Discussion on the revision of the FCM framework legislation

EFSA FCM NETWORK 8th meeting

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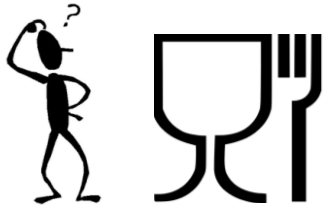
FCM Evaluation

- Staff Working Document published 9 June 2022 (https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials/policy-initiatives/evaluation-eu-rules_en including summaries in FR and DE)
- Provides basis for the revision + political commitments given in Farm to Fork Strategy and Chemicals Strategy for Sustainability
- Overall the current FCM Regulation functions as expected to a certain extent, and partly fulfils its objectives, in particular for plastic FCMs for which specific EU rules apply
- There is EU added value and it also remains relevant for all stakeholders

FCM Evaluation

- Main problems identified:
  1. Rules for many materials remains poorly defined → uncertainty over safety and problems concerning functioning of EU market
  2. Issues with current approach –
     - Resource intensive and not optimally efficient
     - Has led to technically complex rules
     - Lack of prioritisation of hazardous substances and focus on safety of final article
  3. Rules geared only towards traditional chemistry e.g. manufacture of polymers rather than rules that also encourage sustainable alternatives
  4. Exchange of compliance information poor, enforcement challenging and generally weak
  5. Lack of support for specifically SMEs
  6. Room for better coherence e.g. with REACH
  7. Lack of understanding and information to consumers

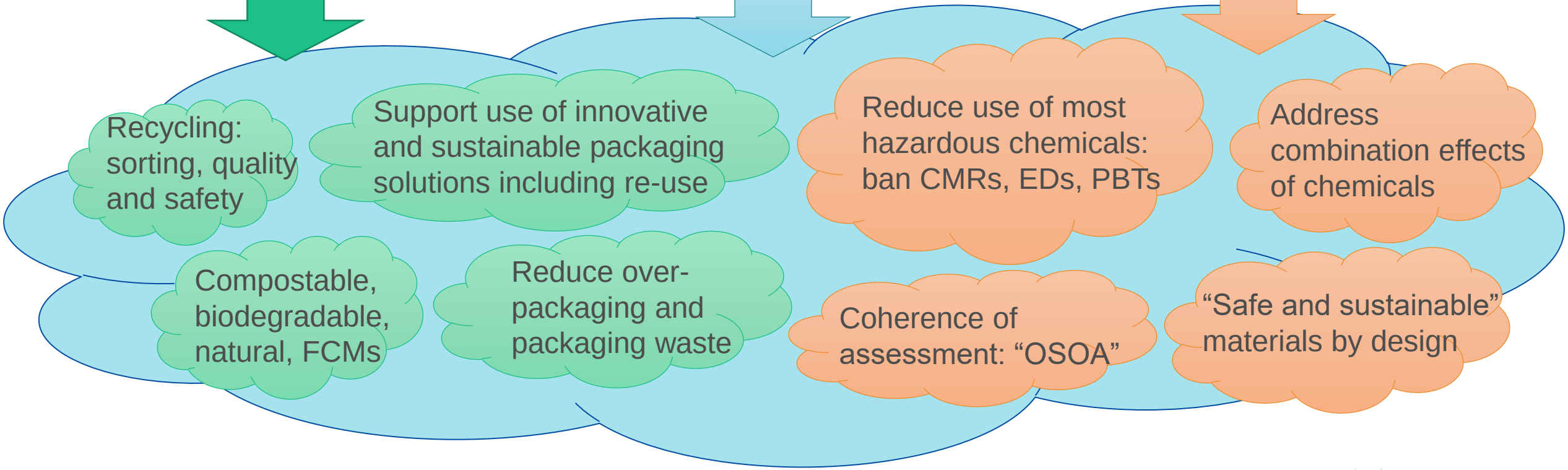


European Commission's commitments

Circular Economy Action Plan (CEAP)
March 2020

Farm to Fork strategy
Revision of FCM legislation
May 2020

Chemicals Strategy for Sustainability (CSS)
October 2020



Relevant COM initiatives

- **'One Substance, One Assessment' (OSOA)** Mechanism for data generation, streamlining data flows on chemicals and increasing data sharing and re-use across legislation, better use of academic data
- **Safe and sustainable by design** Ensure the development, commercialisation, deployment and uptake of safe and sustainable-by-design substances, materials and products
- **Non-toxic material cycles** Decontamination of waste streams, increase safe recycling
- **Extension of GRA and essential use criteria** Operationalisation of ESU concept in legislation
- **Targeting of EDs – revision of CLP Regulation** To be banned in consumer products subject to essential use
- **Targeting of PFAS** General ban under REACH including FCM and packaging;
- **Combination effects ('mixtures')** Provisions to take account of the combination effects in FCM legislation
- **Revision of CLP** ED identification and other new hazard classes
- **Revision of REACH** Simplifying communication in the supply chains, extension of the GRA, control and enforcement
- **Implementation of requirements in Directive (EU) 2020/2184** Including a positive list of substances for materials in contact with drinking water

FCM revision: Main policy themes and pillars

Safety and sustainability

A. Shifting focus onto final material

- Rules to better define level of safety required aimed at addressing the full characteristics of all final FCM articles
- Refocus on broader material types (e.g. synthetic, inorganic, natural fibres etc); include composite FCMs

B. Prioritisation of substances

- All substances to which consumers may be exposed regardless of origin, substance groups
- Tiered approach, with precedent given to certain hazard classes (CMRs, EDs, PBTs and vPvBs)
- EU regulation of other substances
- Self-assessment of more benign substances and/or those migrating in low amounts

C. Supporting safer and more sustainable alternatives

- Ensure safety, less hazardous chemicals → sustainability
- Expand rules to prioritise and support sustainability
- Rules on sustainability e.g. packaging use

Information exchange, compliance and enforcement

D. Improving quality and accessibility of supply chain information

- Clear and consistent rules on data requirements and information transfer throughout the supply chain, including a DoC for all FCMs
- Digitalisation to help businesses, including SMEs to ensure compliance and for Member States to enforce

E. System for verifying compliance

- Delegated bodies under Official Control Regulation 2017/625
- Notified Bodies tasked with conformity assessment
- Further development of test methods and technical standards as required

Possible options for FCM rules A: Shifting the focus onto the final material

- Strive for **direct assessment of all final food contact articles**
- EU to **define the level of safety** that needs to be achieved; possibility of industry input on how to achieve this (needs to recognise sector specificity) e.g. possible strengthening of rules on GMP
- **Refocus on broader material types e.g.**
  - (1) Synthetic organic type materials (plastics, rubbers, coatings, inks, adhesives)
  - (2) Natural organic type materials (paper, wood, fibres, plant-based)
  - (3) Inorganic based materials including metals
  - (4) Recycled materials
  - (5) Active FCM

  (6) Composite and multi-material final FCM articles
- **Information requirements**
  - ➢ Responsibility on industry to [eventually] identify all migratable substances e.g. screening methods, exclusion of substances that may be hazardous below threshold – e.g. genotoxic substances
  - ➢ For consumers e.g. labelling

Possible options for FCM rules B: Prioritisation of substances

- **All substances** that may pose a risk to consumers, regardless of origin, including non-intentionally added substances (NIAS) and groups of substances as relevant
- **Tiered approach, with precedence given to certain hazard classes**

EU/ public risk assessment bodies

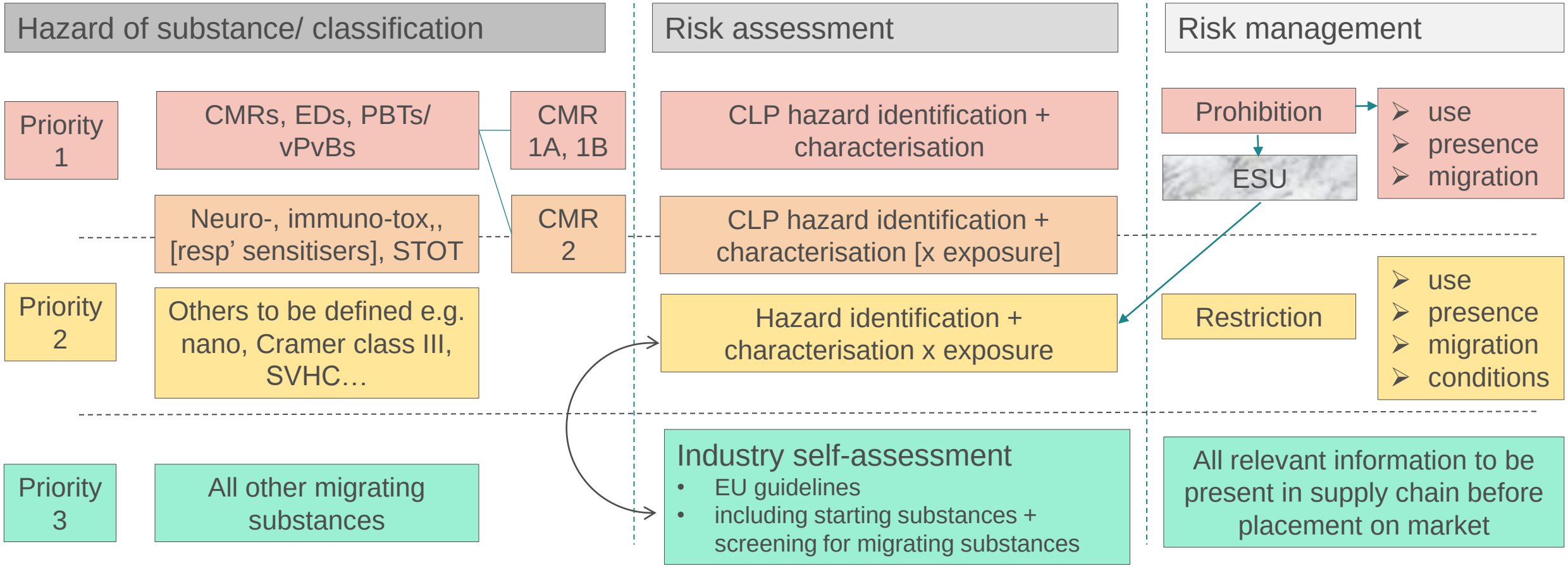
1. Generic risk approach/ hazard-based: CMRs, EDs, PBTs and vPvBs.
2. Generic risk approach/ hazard-based or specific risk assessments: Other substances with specific properties such as neurotoxins, immunotoxins or e.g. substances in nano-form or that migrate in high amounts

Self-assessment

3. More benign substances and those migrating in low amounts

- **Dialogue with and input required from EFSA and MS/ national risk assessment bodies** to inform on priorities and capacity for future risk assessments

Overview for possible prioritisation of substances



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Some key issues for discussion – risk assessment

- On what basis should FCM substances be prioritised for risk assessment and subsequent EU risk management?
  - Hazard classes inc. genotoxicity, CMRs, EDs, PBTs/ vPvB, immunotoxicity, neurotoxicity
  - Material types
    - How to tackle ‘natural’ materials, taking into account the potential unknown substances present? See recent EFSA opinions on wood and bleached cellulose
  - Use and exposure
    - via FCM and via other sources
    - vulnerable populations and
    - how to better address combination effects

Some key issues for discussion – risk assessment

- EU risk management needs to be based on independent and transparent risk assessment processes, taking into account the requirements of the TR
- Who should do this? Capacity for risk assessment
  - EFSA
  - ECHA in the context of 'one substance, one assessment' and coherent with other chemicals legislation e.g. REACH
  - Member State level
  - What should be the responsibility of business operators?
- What data needs to be made available eventually and by whom?
  - Currently plastic substances for which an authorisation is not required should be risk assessed according to "internationally recognised scientific principles on risk assessment"

Some key issues for discussion – risk management

- Which current tools are important for risk management of FCMs?
  - SML
  - OML
  - 10ppb limit
- What does it meant to prohibit/ ban a substance? Point of risk management (use of substances, manufacturing process, final FCM article)
- Who should be responsible for determining whether the use of an FCM substance is essential?
- Analytical capabilities: individual substances or multi-analyte methods
- What testing requirements are necessary?
- What is the ultimate capacity of Member States to carry out official controls to verify FCMs on the market are compliance and therefore safe?

Possible options for FCM rules C: Possible options supporting more sustainable alternatives

Beyond ensuring their safety including recycling, we may additionally consider to:

- Prioritise the safety assessment of substances used in innovative sustainable materials and natural materials (e.g. plant or food-derived) over non-sustainable ones
- Increase safety and legal certainty of re-use systems (hygiene, quality control)
- Set incentives supporting the placing on the market of sustainable FCM (e.g. sustainability information on FCM, positive list of natural materials)
- Set requirements supporting the recycling and reuse of materials (e.g. reduce complexity)

Possible options for FCM rules D & E: Information exchange, compliance and enforcement

Considerations

- Requirements will be set up for all types of FCMs
- Specification of content (present Annex IV to R 10/2011) or template?
  - level of detail regarding substances?
  - confidential or public?
  - paper based or fully digital?
  - perpetually valid, expiration requirements, or batch based?
- Use Declarations of Compliance directly to enforce requirements
  - e.g. QR codes on products
  - do not allow specification of unauthorised substances or for which no risk assessment
- Further development of test methods and technical standards – “fingerprinting”
  - Analytical results incorporated in DoC?

Some of the next steps

- **Public Consultation** (14 weeks duration)
  - Questions for citizens (consumers)
  - Questions for stakeholders (MSs, business associations, businesses etc)
  - https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12497-Revision-of-EU-rules-on-food-contact-materials_en
- Parallel/ follow-up work → **citizen engagement group** (autumn 2022)
- **Study** to support objectives A, D and E
  - Develop options for an IT infrastructure required for information exchange
  - Define the roles of the various actors (operators participating in the FCM production chain, food business operators, competent authorities in the EU and abroad, notified bodies, delegated bodies and consumers)

Some of the next steps

- Further work on options for **sustainability** (objective C) taking account of other EU policies e.g. single use plastic, revision of packaging and packaging waste legislation; eco-design and green claims
- **Continuation of work from Chemicals Strategy** e.g. the ‘essential use’ concept, combination effects, 1S1A including use of ECHA
- Define **analytical (laboratory) methods** that can support efficient verification of compliance and controls of final FCMs with the safety requirements
- **Further consultation work** foreseen (e.g. targeted questionnaires, case studies, focus groups, working group, discussion forum). Stakeholder contributions welcome, including data and working examples