



The Impact of the EU Chemicals Strategy for Sustainability on the Future Shaping up of the Food-Contact Legislation

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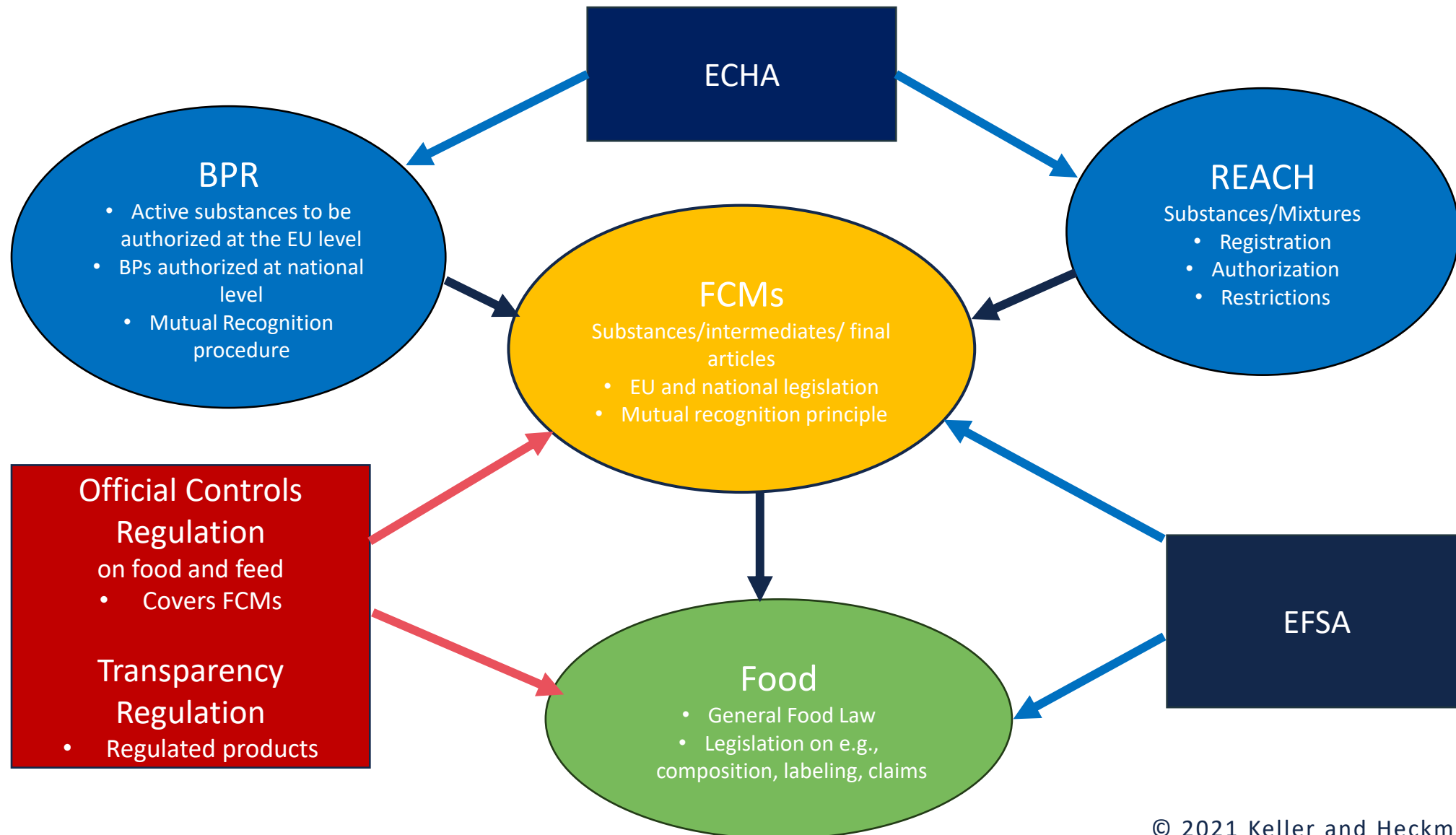
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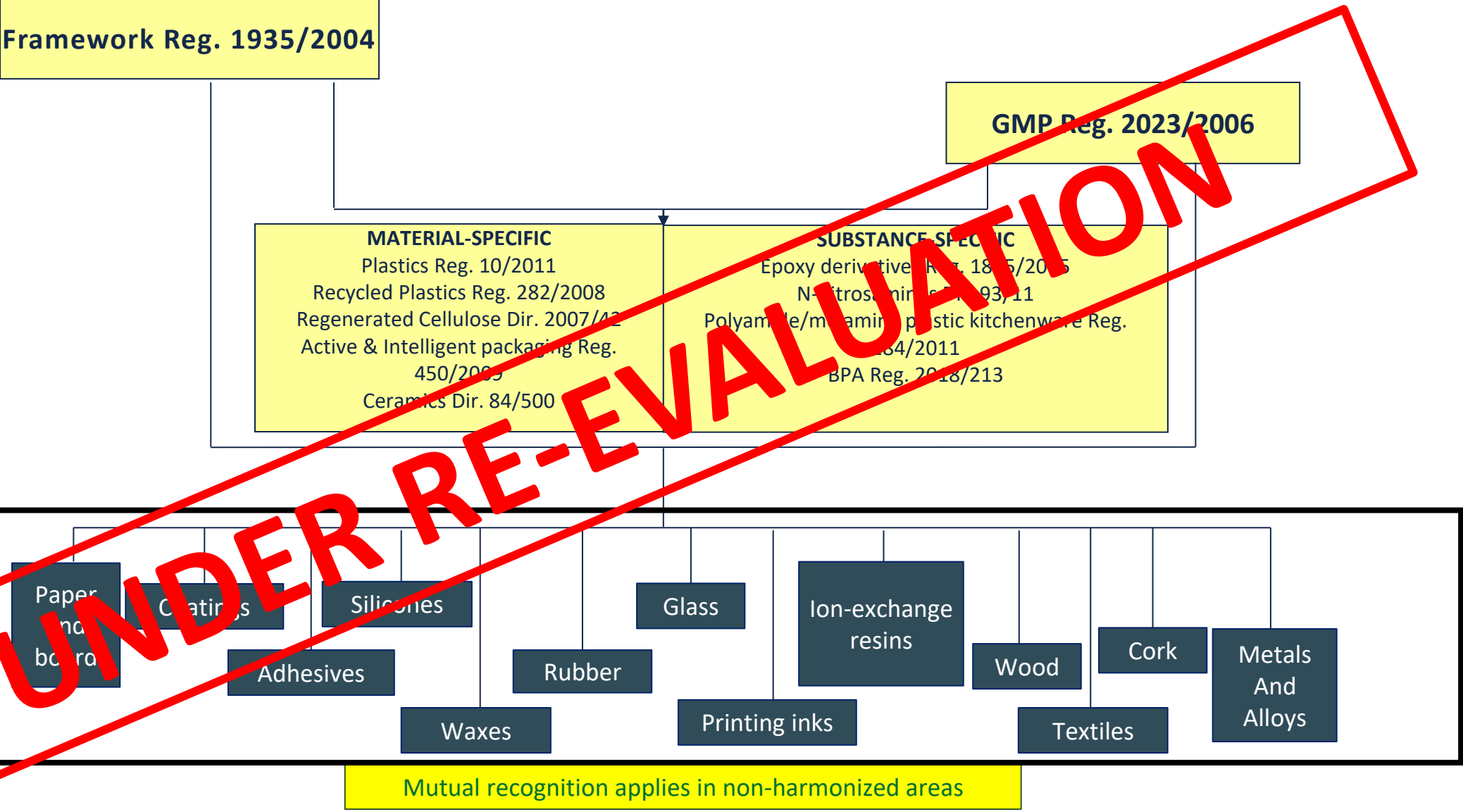


The Re-Evaluation of FC Legislation: General Background & Current Status

Food Contact Legislation in Context



Current EU Food-Contact Legislation



EU Re-evaluation of FCM Legislation in a Changing Legislative Environment



Plastics Strategy

Farm to Fork Strategy



Chemicals Strategy for Sustainability (CSS)

Ecorys report

Roadmap of the EC

Eight Key Problems Identified in Roadmap

- ◆ 18 December 2020
- ◆ 322 responses

 Ref. Ares(2020)7731375 - 18/12/2020

INCEPTION IMPACT ASSESSMENT	
<p>Inception Impact Assessments aim to inform citizens and stakeholders about the Commission's plans in order to allow them to provide feedback on the intended initiative and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have, including on possible impacts of the different options.</p>	
TITLE OF THE INITIATIVE	Revision of EU rules on food contact materials (FCMs)
LEAD DG (RESPONSIBLE UNIT)	DG SANTE E2
LIKELY TYPE OF INITIATIVE	To be determined
INDICATIVE PLANNING	Q4 2022
ADDITIONAL INFORMATION	Evaluation of food contact materials (FCM) legislation
<p>The Inception Impact Assessment is provided for information purposes only. It does not prejudice the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the Inception impact assessment, including its timing, are subject to change.</p>	

Eight Key Problems Identified in Roadmap (2)

- ◆ 1. **Lack of functioning of the internal market** and possible safety issues for non-plastics FCMs
- ◆ 2. Current approach based on positive lists of substances and **lack of focus on the final article**
- ◆ 3. **Lack of prioritization of the most hazardous substances** and up-to-date assessments
- ◆ 4. **Exchange of safety and compliance information** in the supply chain is **poor** and the ability to ensure compliance is compromised

Eight Key Problems Identified in Roadmap (3)

- ◆ 5. **Enforcement** of rules on FCMs is generally **poor**
- ◆ 6. Rules do not sufficiently take into account the specificity of **SMEs**
- ◆ 7. Rules do **not encourage development of safer and more sustainable alternatives**
- ◆ 8. Subject matter is not always clear and definitions need to be reviewed

Future Changes?

Shift from substances to final materials

Prioritization of assessment

- **Tier 1 Substances:** CMRs, EDs, PBTs, and vPvBs
- **Tier 2 Substances:** Substances with specific concerns: e.g., substances in nano-form
 - **Authorities assessment: ECHA/EFSA**
- **Tier 3 Substances** of less concern
 - **Self-assessment by business operators**

Future Changes? (2)

EC is considering putting in place

- **Delegated bodies** for the enforcement
- **Notified bodies** for the compliance assessment

Next Steps for the EU Re-evaluation of FC Legislation

2021

2022

- Development of impact assessment detailing policy options
- 12-week public consultation (Q2 2021?)
- Targeted consultation activities with stakeholders

Q4 2022

- Proposal for a revision of EU legislation

CSS – Towards a Toxic-Free Environment

- ◆ Published: 14 October 2020
 - ◇ Communication from the EC
 - ◇ Action Plan: Key actions to be taken by the Commission
 - ◇ Six Staff Working Documents



<https://ec.europa.eu/environment/pdf/chemicals/2020/10/chemicals-strategy-factsheet.pdf>

- ◆ **Part of the European Green Deal program**
 - ◇ Presented in December 2019 as a priority of the new Commission President Ursula von der Leyen
 - ◇ Zero-pollution, toxic-free environment
 - ◇ Tackles also: climate change, biodiversity, pollution, sustainability of food chain
- ◆ **Impact on REACH and CLP, but also on food contact legislation**

Implications of the CSS on FCMs

A few key actions to be taken by EC relevant for FCMs	Planned timeline
Phase-out of the most harmful chemicals for ‘non-essential uses’ + grouping	2022
Define criteria for essential uses to ensure that most harmful chemicals are only allowed if use is necessary and if no alternatives are acceptable	2021-2022
Establishment of « One Substance, One Assessment »	2021
Generic approach for risk management for most harmful chemicals in consumer products, incl. in (recycled) FCMs	2022
Registration of polymers	2022
Establishment of legally binding criteria for the identification of endocrine disruptors in relevant legislation, incl. FCMs	2022
Provisions to take account of combination effects of chemicals in products, incl. FCMs	2022
New hazard classes, changes in classification and labeling	2022

Future Amendments to REACH Impacting FCMs

Roadplan for REACH Revision

◆ Timing:

- ◆ Inception impact assessment published May 4, 2021, provide feedback until June 1, 2021
- ◆ Impact assessment: Autumn 2021 – Early Autumn 2022: public consultation end 2022
- ◆ Draft proposal for revision of REACH – 2022
- ◆ Commission adoption of proposal – end 2022

Restriction of Substances For Non-essential Uses+ Grouping

- ◆ Substances of concern to be restricted for ‘non-essential societal uses’ (to be identified specifically!) + criteria for granting derogations
- ◆ Group assessment of chemicals with similar hazard, risk, or function (e.g., to tackle substitution by similar substances of concern)
- ◆ First battlefield: a poly- and perfluoroalkyl substances (PFAS) REACH restriction proposal
- ◆ Bisphenols, phthalates also mentioned specifically (for grouping)

Definition of ‘Essential’ Uses: Latest Development

- ◆ **March CARACAL document: ‘Summary of and response to comments to CA/61/2020’** provides more insight:
 - ◇ Concept goes beyond REACH (FCM)
 - ◇ Concept of essentiality in the Montreal Protocol (MP) as a starting point to initiate discussions
 - ◇ MP takes into account four elements: criticality, alternatives, use (emissions already minimised?), and availability of the controlled substance from existing stocks/recycling (not relevant to REACH)
 - ◇ Client Earth: luxury, convenience, leisure, cosmetics, toys, or decorative products

Proposed Client Earth's Criteria For Granting Derogations



- ◆ Is the use relevant for safety or health?
- ◆ Are material, energy, performance efficiency affected?
- ◆ Alternatives accessible?
- ◆ Whether or not the use significantly extends the lifetime of a product, improves durability, less consumption of raw materials, less consumption of energy (i.e., does it contribute to sustainability?)
- ◆ Hazardous waste after a short lifetime?

Summary Relevant to FCM

- ◆ Change of current approach: currently, only safety is a relevant criterion for FCM, not 'essentiality'
- ◆ Risk assessment by EFSA will continue only for substances not identified for a ban, or derogated from a ban
- ◆ FCM is a sector for which derogations will likely be available based on essentiality if justified (arguments: criticality for society, environmental benefits (better biodegradability, compostability...))
- ◆ Risk assessment factor in the assessment? Role for EFSA?
- ◆ Grouping very relevant to FCM (phthalates, bisphenols)
- ◆ Advocacy activities will be essential for FCM!

PFAS: One of the Priorities of the CSS

- ◇ One of the priorities of the CSS, also on a global scale
- ◇ Some PFAS already in the REACH restriction process: PFOA and PFOS already restricted, PFHxA, PFHxS, C9-C14 PFCAs in the process
- ◇ Denmark already restricted all PFAS in food packaging (unless behind functional barrier)
- ◇ The Netherlands is working on a similar ban

Scope of the PFAS Restriction

- ◆ PFAS to be restricted on their own, in mixtures and in articles (incl. FCM) above a specific threshold (between ≤ 1 mg/kg and 0.1 % w/w in our view)
- ◆ PFAS to be banned for all 'non-essential uses': essentiality in FCM?
- ◆ ECHA presentation of 29 October 2020 entitled 'Restriction of per- and polyfluoroalkyl substances (PFAS) under REACH':
https://echa.europa.eu/documents/10162/31366392/pfas_webinar_slides_en.pdf/361234ba-5b0c-d5d0-df0d-4145c3e08c73
- ◇ Substances that contain at least one aliphatic -CF₂- or -CF₃ element
- ◇ Includes precursors that can be transformed/degraded to PFAS

Timing of PFAS Restriction

- ◆ Timing of the PFAS restriction proposal:
 - ◇ Announcement of restriction intention to ECHA: during the first half 2021
 - ◇ Publication of actual proposal expected first half 2022
 - ◇ The final restriction should be adopted by the European Commission in 2025
- ◆ Check: <https://echa.europa.eu/registry-of-restriction-intentions>
- ◆ There will be two public consultations (six and two months)
- ◆ Possibility for advocacy – exemptions, derogations, sell-off periods

‘One Substance, One Evaluation’ Principle

- ◆ Good example of impact: food packaging
- ◆ Currently: restriction based on hazard assessment under REACH and/or risk assessment by EFSA (example: REACH ban of phthalates not applicable to FCM, subject to EFSA risk assessment)
- ◆ CSS envisages one evaluation per one substance
- ◆ Current REACH/CLP PACT list is mentioned as a basis (mainly hazard oriented!)
- ◆ **Concern: substances would be banned at the REACH level based on their hazard profile** (but again: potential role for EFSA if there is a risk assessment factor in the essentiality assessment? – example of phthalates?) – advocacy necessary!

Extension of Generic Approach to Risk Management

- ◆ What is it? Fast tracking of restriction measures (Article 68(2) REACH restrictions, plastic packaging requirements etc.): currently only for CMR and for consumer uses
- ◆ CSS wants to extend it to:
 - ◇ ED, PBT/vPvB
 - ◇ Immunotoxicants, neurotoxicants, respiratory sensitizers, STOTs (later)
 - ◇ professional uses
- ◆ But: derogation of essential uses also mentioned here!
- ◆ Assessment of the need for specific criteria for immunotoxicity and neurotoxicity currently covered under STOT and Reprotox categories

Combination Effects of Chemicals in Products

- ◆ New provisions to take account of combined effects: the introduction of a mixture assessment factor in Annex I of REACH (safety assessment)
- ◆ But: additional allocation factor used by EFSA in latest evaluations of FC substances to take into consideration the contribution of exposure of evaluated substances from other sources than plastics
 - ◆ A double application of the factor should be prevented!

REACH Registration of Polymers

- ◆ Polymers should be subject to REACH registration except for Polymers of Low Concern
- ◆ Currently: based on classification (11 classes of severe hazards under CLP), molecular weight, cationicity, anionicity or amphoteric properties, surface-active properties, and certain reactive functional groups
- ◆ Estimate: 11,000 "unique polymers" subject to registration
- ◆ Recently, the European Commission suggested incorporating Canadian criteria for identification of polymers of low concern (PLCs)
- ◆ Consequence: in most of the cases, there will be a duplication of registrations for monomers/polymers

Future Amendments to CLP Impacting FCMs

Current Status of CLP Revision

- ◆ Inception impact assessment published on 04 May 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

Endocrine Disruptors

- ◆ CSS proposes to establish hazard identification of endocrine disruptors, based on the WHO definition, building on criteria already developed for pesticides and biocides
- ◆ Proposed classification: known/presumed/suspected
- ◆ After classification: ban endocrine disruptors in consumer products (for non-essential uses), incl. FCM (how about 'suspected' ED?)
- ◆ i.e.: ED will likely be affected by the 'one substance one evaluation principle'!
- ◆ 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>

New Hazard Classes: PBT, vPvB, PMT, vPvM



- ◆ PBT and vPvB currently addressed by REACH, but not a hazard class as yet
- ◆ Future classification 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
 - ◇ Criteria/guidance developed by German Environmental Agency (UBA)
- ◆ If PMT/vPvM considered under the same regime as PBT: restriction for non-essential uses, including in FCM

Changes to Harmonized C&L

- ◆ Introduce a mandate for Commission to request ECHA to develop new harmonized classification and labelling dossiers
- ◆ Introduce a prioritization mechanism for harmonizing the classification of certain chemicals (now: only CMR + biocides/pesticides: how about FCM?)
- ◆ Additional opportunity for interested parties to comment in the Harmonized C&L procedure (repeat public consultation?/introduce possibility for companies to initiate a change of harmonized C&L)

Final Thoughts

Internal Pushback Within the Commission Services

- ◆ The CSS driven by DG Environment
- ◆ Criticized by DG Grow (interests of Industry)
 - ◇ Concept of 'essential uses': not for the Commission to make societal decisions
 - ◇ Difficult to set objective criteria
 - ◇ Mixture assessment factor: 'step too far'
 - ◇ Wish for 'predictability and transparency'
 - ◇ Proposes other approach: 'formalizing and enhancing' the risk management options analysis (RMOA) process.
- ◆ First indication: withdrawal of registrations dossiers in case of non-compliance (one of the elements of the CSS) struck down by the Commission legal service

Opportunities for industry

- ◆ One of the goals of the CSS: development of safer alternatives + sustainable-by-design substances
- ◆ Business opportunity in developing safer alternatives
- ◆ Not only EU: EU priority is to address relevant international fora (Stockholm Convention, Basel Convention, GHS...)
- ◆ Opportunities to receive financial support under EU research and innovation programs (already in place for remediation of PFAS)

Final Considerations

- ◆ Not an easy task for EU authorities, questionable from the EU legal principles perspective
- ◆ Long process: there will be numerous opportunities to participate in public consultations/ad hoc advocacy activities
- ◆ How ECHA and EFSA will work together?
- ◆ Let your voice be heard

Thank you

Any questions?

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