday, December 14, 2022

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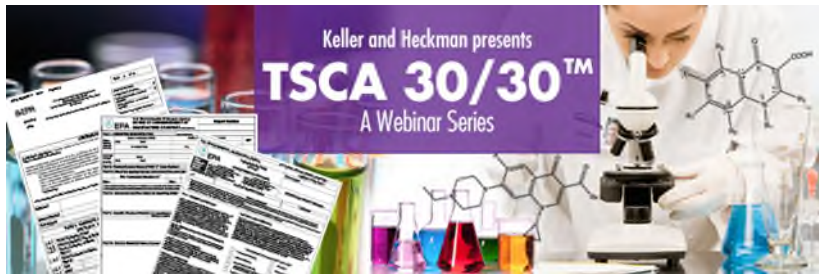

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Wednesday, December 14, 2022

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Keller and Heckman is hosting its TSCA Basics Course on Thursday, November 3, 2022, in Washington, DC.

More information at:
https://www.khlaw.com/events/2022-tsca-basics-course

Thank You

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