



Regulatory Update: EC 10/2011 and EU 2022/1616, SUP and Reach

Dr. M. Leonor Garcia

Agenda



- Food Contact Materials:
 - Revision FCM legislation
 - BPA restriction
 - (EU) 2022/1616
 - (EU) No 10/2011
 - GMP (EC) 2023/2006
- Pending actions under SUP
- REACH revision

Food Contact Materials



- Revision of the FCM legislation

EC Legislative proposal expected in 2025?

- BPA measure in preparation:

- BPA ban on intentional uses. Monitoring on non-intentional uses. 18 months transition period. Possible derogations.
- 4 weeks consultation close to year end?
- Vote in PAFF in November unlikely. 1Q 2024?

- Regulation (EU) No 2022/1616:

- Recent transition deadlines:
 - ✓ 10th July 2023 – EFSA submission of mechanical recycling processes
 - ✓ 10th October 2023 – Monitoring reports (Novel technology)
- Amendments: First amendment + certification amendment

- Plastics Regulation (EU) 10/2011 amendments:

- 16th & 17th amendment adopted: (EU) 2023/1442 and (EU) 2023/1627
- 18th & 19th amendment in preparation. Will address:
 - styrene, new authorised substances.
 - “Quality amendment” see next slides

Plastics Regulation (EU) 10/2011: “quality” amendment



- Main motivation is alignment with recycling regulation R 2022/1616:
 - Manufacture of substances (in 10/2011) from waste outside the scope of R 2022/1616 – need of purity requirements
 - Reprocessing of plastic (off-cuts and scraps when **considered as by-products** under waste legislation)
 - ❖ GMP requirements (amendment of the Annex to Regulation (EC) 2023/2006)
 - ❖ No constituents from foods, inks, coatings, adhesives and lubricants
 - Declaration of compliance
 - introduction of recycled content; reporting requirements of NIAS, explicit compliance statement if FB
- Revision of plastic layer concept, clarification of statute for certain additives, SML/OML for multi-material multi-layer if plastic is the food surface, aging conditions for repeat use.
- Natural materials:
 - Purity of substances + clarification on the use of authorised natural materials
- Biocidal substances – possibly:
 - Removal of provisional list + derogation for substances authorised under BPR

Plastics Regulation (EU) 10/2011: “quality” amendment



Where is one of the key bottlenecks?

- Purity criteria – NIAS
 - Above 50 ppb (or 90 ppb?) full risk assessment
 - Between 0,15 and 50 ppb limited toxicological assessment - exclusion of genotoxicity is a minimum
 - Below 0,15 ppb no evaluation
- Main issue: the workability of these limits
 - Limit applies to content or migration?
 - Detected substances not always identifiable
 - NIAS not available in quantities for tox testing

SUP directive (EU) 2019/904 - draft implementing decision



Background:

Two pending Implementing decisions laying down:

- A. the methodology for the calculation and verification of the recycled content targets -in PET bottles by 2025 and in SUP beverage bottles by 2030, and
- B. the format in which the Member States are to report these data on recycled content each year.

Status:

Decision to merge the two implementing decisions (A and B) into one addressing both methodology and format.

BUT methodology for the calculation and verification of recycled content to be regulated in two phases:

- **Phase1** intended for the 25% rPET in beverage bottles by 2025.
- **Phase2** intended for the 30% recycled plastic in beverage bottles by 2030. To be adopted by 31 March 2024 at latest.

SUP directive (EU) 2019/904 - draft implementing decision – PHASE 1



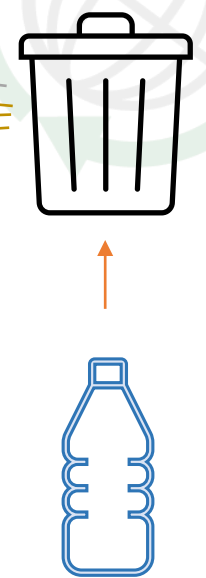
STATUS:

- First draft distributed by EC to Committee members on 27 June 2022
- Second draft submitted for public consultation (02 May 2023 - 30 May 2023)
- “Amended second draft” submitted for vote in June 2023. Sufficient majority was not reached.
- “Third” draft. Vote rescheduled for 17 October 2023.

CONTENT:

- Can only include material that has been post-consumer plastic waste before being recycled.
- Labels and sleeves considered as being part of beverage bottle in addition to caps and lids.
- Takes only recycled plastic into account that is in the scope of Recycled Plastics Regulation (EU) 2022/1616 –
[See next slide](#)
- Different interpretations exist regarding rPET obtained using notified Novel Technologies in scope of (EU) 2022/1616.
- This implementing act is to be amended by 31 March 2024 to include recycled plastic resulting from additional types of recycling as defined in the WFD, appropriate chain of custody, traceability and verification criteria.

A graphic featuring the number '616' in a large, bold, orange font. Below the number is a stylized illustration of a black trash can with a white lid and a handle. To the left of the trash can are three horizontal lines (two yellow, one grey) suggesting motion or a stream of items. In the background, there is a large, faint, light green recycling symbol (a triangle of arrows) and a globe with a grey 'X' over it, indicating a ban on recycling or a specific waste management rule.



Recitals in SUP Implementing Act



(9) Recycled plastic in beverage bottles is either subject to Regulation (EU) 2022/1616, or to Commission Regulation (EU) No 10/20114, depending on the recycling technology by which it is obtained. **Under Regulation (EU) 2022/1616 the only suitable recycling technology that at present can be used to obtain recycled plastic for beverage bottles is mechanical recycling of post-consumer PET waste.** Plastic resulting from chemical recycling technologies that break down the input waste into substances listed in Annex I to Regulation (EU) No 10/2011, and which is subsequently used in the manufacture of new plastic in accordance with that Regulation, cannot be distinguished from virgin material. Therefore, compliance documentation issued in accordance with that Regulation presently does not indicate the amount of recycled content therein. **This Decision takes only into account recycled plastic in beverage bottles that is in the scope of Regulation (EU) 2022/1616.**

(10) In order to take into account also recycled plastic in beverage bottles that has not been obtained by mechanical recycling of PET waste, the Commission plans to draft an amendment of this Decision to include a methodology to calculate, verify and report recycled plastic content in beverage bottles that is based on the application of certain chain of custody models as defined in ISO 22095-2020 (Chain of custody — General terminology and models). In particular, controlled blending, which allows to account also for non-mechanically recycled PET, is a possible chain of custody model. In addition, a mass balance approach may be included as an admissible chain of custody model to also account for plastic in non-PET bottles resulting from feedstock recycling.

REACH REVIEW



Identified issues

- REACH is the most advanced knowledge base globally but there are still gaps in knowledge of many substances.
- The registrants' safety assessments do not take combination effects of chemicals into account.
- The communication in the supply chains is inefficient.
- The evaluation of registration dossiers and substances is too complex and insufficient.
- The authorisation procedure is too heavy and inflexible.
- The current restriction process is too slow to sufficiently protect consumers and professional users against risks from the most hazardous substances.
- The control and enforcement is not equally effective in all Member States.



Envisaged solutions

- Revision of the registration requirements
 - **registration of certain polymers**
 - **information on the environmental footprint.**
- Introduction of a Mixtures Assessment Factor (MAF).
 - **improving the interface with other pieces of legislation** (complementing actions under the one-substance one-assessment action under the Chemicals Strategy)
- Simplifying communication in the supply chains.
- Revision of the provisions for dossier and substance evaluation.
- Reforming the authorisation and the restriction processes including the concept of essential use.
- Revision of provisions for control and enforcement.

REACH Revision - State of Play



- 14 Oct 2020 : Chemicals Strategy for Sustainability announces REACH revision
- 4 May – 1 June 2021: Inception Impact Assessment
- 20 Jan 2022 – 15 April 2022: Open Public Consultation on the REACH revision
- End of 2023?: Commission to present proposal for the REACH revision. Was initially due for end 2022
- 17 October 2023 : REACH is not mentioned on Commission work programme 2024

Back up



GMP



- Section A: Better control of cross contamination
- Section B: Quality assessment stages in a recycling process
- New section C:
 - Rules for internal collection of off-cuts and scraps
 - Meant to prevent contamination



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

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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 than 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

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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



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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
will include discussions in experts/stakeholder groups 2024
4. Conclude on preferred policy options 2025 and beyond
5. Work towards legislative proposal

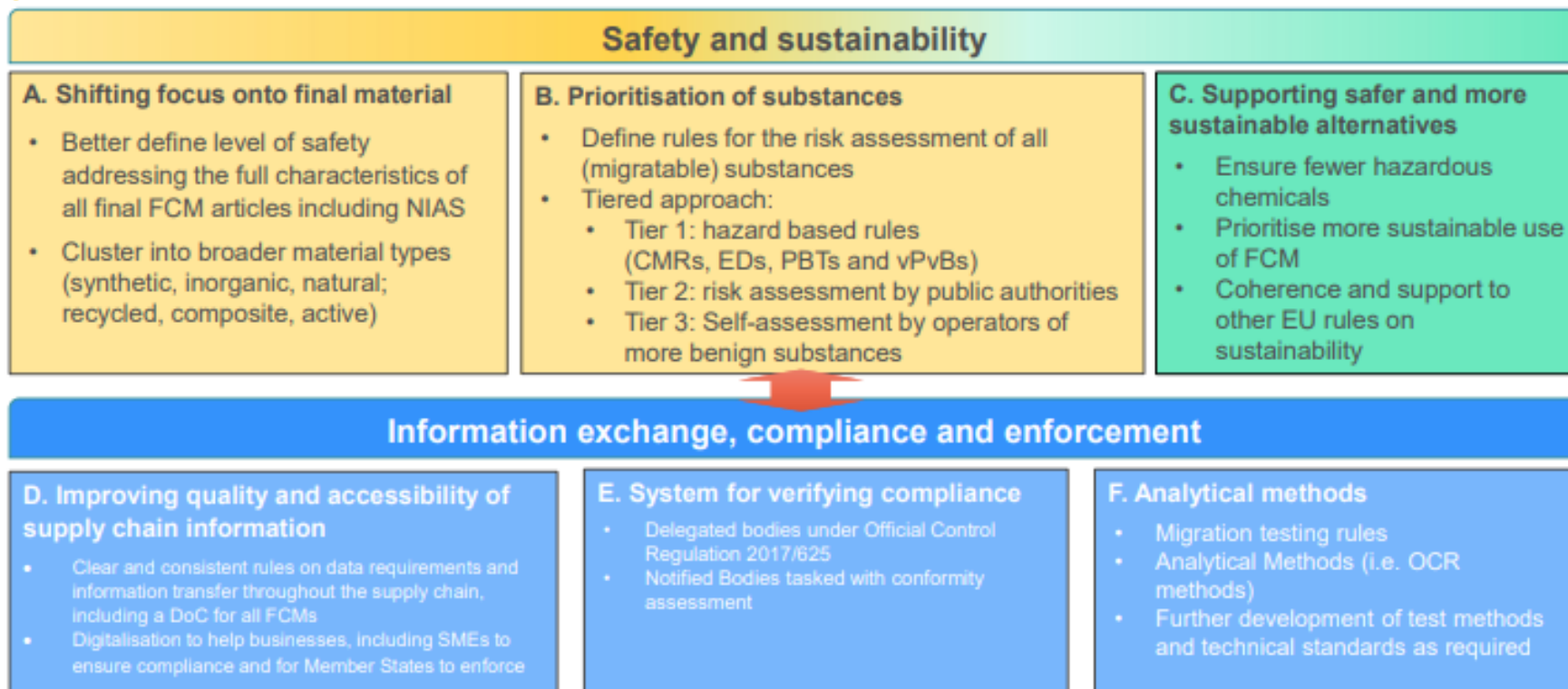


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FCM revision: Main policy themes and pillars



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Completed/Pending actions under SUP directive (EU) 2019/904



- ✓ 1. Implementing act with methodology for the calculation and verification of the annual consumption of SUP beverage cups (&lids) and food containers for immediate consumption for which consumption reduction objectives have been set – Initial deadline following the Directive: 3 Jan 2021 Current status: finalised = **Decision (EU) 2022/162**
- ✓ 2. Implementing act on the format for the reporting of data on consumption reduction targets and measures (art 4) – Initial deadline following the Directive: 3 Jan 2021 Current status: finalised = **Decision (EU) 2022/162**
- ✓ 3. Implementing act with the methodology for the calculation and verification of the collection targets of single-use plastic products for which separate collection targets have been set – Current status: finalised = **Decision (EU) 2021/1752**
- ✓ 4. Implementing act with the format for the reporting of data on beverage bottles with a capacity up to 3 L, including caps and lids, (list F) that have been separately collected in MS each year – Current status: finalised. Is part of **Decision (EU) 2021/1752**
- ✓ 5. Implementing act with specifications for the marking to be affixed on certain single-use plastic products (i.a. beverage cups) – Current status: finalised = **Regulation (EU) 2020/2151**
- ❑ **6. by 1 June 2022: Implementing act with the rules for the calculation and verification of the attainment of the targets on minimum recycled content for single-use plastic beverage bottles**
- ❑ **7. by 1 Jan 2022: Implementing act with the format for the reporting of data on recycled content in beverage bottles to demonstrate attainment of targets**