One Substance – One Assessment; Update on Essential Use Concept

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Ales Bartl, Ph.D.

- 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.

Herb Estreicher, 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 US 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 US-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.

Agenda

1. One Substance – One Assessment
2. Update on Essential Use Concept

One Substance – One Assessment

December 2023 Commission Package

- On 7 December 2023, the European Commission issued three 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

Common Data Platform – Basics

- Proposal for a Regulation establishing a common data platform on chemicals + Annexes
- Creation of a common data platform centralizing and consolidating data generated by the four agencies (ECHA, EFSA, EMA and EEA)
- Will be managed by ECHA, aim to create a ‘one-stop shop' access to data on chemicals
- To be established within 3 years after EiF

What will be Included – Submitted Data

- **Will include:** all data generated or submitted as part of the implementation of Union acts listed in Annex I of the Proposal (all relevant EU pieces of environmental/product regulatory areas)
  - E.g. REACH, BPR, PPPR, food additives Regulation, Framework Regulation for FCMs
- Information about new studies
  - Laboratories would also be subject to a notification duty, including those located in third countries

What will be Included – Repository

- Establishment of a centralized repository for limit values (e.g., PNECs - predicted no effect concentration, DNELs – derived no effect levels, occupational exposure limit values, maximum total daily intake, etc.)

Access to Data Under the Proposal

- Data would be accessible **to the authorities** without limitation (incl. full study reports)
- **To the general public:** within the limitations set out under the specific legislation
- **But:** often no provisions regarding confidentiality in specific legislation
  - Not clear what is the mechanism under the Proposal (prior information of data owner as under Regulation 1049/2001? Probably not)
  - There should be a procedure (example of EFSA Transparency Regulation)
- Recommendation to always mark information as ‘confidential’ under respective legislative acts, with sound justification

Initiation of New Studies

- The proposed Regulation would enable ECHA to commission studies itself of its own motion or at the request of the Commission.
  - Only if results cannot be obtained through existing legal provisions or processes
- The Proposal is silent about the use which shall be made of the results, and about possible remedies.

Content of the Proposal (1)

- The Proposal for a Regulation on the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals
  - Stronger role for ECHA: the Proposal refers to (future) specific legislation that will reattribute tasks from Commission services to ECHA regarding POPs, WFD, PPWD, cosmetics, observatory for nanomaterials, toy safety, medical devices
  - Scientific committees (SCCS, SCHEER) to gradually disappear

Content of the Proposal (2)

- Proposal introduces provisions enhancing the cooperation and coordination of EU Agencies, including ECHA and EFSA
  - ECHA to monitor an identify potential sources of divergence
    - In case of potential divergence ECHA contacts the body concerned to exchange information
    - Both should cooperate, if divergence persists they draw up a joint report that is presented to COM
  - In case of divergence re hazard classification COM may request ECHA to prepare a classification proposal
    - ECHA and EFSA cooperate in the development of the proposal

Third Proposal: RoHS Tasks

- **Third proposal reattributes tasks to ECHA that are currently performed by the COM unde RoHS**
  - Includes applications for granting, renewing or revoking exemptions from the restrictions
  - Process to mirror REACH restriction process: COM or MS launch the process, RAC and SEAC issue opinions, consultations are conducted, then COM takes the final decision
- Criticism by NGOs pointing at experiences made under REACH in the context of authorization: SEAC lacks expertise to judge substitutability; consequence: companies are almost automatically granted the authorisations

Workability Concerns (1)

- Public consultation on the proposals: concerns over workability
  - RAC under significant workload already
  - Expect further delays in scientific assessment, detrimental to quality of work
- Long overdue proposal for ECHA founding regulation that would redefine the agency's financing and operating model
  - New sources of financing (SVHC annual fee?)
  - Use of external experts?

Workability Concerns (2)

- New structures, committees or working groups at ECHA likely to be necessary
- Risk of loss of significant know-how by COM Committees
  - NGO Humane Society International: SCCS has “historically provided decisions that focus on holistic risk assessment, including leveraging detailed exposure information”
  - COM Committees “open to the use of non-animal methods”

Impact of the OSOA Principle

- In the future assessment, hazard may prevail over risk
- The OSOA approach is likely to significantly decrease the role of EFSA and other agencies in risk assessment
  - Since the limit values would be set by ECHA, the risk assessment would be limited to exposure assessment
- Lower likelihood of avoiding a ban in a specific application (banned in food, but allowed in toys or cosmetics – maybe not)

CLP as a Cornerstone for Assessment Under OSOA

- The CLP Regulation would become the central piece for hazard classification, with a centralized hazard assessment performed by ECHA, serving as a basis for risk assessment and limit value setting
- **2023 CLP revision:** introduction of new hazard classes PBT, PMT and ED – obligation to classify and label substances after the transition period (2025-2028)
- **Likely:** classification of a substance as CMR and ED (likely also PBT and PMT, possibly neurotox/immunotox) would become an automatic showstopper
  - = risk assessment limited to substances that pass the REACH/CLP test

Essential Uses

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- **Concept to be used horizontally in all legislation for derogations from restrictions of ‘substances of concern’**
  - Cosmetics, food contact materials and toys mentioned specifically in CSS
  - But also: derogations from substances ‘affecting the re-use and recycling of materials’ or potential prohibition of green claims

WSP Report

- WSP Report of April 2023: quite vague definition:

1. Necessity for health and safety, AND/OR critical for the functioning of society,
2. AND there are no alternatives that are acceptable from the standpoint of environment and health
   - How about environmental benefits?

Some hints: ‘Sustaining basic conditions for human life and health issues’/’Protecting and restoring the natural environment’

   - Risk factor not built in (calls for ‘safe use’ definition to limit EU essential use bans)

Current Development of the Definition of Essential Uses

- Commission's non-binding document with criteria overdue
- Should be subject to public consultation as a draft (or, at least, there should be advocacy in this respect)
- Will include: Definitions and basic principles on how the concept should be used in authorisation and restriction decisions, with many examples of essential and non-essential uses.

Recent Media Report

- Recent Chemical Watch report: internal COM pushback will cause a delay (for the new Commission?)
  - DG GROW: EUC should facilitate derogations for certain uses to continue; avoid creating a perception that the concept is a tool for fast-tracking the phase-out of all harmful chemicals.
  - DG SANTE: asks for upfront exemptions for some uses (enzymes)
  - DG Environment: wishes to leave room for Commission to implement it in specific legislation and for member states to scope restriction proposals
- More and more media attention to the term ‘Industry Deal’ to complement (replace?) Green Deal

Please join us at 10:00 AM Eastern U.S.
Wednesday, June 12 , 2024
www.khlaw.com/REACH-3030

Please join us at 1:00 PM Eastern U.S.
Wednesday, April 24, 2024
www.khlaw.com/OSHA3030

Please join us at 1:00 PM Eastern U.S.
Wednesday, April 10, 2024
www.khlaw.com/TSCA-3030

Thank You

Any questions?

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