European Commission SANTE activities: update on the revision of EU FCM rules and current implementation work

EFSA NETWORK ON THE COOPERATION AND HARMONISATION OF RISK ASSESSMENT OF FOOD CONTACT MATERIALS (FCM)

10th meeting, 17 – 19 October 2023

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Revision

Objectives of the Revision (‘aspirations’)

- Strengthen Article 3 – **FCMs are to be inert**
- Ensure we can effortlessly know **that a final material is safe**
- Keep **new rules** simple, practicable, enforceable and **achievable**
- Ensure there is **full harmonisation**, level playing field, including imports
- Ensure **high level of transparency** over composition and sustainability

EU FCM revision: Main policy themes and pillars

Safety and sustainability of food contact materials (FCMs)

A + B together to become the core of the future risk management approach + new material categories to apply that approach

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- + new material categories to apply that approach

A. Redress focus onto final material

- Better define the level of safety required, addressing the overall safety of the final FCM articles and migrating substances
- Cluster into broader material types (synthetic, natural, recycled, composite, active)

B. Prioritisation of substances

- Define rules for the risk assessment of all substances contained in FCMs
- Tiered approach:
  - Tier 1: generic risk (hazard) based (CMRs, EDs, PBTs and vPvBs)
  - Tier 2: risk-based (exposure) for other substances
  - Tier 3: Self-assessment by business operators of more benign substances

C. Supporting more sustainable alternatives

- Ensure fewer hazardous chemicals
- Prioritise more sustainable use of FCMs
- Coherence and support to other EU rules on sustainability, including packaging and food

Information exchange, compliance and enforcement of FCMs

To verify safety, sustainability and ensure smooth functioning of the internal market

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 and undertaking of official controls

- Delegated bodies under Official Control Regulation 2017/625
- Notified Bodies tasked with conformity assessment

F. Analytical methods

- Migration testing rules
- Analytical methods (i.e. for official controls)
- Further development of test methods and technical standards as required

A: Rebalance focus: final material

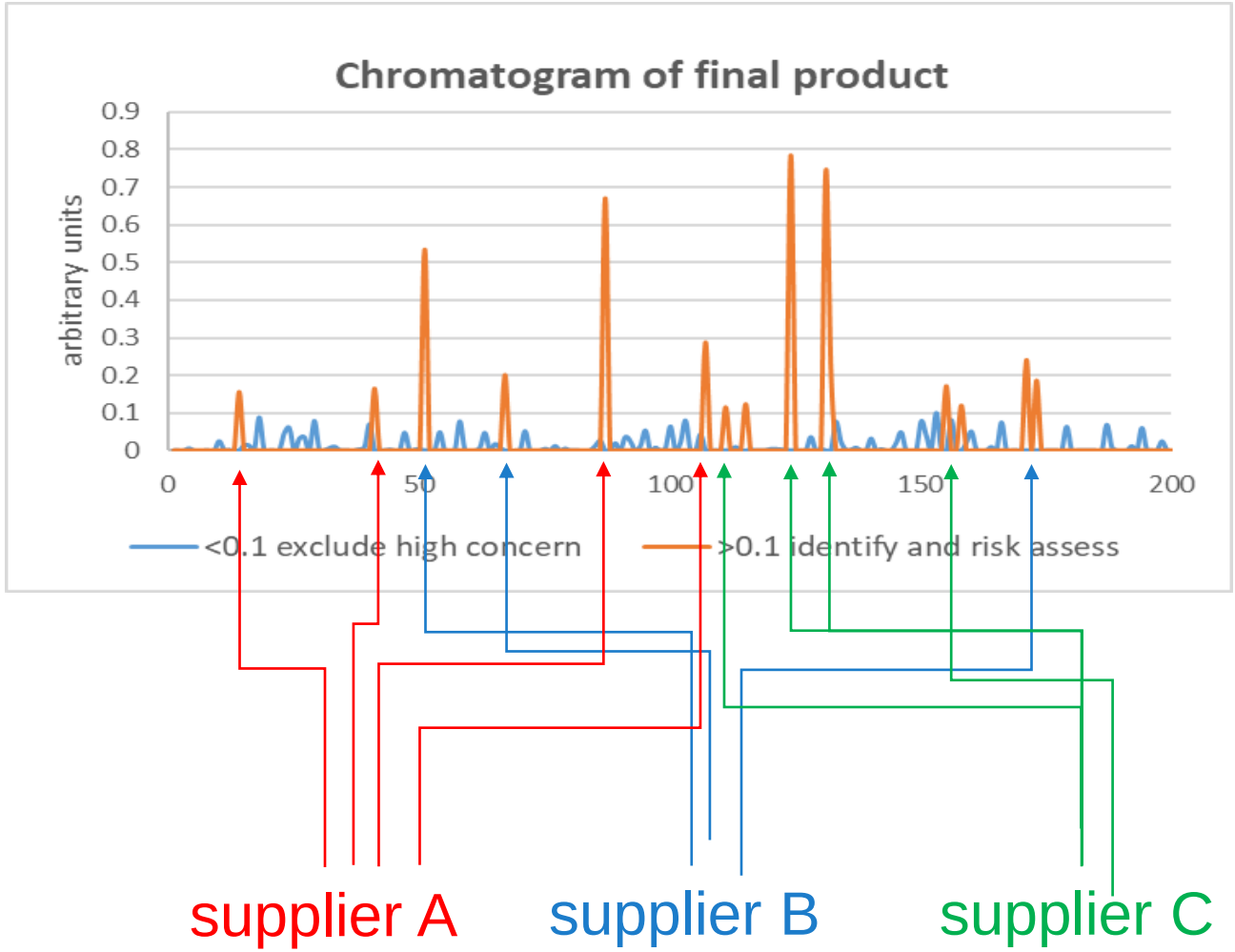
- **all substances that may migrate should be known to the producer of the final material or article**
  - the maximum migratable quantity is known and under control of GMP
  - substances have been risk assessed – exposure below resulting limit
  - no difference between NIAS and IAS (or the transfer of any constituents)
- **the information is (largely) to be provided by the supply chain**
  - high level of transparency required
- **expertise on chemistry needed with final producer**
  - (or with their consultants/ provider)

A: Rebalance focus: final material - Inertness

- Reversal of thinking
  - past: Constituents may transfer from FCMs unless that is a risk to human health
  - future: Constituents may not transfer from FCMs unless that does not cause a risk
- FCM legislation to require that FCMs are inert, however
  - it is about the way of thinking about FCMs
  - principle will be applied during drafting of all detailed rules
  - rules will favour FCMs that show low health **risk** caused by transfer (hazard * quantity)
- Drive innovation towards inherently safer materials
  - it should become **profitable** to manufacture cleaner & safer FCMs
  - and expensive to manufacture the opposite

A: In practice

- **<u>If</u>** the **final** producer were to make a ‘forest of peaks’ style chromatogram:
- They would need to be able to explain all peaks give rise to safe migration level
- Information can’t come from (present) analytical techniques **(→F)**
- Information to come from suppliers as shown on right→



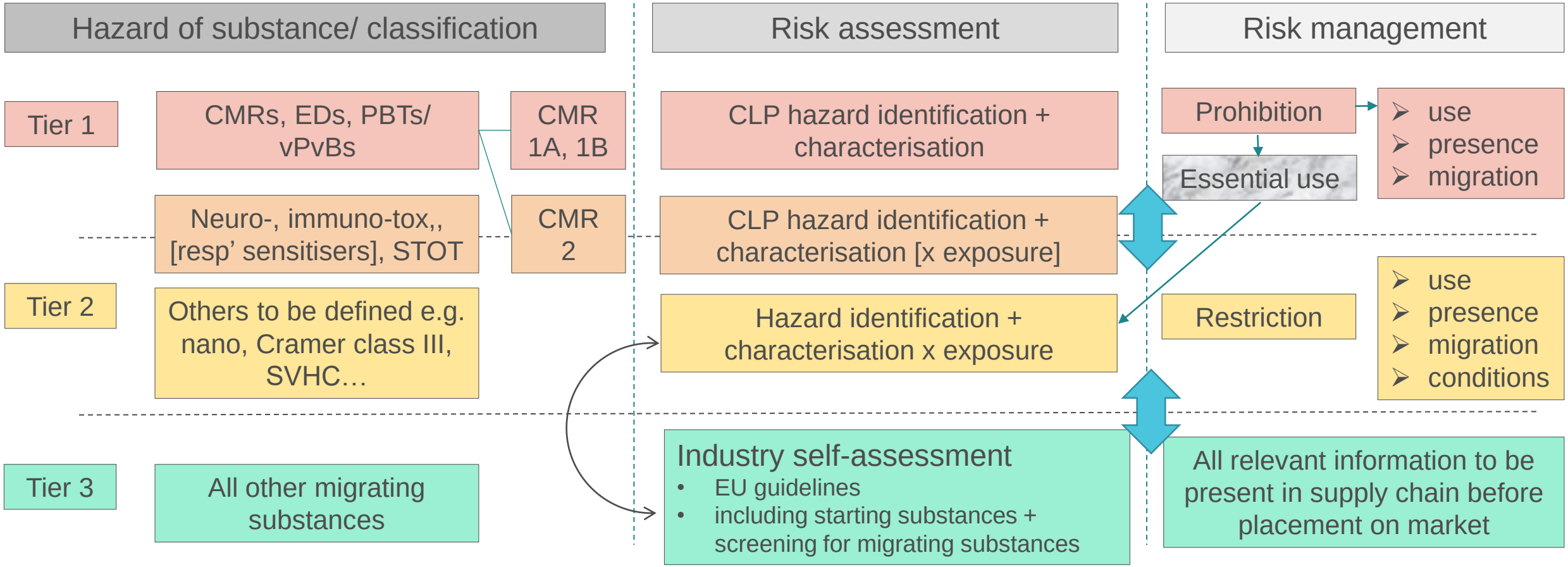
B: Prioritisation of substances

What does this mean?

- Substances are no longer prioritised for risk assessment and risk management purely based on the need to authorise their use in the manufacture of FCMs
- Rather, ‘migratables’ should be assessed for all FCMs according to a number of criteria including identified hazardous properties, use, formation, presence, migration, exposure, grouping and combination effects, vulnerable populations, essentiality
- Different levels of risk assessment and possible risk management depending on these criteria

B: Prioritisation of substances

A basic tiered system…



B: Prioritisation of substances

Where should the information come from?

- Supply chain/ business operators
  - Information on starting substances and other migrating substances via screening
  - Toxicological information, migration data, risk assessments
- Member States
  - National lists and existing risk assessments
- EFSA (existing data and risk assessments)
- ECHA
  - Information on substances registered under REACH, substances under evaluation and those of concern, risk assessments on drinking water materials etc

One substance, one assessment

Applying A+B to specific material groups

Simplification of material groups

- Main Materials
  1. Synthetic organic type materials (plastics, rubbers, coatings, inks, adhesives…)
  2. Natural organic type materials (wood, fibres, plant-based)
  3. Inorganic based materials including metals

- Special materials (made from 1, 2 and 3)
  4. Active and Intelligent materials
  5. Recycled materials
  6. Composites (paper, multi-material)

Grouping is done on the basis of a high similarity in applicable rules i.e. if substances can be regulated in the same way, they will be in the same group. Grouping is not to set different safety standards, rather to reflect similarities between the groups and practicable and achievable approaches for RA and RM

Pillar C – ‘Sustainable FCM’

- This pillar to focus on **rules** that would facilitate sustainability through:
  - production of FCM, e.g. information on impact / prioritisation
  - use of FCM, e.g. re-use, hygiene, support food systems
  - disposal of FCM, e.g. recycling (focus likely on natural fibres)
- Study under preparation to
  - articulate what sustainability means in context of FCMs
  - consider gaps, needs and opportunities in present and future Union legislation and policies
  - list potential policy measures, characterise promising policy measures
- Resulting measures to be integrated in legislation
  - basis will then become safety, internal market, and sustainability

Pillars D+E, information and enforcement

- Pillar D: Information system
  - to ensure that the objectives of pillars A and B can be met
  - A: transfer information in supply chain digitally / provide access to supporting documentation
  - B: provide access to existing risk assessments
  - Challenges: To design a system, To manage proprietary information
- Pillar E to consider
  - aspects that need enforcement
  - the role of competent authorities, in view of available resources
  - the use of notified bodies, designated bodies

Pillar F: Analytical methods

- Present: focus on enforcement of migration limits under OCR
  - in practice, only a very limited number of substances is routinely subject to verification of compliance by competent authorities on the basis of analytical methods
  - in many cases methods do not exists, or accreditation does not exist
- Future:
  - lower importance of migration testing **(→A)**
  - rules to be made specific to the tiered approach **(→B)**
    - **Tier 1: confirm absence**
    - **Tier 2: the present approach?**
    - **Tier 3: screening**
  - consider novel approaches (e.g. screening / non-targeted approaches)
  - rework migration testing (Annex III + V to R 10/2011) to become generally applicable

Important Disclaimer

- The previous slides describe the ‘aspirations’ of the revision
- These do not necessarily reflect the reality of what will be final legislation
- Some of these aspirations may not be achieved, or be differently achieved
- Discussions with EFSA, Member States and Stakeholders are very important

How will we work?

- Step 1: discussion paper to support work and on which elaboration/ options required
  → based on view of Commission Services
- Step 2: Possible focus/ expert task groups for main pillars (principally A, B, and F)
  - pillar C + D and E subject to separate studies
- Step 3: Such groups to refine and steer the discussion paper
  →add their view and collect information to substantiate support of possible options
- Step 4: Consolidate views in revised discussion paper
- Step 5: Commission to continue impact assessment on basis of that paper
- Step 6: Discussion and assessment on policy options (IA)
- Step 7: Final report (SWD) → basis for Commission proposal

FCM revision timeline

1. Define main policy themes and broad initial solutions — 2022
2. **Refine solutions and define more detailed policy options** — 2023
3. Assess feasibility and impact of policy options — 2024
   will include discussions in experts/stakeholder groups
4. Conclude on preferred policy options — 2025 and beyond
5. Work towards legislative proposal

Current implementation work

Draft amendments to Regulation 10/2011 + GMP

- Change of ‘plastic layer’ concept
- Address biocidal substances (also Decisions on silver substances)
- Major change considered to general requirements on substance (Article 8)
  - all substances to be of high degree of purity – including those originating from chemical recycling
  - genotoxicity to be ruled out for most NIAS – precise rules still under consideration
  - clarification of natural origin – high degree of purity if extracted substance
  - potential significant impact if Article 19 has not been given sufficient consideration
- Substances are additives even if their surface is covalently bound to polymers
- SML and OML to apply multi-material multi-layer materials if plastic food surface

Draft amendments to Regulation 10/2011 + GMP

- Reprocessing of plastics only to be allowed if strict conditions are met
  - subject to new GMP requirements on collection only if by-product under waste legislation
  - no constituents from foods, inks, coatings, adhesives, and lubricants
- Aging condition for plastics intended for plastics intended for repeat use
  - no long-term increase in migration, instructions to users
  - report in supporting documentation under Article 16
- Annex III – new assignment for cheeses
- Annex IV – Declaration of compliance
  - stricter reporting requirements for the presence of NIAS
  - explicit compliance statement if functional barrier is present
  - provisions to indicate recycled content if under Article 1(3) of Regulation (EU) 2022/1616
- Annex V
  - performance criteria for testing – calibration range and standard measurement uncertainty
  - clarified criteria for repeated use

Presently foreseen amendments to GMP Annex

- Section A under review – better control of cross contamination in general?
- Section B
  - ‘quality assessment stages’ in a recycling process
- New section C
  - to set out rules for internal collection of off-cuts and scraps
  - meant to prevent contamination

➢Publication for feedback expected end of year

Prohibition of bisphenol-A ('BPA')

- Commission intends to prohibit intentional use of BPA to manufacture FCMs
  - ban affects all materials in which it is known to be used
  - ban may affect other bisphenols
  - BPA as an impurity/contaminant subject to monitoring requirements – reduction at source
- Transition approach – ban would in practice be applicable after 18 months
- Some products to stay longer, provided the following evidence provided and accepted
  - no immediate alternative, long re-development and certification timeline for replacement
  - low risk (migration controlled in view of expected exposure)
  - another food risk likely to emerge (e.g. hygiene issue) risking security of supply
- Drafting time-line same as for amendment to R 10/2011

Recycled plastics
Implementation of Regulation EU 2022/1616

- Register (Article 24)
  - preparation of the next update to already published lists
  - development of proper system on website
  - many more applications then initially foreseen
- Novel Technology (Article 10)
  - inventory being completed – being hampered by issues with register
- Authorisation Decisions (Article 19)
  - final drafting stages
  - foreseen in 2023

Thank you

Happy to receive questions…