



European Commission SANTE activities

EFSA FCM NETWORK 8th meeting

22 – 24 November 2022

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European Commission**

Contents

- Current EU legislation
- New legislation on plastic recycling
- Update on present and future amendments to Commission Regulation (EU) No 10/2011
- Other issues

EU legislation on FCMs



- **'Framework' Regulation (EC) No 1935/2004**

1. Ensure a high level of protection of human health and the interests of consumers
2. Ensure the effective functioning of the internal market

- Applicable to all FCMs: already in contact with food (e.g. packaging), intended to be in contact (kitchenware, food processing equipment) or likely to transfer constituents
- General rules and procedures for FCMs including safety and role of EFSA, definitions, labelling, traceability, inspection and control

- Basis for specific measures e.g.

- Regulation (EU) No 10/2011 on plastic FCM authorising substances with restrictions e.g. SMLs
- Regulation (EU) 2022/1616 on recycling of plastic

- Good Manufacturing Practice (GMP) required for all FCMs

- Quality assurance system, quality control system, documentation (Commission Regulation 2023/2006)

EU legislation on FCMs

Regulation (EC) No 1935/2004 (objectives: human health and functioning of EU market)
Basic rules on safety, labelling, traceability, inspection and control, authorisation process



Guidance
on plastic FCM &
documentation

Regulation (EC) No 2023/2006
on good manufacturing practices

**Regulation (EC)
No 10/2011**
on plastic FCM

**Regulation (EC)
No 2022/1616**
on plastic recycling

**Regulation (EC)
No 450/2009**
on AIM

**Directive
84/500/EEC**
on ceramics

**Directive
2007/42/EC**
on RCF

**Regulation
284/2011**
on plastic
kitchenware

**Directive
93/11/EEC**
on nitrosamines

**Regulation (EC)
No 1885/2005**
on epoxy derivatives

**Regulation (EU)
No 2018/213**
on bisphenol A

**Directive
78/142/EEC**
on VCM

Regulation (EU) 2022/1616 on recycled plastic FCMs

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New Recycling Regulation

20.9.2022

EN

Official Journal of the European Union

L 243/3

COMMISSION REGULATION (EU) 2022/1616

of 15 September 2022

on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008

(Text with EEA relevance)

- The new Regulation entered into force on 10 October 2022
- See <http://data.europa.eu/eli/reg/2022/1616/oj>
- This presentation tries to explain it in 8 slides – the Regulation is more complex

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1: scope and purpose

- The new Regulation replaces Regulation (EC) No 282/2008
 - Regulation (EC) No 282/2008 is the present Regulation, **it ceases to exist**
 - the new Regulation sets out transitional provisions
- The new Regulation requires that:
 - **All** recycled plastic **content...**
 - in materials and articles that **foreseeably** come in contact with food...
 - is manufactured with a **suitable recycling technology!**
- There are two exceptions:
 - manufacture of **pure** substances listed in Annex I to Regulation (EU) No 10/2011
 - manufacture of recycled content **with a novel technology**

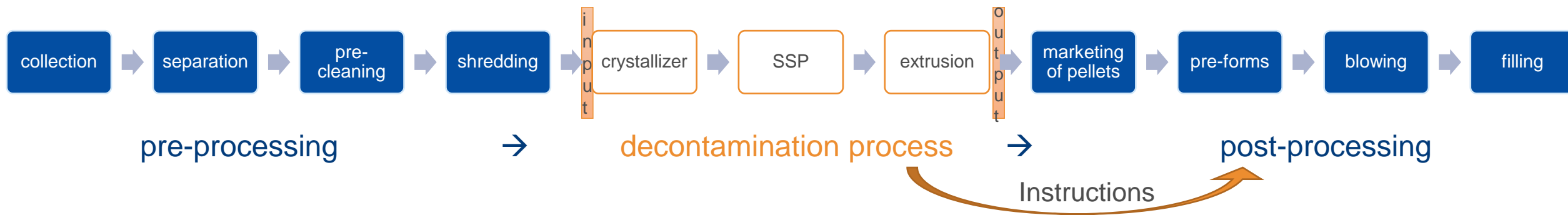
2: Technology – Process – Installation

- Recycling **Technology**
 - generic concepts, principles and practices to recycle a defined input into a defined output
- Recycling **Process**
 - specific sequential operations using a recycling technology
- Recycling **Installation** (applying a recycling process)

- Three associated procedures to establish safety
 - ‘establish’ suitable recycling technologies (EFSA + COM)
 - ‘authorise’ recycling processes (EFSA + COM)
 - ‘control’ recycling installations (audits) MS Competent Authorities

3: Focus on decontamination

- Under New Regulation a recycling process has **always three parts**
 - pre-processing → decontamination → post-processing
 - subject to specific rules
- The **required amount of decontamination** depends on pre- and post-processing
 - residual contamination in final plastic material sufficiently low so that no harm can occur
- **Decontamination is relevant for all recycling technologies**
 - not only for mechanical PET recycling (example below)



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4: Suitable technologies

- Two suitable technologies:
 - Mechanical PET Recycling → requires authorisation of individual processes
 - restrictions in Article 6-8, Annex I, Authorisations, use of CMSS
 - Recycling from a closed and controlled loop → requires recycling schemes
 - restrictions in Article 9 and Annex I – note level of detail in Annex I
 - plastic not to be used outside the premises of food business operators (e.g. at home)
- All other technologies
 - need to be used in accordance with Chapter IV ('novel technologies')
 - Article 32 on functional barriers requires organisation of applicants and special tes

5: Establishment of suitable technologies

- Suitable technologies are established on basis of novel technologies
 1. **publication of safety report** showing the technology results in safe plastic
 2. placing on the market and **monitoring of contaminants** (publication of reports)
 3. **EFSA evaluation** (this will be very strict → take note under 1. and 2.)
 4. if favourable, **technology established** in Annex I to the Regulation (for anyone to use)
- Any technology is defined by input, decontamination principles, use of output
 - if technology so requires
 - individual recycling processes shall be authorised and/or
 - use recycling schemes (Article 9)

6: Authorisation of Processes

- For now, only mechanical PET processes require authorisation
- The 230+ processes that applied for authorisation will be authorised
 - authorisations to follow quickly after entry into force of new Regulation
 - only small changes to regime under Regulation (EU) No 282/2008
- Slightly different regime for future applications, only by developers

- Recycling installations to be registered and audited
 - registration shall be **immediately after entry into force** of the new Regulation
 - Compliance Monitoring Summary Sheet to be agreed with competent authorities
 - **batch based** declarations of compliance

7: Application beyond the EU

- Recycled Plastic FCMs placed on the EU market to comply with R 2022/1616
 - Also plastics with recycled content
- If recycled plastic is manufactured outside the EU:
 - suitable technology, authorised process, registered installation
 - waste shipped to the EU also to comply with the Regulation (Article 6)
- Rules the same outside the EU as inside the EU
 - Regulation 10/2011 applies to plastic input
 - registration of installations, facilities, and recycling companies
 - establishment of 'compliance monitoring summary sheet' with local competent authorities

8: Transition

- Many requirements set out in the Regulation are applicable from its entry into force
- Mechanical PET recycling processes:
 - processes subject to an application received by European Food Safety Authority (EFSA) **before 10 July 2023** may continue after that date to be used to place recycled plastic on the market without authorisation, until they are notified of a decision on their authorisation;
 - from 10 July 2023 onwards, processes for which EFSA did not receive an application before that date may not be used to place recycled plastic on the market, they must be authorised first;
- from 10 July 2023, only plastics containing recycled plastic manufactured with a suitable recycling technology may be placed on the market,
 - unless manufactured with a novel technology and in accordance with Chapter IV of the Regulation;
 - the Regulation lays down two suitable technologies:
 - post-consumer mechanical PET recycling; this requires authorisation of individual processes
 - recycling from product loops which are in a closed and controlled chain; this requires the use of a recycling scheme
- from 10 October 2024, quality assurance systems used to collect and pre-process plastic input need to be certified by a third party, and participation in proficiency testing for analytical methods used under chapter IV

Amendments to Regulation (EU) No 10/2011 on plastic FCM

16th – 17th – 18th amendment

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16th amendment

- The 16th amendment:
 - Updates rules for phthalates, particularly group restrictions, SML (allocation factor 20%)
 - Clarify substance 1059 ('PHBH')
 - Extend use/Authorise substance 1076, 1078, 1080 – 1083
 - Revokes authorisation from FCM 96 (wood) and FCM 121 (salicylic acid)
- Adoption procedure:
 - Voted in standing committee on 19 October
 - 2 months standstill for scrutiny by European Parliament and Council
 - Adoption expected early 2023, entry into force still Q1 2023

17th amendment

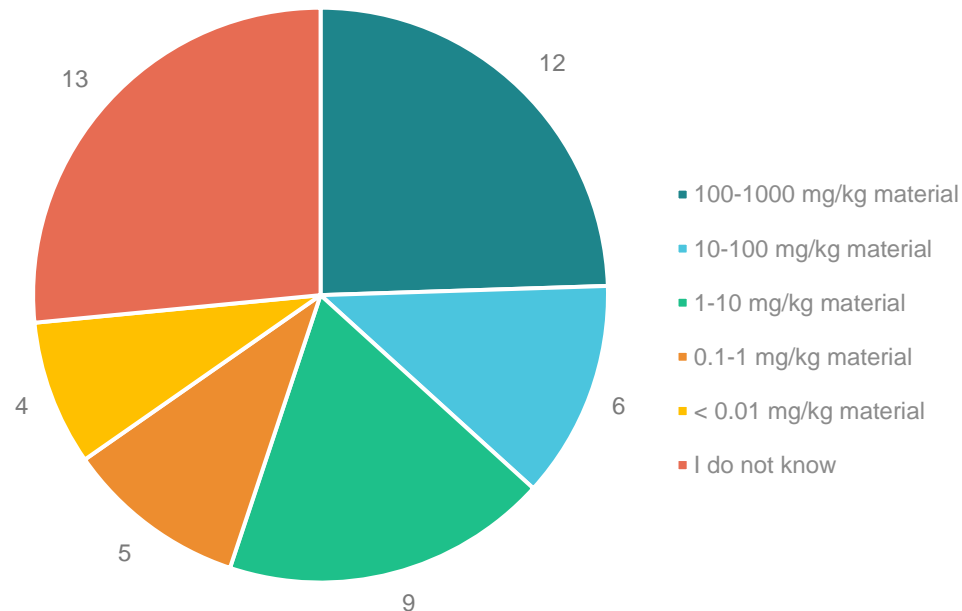
- Planned update in view of new recycling regulation
- We are considering to:
 - clarify that the Regulation applies to the manufacture of plastic without recycled content
 - introduce purity requirements
 - clarify rules on natural materials (nothing to do with recycling, but with purity)
 - set limitations on off-cuts and scraps (composition)
 - adapt rules on migration testing concerning multi-layer multi-material materials (!)
 - deletion of EU provisional list and alignment with BPR
- It also adds rules on quality control and the handling of offcuts and scraps to Regulation (EC) No 2023/2006 on good manufacturing practices for FCMs.

18th amendment

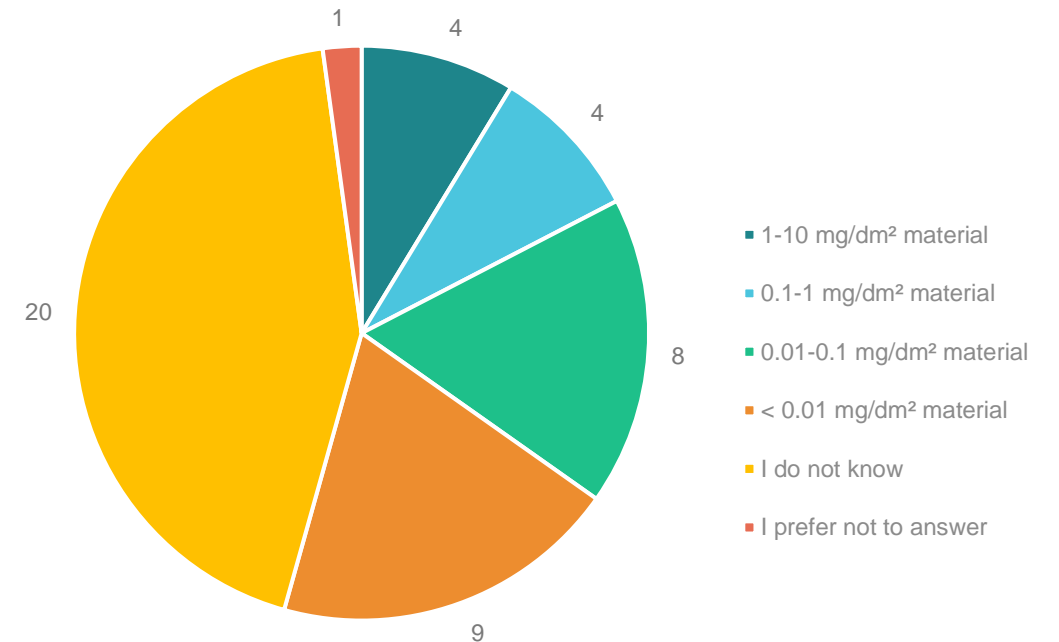
- To introduce 'ND' limit for TiO₂ (10 ppb detection limit, only on FCM)
- To authorise possibly other substances for which favourable EFSA opinions have been published
- To introduce limit on styrene (FCM 193)
 - presently no limit, concerns over genotoxicity, precautionary approach
 - a limit between 10-50 ppb is presently being considered
 - testing in the food, no use of simulants,
 - in cases food testing too difficult, extraction +100% migration

Residual styrene and styrene migration

Residual free styrene concentration in the materials



Migration under typical testing conditions



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Additional information provided by stakeholders

- Presence of free styrene monomer can be above 500 mg/kg polystyrene, which leads to a theoretical maximum amount of migratable styrene above the regulatory limit.
- Testing the migration into food is possible but very challenging, especially since there are no defined standards.
- There can be a high variability between laboratories when measuring the free styrene content of the same sample with the same method.
- Migration of styrene into food was analysed for following product categories:
 - Dairy products (migration from PS below 10 ppb – 30 ppb, from ABS around 100 ppb, from SAN below 10 ppb)
 - Fish and meat (migration from EPS below 10 ppb – 30 ppb)
 - Oil (migration from ABS around 200 ppb, from SAN below 20 ppb)

Other activities

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Bamboozling enforcement action

- Ground bamboo/ powder not in annex I to Regulation 10/2011 and cannot be used in the manufacture of plastic FCM
- 21 countries participated
- In total 716 cases of food contact material containing unauthorised bamboo powder were notified (612 on the market, 104 rejected at the border)
- A total of 551 cases presented an e-commerce aspect, meaning the product was also or exclusively traded online by e-traders or e-platforms.
- Other plant based additives: wheat, including wheat straw (22 notifications), rice husks, maize, vegetable fibres and plant parts.
- Publication of the final results of the coordinated action shortly
 - Q&A
 - Publicising

Controls and monitoring

- Regulation (EU) No 284/2011: Official controls on consignments of plastic kitchenware from China and Hong Kong
- Unsatisfactory physical checks and rejected consignments increased again in recent years
 - 2020: Total physical check failures = 16/212 (7.5%) (melamine = 3, polyamide = 9, mixed consignments = 2)
 - 2021: Total physical check failures = 15/166 (9.0%) (melamine = 9, polyamide = 6)
- Updating of reporting
- Controls under Commission Recommendation 2019/794
 - 2019 → 5381 samples → 184 samples non-compliant (3.4%)
 - 2020 → 4762 samples → 80 samples non-compliant (1.7%)
 - Main non-compliances → Melamine/ formaldehyde (122 samples) and metals (67 samples)

Thank you

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