State of Play of the REACH Revision

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- 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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- 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).

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Timeline of the Revision

Timeline

- Commission proposal to revise REACH: *4Q 2023*
- Followed by full legislative procedure (EP, Council)
- Final adoption: *2026/2027*
- Latest update as to the content of the revision: Commission presentation at CARACAL (CARACAL-48 (28 March 2023) AP 4.1)

Restrictions & Authorisations

Current State of the REACH Restrictions (1)

- Current types of REACH Restrictions:
  - Ad hoc restrictions (based on risk assessment + socio-economic analysis) – Annex XVII REACH, limited number (Article 68(1))
  - Generic restrictions (not based on risk assessment + socio-economic analysis, but based on classification as CMR) (Article 68(2))
  - In general, restrictions are applicable to FCMs unless explicitly derogated or exempted

Current State of the REACH Restrictions (2)

- Increased reliance on grouped restrictions:
  - Group assessment of chemicals with similar hazard, risk, and/or potential for substitution
  - First battlefield:
    - Poly- and perfluoroalkyl substances (PFAS): proposal published in March 2023 (consultation ongoing)
    - Bisphenols: proposal published in October 2022 (consultation ongoing)
    - Intentionally added microplastics (adopted April 2023)
  - Upcoming:
    - Phthalates (Ortho-phthalates (C4-C6)): proposal expected in 2023

Revised Restriction Process – Essential Use Concept (1)

- Functioning of the concept
  - Replacing the current concept where exemptions from restrictions are granted ad hoc, based on a risk assessment and socio-economic analysis
  - Horizontal concept
    - To be included in sectoral legislation i.e., cosmetics, BPR, FCM
      - Case-by-case assessment based on the sector (e.g., what is essential in one sector may not be in another)
  - Derogations in principle time-limited: the goal remains phasing out
    - Industry must demonstrate appropriate efforts are made to substitute the controlled substance

Revised Restriction Process – Essential Use Concept (2)

- Wood Report of April 2023
- To be defined as 'essential,' the use shall be:
  1. Necessary for health and safety, AND/OR critical for the functioning of society
  2. AND no alternatives that are acceptable from the standpoint of environment and health

Revised Restriction Process – Essential Use Concept (3)

- Necessary for health and safety
  - For example: preventing, monitoring, or treating severe health issues; sustaining basic conditions for human life and health; managing and preventing health crises and emergencies; personal safety; public safety
- Critical for the functioning of society (incl. environmental benefits?)
  - Element to be further defined by way of a horizontal guidance
    - Some hints: managing societal risks and impacts from natural and man-made crises and emergencies; protecting and restoring the natural environment

Revised Restriction Process – Generic Risk Management Approach (GRA)

- Fast track restrictions: do not require a risk assessment or a socio-economic assessment; just Commission Regulation
  - Right now, only for CMRs and only for consumer uses
- Extension of the GRA:
  - New categories:
    - Endocrine Disruptors (ED); Persistent Bioaccumulative and Toxic (PBT); vPvB; Substances with specific target organ toxicity (single exposure (STOT SE) or repeated exposure (STOT RE)), immunotoxic substances; respiratory sensitisers; and possibly Persistent, Mobile and Toxic (PMT) and vPvM
  - Likely tied up to harmonized C&L
  - Including professional uses!
- Restrictions in articles: priority to those with exposure (potential 'safe use' exemption?)

Revised Restriction Process – Derogations

- Derogations from both generic restrictions (Article 68(2) and ad hoc restrictions (Article 68(1) only granted for ‘essential uses’)
- Commission is considering two types of derogations:
  - Some essential use derogations directly in the text of REACH (for clearly essential uses); and
  - Ad hoc derogations

Impact of REACH Revision on FCM

- New hazard classes for phase-out and/or generic assessment;
- Essential use concept likely to apply as well

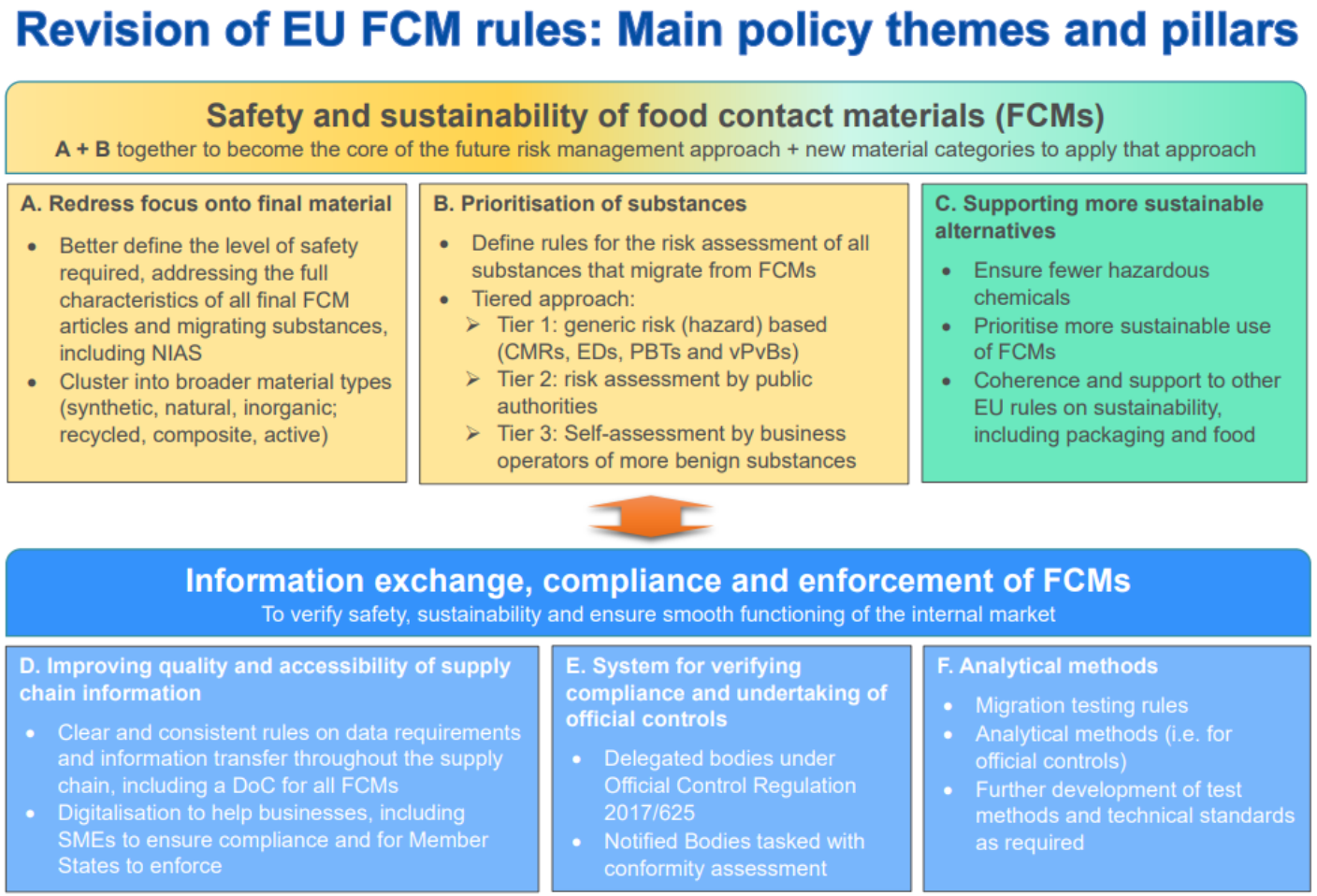

Image from the European Commission's website

Reform of REACH Authorization

- REACH authorization likely to remain in REACH
- New: essential use derogation upfront

Polymer Registration

Polymers Requiring Registration (PRR)

- Following debates in CARACAL, Commission dropped initially considered concept of Polymers of Low Concern (PLC) – **Amended PRR criteria, version 1 April 2022**
- Consequence: all polymers assessed against PRR criteria
  - PRR: **all** fluorinated polymers; certain cationic polymers; polymers meeting molecular weight criterion; polymers in certain hazard classification; certain polymers presenting surface activity and polymers suspected to degrade into substances of concern
  - **Two exceptions** (i.e., not assessed against PRR criteria):
    - Polymeric precursors handled like intermediates under SCC to produce other polymers or articles
    - Polyesters made out of an EU-list of monomers made by COM, containing only 'low hazard' monomers

Grouping

- Estimate: 70,000 - 400,000 ‘unique polymers’ subject to registration, focus on PRRs could lead to the registration of 30,000 polymers, which could be grouped into circa 10,000

  → **Grouping will be essential!**

- Insights from the European Chemicals Agency (ECHA):
  - Grouping of polymers to be primarily based on the identity of the starting materials contributing to at least 2% of the polymerized part of the polymers (i.e., chemical similarity), possibly complemented with phys-chem data
  - Hazard data provided assumed to be applicable for all polymers in the group
  - Validation of the proposed grouping at the stage of an assessment of a testing proposal or compliance check
- **Grouping is the responsibility of the industry → New Consortia to tackle grouping and group registrations**!

Notification Obligation for All Polymers

- Limited information: identification of polymers, assess if a polymer is a PRR, information allowing to define grouping criteria
  - More info for PRR, less for non-PRR
- **Timing:** earliest three years after entry into force for polymers on the market (tbd) + before start of marketing for new polymers

Placeholders for Registration Obligation

- There will be a new Annex for polymer registration requirements
- *Placeholder* for information requirements – by a delegated act
  - Depending on molecular weight – low MW polymers: similar to non-polymeric substances; medium and high MW polymers: very limited requirements
  - **Timing**: eight years for low MW polymers; twelve years for medium and high MW polymers
  - Monomers and other precursors still requiring registration?
    - Probably yes, unless handled under ‘strictly controlled conditions’
- *Placeholder* for criteria for grouping of PRRs – delegated act or via a guidance
- These elements will be defined mainly based on notifications

Other Aspects

SVHC Listing

- Currently: 233 substances in the Candidate List of Substances of Very High Concern (SVHC); below the goals
- New elements:
  - Harmonized classification and labelling as ED, PBT, vPvB, PMT, and vPvM: sufficient for Candidate List
  - Additional notification by registrants and downstream users (publicly available): including emission and waste management data and possible alternatives
  - Annual fee

Extension of REACH Data Requirements

- New REACH data requirements related to:
  - New endpoints – particularly endocrine disruption (imunotoxicants? neurotoxicants?) – will lead to more substances being identified as such
  - Extension of data requirements for the 1 - 10 tons band (the same as 10 - 100 tons and CSR)
  - Information on environmental footprint (?)
- Expected cost sharing issues (related to existing registrants)

Mixture Assessment Factor

- Account for the cocktail effect of chemicals when assessing risks from chemicals (downstream uses often unknown to registrants)
- Introduction of a mixture assessment factor in Annex I of REACH (safety assessment)
  - CSR must document that each individual use is safe, i.e., that exposure ≤ DNEL or PNEC
- Will be introduced by Commission Regulation!
  - RCR ≤ 1/MAF
  - Proposed MAF = 5
  - Only substances registered at ≥ 1,000 t/y
  - Derogation possible with a specific risk assessment

Improve Enforcement

Enforcement of Registration Requirements

- Revocation of registration numbers in case of persistent non-compliance or expiry of technical dossier
  - Persistent non-compliance = even delay with submitting requested data
- Technical dossier should be updated (and subject to compliance check) at least every [ten] years
- Whistleblowing

Thank You

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