WORKING GROUP of the SCoPAFF ON FOOD CONTACT MATERIALS (FCMs)

6 – 7 February 2025

DG SANTE
European Commission

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Agenda

Today

1. Welcome and determination AoB
2. Regulation (EU) 2022/1616
3. State of Play revision

Tomorrow

4. Regulation (EU) No 284/2011
5. Implementation at National level
6. Regulation (EU) No 10/2011
7. Bisphenols
8. AoB and closing of the meeting

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AoB

New points?

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Discussion on topics relevant under Regulation (EU) 2022/1616

Agenda item 2

a. Discussion on Authorisation Decisions under preparation
b. Functionality of Register under Article 24
c. Correction to the Regulation
d. Possible Amendment to the Regulation
e. Progress novel technologies

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Access to FFSPM – full info available in register

- FFSPM is the system that contains all information in the register
  - online public visibility is more restricted
  - (please do not bother about the acronym)
- Objective of the access to this system is to ensure:
  - your access to non-public information, such as contact persons – e.g. for audits
  - efficient feedback to the Commission in case of incorrect or missing information
- Demo by IT colleagues who implement FFSPM + Q&A
- Demo of the use of exported data by FCM Team + Q&A
  - not all data can be exported, but it gives

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How to work if you want to report incorrect data

- Identify the records that are incorrect, and how they should be corrected
  - preferably include exported data in excel, or using an exported PDF indicating the issues
- Send it by e-mail to us – please use the recycling mailbox
- A more detailed guide will follow – we may need to build a little experience
- Full access (so that you can edit without our intervention) is to follow

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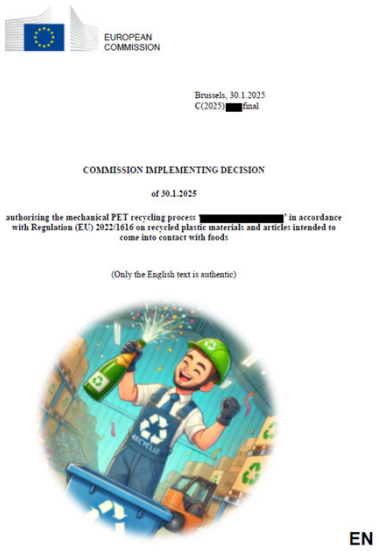
Recycling Processes

- Approximately 300 require authorisation
  - latest publication is RECYC328
  - only developers can now apply
- Authorisations are in progress
  - **First 51 authorisation Decisions have been notified to applicants**
  - 'RAN' numbers assigned but not yet in register
  - Authorisations to continue over 2025
- Remember the transition
  - Operator uses process subject to an application before 10 July 2023 → No authorisation is needed, until the notification of a decision
  - Only 3 applications received thereafter



EUROPEAN COMMISSION

Brussels, 30.1.2025
C(2025) [redacted] final

COMMISSION IMPLEMENTING DECISION

of 30.1.2025

authorising the mechanical PET recycling process '[redacted]' in accordance with Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with foods

(Only the English text is authentic)

EN EN

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Ongoing work on authorisations

- We expect every standing committee a new group of Decisions
  - About 250 Decisions to go…
- Next standing committee may need to be skipped
- Same procedure as in the specially organised standing committee
- First group of 180 was consulted with you
  - → only consultation in weeks ahead of the vote (14 days minimum)
  - Please let us know any discrepancies without delay
- Second group will be consulted possibly after the summer

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Correction to the Regulation

- Corrections involve:
  - Article 5(3) there is a reference to '*containers of recycled plastic*', this should be corrected to '*containers containing recycled plastic*'
  - Article 10(4): *'…At the time of the notification, ~~the recycler~~* ***the developer*** *shall also publish a detailed initial report on…'*
- However mostly corrections to references, Article 4 + several in Chapter IV
  - in Article 10(8), 11(6), 12(3), 14(5), 14(6), 14(7), 14(8)
  - the change in 14(6) actually clarifies the requirements on confidential information

> 8. A competent authority that was notified in accordance with paragraph 2 shall verify within 5 months from the notification whether the requirements set out in paragraphs 1 to 7 are met, and verify the requirements forthcoming from paragraph 8 regularly thereafter.

- Text is ready but procedure too far behind for vote in SC-PAFF in February

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Background to amending R 2022/1616

- Rapid growth foreseen of recycled plastic market
  - PPWR now published, further targets for recycled content → novel technologies
  - 10% for all plastics
- Ensuring food safety in view of growth
  - audits of installations need to be completed → suspensions
  - quality of input material → ensuring separate collection
  - keep control over imported material, both input as well as recycled material
  - traceability
- We need to ensure that the Regulation facilitates efficient enforcement
  - main reason for amending

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Amendment to the Regulation

- We are defining its scope
  - Several amendments are already being foreseen
- Main amendments relevant now
  - Requirement of DoC/Certificate for input material (input into recycling process)
  - Clarification of DoC requirements for output material
    - recycled plastic materials (intermediate)
    - recycled plastic materials and articles (final product)
    - ensure full documentation trail
  - Support to third party certification of input material (Article 6(3))

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Suspension of recycling installations

Article 4

Requirements for recycled plastic materials and articles

1. Recycled plastic materials and articles shall only be placed on the market where the requirements set out in paragraphs 2 to 7 are met during their manufacture.

7. Where relevant, the status in the Register established in Article 24 of the authorised recycling process used for the manufacturing is not 'suspended' or 'revoked'.

- Why suspend?
  - legal requirement
  - to prevent fraud
  - to ensure the proper operation of recycling installations
  - to ensure level playing field in particular regarding imports from outside the EU
- Why is it necessary?
  - No direct quality control of recycled plastic possible, e.g. by means of analytical methods
  - Requirements of authorisation on the operations strictly controlled under GMP
  - Records related to quality need to be traceable
- Why is it not yet implemented?
  - signals from Member States that audits haven't been completed
- No plans to change the Regulation in view of this problem

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procedure

2. Recyclers shall submit the compliance monitoring summary sheet to the competent authority in the territory where the decontamination installation is located within 1 month from the start date of the production of recycled plastic with that installation. The competent authority shall notify the reception of the compliance monitoring summary sheet without delay to the Commission. The status of the registration in accordance with Article 24(2), point (g), shall change to 'being established'.

- Step 1: addition of column with registration status to register
  - status is either: 'newly registered', 'being established', or 'active'
  - it will be visible if deadline has been passed
  - expected Q1 2025
- Step 2: suspension will be activated
  - if deadline passed then 'being established' → 'suspended'
  - expected Q2/3 2025

Recycling installations (762 matching records)

(note: RIN - 'Recycling installation number'; RFN - 'Recycling facility number; RON - 'Recycling operator number')

RIN	Name of Recycling installation	Country	RFN	RON
AE9-HND-1I5	HORIZON TECHNOLOGIES FZC - STARLINGER IV+	United Arab Emirates	AE9-1CK-1FN	AE5-1CK-1OJ
ANG-99C-0I8	Glopol Angola – Indústria, Lda. recoSTAR PET 125 HC iV+ (machine number MA 2014317)	Angola	ANG-6JD-0FS	ANG-6JD-0OQ
AT1-1FL-0IG	PET to PET Granulierungsanlage 1	Austria	AT1-61T-0FC	AT1-61T-0OA
AT1-3T5-0I7	Production Line SSP	Austria		AT1-61T-0OK
AT1-4PL-0IN	Production Line EX1			AT1-61T-0OK

4. If the competent authority does not inform the Commission that compliance is established within 1 year from the start date of the production of recycled plastic in the decontamination installation, the status of the registration in accordance with Article 24(2), point (g), shall be changed to 'suspended'.

If the status of a decontamination installation is 'suspended' for 1 year, the entry concerning the installation shall be removed from the Register.

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Outlook on Novel technologies

- Just over 40
- Commission services will continue validation with individual MS
  - let us know if the numbers appear incorrect to you
- Register should be on-line soon – NTN numbers available
- Discussion with EFSA to prepare the first evaluation mandates
- Industry warned us of significant grow of the number of technologies
  - PPWR sets recycled content target for all plastics

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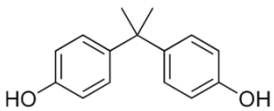
Analysis of Novel Technologies Dossiers

- Analysis is on-going
  - PET (input restrictions); PET (barrier); PET (chemical); LDPE, HDPE, PP, PS
- Mixed quality of dossiers
  - Some are meeting just the minimum requirements, others really good
  - We are working on a small report
  - Issues with definition of input material (where from) and output material (what for)
  - in the poor dossiers, limited or no justification of why the process is safe
    - just poor basis for further EFSA assessment (e.g. FDA non-objection letter)
    - poor assessment of safety
- Good news: PT is available
  - Article 13(2)
  - this can be enforced as part of audits under Article 26
  - remember that Article 25 and 26 apply also to recyclers using novel technologies

> 2. For the analyses and tests required to determine the contamination level in accordance with paragraph 1, laboratories performing these activities shall take part regularly and with satisfactory performance in proficiency tests appropriate for this purpose. The first time a laboratory participates in such a proficiency test shall be before the start of the operation of the recycling facility.

BPA



- Commission Regulation (EU) 2024/3190 entered into force 20 January 2025
- Bans the use of BPA in manufacture of FCMs (only in FCMs!)
  - transition periods spanning about 4 years
  - the presence of BPA is in principle not banned → important for recycling
  - no BPA to be present in FCM made using other bisphenols (including BADGE)
- For recyclers it is important to:
  - ensure proper input → plastic from food packaging should not contain BPA
    - at least the level should go down over the next few years
    - take Article 4 and 6 of Regulation (EU) 2022/1616 seriously
  - special considerations for novel technologies
  - we suggest to monitor for BPA content, and let us know what to expect

On-going discussion

- Imports from third countries (last meeting)
- Article 6 (last meeting)
- Enforcement → for today

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Discussion on imports of recycled material from 3rd countries

- Imported material consists of the following
  - recycled material: traceability and enforcement in accordance with R 2022/1616
  - input material: should be certified in accordance with Article 6(3)
- Growth expected
  - PPWR sets recycled content target of at least 10% for all plastics by 2030
- Possible health risks
  - not properly collected material, not properly recycled material
  - fraud which undermines the system, and undermines the EU market
- Border controls difficult because of lack of appropriate commodity codes
  - commission is establishing commodity codes
  - to facilitate proper statistics
  - to ensure traceability through check of documentation

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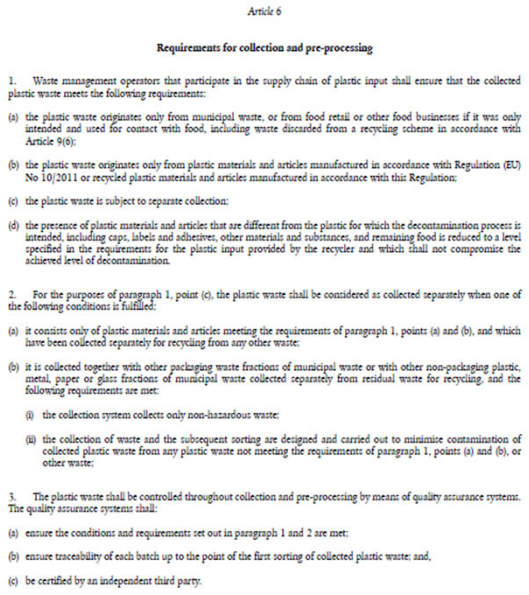
Discussion on Article 6 of R 2022/1616

- Article 6 should help ensuring a proper quality of the input material
  - poor input quality = poor output quality
- Article 6(1): only FCM plastic from separately collected municipal waste
- Article 6(2): separately collected plastic
  - consist only of FCM plastic, separately collected from municipal waste
  - is collected with other packaging waste fractions that exclude hazardous materials and minimise through subsequent sorting the presence of non-FCM plastics
- Article 6(3): GMP requirement on the input material
  - ensuring Article 6(1) and (2) and traceability
  - to be certified by a third party (applicable since October)
  - Regulation (EC) No 2023/2006 applies *'mutatis mutandis'*



Article 6

Requirements for collection and pre-processing

1. Waste management operators that participate in the supply chain of plastic input shall ensure that the collected plastic waste meets the following requirements:

(a) the plastic waste originates only from municipal waste, or from food retail or other food businesses if it was only intended and used for contact with food, including waste discarded from a recycling scheme in accordance with Article 9(6);

(b) the plastic waste originates only from plastic materials and articles manufactured in accordance with Regulation (EU) No 10/2011 or recycled plastic materials and articles manufactured in accordance with this Regulation;

(c) the plastic waste is subject to separate collection;

(d) the presence of plastic materials and articles that are different from the plastic for which the decontamination process is intended, including caps, labels and adhesives, other materials and substances, and remaining food is reduced to a level specified in the requirements for the plastic input provided by the recycler and which shall not compromise the achieved level of decontamination.

2. For the purposes of paragraph 1, point (c), the plastic waste shall be considered as collected separately when one of the following conditions is fulfilled:

(a) it consists only of plastic materials and articles meeting the requirements of paragraph 1, points (a) and (b), and which have been collected separately for recycling from any other waste;

(b) it is collected together with other packaging waste fractions of municipal waste or with other non-packaging plastic, metal, paper or glass fractions of municipal waste collected separately from residual waste for recycling, and the following requirements are met:

(i) the collection system collects only non-hazardous waste;

(ii) the collection of waste and the subsequent sorting are designed and carried out to minimize contamination of collected plastic waste from any plastic waste not meeting the requirements of paragraph 1, points (a) and (b), or other waste;

3. The plastic waste shall be controlled throughout collection and pre-processing by means of quality assurance systems. The quality assurance systems shall:

(a) ensure the conditions and requirements set out in paragraph 1 and 2 are met;

(b) ensure traceability of each batch up to the point of the first sorting of collected plastic waste; and,

(c) be certified by an independent third party.

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General discussion on enforcement

- Main points for enforcement
  - Quality of Input materials
  - Audits of recycling installations (775, of which about 527 in the EU)
  - Recycled material on the market
- How is this different regarding imported materials
  - input material
  - recycled mechanically recycled PET
  - other materials
- What are the issues with recycling schemes and novel technologies
  - scheme managers, technology developers, recyclers
- How would the Regulation help you better if it were different → amendment

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State of play of revision of EU FCM rules

Agenda item 3

State-of-play Revision

- *Present Activities*
  - **Scoping paper** being prepared internally → internal discussion → external elaboration
  - external elaboration being prepared → elaboration by groups of independent experts
  - **Sustainability study** : Last phase of the study : targeted meeting with stakeholders on the basis of the 4 measures further elaborated by ICF
- *Foreseen timing*
  - Scoping paper first quarter 2025, policy paper late 2025, IA mid 2026, legislative proposal est. 2027
  - [re-]validation by new Commission first step

Elements of the revision

1. **Shifting from the need to authorise all starting substances to more emphasis requiring information on the composition of the final product (materials, articles)**.
   - Better accountability and knowledge on the safety of the FCM
   - Whole of the supply chain must provide food grade materials containing known and risk assessed substances
   - provide better balance for the responsibilities for the safety of the final FCM in the supply chain
2. **Prioritising and allocating responsibility and control for risk assessment accordingly**
   - Tier 1 – most hazardous substances to be banned in principle)
   - Tier 2 – other substances for which some risk assessment/ management is required at EU level

These two elements are complemented by elements on digitising information in the supply chain, ensuring compliance and enforcement can be achieved in practice and supporting sustainable FCMs.

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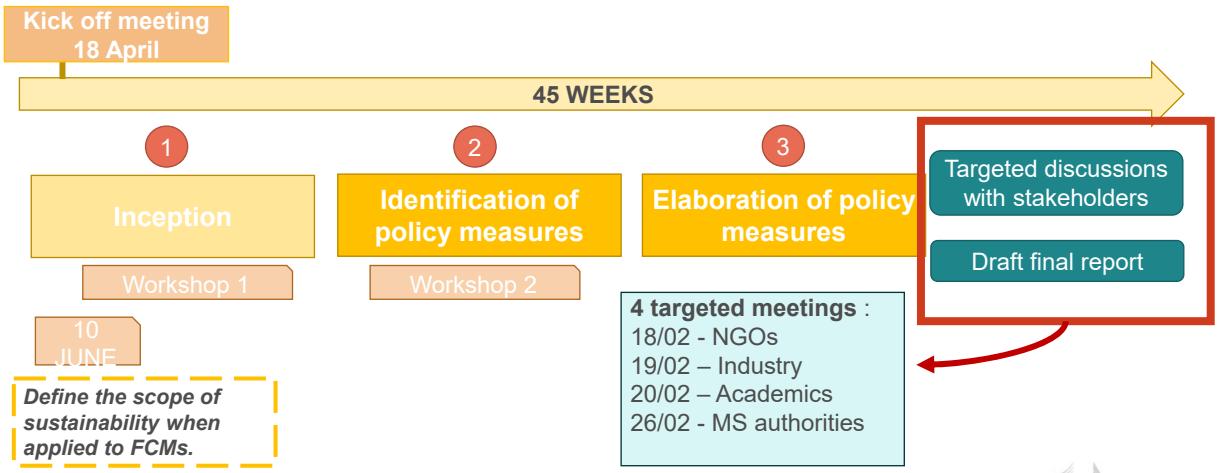
Sustainability study

Study Timeline



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Sustainability study

3rd phase of the Study : **Targeted meetings with stakeholders (December 2024-March 2025)**

Presentation of the 4 measures further elaborated :

- **M9** – Set and update standards on hygiene, safety and traceability for reusable FCMs.
- **M7** – Set sector wide, science-based sustainability targets.
- **M4** – Introduce an "essentiality test" to determine if specific products streams meet a critical need that cannot be met by more sustainable alternatives.
- **Possible combination of M5–** Set eco-design guidance specific to FCM categories **and M6**-Develop guidance to help FCM manufacturers and users to choose between alternatives

Sustainability study

3rd phase of the Study : **Elaboration of the policy measures (December 2024-March 2025)**

1. **Development of the measures and their feasibility :** How the measure could be expected to be implemented (e.g. identification of the requirements to implement such measures – dedicated IT systems, administrative or economic needs, expected time, etc)? **Practical aspects for establishing the measure** (qualify relevant effects on the production and use of a related sustainable FCM or product stream including **possible negative effects** (for example administrative burden, costs, food safety))
2. **Qualitative and quantitative analysis** (SWOT analysis, analyse whether such measures would be best approached by regulatory interventions, or by softer measures such as guidance or funding mechanisms, analyse the need and efficacy of the measure on the basis of the collected data on phase 2- market analysis)

Commission Regulation (EU) No 284/2011

Discussion points

Agenda item 4

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Reminder and overview

- Commission Regulation (EU) 284/2011 introduced in 2011 following high rates of non-compliance of melamine and polyamide kitchenware from China and Hong Kong
- Regulation requires
  - specific pre-import declaration (set out in annex) with analytical rules for formaldehyde from melamine and PAAs from polyamide
  - documentary checks to be performed on 100% of consignments;
  - identity and physical checks performed on around 10%

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Ongoing issues

- Alignment with Regulation (EU) 2017/625
- Alignment with Regulation (EC) No 10/2011
- Recording and reporting of results
- Terminology and commodity codes

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Alignment with Regulation (EU) 2017/625

- Consistency with corresponding Articles and updating references to legal basis Article 48(1) [Reg 882/2004] → Article 126(1) [Reg 2017/625]
- Terminology e.g. first point of introduction ≠ border control post (BCP)
- Use of the Common Health Entry Document (CHED)
- Use of Information Management System for Official Controls (IMSOC)

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Alignment with Regulation (EU) No 10/2011

- Detection limit for primary aromatic amines (PAAs)
  - Article 3(3)(a) lays down the detection limit for PAAs at 0,01 mg/kg food or food simulants
  - Commission Regulation (EU) 2020/1245 of 2 September 2020 amending that limit in Regulation (EU) No 10/2011
  - New detection limit of 0,002 mg/kg food or food simulant for individual PAAs to reflect advances in analytical capabilities (sum of PAAs → ND 0.01 mg/kg)
- 'softer' matters leading to potential enforcement issues
  - limit for melamine not specified under R 284/2011 – but relevant for the same items
  - no clear reference to applicable methods for verification of compliance (but guidance)
  - guidance for verification of compliance under R 284/2011 is outdated (e.g. consecutive testing)
- Declaration in Annex to R 284/2011 reinforces these matters by requiring compliance with old system

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Recording and reporting of information

- Implementing Regulation (EU) 2019/1715 — rules for the functioning of the information management system for official controls and its system components (the IMSOC Regulation)
  - Includes iRASFF and TRACES
- Experience of using TRACES – what are the issues, if any?
  - Lack of alignment (e.g. only BCPs set up to use TRACES – not 'first point of introduction')
  - CHED-D not mandatory for reporting of FCMs (but has been used)
- Ongoing amendment to IMSOC Regulation concerning TRACES, Article 40 (format of the CHED), paragraph 1, point (d) for CHED-D:
  - (d) a CHED-D drawn up in accordance with the template in Section D of Part 2 of Annex II to this Regulation, for consignments of feed and food of non-animal origin and food contact material subject at their entry into the Union to any of the measures or conditions provided for in points (d), (e) or (f) of Article 47(1) of Regulation (EU) 2017/625.

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Ongoing amendment to CHED-D (including for FCM subject to official controls at BCP)

	Country	ISO country code			Commercial document references		
I.10	**Prior notification**	Date			Time		
I.13	**Means of transport** ☐Airplane ☐Vessel ☐Railway ☐Road vehicle	Identification			I.11	**Country of origin**	ISO country code
					I.12	**Region of origin**	Code
I.14	**Country of dispatch** Country ISO country code		I.15	**Establishment of origin** Name Address		Registration/Approval No Country	ISO country code
I.16	**Transport conditions**	☐Ambient		☐Chilled		☐Frozen	
I.17	**Container number/Seal Number** **Container No**	**Seal No**				**Official Seal** ☐	
I.18	**Certified as or for:**	☐Human consumption	☐Food contact material ☐Laboratory samples		☐Feedstuff	☐Trade samples	☐Display items for exhibition ☐Other
I.20	☐**For transfer to:**		**Details of controlled destinations for I.20 and I.21**				

Reporting via CHED-D

- PART I – DESCRIPTION OF CONSIGNMENT to be completed by business operator
- Option to add/upload certificate (Annex I) required by Regulation 284/2011
  - Declaration of the contents of the consignment
  - Analytical test results for PAAs
  - Analytical test results for formaldehyde
- PART II – CONTROLS to be completed by competent authority at BCP

Reporting requirements

- Member States shall submit to the Commission a report quarterly by the end of the month following each quarter (Article 9)
- SANTE Data Collection Platform (SDCP): https://webgate.ec.europa.eu/sante-xmlgate
- Discussed in 2022 as many data missing
  - Action for MSs to ensure 'editor' profiles to generate a report and at least one 'senior user' access for submitting the report(s) to the Commission
  - Retrospective completion of data via the SANTE Data Collection Platform autumn 2022
- Some Member States have indicated they use TRACES
  - Who is now using TRACES and who is still using SDCP?

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Terminology and commodity codes

- FCM terminology including JRC guidelines on testing migration of PAAs from polyamide kitchenware and of formaldehyde from melamine kitchenware
  - Polyamide kitchenware cooking spatulas, slotted spoons, tongs and pasta tongs, whisks
  - Melamine kitchenware; illustrations shown include articles such as picnic sets, children plates, bowls cups, ladles, spoons, etc

- Six-digit codes based on harmonised system also refers to 'tableware'

  3924 10 - Tableware and kitchenware
  - - Kitchenware containing polyamide or melamine :
  3924 10 00 11 - - - Consigned from China or Hong Kong
  3924 10 00 19 - - - Other

- Addendum in 2022 to existing EU Guidelines to try to clarify

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Discussion

- Practical issues in Member States
- Evaluate current rates of non-compliance
  - Quarterly reports from Member States needed
- Views on the future of the Regulation
  - Extent of issues in practice
  - Need for measure
  - Future of controls

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Implementation on National level

Agenda item 5

a. Upcoming measures under National legislation

b. Matters related to EU legislation

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Discussion on National Measures

- work on National measures is welcome
- Several projects are on-going
  - we noted we did not have good overview and
  - interesting to all
- Action for Commission?
  - Tris, SPS, TBT
  - to check whether Article 18 would apply

Article 18

Safeguard measures

1. When a Member State, as a result of new information or a reassessment of existing information has detailed grounds for concluding that the use of a material or article endangers human health, although it complies with the relevant specific measures, it may temporarily suspend or restrict application of the provisions in question within its territory.

It shall immediately inform the other Member States and the Commission and give reasons for the suspension or restriction.

2. The Commission shall examine as soon as possible, where appropriate after obtaining an opinion from the Authority, within the Committee referred to in Article 23(1) the grounds adduced by the Member State referred to in paragraph 1 and shall deliver its opinion without delay and take appropriate measures.

3. If the Commission considers that amendments to the relevant specific measures are necessary in order to remedy the difficulties referred to in paragraph 1 and to ensure the protection of human health, those amendments shall be adopted in accordance with the procedure referred to in Article 23(2).

4. The Member State referred to in paragraph 1 may retain the suspension or restriction until the amendments referred to in paragraph 3 have been adopted or the Commission has declined to adopt such amendments.

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Updates from Member States

- *Denmark:*
  - Update of the Danish FCM order: delete the list of biocides, general “quality amendment” of the order, new national migration limits for lead and cadmium from ceramics (and glass and enamel) with a reference to the Safeguard measures in Art. 18 of Regulation (EU) 1935/2004.
- *France:*
  - Update of Recommendations on Paper and Board.
  - New Recommendation on Textile FCM.
  - Reflection on an update of our Recommendation on Wood FCM with some work from our national agency (Anses) to provide guideline for the risk assessment of wood essence.

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Updates from Member States

- *Greece:*
  - Regulatory initiative to replace Article 24 ‘Packaging paper’ of the Greek Codex for Foodstuffs and Beverages. The new rules aim to update the provisions regulating paper and board as food contact materials, taking into account new scientific knowledge, based on the Council of Europe Technical Guideline for Paper and Board used in contact with food "PAPER AND BOARD used in food contact materials and articles, 2021“.
- *Netherlands:*
  - Amendment of the Commodities Act Regulation on packaging and consumer products, Chapter IV on metals.
  - A current amendment is notified to the EU (standstill period until 22/4/2025) for adding new substances to part A of the Annex to the Commodities Act Regulation on packaging and consumer products and a number of technical amendments and alignments with Regulation (EU) 10/2011.

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Current
FCM legislation in Belgium

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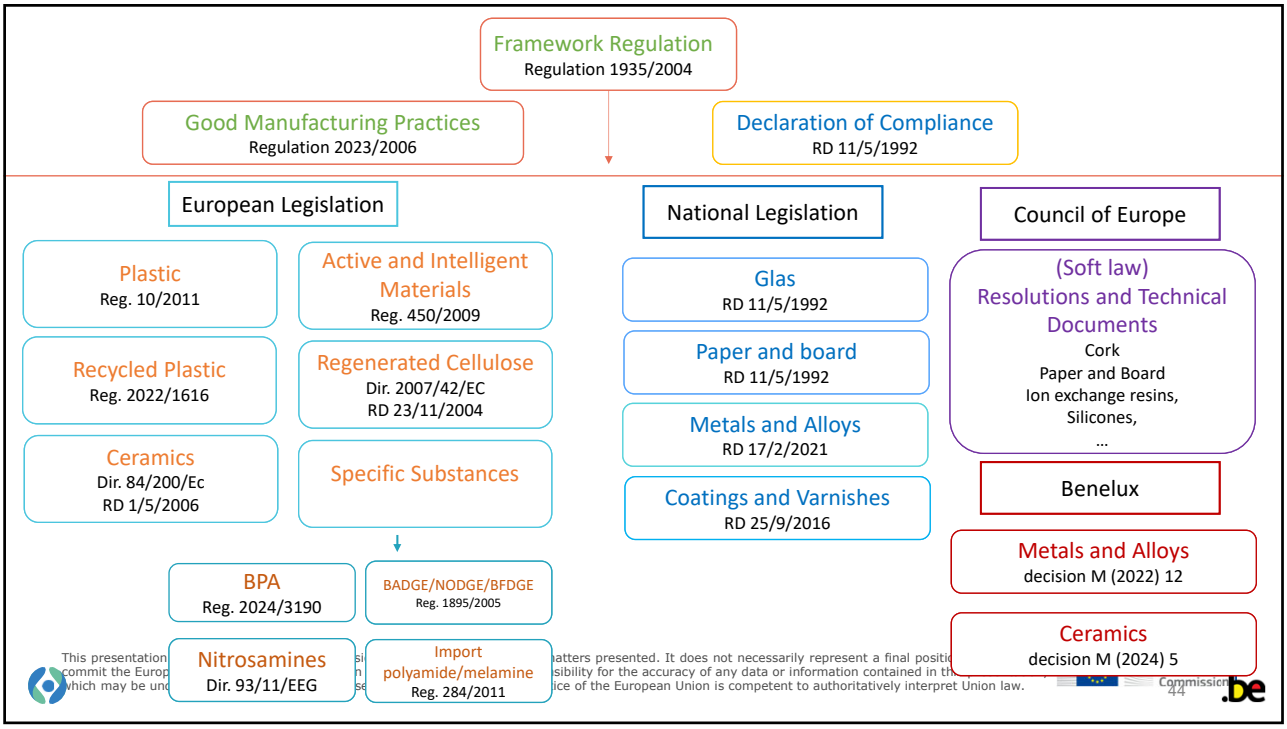

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Future
FCM legislation in Belgium and Benelux

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Benelux Decision M (2024)5 on ceramics

- *BESCHIKKING van het Benelux Comité van Ministers houdende vrijwaringsmaatregelen ten aanzien van keramische voorwerpen bestemd om met levensmiddelen in aanraking te komen*
- *DÉCISION du Comité de Ministres Benelux sur des mesures de sauvegarde relatives aux objets céramiques destinés à entrer en contact avec les denrées alimentaires*
- Signed on 29/11/2024
- 18 months to transpose the decision into national law by Belgium, The Netherlands and Grand Duchy of Luxembourg
  => TRIS + publication 2025 (early 2026)
- Safeguard measures Art 18 Regulation (EC) 1935/2004 on migration limits in Commission Directive 2007/42/EC
- Lowering limits Cd and Pb in Directive

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- Scientific bases
  - EFSA
    - Scientific Opinion on Lead in Food, EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on Lead in Food - - 2010 - EFSA Journal - Wiley Online Library
    - Scientific Opinion on cadmium in food; Cadmium in food - Scientific opinion of the Panel on Contaminants in the Food Chain
    - Statement on tolerable weekly intake for cadmium; Statement on tolerable weekly intake for cadmium
  - BfR
    - Geschirr aus Keramik: BfR empfiehlt niedrigere Freisetzungsmengen für Blei und Cadmium; Stellungnahme Nr. 043/2020 des BfR vom 21. September 2020 https://www.bfr.bund.de/cm/343/geschirr-aus-keramik-bfr-empfiehlt-niedrigere-freisetzungsmengen-fuer-blei-und-cadmium.pdf
  - FCM-EURL
    - Simoneau C., Beldi G., Peltzer M.A., Jakubowska N. (2017) Towards suitable tests for the migration of metals from ceramic and crystal tableware: Work in support of the revision of the Ceramic Directive 84/500/EEC . Publication Office of the European Union, Luxembourg, JRC Scientific and Technical Research Reports, EUR 28872 EN. JRC Publications Repository
    - Jakubowska N., Beldi G., Simoneau C., Hoekstra E.J. (2017) Report on the inter-laboratory comparison exercise organised by the European Union Reference Laboratory for Food Contact Materials - Publications Office of the EU : Determination of elements in acetic acid solutions and in migration from ceramic and glass tableware . Publication Office of the European Union, Luxembourg, JRC Technical Report, EUR 28690 EN.

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Specific Migration Limits

Benelux Decision M (2024)5

- Cat. I (articles can not be filled):
  - Pb 6 µg/dm2
  - Cd 4 µg/dm2
- Cat. II (articles can be filled):
  - Pb 30 µg/l
  - Cd 20 µg/l
- Cat. III (cooking ware, V > 3L):
  - Pb 10 µg/l
  - Cd 7 µg/l

Directive 84/500/EEG

- Cat. I (articles can not be filled):
  - Pb 0,8 mg/dm2
  - Cd 0,07 mg/dm2
- Cat. II (articles can be filled):
  - Pb 4 mg/l
  - Cd 0,3 mg/l
- Cat. III (cooking ware, V > 3L):
  - Pb 1,5 mg/l
  - Cd 0,1 mg/l

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Method of analysis

- Other possibilities:(origin article 11 of the COM draft)
  - Calculation
  - Estimation

    a) Composition of substances & documentation of the substances

    b) Use/non-use of substances containing Cd and/or Pb for the manufacturing (including mouth contact, interior, underglaze, exterior)

    c)additional documentation & information from the supplier (including instructions for processing)

    d) Analytical verification on similar ceramic FCMs (max. release per the surface when certain decoration technics or specific materials are used)

    e) Quality control during the manufacturing (including final product, manufacturing process (such as glazing & firing conditions), composition of substances, contamination control)
- Analytical check if the other possibilities do not provide enough assurance (article 2.2 of Directive 84/500/EEC applies)

Mutual recognition (non-official translation)

- Ceramic articles within the meaning of this Decision shall be assimilated to ceramic articles lawfully manufactured or placed on the market in a Member State of the European Union not belonging to the Benelux or in a non-Member State of the European Union party to a customs union treaty, or lawfully manufactured in a State party to a free trade area treaty linking the Benelux countries, **and which meet requirements offering a level of protection at least equivalent to that resulting from the requirements referred to in this Decision.**

Amendment Belgian Royal Decree of 17/02/2021 on metals and alloys + Benelux Decision M (2022)12 on ceramics

- TRIS + Publication 2025
- Adaptation of certain limits to the second edition of the EDQM technical guide on metals and alloys used in FCM [Metals and alloys used in food contact materials and articles" – Second edition of the EDQM technical guide now available - European Directorate for the Quality of Medicines & HealthCare]

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Specific Migration Limits

Current limits

Metal	SRL (mg/kg food)
Al	5
Sb	0,04
Ag	0,08
Cr	0,250
Co	0,02
Cu	4
Sn*	100
Fe	40
Mg	-
Mn	1,8
Mo	0,12
Ni	0,14
Ti	-
V	0,01
Zn	5

Metal contaminant	SRL (mg/kg food)
As	0,002
Ba	1,2
Be	0,01
Cd	0,005
Li	0,048
Hg	0,003
Pb	0,010
Tl	0,0001

Future limits

Metal	SRL (mg/kg food)
Al	5
Sb	0,04
Ag	0,08
Cr (III)	1
Co	0,02
Cu	4
Sn*	100
Fe	40
Mg	-
Mn	0,55
Mo	0,12
Ni	0,14
Ti	-
V	0,01
Zn	5
Zr	2

Metal contaminant	SRL (mg/kg food)
As	0,002
Ba	1,2
Be	0,01
Cd	0,005
Li	0,048
Hg	0,003
Pb	0,010
Tl	0,001

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Belgian legislation on Paper and Board

- Preliminary stage
- TRIS 2026?

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More information

Belgium - https://www.health.belgium.be/nl

The Netherlands - Ministerie van Volksgezondheid, Welzijn en Sport | Rijksoverheid.nl

Grand Duchy of Luxembourg – https://agriculture.public.lu

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Matters related to EU legislation

- What is the legal basis for requiring food businesses to use suitable FCM and follow the labelling or other instructions of use?
  - See Article 17(1) of Regulation 178/2002: FBOs must '*satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met*'
- What is the legal basis for traceability of FCM used by the food business but not distributed to the consumers, e.g. restaurants and canteens?
  - If FBO is only a 'user' of an FCM and therefore not an FCM business → no further distribution?
  - If FBO distributes e.g. take-away packaging to a consumer → covered by Regulation (EU) 1935/2004
- What is the legal basis for withdrawal and recall of FCM? (see also next question)
  - Article 17(1) in Regulation (EU) 1935/2004: '*The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility*'
  - However, no equivalent of Article 19 in Regulation 178/2002 (withdrawal concerns the food itself)

Matters related to EU legislation

- Specific case as regards traceability and recall:
  1. Consumer complaint, parts of internal coating of a tomato can were detached.
  2. The concerned FCM BO had been aware of the issue for many years but decided not to take any action as it happened rarely and according to their risk assessment the presence of these detached pieces in food does not present any risk.
  3. The concerned FCM BO did not inform the can maker although it may be a GMP issue nor CA (article 17(1) of Regulation (EU) 1935/2004, FCM BO are not obliged to inform CA about defects)
  4. Nevertheless, article 19 of Regulation (EU) 178/2002 should apply but it obligates only FBO to notify defects to CA and to withdraw them from the market if foreign bodies are present in food.

Matters related to EU legislation

- Article 16 of Regulation 1935/2004 on declaration of compliance:
  1. The specific measures referred to in Article 5 shall require that materials and articles covered by those measures be accompanied by a written declaration stating that they comply with the rules applicable to them.
  2. Appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to the competent authorities on demand.
- COMMISSION REGULATION (EC) No 2023/2006 based on Article 5(1) i.e. specific measure but does not require a DoC
- Therefore no requirement per se for a DoC to be generated on GMP and passed on in the supply chain
- Controls on documentation at the FCM BO as regards compliance with Reg 2023/2006
- All points to reflect on for revision!

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Matters related to EU legislation

- Concerning small polyamide parts of household appliances (e.g. consumer coffee machines): Do these polyamide parts of household appliances fall under Reg. (EU) 284/2011?
  - According to point 2.1.3 (iv) of Annex V to Regulation (EU) 10/2011, the parts themselves can be tested. However, if the substance migrates from the part in question above the SML, it doesn't necessarily mean the whole appliance is non-compliant.
  - Whilst such parts of coffee machines are not excluded, in practice, they cannot always be tested alone.
  - MS CA are not obliged to test (physical sampling at 10%) unless it is practicably reasonable to do so
  - Business operator should be able to reason or demonstrate that the part is not FCM or that migration is compliant, taking into account the whole equipment, and that the business operator should provide supporting documents for that purpose.
- Oven grids: there is no harmonized legislation, however national legislation is applied, when it exists. In this case Italy does not have legislation for non-stainless steel, but only for stainless steel, and there are problems with analytical testing. Suggestions on how to conduct testing and which SMLs apply?

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Matters related to Reg EU 10/2011

- BOs often reuse FCMs. The DoC of these reused FCM is often missing a reference to the analysis method. As there is no mandatory field in the DoC for the tests according to the point: 2.1.6. Repeated use materials and articles, how can we ensure that those articles can be reused? These are often small operators who do not know how to analyse test reports.
- Should the summary limit value for PAAs of 0.01 mg/kg food or food simulant be tested in the first or third migrate? According to an initial assessment, the result of the first migrate should be used. Suggest to clarify this issue in the text of the Regulation (EU) No 10/2011.
  - The last sentence of point 2.1.6 of Annex V to the Plastics Regulation states: ' 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.'
- Point 7 of Annex IV (DoC) of refers to old Directives (on purity criteria for food additives) repealed by Regulation (EU) 231/2012. Can the DoC in Annex IV be updated?

GMP Discussion

GMP

- The aim of GMP is to ensure that the quality of the produced materials and articles stays within the bounds of risk assessment done for that material or article.
- The concept of and requirements for GMP will become deeply integrated in FCM legislation, in particular to support inert FCMs and better account for NIAS. Thereto, in addition to the present requirements, the GMP system will define specific quality control operations that need to take place at specific moments during the production, much along the lines of Regulation (EU) 2022/1616.

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Discussion on topics relevant under Regulation (EU) No 10/2011

Agenda item 6

a. Applications for authorisation of untreated wood

b. Approach to MOAH

c. Future Amendments

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Applications in accordance with Article 2(3) of Regulation (EU) 2023/1442

- Four conditions need to be fulfilled in order to continue to be first placed on the market after 1 February 2025

3. Plastic materials and articles manufactured with salicylic acid (FCM No 121) or manufactured with untreated wood flour or fibres from a specific wood species may continue to be first placed on the market after 1 February 2025 provided that the following conditions are fulfilled:

(a) an application for the authorisation of that substance or of that untreated wood flour or fibre from a specific wood species has been submitted to the competent authority in accordance with Article 9 of Regulation (EC) No 1935/2004 before 1 August 2024;

(b) the use of that substance or of that untreated flour or fibre from a specific wood species to manufacture a plastic material and article, and the use thereof, is limited to the intended conditions of use described in the application;

(c) the information provided to the Authority in accordance with Article 9(1)(b) of Regulation (EC) No 1935/2004 includes a statement that the application is an application in accordance with this paragraph; and

(d) the Authority has considered the application valid.

4. Plastic materials and articles manufactured with the substance or the untreated wood flour or fibre subject to an application may then continue to be used until the applicant withdraws its application or until the Commission adopts a decision granting or refusing the authorisation for the use of that substance or wood flour or fibre pursuant to Article 11(1) of Regulation (EC) No 1935/2004.

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Applications in accordance with Article 2(3) of Regulation (EU) 2023/1442 (2)

Untreated wood flour or fibres

1. FCM-2024-28710
2. FCM-2024-29050
3. FCM-2024-25811
4. FCM-2024-27410

Salicylic acid

5. FCM-2024-29748

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Applications in accordance with Article 2(3) of Regulation (EU) 2023/1442 (3)

- The intention is to change the date in Article 2(3) from 1 February 2025 to 1 February **2026**
- This will give applicants enough time for preparing lacking or incomplete information in their applications

Article 1

Article 2 of Commission Regulation (EU) 2023/1442 is amended as follows:

(1) → The third paragraph is replaced by the following:

'Plastic materials and articles manufactured with salicylic acid (FCM No 121) or manufactured with untreated wood flour or fibres from a specific wood species may continue to be first placed on the market after 1 February 2026 provided that the following conditions are fulfilled:'

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Amendment to Regulation (EU) No 10/2011: 'substances amendment'

-9 substances to be included in the Union list:

chopped carbon fibre; nanoprecipitated calcium carbonate; oligomeric lactic acid; triphenyl phosphite; calcium tert-butylphosphonate; mixture of nonamethylenediamine and 2-Methyl-1,8-octadiamine (NMDA and MODA); oxidised rice bran; 2,2'-oxydiethylamine

-to change the SML for nickel in Table 1 in point 1 in Annex II

-to consider adding a point 3 on MOAH in Annex II

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Amendment to Regulation (EU) No 10/2011: 'substances amendment' (2)

- Potential approach to dealing with MOAH in plastic FCMs
  - EFSA adopted an update of the risk assessment of mineral oil hydrocarbons* and concluded that there is a concern on the presence of genotoxic and carcinogenic fraction in MOAH
  - Migration into food should be as much as possible prevented
  - Setting a level that can be quantified in food simulant: 0.5 mg/kg for food simulants A, B, C, D1 and E and 2 mg/kg for D2
  - Levels similar as proposed for contamination of MOAH in foodstuffs

*EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on an update of the risk assessment of mineral oil hydrocarbons in food. EFSA Journal EFSA Journal 2023;21(9):8215, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2023.8215.

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Amendment to Regulation (EU) No 10/2011: 'substances amendment' (3)

1. Specifying mineral oil aromatic hydrocarbons:

Total mineral oil aromatic hydrocarbons (MOAH) is **defined as** the total mass fraction of MOAH after separation from mineral oil saturated hydrocarbons (MOSH) and removal of all possible interferences in the extract, as quantified by integration of the whole signal interval in the GC/FID chromatogram between the retention times of the peak start of n-C10 and the peak end of n-C50 separated on an apolar GC column (dimethylpolysiloxanes with ≤ 5 % phenyl substitution) after trimming the identified sharp peaks not belonging to MOAH and after subtraction of the reagent blank.

2. Setting a limit of quantification of 0.5 or 2 mg/kg for total MOAH migrating from plastic FCMs :

The mass fraction of total MOAH migrating from plastic materials and articles to the food or food simulant **shall not exceed the limit of quantification** of 0.5 mg/kg in food simulants A, B, C, D1, and E, and shall not exceed the limit of quantification of 2 mg/kg in food simulant D2. Due to the fatty nature of MOAH the migration to food simulant D1 and D2 is more relevant rather than the more aqueous food simulants A, B and C.

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Amendment to Regulation (EU) No 10/2011: 'substances amendment' (4)

3. To use ethanol 95% and isooctane if use of food simulant D2 is not feasible:

If the testing conditions representative for the worst foreseeable conditions of intended use of the material or article, are **not technically feasible using food simulant D2**, migration tests shall be done according to section 2.1.3 of Annex V and the migration to ethanol 95 % and isooctane shall not exceed the limit of quantification of 0.5 mg/kg.'

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Bisphenol A/ bisphenols

Agenda item 7

a. Discussion on implementation of Regulation (EU) 2024/3190 + short presentation from France

b. Monitoring measure (jointly with contaminants)

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Implementation of Regulation (EU) 2024/3190

- Entered into force 20 January 2024
- Questions for clarification concerning the scope, other bisphenols and their derivatives, compliance and testing, placing on the market and transitional provisions
- Need to ensure common understanding for compliance and enforcement
- Draft Q&A

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DG CCRF

French Law on BPA Law n°2010-729 and regulation 2024/3190

6 and 7 February 2025

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Comparison of the scope

Regulation 2024/3190	Law 2010-729
All type of FCM	Containers, packaging and utensils
Adhesives, rubbers, IER, plastics, printings inks, silicones, varnishes and coatings	Every group of FCM
All contact	Direct contact
BPA and other hazardous bisphenols and bisphenols derivatives	BPA
Prohibition of use of BPA and residual BPA in other bisphenols	No presence of BPA
Transitional periods	Already applicable
Some Exemptions but for industrial equipment	Not in the scope

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Type of FCM concerned

The French law prohibite the placing on the market and the import of « packaging, container or utensil containing bisphenol A »

The European regulation has a broader scope since it covers all categories of FCM, including industrial equipment (outside the scope of French law).

Also deals with BPA behind functional barrier (ie coating on the exterior of a metallic can) while in France only the direct contact is forbidden (so functional barrier were acceptable)

=> The French Law is less restrictive than the regulation on these points

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Other bisphenols and type of materials

1) Other Bisphenols

The European regulation takes into account the bisphenols derivatives and other hazardous bisphenols.

Not forbidden by the French law so far even if hazardous bisphenols are not expected to be used in France in replacement of BPA (bad image and mainly replaced by non-epoxy resin coatings).

2) Type of material

No distinction in France. But in practice the use and presence of BPA come from plastics, varnish, coatings, adhesives or inks that are included in the scope of regulation 2024/3190

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Verification of the compliance

Even if the presence of BPA is forbidden by the french law the implementation of the law according to our guidelines only focus on the intentional use of BPA (because of the impossibility to have 0% BPA in recycled FCM for example).

The verification of the compliance to the French law is based on our extraction method (extraction of BPA with 100mL of acetonitrile 24h 23°C with a detection limit of 0,1 mg/kg of paper and board). Can be used for all materials especially plastics of coatings.

Actually, the aim of the regulation with the proof of absence of residual BPA and the french method will be the same (depending on the method chosen by the EU-RL).

For recycled Paper and Board, we have a limit of 2mg BPA/kg of paper which is a clue of GMP

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Transition periods

The French Law fixed a transitional period of 3 years that expired in 2015.

As a result, the presence of BPA in FCMs, particularly cans, is already banned in France.

The Regulation 2024/3190 has transitional period of 18 months and some specific transition of 36 months for :

- Single use FCM in contact with fruits or vegetables and fishery products (already ban in France)
- Single use FCM with BPA on the exterior of the metal surface (not in the scope of the law)
- Repeat-use FCM used as industrial equipment (not in the scope of the law)

Minor differences and impact with the regulation and the law

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Conclusion

The European regulation has a broader scope than the French Law

The ban is already applicable in France for cans and packaging but not for industrial equipment that will be subject to the new ban and restriction stated in the regulation 2024/3190.

There will be no incompatibilities or inconsistencies between the current French Law and the European ban.

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Thanks for your attention

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Monitoring measure

- Proposed joint exercise to investigate levels of BPA and other [relevant] bisphenols as contaminants in food and arising through adventitious sources from FCM (not enforcement of Reg 2024/3190)
- Coordinate Member States activity with active involvement of industry
- First draft document MS WG on Industrial and Environmental contaminants
- Points for further reflection:
  - Purpose
  - Scope – which bisphenols, specific food categories or FCMs
  - Number of samples
  - Methods of analysis
  - Action on follow up
  - Timing

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Any remaining AoB

Agenda item 8

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AOB: Labelling requirements for FCMs

- GPSR (Regulation (EU) 2023/988)
  - Manufacturers [Art.9: 6.] Importers [Art.11: 3.] shall indicate their name, their registered trade name or registered trade-mark, their postal and **electronic address** and, where different, the postal or electronic address of the single contact point at which they can be contacted.
- FCM (Regulation (EC) No 1935/2004)
  - Art.15: the name or trade name and, in either case, the address or registered office of the manufacturer, processor, or seller responsible for placing on the market established within the Community [Union];
- FCMs within the scope of GPSR where no specific provisions with the same objective under Union law
  - effective functioning of the internal market and a high level of protection of human health

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AOB: 1S1A

- Expert Group on One Substance, One Assessment (E03792) (see ToR)
- 1-2 meetings per year, last one 14 – 15 November 2024
- Melamine discussed:
  - Authorised monomer in plastic FCM (SML = 2,5 mg/kg)
  - CLP harmonized classification Carc. 2 STOT RE 2 (ATP18 applies since December 2023)
  - REACH candidate list > possible inclusion in Annex XIV (authorisation) (for discussion early 2025) after SVHC identification (January 2023)
  - Maximum level as contaminants in food
- EFSA Study Mapping Data Requirements and Risk Assessment Methodologies

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Thank you

Close of meeting

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