



**WORKING GROUP
ON FOOD CONTACT MATERIALS**

15 December 2022

DG SANTE
European Commission

Agenda

10:00-13:00

1. Welcome
2. Update on the Revision
3. Regulation (EU) No 10/2011 – discussions on 17th + 18th amendment
4. AoB – please submit points ahead of the meeting
(Bamboo action and Regulation (EU) No 284/2011)

14:00 – 17:00

5. Follow-up and progress on Recycling

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Revision of FCM Legislation

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FCM revision approach

- | | |
|---|-----------------|
| 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 | 2023 |
| 4. Conclude on preferred policy options | 2024 |
| 5. Work towards legislative proposal | 2024 and beyond |

Next slides:

our present thinking under point 1 → starting point further development

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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

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A: shifting focus on final materials

What does this mean?

- **Producers of final FCM to have full knowledge on 'migratables'**
- All 'migratables' to be risk assessed
'migratables': substances that can foreseeably migrate into food under foreseeable conditions of use
- Same for NIAS and IAS
NIAS/IAS: '(non) intentionally added substances' (term originates from R 10/2011)

Drivers

- Safety
- Simplification
- Transparency
- Need to prevent 'surprises'

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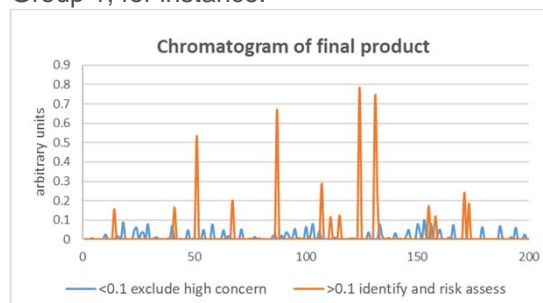
A: specific materials

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

Specific rules for

- Group 1, for instance:



- Group 2: collective positive list
- Group 3: limits on migration of metals
- Group 4-6: special and specific rules

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B: Prioritisation of risk assessment

• Tiered system

- Tier 1: Prohibition of use/presence
- Tier 2: Risk assessment by authorities
- Tier 3: Risk assessment by operators

• Based on generic risk / hazard:

- Tier 1: e.g. CMRs, EDs, PBTs and vPvBs.
- Tier 2: Other substances of concern, e.g. neurotoxins, immunotoxins, substances in nano-form or that migrate in high amounts
- Tier 3: More benign substances

Drivers

- Prioritisation / resources
 - Harmonisation (more materials)
 - Focus on final material (more substances)
- Commission policy on substances of concern
- One Substance One Assessment

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How do FCMs fit into the wider EU sustainability picture?

Green Deal ‘Striving to be the first climate-neutral continent’



Regulation on packaging and packaging waste

Recommendation on bioplastics

Regulation on eco-design for sustainable products

Green claims and empowering consumers



FCM revision is part of Farm to Fork strategy

Food waste reduction targets

Framework for sustainable food systems

Food labelling (FoP, nutrition)



Essential use

Safe and sustainable by design

OSOA and Generic risk assessment

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FCM revision: Main policy themes and pillars

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Information exchange, compliance and enforcement

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C: Sustainable FCM

Extension of scope beyond safety!

- Support for re-use
 - Rules for reusable FCM (packaging)
 - hygiene (cleaning, communication)
 - safety (aging) of materials
 - labelling, traceability, liability
- Information on resource use
 - footprint of a certain FCM (CO₂, water/land-use, ...)
 - from supply chain

Drivers

- General Commission policy
- Environmental legislation → reuse
- Enforcement problems
 - lack of rules makes hard enforcement
- Internal market → common rules

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Background Eco-design for sustainable products

- Umbrella framework (lex generalis)
- Minimum sustainability (environmental) requirements for 1) non-harmonised consumer products 1) where product-legislation insufficiently addresses sustainability
- Requirements set via future delegated acts

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Background 2: Packaging and packaging waste

- Directly applies to contact sensitive consumer packaging = mainly food packaging
- Broad definition of ‘packaging’ i.e. fruit stickers, tableware and cutlery, baking cases and paper, cling film, coffee pods, cups, stirrers, single use condiments
- Main requirements
 1. Recyclability (Art 6) and recycled content (Art 7)
 2. Reuse and refill targets (Art 26), definition of reusable packaging (Art 10), obligations on operators (Art 23 & 25) and reuse/refill systems (Art 24).

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Packaging and packaging waste

- Recyclability: Article 6 requires all packaging to be recyclable (design, separate collection, same application quality, recycled at scale).
- Recycled content: Article 7) sets mandatory minimum recycled content requirements from post consumer waste per unit of packaging (!)
 - E.g. 30% for food contact PET packaging other than bottles
- No suitable technologies for other polymers for food contact (cf. Reg (EU) 2022/1616)
- Drive towards PET
- Heavy reliance on import of waste PET

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Packaging and packaging waste

- Reuse and/or refill targets (Art 26)
 - Take-away drinks – 20% by 2030 and 80% by 2040
 - Take-away food – 10% by 2030 and 40% by 2040
 - Exemption for micro-businesses
- Hygiene legislation covers food hygiene and food business operators
- No specific hygiene rules for FCM and FCM operators
- What about role of consumers?

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Conclusion

Addressing sustainability in FCM in concrete terms

- New objective (no experience – extension of scope)
- Adds to work to ensure safety of sustainable materials
 - Study planned for WP2023
- Measures to enable sustainability targets set by PPWR and possibly Ecodesign and Sustainable Food Systems
 - Material consequences and response – e.g. recycling of paper and board
 - Food supply chain consequences and response – e.g. hygiene rules (GMP)
- Going beyond – setting FCM eco-design requirements, reduction targets, best practices/restrictions to facilitate recycling/reuse

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D + E: Information and enforcement

- To cover entire value chain
 - Digital Compliance and supporting documentation
 - Digital repositories of risk assessment
 - Use of notified bodies for verification of compliance (process/product) and handling of proprietary information
- Automatic enforcement by means of obligatory information
- QR code on packaging for easy access
 - including for consumers

Drivers

- Needs of objectives A-C (previous slides)
- One Substance One Assessment
- Increase enforcement (without increasing resources)
- Transparency

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Studies

- Commission to focus on the main regulatory issues
 - materials, tiered system, analytical methods, verification of compliance
 - specific study on analytical methods
- Other studies
 - Study on IT architecture and enforcement – contractor – EY – kicked-off last week
 - Study on consumer perceptions – final phase
 - Study on sustainable FCM – to be defined – planned middle 2023

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Ongoing study work for revision of EU FCM rules

- **Study** with EY to support objectives (A), D and E launched
 - Overall objective of the study is to develop options for a digital information system that facilitates information transfer in the supply chain, enforcement, and transparency
 - Assess the impacts of such options
 1. Centralised system e.g. managed by EU institution
 2. Decentralised system e.g. managed by (a) Member States and/ or supporting bodies (b) industry
 - Focus on the need for final producers to be accountable for all migrating substances and for information to be generated and available on these substances and an appropriate risk assessment throughout the FCM production chain
 - Consultation with wide range of stakeholders necessary including Member States
 - Will include written questionnaire, online survey, targeted interviews, stakeholder workshop
 - For completion end 2023

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Ongoing study work for revision of EU FCM rules

- **Citizen focus groups study. Objectives:**
 1. Gain understanding of the habits and behaviours of consumers with regards to FCM, particularly on the topics of safety, hygiene and sustainability;
 2. Obtain in depth understanding of the needs and preferences of consumers with regards to FCM; particularly on the topics of safety, hygiene and sustainability;
 3. Understand the information needs with regards to FCM: the type of information that is needed, the way it should be communicated
 - Practical exercises completed in 8 Member States
 - Draft final report due shortly; presentation of results early next year
- **Public Consultation (14 weeks duration): ends 11 January 2023**
 - Results to be analysed with further consultation activities to build on responses received

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on-going open public consultation

- Until 11 January 2023!
- https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12497-Revision-of-EU-rules-on-food-contact-materials/public-consultation_en
- Participation per 11 December 270 valid contributions:

By category of respondent



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represent a final position and does not



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17th Amendment to Regulation (EU) No 10/2011 on plastic FCM

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purpose of this discussion

- Presently foreseen time-line
 - still this year: initial consultation over **certain specific provisions** (DL mid January)
 - January: Internal consultation in the Commission
 - Feedback consultation with stakeholders (earliest mid February)
 - Discussion next WG (mid February)
 - Vote in April
- To note: priority on recycling (authorisation decisions / register)
- ‘Certain specific provisions’ → initial discussion today

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Background 17th amendment

- Main motivation alignment with recycling regulation
 - Manufacture of substances from waste (Article 1(3) R 2022/1616, ‘chemical recycling’)
 - (revision of ‘layer approach’) + SML for plastic inner layers under Article 14
 - reprocessing of plastic (off-cuts and scraps)
 - GMP requirements (amendment of Annex to Regulation No (EU) 2023/2006)
 - DoC – introduction of recycled content
- Natural materials
 - purity of substances + use of authorised natural materials
- Biocidal substances – possibly
 - removal provisional list + derogation for substances authorised under BPR

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Alignment with Recycling

- Link between the two Regulations on plastic and recycled plastic
- Article 4 of Regulation to say
 - *'f. comply with Regulation (EU) 2022/1616 on recycled plastic materials and articles if they are in the scope of that Regulation'*
 - Still subject to internal discussions in Commission
- note that R 2022/1616 requires partial compliance with R 10/2011
 - Compliance documentation in accordance with R 2022/1616

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Layer issue

- main alignment may cause problem with 'layer' approach under R 10/2011
 - at present we consider this likely not problematic for alignment with recycling, should we still change it?
- E.g. Article 5 says:
 - *Only the substances included in the Union list of authorised substances [...] set out in Annex I may be intentionally used in the manufacture of plastic layers in plastic materials and articles.*
 - Also Article 6 and 8 refer to layers in this way
 - the Regulation doesn't say that layers need to be flat
- Why? Because R 10/2011 includes plastics that are printed or coated
 - to apply the OML and SML to printed or coated plastics, but not the other compositional requirements
- Alternative approach is to remove references to 'plastic layers' in Article 5, 6, 8
 - and include a derogation for substances in printing inks and coatings in Article 6
 - *'substances other than those included in the Union list may be used in the manufacture of coatings and printing inks applied on plastic materials and articles subject to other applicable specific measures and national law,*

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Article 8 - purity

Article 8

General requirement on substances

Substances used in the manufacture of plastic layers in plastic materials and articles shall be of a technical quality and a purity suitable for the intended and foreseeable use of the materials or articles. The composition shall be known to the manufacturer of the substance and made available to the competent authorities on request.

- We consider the purity requirement requires strengthening
- Article 1(3) of R 2022/1616 states:
 - This Regulation shall not apply to the use of waste to manufacture substances included in the Union list of authorised substances in accordance with Article 5 of Regulation (EU) No 10/2011 [...], when intended for subsequent use **in accordance with that Regulation**
- Recyclers need legal certainty: 'novel technology' or Article 1(3)?
 - main issue is level of contaminants – when is the 'purity suitable'?

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Ensuring the safety of plastic FCMs - impurities

- Only authorised substances may be used to manufacture plastics
 - EFSA assesses all starting substances (monomers) and additives (+ related impurities)
 - they are authorised subject to restrictions (e.g. permitted use, limits,...)
 - impurities are permitted without authorisation ('NIAS'), but subject to risk assessment
- What about those 'permitted' impurities?
 - originating from the manufacturing process
 - individual impurities must be risk assessed
→ they **must be identifiable**
 - contaminants (from waste) ≠ impurities (from manufacture)!

Article 19
Assessment of substances not included in the Union list
Compliance with Article 3 of Regulation (EC) No 1935/2004 of substances referred to in Articles 6(1), 6(2), 6(4), 6(5) and 14(2) of this Regulation which are not covered by an inclusion in Annex I to this Regulation shall be assessed in accordance with internationally recognised scientific principles on risk assessment.

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Update of Article 8; purity

Reasons

- ‘**chemical recycling**’ (quantifiable maximum contaminant level)
- natural substances
- NIAS (when to apply Article 19?)

• New structure of Article 8

1. substance to correspond to its identification and specification in table 1 of Annex I
2. shall be of a technical quality and suitable for the intended and foreseeable use of the materials or articles, and **shall be of a high degree of purity**
3. Substances recovered from waste in accordance with Directive 2008/98/EC may only be used in the manufacture of plastic materials and articles in accordance with Article 1(3) of Regulation (EU) No 2022/1616, **and shall be of high degree of purity.**

• So, what is a high degree of purity?

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Updated purity requirement; core provision

Article 8 General requirement on substances

Substances used in the manufacture of plastic layers in plastic materials and articles shall be of a technical quality and a purity suitable for the intended and foreseeable use of the materials or articles. The composition shall be known to the manufacturer of the substance and made available to the competent authorities on request.

- the **draft wording** of the core provision is to help you to start your thinking
- What are your views?
- What should A and B be?
- What is reasonable?
- this approach is also relevant for the revision

4. For the purpose of paragraph 2 and 3 a high degree of purity shall mean that any substance used in the manufacture of plastic materials and articles in accordance with Article 5 or 6 contains only impurities that individually either:
 - (i) are in accordance with specifications or restrictions specified in the authorisation of the substance in table 1 of Annex I, if any; or,
 - (ii) have been subject to an individual risk assessment in accordance with Article 19; or,
 - (iii) have been subject to a **limited toxicological assessment that at least rules out genotoxicity**, and are present at a level that cannot give rise to an individual migration from the final plastic material or Article exceeding **A** mg/kg food, assuming their full migrating into the food; or,
 - (iv) **are unknown or unassessed, such as contaminants from waste**, but are present at a level that cannot give rise to an individual migration from the final plastic material or Article exceeding **B** mg/kg food, assuming their full migration into to the food.

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Clarification of Natural substances also in Art. 8

- Article 8(1) to include the following:
 - substance to correspond to its identification and specification in table 1 of Annex I
 - In case the substance originates from a material that has been obtained from natural sources, including from food sources, and it is identified by a chemical name, the substance identified by that name shall be of a high degree of purity.
 - lignocellulose ≠ random plant material that happens to have a high lignocellulose content
 - However, where the substance name includes the name of the natural material, that material may be used as obtained from nature provided it has been separated from other natural matter not identified by the substance name. In this case, it may contain all substances that are naturally present in the natural matter identified by the name of the substance.
 - cotton fibres (FCM 24) do not need to be purified to contain only one substance, but cannot contain other parts of the cotton plant

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Can particles be starting substances?

- Certain filler materials are covalently bound to the polymer chains
 - Glass fibres using Glymo, organic materials may be bound in a similar way
 - does that chemical link make them starting substances?
 - No, they remain additives, bulk (most of the polymers contained in them) do not react
- We will consider to add to Article 9 the following:

‘3. Substances meeting the definition of ‘additive’ which are in the form of solid particles or fibres of which only the surface is covalently bound to the polymers contained in the plastic shall be considered additives.’

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Reprocessing of plastics – off-cuts and scraps

- Rules on the composition
 - next slide
 - discussed before
- Rules on handling
 - new section in Annex to Regulation (EC) No 2023/2006
 - draft initial wording on left

- ‘C. Reprocessing of plastics in the scope of Regulation (EU) No 10/2011
1. Plastic offcuts, scraps, and similar by-products of plastic manufacturing processes and intended to be reprocessed in accordance with Article 10(1) of Regulation (EU) No 10/2011 (‘materials intended for reprocessing’) shall be collected as close to their point of first production, i.e. the point where they are cut or scrapped, as technically achievable.
 2. Materials intended for reprocessing shall be collected in clean bins, bags, or other containers designated to this purpose and which can easily be recognised as being intended only for this purpose. Those containers shall be closed as soon as they are fully filled with a lid or closure that prevents mixing with plastic of another composition, other materials, or with waste materials until they are inserted for reprocessing back into the plastic production process.
 3. Such bins, bags or containers may be transferred to reprocessing individually or be grouped in secondary packaging. The resulting unit shall be considered as a batch of material intended for reprocessing. The definition of ‘batch’ as defined in Article 2(20) of Regulation (EU) 2022/1616 shall apply.
 4. At any stage of production or reprocessing operations until the actual return to the plastic production process, operators shall ensure that the quality assurance system prevents that materials intended for reprocessing are mixed with batches of plastic of another composition, other materials,

(20) ‘batch’ means a quantity of material of the same quality, and produced using uniform production parameters at a certain manufacturing stage, stored and contained to exclude mixing with other materials, or contamination, and designated as such by a single production number.

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Reprocessing

- Rules to ensuring the plastic still meets Regulation 10/2011
- concerns ‘off-cuts’ and ‘scraps’
 - that are not waste
 - but by-products
- previously consulted with industry
 - IND not happy with point (d)

‘Article 10 general restrictions on the composition of plastic materials and articles

1. Plastic materials and articles may contain reprocessed plastic, if the reprocessed plastic meets the following conditions:
 - (a) it is collected in accordance with point C of the Annex to Regulation (EC) No 2023/2006;
 - (b) it originates only from off-cuts and scraps from plastic materials and articles referred to in Article 2(1)(a) that meet the compositional requirements set out in chapter II of this Regulation, and which are considered to be a by-product in accordance with Article 5 of Directive 2008/98/EC;
 - (c) it does not contain substances in an amount which could:
 - (i) exceed migration limits applicable to the plastic materials and articles to which the reprocessed plastic is added; or,
 - (ii) cause any other non-compliance of those plastic materials and articles with Article 3 of Regulation (EC) No 1935/2004;
 - (d) it does not contain residues of:
 - (i) food;
 - (ii) printing, coating, or adhesives;
 - (iii) substances used for processing the plastic from which the offcuts and scraps originate, such as lubricants or cutting fluids;

unless for all substances contained those residues compliance with the conditions referred to in point (d) is demonstrated on the basis of an assessment in accordance with Article 19;

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Clarification of stability rule

- Point 2.1.6 of Annex V
- Discussion on-going with EURL
- Choice between descriptive text or hard rules
- We tend towards hard rules – no possibility for interpretation – for instance:
 - Validation range of method: 0.2 SML – 2 SML, LOD > 0.05 SML
 - If $m_1 < m_2$ or $m_2 < m_3$ or $m_1 < m_3$ for all $m > 0.2$ SML
 - IF $(m_j - m_i) / [u(m_j) + u(m_i)] > 1.64$ THEN $m_j > m_i$
 - IF $(m_i - \text{SML}) / u(m_i) > 1.64$ THEN $m_i > \text{SML}$
- Alternative is to maintain but clarify present descriptive wording (next slide)

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Clarification of stability rule

similar approach for OML 3.3.2

2.1.6. Repeated use materials and articles

If the material or article is intended to come into repeated contact with foods, the migration tests shall be carried out three times on a single sample using another portion of food simulant on each occasion.

Compliance of the material or article shall be verified on the basis of the level of the migration found in the third test and on the basis of the stability of the material or article. The stability of the material shall be considered sufficient if the specific migration in the second test shall not exceed the level observed in the first test, and the specific migration in the third test shall not exceed the level observed in the second test and taking the measurement uncertainty into consideration. In case of insufficient stability, compliance of the material shall not be established even when the specific migration limit is not exceeded in any of the three tests. All migration levels above or equal to 20 % SML shall be reported with their associated expanded measurement uncertainty. When migration results below 20 % SML are observed they shall be reported as 20 % SML with the corresponding expanded measurement uncertainty.

However, if there is conclusive scientific proof that the material is stable and if the specific migration limits are not exceeded in the first test, no further migration test is necessary.

Irrespective of the above rules, a material or article shall never be considered to comply with this Regulation if **in the first test** a substance that is prohibited from migrating or from being released in detectable quantities under Article 11(4) is detected in any of the migrations.

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Clarification of stability rule

- On-going discussion internally – wording likely to change
- Decision on
 - whether to use descriptive approach
 - or hard decisions how rules will affect migration testing in general
- It will also affect how your laboratories in general verify compliance
- We will consult you separately

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Changes to DoC

- new point 10 – indication that material is intended for reprocessing
- new point 11 – indication of recycled content
 - substance manufactured in accordance with Article 1(3) of R 2022/1616 being used
 - expressed as weight / weight
 - Why?
 - Safety – it should be possible to know these substances are used
 - Environment – administrative reasons to count recycled content

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Other matters

- Introduction of verification of compliance under Article 14
- Certain matters that have been discussed under the 16th amendment
 - Labelling of conditions of use
 - Assignments of testing conditions for cheeses
- Change to Annex to Regulation (EC) No 2023/2006
 - introduction of quality assessment stages in support of recycling
 - new point 3 in section B

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17th amendment planning

- Drafting expected to be finished mid-January
 - texts are already advanced,
 - some questions over risk management → discussion with Member States
 - needed for certainty over alignment with recycling regulation
- Feedback period in February
 - public feedback from the general public (but mostly associations and operators)
- Likely voted in Q2 2023 – publication in Q3
- You will be consulted on the purity requirement

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18th Amendment to Regulation (EU) No 10/2011 on plastic FCM

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18th amendment

- ❖ Precautionary measure that lays down a limit for styrene. (long period 36months)
- ❖ ~~TiO₂~~ (further study)
- ❖ Authorisation of one new substance

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18th amendment

Precautionary measure that lays down a limit for styrene

- EFSA could not exclude the potential genotoxicity of styrene
- Results from the survey : possible of migration at range ...
- **Guidance value of 20 ppb determined by the WHO for drinking water** on the basis of a TDI and a 10% allocation factor (exposure from food is half of that from drinking water).
 - **precautionary limit of 40ppb should be achievable in many materials.**
- Better quality control and production practices, in order to lower the residual monomer concentration
- Testing in the food, or estimated from the residual concentration of styrene monomer in the plastic, assuming 100% migration.

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18th amendment

Precautionary measure that lays down a limit for styrene

Transition period : A relatively long transition period before this limit is applied will be foreseen.

36 months : to allow the industry to improve practices,

After 9 months (out of 36 months in total): producers must notify the residual styrene content to the producers of the final FCM made with styrene, to facilitate the quality improvements.

EFSA Mandate : Safety assessment on the basis of the information already available and the new data provided by the industry.

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18th amendment

Authorisation of one new substance

- Substance bis(2-ethylhexyl)cyclohexane-1,4-dicarboxylate (DEHCH, FCM No 1079)
- Additive (plasticiser) in poly(vinyl chloride) (PVC) at up to 25% w/w in contact with aqueous, acidic and low-alcohol foods for long-term storage at room temperature or below (refrigerated and frozen).
- Uncertainty on the potential for accumulation of the substance in human, consequently, the migration of the substance should not exceed 0.050 mg/kg food

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AoB

- Bamboo
- Kitchenware

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kitchenware

- Interpretation send around last week
- under Regulation (EC) No 284/2008 kitchenware includes tableware
- are there any specific issues?

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recycling

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Topics

- Overview of activities – timeline
- Feedback from you – experiences thus far, needs
- Detailed discussion on register
 - validation of information

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Time-line mechanical PET

- At least 30 working days prior to the start on an installation it shall be notified
 - Article 25 (1)(a)
 - Entry into force: start-date is 10 December – notification by beginning of November
- Within one month from the start date – 10 January – CMSS to be submitted
 - recycler to submit only to competent authority
 - competent authority to notify the Commission without delay
 - if the competent authority does not inform the Commission within 1 year the CMSS is agreed, installation suspended
- from 10 July no more mechanical recycled PET without ongoing application

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Novel technologies

- plastic obtained without suitable technology may be placed on market until 10 July
- installations to notify by 30 working days before 10 June under Article 25
 - Article 31(4)
- Article 31(4) + Article 10(2):
 - 6 months prior to 10 June (i.e. last weekend) developers to notify novel technology
 - however information under Article 10(3) and 10(4) only by 10 April
 - the competent authority has 5 months from the reception of the information under Article 10(3) for its tasks under Article 10(8)

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our present activities

- Preparing authorisation Decisions – to be ready in Q1
- Union register
 - many notifications received – we are processing
 - delayed – data not of sufficient quality yet to publish the register
- Delay is problematic
 - numbers needed for compliance documentation
 - novel technologies cannot really notify at the moment
- We will explain the work we are doing after a more general discussion on your experiences so far

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Round table on your experiences

- Please explain:
 - How many notifications did you receive?
 - Are they of a good quality?
 - What are your experiences with enforcement?
 - Do you experience particular difficulties?
 - Did you observe specific problems in the interpretation of Regulation (EU) 2022/1616?

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Register and Registration

- The **Register and Registration** section could be found on this webpage (Commission website, basis Article 24) : https://food.ec.europa.eu/safety/chemical-safety/food-contact-materials/plastic-recycling/resources-plastic-recyclers_en
- **Forms (word) available** since 04th of October
- **Forms upgraded in EU Survey** online forms since 27th of October
- **Almost 700 forms received from recyclers** in order to register:
 - Installations
 - Facilities
 - Companies
 - and Schemes


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The Register: Forms received from EU Recyclers

Member States	Recycling installation	Recycling facility	Company name	Scheme
Austria	12	9	10	1
Belgium	7	3	3	3
Bulgaria	3	2	2	1
Croatia	1	1	1	
Czech Republic	2	1	1	
Denmark	0	0	0	1
Estonia	1	1	1	
France	18	6	7	4
Germany	34	17	13	3
Greece	1	1	1	
Ireland	1	1	1	2
Italy	53	39	35	8
Latvia	2	1	2	
Luxembourg	3	1	1	1
Netherlands	8	5	4	
Poland	10	7	7	
Portugal	10	4	4	2
Romania	4	4	4	
Spain	38	21	22	7
Miscellaneous	17	28	19	
Grand Total	225	152	138	33

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The Register: Forms received from non- EU Recyclers

Non-EU Countries	Name of recycling installation	Name of recycling facility	Company name	Scheme
Australia	2	2	2	
Bangladesh	2	2	2	
Egypt	2	1	1	
Equator	3	1	1	
Indonesia	5	5	5	
Japan	2	2	2	
Malaysia	1	1	1	
Maroque				1
Mexico	2	1		1
Northern Ireland	1	1	1	
Norway	1	1	1	
Oman				1
South Korea				1
Thailand	1	1	1	
Turkey	1	1	1	
United Kingdom	25	11	12	2
United States of America	1	1	1	
Grand Total	49	31	31	6

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Placing on the market of recycled plastic and recycled plastic materials and articles

Article 4

Requirements for recycled plastic materials and articles

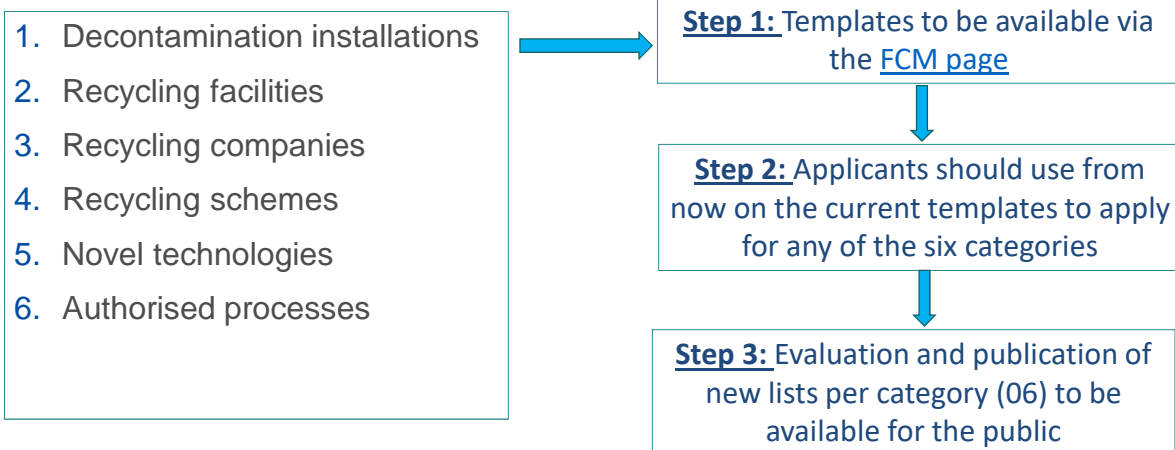
6. **The Union register** established in Article 24 includes the following information regarding the manufacture of the recycled plastic:

- (a) the **decontamination installation** where the recycled plastic was manufactured, the address of the **recycling facility**, and the identity of the **recycler operating it**;
- (b) the applied authorised recycling process, if the applied suitable recycling technology requires the **authorisation of recycling processes**;
- (c) the name of the **recycling scheme** used, the identity of the entity managing it, and the applied markings, if the applied recycling technology requires the use of a recycling scheme;
- (d) the name of the **novel technology**, if the manufacture of the recycled plastic uses a novel recycling technology.

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The Union register to be established (Article 24) will include the following information regarding the manufacture of the recycled plastic:



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Registration of installations

- recyclers to register 30 working days prior to start date of installation
 - note: for existing installations this is about **3 weeks** after entry into force
 - notify the installation and address and other information to CA and Commission
- Commission to update Register – status ‘newly registered’
- Establish compliance monitoring summary sheet to CA
 - recycler needs to have this at the start date of the installation
 - and submit it within one month from start date (wording in Article 25(1)(c) and 26(2))
- Competent authority to verify correctness
 - notify the reception of the CMSS to Commission upon submission; status to become ‘being established’
 - verify the information and perform ‘a control’ (i.e. audit) in accordance with Article 27
 - inform the Commission that compliance is established within one year
 - status to become ‘active’ (or ‘suspended’)
- It is important that recyclers know to which CA they shall notify
 - Use list on our website? Are they to register more locally?
- SANTE-FCM-RECYCLING-REGISTER@ec.europa.eu

Commission stimulates quick registration, open from next week

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The Register: https://food.ec.europa.eu/safety/chemical-safety/food-contact-materials/plastic-recycling/resources-plastic-recyclers_en

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- Introduction**
- Register and Registration
- Templates for Annex II and III
- Member State specific information and language versions of templates
- Correction to Regulation (EU) 2022/1616
- Other resources
- Contacts

Register and Registration

From the entry into force of the Regulation (expected first week of October) this section will hold the Register established under Article 24.

Several provisions require registration, particularly of **recycling installations**, of the recycling facilities where these installations are located, of recycling companies, of recycling schemes and of novel recycling technologies. Recyclers are strongly encouraged to register recycling installations and recycling schemes without delay. **Registration numbers are required in compliance documentation from entry into force.**

How to register:

Please complete the following online forms as appropriate:

- [Recycling installations, complete the online form](#)
This will result in a Recycling Installation Number ('RIN'), [you could find attached an example of a complete form for recycling installations](#) (EN) (+)
- [Recycling facilities, complete the online form](#)
This will result in a Recycling Facility Number ('RFN')
You send this form when you register the first recycling installation. In case multiple recycling installations are located at that facility please send the form only once, but ensure that it is clear that all installations are located at this facility. [You could find attached an example of a complete form for recycling facilities](#) (EN) (+)
- [Recyclers, complete the online form](#)
This will result in a Recycling operator number ('RON')
In case you are registering multiple recycling installations or facilities operated by the same recycling company, please coordinate the registration thereof internally in the recycling company and send the form only once. [You could find attached an example of a complete form for recycling companies](#) (EN) (+)
- [Recycling Scheme Managers, complete the online form](#)
Please also include the above form for obtaining a Recycling operator number (Please note that recyclers participating in the scheme should register their recycling installation independently register using the forms provided above. Where the manager of the scheme is also the recycler, they need to both register the scheme, the installation, facility and the

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and does not represent, non law.



The Register: Eu Survey – Form 1

EU Survey
 Save a backup on your local computer (disable if you are using a public/shared computer)

1. Registration form for decontamination installation

Anonymous mode
The anonymous option has been activated. As a result, your contribution to this survey will be anonymous as the system will not save any personal data such as your IP address.

1. Name of recycling installation*
2. Recycling Facility Number (RFN)
(upon first registration of any installation on a facility, the Commission did not yet assign a Recycling Facility Number (RFN), please include form 2 to register also the facility)
3. Recycling Operator Number
(upon first registration of any installation operated by a recycling company, the Commission did not yet assign a RON, please include form 3 to register also the operator)
4. Indicate whether this is the first registration of this installation or an update (if an update, RFN, RON and the recycling installation number (RIN) must be provided)
5. If known and applicable, please add the EFSA Question number related to the EFSA opinion applicable to the applied process and the RECYCXXXX Number
6. Name and contact information of person responsible person for the installation (and in charge of providing the information in this form)

Views
Standard ⌵

Language
English ⌵

Contact
Contact Form

Save as

Report Abuse

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Placing on the market of recycled plastic and recycled plastic materials and articles

Article 4

Requirements for recycled plastic materials and articles

note, if no authorised process is applied because not yet authorised, it won't be in the register

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Authorisation of recycling process

- COM invited the applicants (from 2008 and on) with a valid dossier (EFSA opinion & RECYC Number) to revise their personal data
- Batch 1: Out of the 237 applicants, 178 have replied and revised their personal data
- Under evaluation of the Authorisations Decisions and MSs will be informed about the process to be followed soon
- SANTE-FCM-RECYCLING-REGISTER@ec.europa.eu

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Recycling Schemes

- 15 days prior to the start of the scheme its manager must inform us
 - for the purpose of the registration of the scheme in the register
 - considered very light, no further delay
- Registration of recycling process as for PET, but no CMSS
 - but these processes, even if they do little, must register!
- Enforcement to focus at food business operators
 - If FBO uses packaging with label, they should be following the rules of the scheme
 - enforcement at the scheme manager/recyclers is of course possible

Article 9

Requirements for the operation of recycling schemes

1. A single legal entity shall act as the manager of a recycling scheme, and shall be responsible for the overall functioning of the recycling scheme.
At least 15 working days prior to the start of the operation of a recycling scheme the manager of the recycling scheme shall inform the competent authority in the territory where it is established and the Commission for the purpose of its registration in the Union register established in accordance with Article 24.
The manager shall provide its name, address, contact persons, the name of the scheme, a summary of the scheme not exceeding 300 words, the marking referred to in paragraph 5, a list of Member States where business operators participating in the schemes are located, and references to any decontamination installations used by the scheme. Thereafter, the manager shall ensure this information is kept up to date.
2. A compliance monitoring summary sheet shall not be established, and Article 25(1)(c), and Article 26 shall not apply when recyclers notify the production of recycled plastic as part of a recycling scheme, unless column 8 of Table 1 of Annex I requires to establish it. In case Article 25(1)(c), and Article 26 do not apply, the registration status in accordance with paragraph 2, point (g) of Article 24, as referred to in Article 25(2), shall be 'active'.
3. The manager of the recycling scheme shall provide a single document to all participating business operators and other participating organisations. This document shall set out the objectives of the scheme, explain how it functions, provide instructions, and set out the detailed obligations it places on the participants. The explanation shall include a description of the recycling operations.
4. Recycling schemes shall be set up in accordance with the specific requirements applicable to the applied suitable recycling technology as laid down in table 1 in

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Novel Technology (in general)

- 6 months before the start of the operation developer to notify competent authority (Article 10(2))
 - to include the information referred to in Article 10(3)
- Competent Authority to check compliance with requirements in Article 10 within 5 months
 - See Article 10(8) (which has an annoying mistake)
 - CA may delay the start of the first recycling installation
 - CA shall inform the Commission of serious concerns
- Transition for **existing** technologies:
 - time-limit in Article 10(2) applies (6 months before the start of the operation)
 - but, 6 months after entry into force developer to comply with Article 10(3) and 10(4)
 - the start of the operation is 8 months after entry into force
 - i.e. to developer to notify novel technology before 8-6=2 months after entry into force (but additional 4 months for Article 10(3) and (4))
 - **recyclers** to notify **installations** 8 months – 30 working days= about 6.5 months
 - 5 months after CA received info under 10(3) to check compliance (i.e. 11 months after entry into force)
 - start of installations cannot be delayed (they are on the market already)

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Register and Registration

- Next steps in the Register:
 - **EU Survey: All forms under one in 2023**
 - Novel Technology form to be available in the next few days
- Cooperation with the **MSs Authorities in order to double check** and evaluate the Forms received so far per MSs

- [SANTE-FCM-RECYCLING-REGISTER](#)

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Thank you

Happy to receive questions...

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