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## Agenda

**Wednesday**

1. Welcome, AoB points
2. Discussion BPA measure

**(lunch)**

3. Revision of FCM rules
  - discussion on two studies
4. Quality Amendment R 10/2011
5. Update on EFSA's work on phthalates


**Thursday → start at 09:00**

6. CEPI GMP guidelines
7. Discussion implementation R 2022/1616
8. AoB

**AoB:**

- a) Notification of lead migration from ceramics via RASFF (AT)
- b) Coatings on food (HU, NL)

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# Bisphenol A (BPA)

Discussion on a measure restricting the use of BPA in FCMs

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## EFSA opinion on BPA

- Published 19 April 2023
- Based on all the new scientific evidence assessed, EFSA established a TDI of 0.2 nanograms per kilogram of body weight, replacing the previous temporary TDI of 4 µg/kg bw (around 20,000 times lower than before)
- EFSA concluded that consumers with both average and high exposure to BPA in all age groups exceeded the new TDI, indicating health concerns
- EFSA noted that a similar dose range also caused adverse effects for reproductive and developmental toxicity and for metabolic effects, which are therefore also relevant for human health

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## Current EU rules on BPA in FCM

- Authorised as a monomer in plastic FCM with SML of 0.05 mg/kg
- The same SML applies to varnished and coated FCMs
- A prohibition on BPA in FCMs specifically for infants and young children also applies based on the precautionary principle since 2018, except in the case of the ban on BPA in polycarbonate infant feeding bottles, which has applied since 2011

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## Uses of BPA in FCM

- Used to manufacture polycarbonate plastic for use in applications such as food moulding or processing equipment, water dispensers and some reusable drinking bottles for consumers
- Still used extensively to manufacture epoxy resins for coatings to line food and drink cans, metal lids and caps and some large-scale storage tanks for the food industry
- May also be found as a component in other FCMs e.g. inks, adhesives, rubber

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## Risk management of BPA in FCM

- Authorisation of BPA in FCM plastic no longer justified
- An SML is not practical – non-compliance + no reliable analytical methodology for compliance and enforcement purposes
- Prohibition on the intentional use of BPA in FCM
  - plastic
  - varnishes and coatings
  - inks
  - adhesives
  - rubbers



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## Unintentional presence of BPA in FCM & food

- FCM
  - present as a contaminant in the input waste stream used to produce recycled materials e.g. paper and board, plastic
  - unreacted monomer e.g. from process to produce BADGE
  - 'set-off' or 'vapour-phase transfer' from outside of packaging to which a BPA-based coating has been applied
  - unknown origins
- Foodstuffs
  - environmental contaminants (including drinking water)
  - some bisphenols (BPF) as a process contaminant

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## Unintentional presence of BPA in FCM & food

- A prohibition on the unintentional presence of BPA in FCMs (often at low levels) would be disproportionate and impractical
- Efforts should be made to identify sources that contribute the greatest and to address those
- For some sources, contamination levels should in any case decrease over time due to other regulatory measures (e.g. ban in thermal paper, possible further restrictions under REACH Regulation)

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## Unintentional presence of BPA in FCM & food

- Monitoring and reporting requirements should complement the ban on the intentional use
- Determination on what should be included as well as frequency
- Cooperation and support from FCM business operators and food business operators → collection and reporting of aggregated data by Member States
- Analytical detection limit and/ or limit of quantification to be agreed
- Harmonisation of any possible follow up action
- Possible additional measures e.g. GMP



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## Avoiding other hazardous bisphenols

- As well as BPA, BPS and 2,2-bis(4'-hydroxyphenyl)-4- methylpentane are classified in accordance with CLP Regulation as Repr. 1B.
- ECHA has also adopted an opinion on BPAF and its salts; further information generation and investigations on a number of other bisphenols
- Legitimate questions on what should and shouldn't be used to replace BPA → avoid substances with similar and/ or specific hazardous properties to maximise consumer safety and provide regulatory predictability
- Support commitments given as part of the EU's Chemicals Strategy for Sustainability



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## Estimated impacts of ban

- Plastic
  - not expected to present any significant difficulties for replacement of BPA-based polycarbonate or polysulphone plastics in FCM
  - alternatives include co-polyesters with similar properties to polycarbonate. PET, HDPE and PP may also be used as alternatives depending on the function of the FCM article
- Varnishes and coatings
  - impacts anticipated e.g. costs, shelf-life of some products, energy consumption
  - alternatives include combinations of polyester and acrylic
  - transition to all foodstuffs on EU market requires development and certification
- Other FCM
  - not expected to present any difficulties

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## Main requests from industry

- Any ban should target intentional use of BPA
- Sufficient time to transition from one material to another (particularly for varnishes and coatings)
  - development and qualification process to ensure suitability, functionality, quality and safety of replacement
  - some applications will take longer than others (e.g. some acidic foods)
  - avoid waste and destruction of materials and eventual food waste
  - avoid high costs
  - replacement in the case of long-life [repeat-use] applications
- Question on the application to heavy duty coating on large vessels and containers

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## Transitional period and possible derogations

- A fixed transition period of 18 months is foreseen for the [first] placing on the market of affected FCM from the date of entry into force of the measure
  - entry into force currently estimated spring 2024; application date therefore end 2025
- Longer transition times will be considered for specific food contact applications with sufficient justification and data to support
- Elaborate information to be requested from industry
  - possible impact on food safety (e.g. microbiological & chemical contamination)
  - possible impact on food security and supply chain
  - additional resources inc. costs beyond 18 months
  - status of development of alternatives and additional time required
  - typical migration levels of BPA



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## Compliance, controls and monitoring

- Compliance (i.e. no use of BPA in the manufacture of the FCM) can primarily be verified through a DoC, either by the next BO in the supply chain or by MSs' competent authorities when carrying out controls, including any necessary supporting documentation
- Monitoring by analytical testing, proportionate to the likely frequency and level of contamination
- Follow-up to relevant findings → investigations into the possible sources and proposed remedial action, where deemed necessary



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## Timeline and actions

- Reflect on these points and the discussion today → please signal any major concerns or points within one week i.e. by 12 July
- Stakeholder webinar later this month to inform on the way forward, taking account of these discussions
- Collection of further information from industry, specifically to support potentially longer transitional periods
- Drafting of and discussion on draft measure (autumn)
- Possible vote PAFF November 2023 (earliest)

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# Afternoon Programme

1. Revision of FCM rules  
discussion on two studies
2. Quality Amendment R 10/2011
3. Update on EFSA's work on phthalates



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# Revision of FCM Legislation

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## Challenges (summarised from evaluation)

- **Safety** is **insufficiently** defined at EU level for most FCMs (lack of harmonisation)
- **Safety** of migrating substances is **not transparent** – is an FCM actually safe?
- Public authorities have **insufficient capacity** to
  - **risk assess** all **substances**
  - **harmonise** and manage **specific FCM** rules under the present system
  - comprehensively **enforce compliance** and safety in accordance with current rules
- Specific detailed **rules** with **ever increasing complexity** – problems may be left in fog
- The **use of** certain **chemicals** is increasingly **no longer** accepted
- **Environmental challenges** call for more sustainable production and use
- **New products** are entering the market that **challenge present categories**

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## Objectives of the Revision ('aspirations')

- Strengthen Article 3 – **FCMs are to be inert** – migration to be the exception
  - and as migration is unavoidable, it shall not adversely affect food safety/quality
  - rules to encourage **inherently safer FCMs** – 'limits' no longer driving force
  - rules to drive innovation towards safer materials
- Ensure we can effortlessly know **that a final material is safe**
- Keep **new rules** simple, practicable, enforceable and **achievable**
- Ensure there is **full harmonisation**, level playing field, including imports
- Ensure **high level of transparency** over composition and sustainability


*(inherent safety: materials have been produced fewer substances with particular hazardous properties, so less controls such as limits are needed)*

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## FCM revision approach

- |  |  |
|--|--|
| 1. Define main policy themes and broad initial solutions           | 2022   |
| <b>2. Refine solutions and define more detailed policy options</b> | 2023  |
| 3. Assess feasibility and impact of policy options                 |  |
| 4. Conclude on preferred policy options                            | 2024   |
| 5. Work towards legislative proposal                               | 2024 and beyond  |

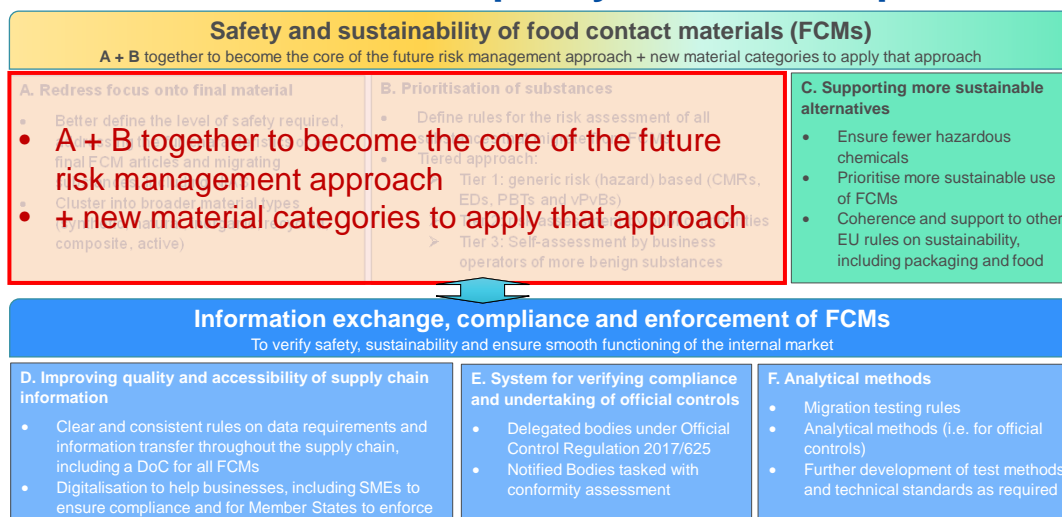
Today more in-depth presentation – *from challenges to options for solutions*

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## EU FCM revision: Main policy themes and pillars



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## On-going work

- Two studies
  - On-going study Pillar D + E  
*information exchange, compliance and enforcement (EY)*
  - Preparation of study pillar C  
*supporting safer and more sustainability alternatives ('sustainability')*
- Two presentations
  - Presentation on C covers terms of reference for study, as well as PPWR

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## Presentation EY

- Study on Pillar D+E

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# Sustainability

Pillar C: Supporting safer and more sustainable alternatives – State of play

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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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## Pillar C: Supporting safer and more sustainable alternatives

### Sustainability applied to FCM regulation

Expand current FCM rules to prioritise and support sustainability

Current FCM Legislation  
Safety of the FCM  
+  
Functioning of Internal Market

Elaborate principles of sustainability when it comes to FCMs  
= sustainable FCM

To what extent the application of those principles to FCMs would have added value?  
In comparison with new environmental and food initiatives

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## Pillar C: Supporting safer and more sustainable alternatives

### Objectives for sustainability in the framework of future EU FCM rules

**Objective 1:** Ensure that the manufacture of FCMs is sustainable, prioritize sustainable materials

**Objective 2a:** Ensure that the use and reuse of FCMs is sustainable, including safe recycling and reuse, making the sustainable choice of consumers possible

**Objective 2b:** Support sustainable food systems

**Objective 3:** To the extent not covered under objective 2 and 3, contribute to the United Nations 2030 Agenda and the objectives of the Green deal

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## Pillar C: Supporting safer and more sustainable alternatives

### Objectives for sustainability in the framework of future EU FCM rules

**Objective 1:** Ensure that the manufacture of FCMs is sustainable, prioritize sustainable materials

Ensure the **safety of sustainable, recycled and reusable** FCMs.

Adapt the risk assessment and management approach to the specificities of those FCM. This includes rules adapted to the difference in composition and production methods of nature-based materials (wood, fiber, agri-waste, bioplastics, materials from fermentation).

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## Pillar C: Supporting safer and more sustainable alternatives

### Objectives for sustainability in the framework of future EU FCM rules

**Objective 2a:** Ensure that the use and reuse of FCMs is sustainable, including safe recycling and reuse, making the sustainable choice of consumers possible

By facilitating the placing on the market of **reusable** products and/or packaging and provide necessary labelling information to ensure their reuse under safe conditions. (Making sure to be in line with the new provisions of the PPWR – articles 10 and 26 )

Expand rules on **recycling** to cover all materials and recycling technologies in order to facilitate the recycling process. (mainly paper and board)

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## Pillar C: Supporting safer and more sustainable alternatives

### Objectives for sustainability in the framework of future EU FCM rules

#### Objective 2b: Support sustainable food systems

In contrast to objective 2a, the focus is not at the sustainability of the FCM itself, but at **its use to support the more sustainable use of foods**.

→ may include reducing food waste, as well as facilitating production practices that help to increase the sustainability of food systems.

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## Pillar C: Supporting safer and more sustainable alternatives

### Objectives for sustainability in the framework of future EU FCM rules

#### Objective 3: To the extent not covered under objective 2 and 3, contribute to the United Nations 2030 Agenda and the objectives of the Green deal

→ contribute to **several goals of the United Nation's 2030 Agenda for Sustainable Development**, which is an ambitious action plan aimed at protecting the people and the environment.

→ contribute to the objectives of the **EU Green Deal** for a climate-neutral and circular economy, healthy and sustainable food and food system, and zero pollution reducing the risk from chemicals to health and our environment

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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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## Pillar C: Supporting safer and more sustainable alternatives

### Scope of the Study

- Establish the **concept of sustainability** when applied to food contact materials.
- **Identify gaps** in existing and developing EU policy initiatives
- **Map and quantify material streams of FCMs and (packed) food products**, with a view to establish where the biggest gains could potentially be achieved
- Develop, taking into account the results of the above analysis, **regulatory measures** that could bring significant added value if introduced under revised FCM legislation
- Propose a ranking of these developed measures on **the basis of their potential to increase sustainable FCM or sustainable use of FCM**



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## Pillar C: Supporting safer and more sustainable alternatives

### Example of potential policy measures

- Providing **guidance and support to Member States on FCM waste management** to improve recycling strategies
- Introducing **guidance and communication tools** to sensitize the consumer on the FCM used and the packaging bought
- Supporting incentives to place on the market more sustainable FCM and to encourage the use of more sustainable production methods and materials

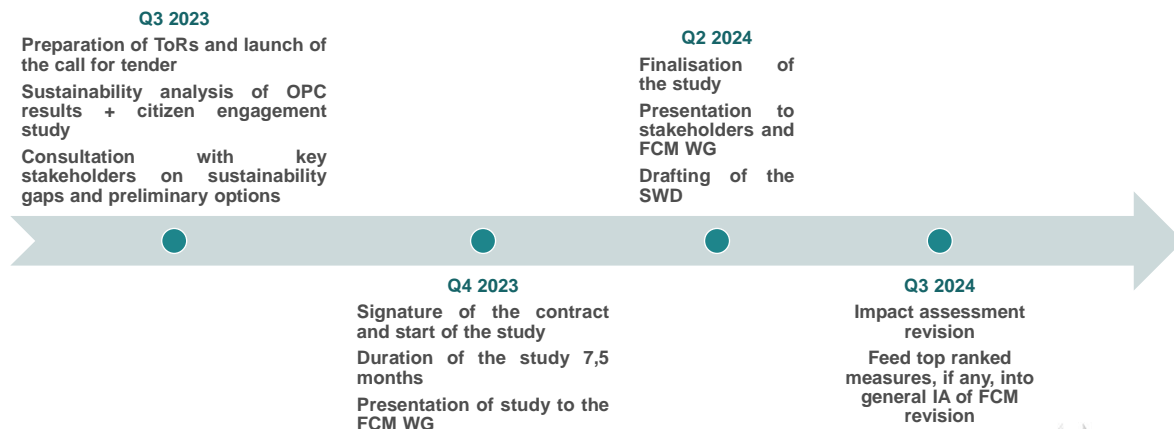
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## Pillar C: Supporting safer and more sustainable alternatives

### Foreseen timeline of study



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# Revision of the Packaging and Packaging Waste Directive and its impact on FCM



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## The Packaging and Packaging Waste Regulation (PPWR)

### Objectives :

- To **prevent packaging waste**, and to promote **reuse of packaging** and recycling
- To **Reduce the disposal of packaging waste** and promote a more circular economy
- To **Ensure that all packaging is reusable or recyclable in an economically feasible way by 2030**, and to address over-packaging and reducing packaging waste

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## The Packaging and Packaging Waste Regulation (PPWR)

### Core measures :

1. A **reduction target of packaging waste** per capita of 19% for 2030 compared to the baseline, equivalent to a 5% reduction from the 2018 values,
2. EU **wide mandatory reuse or refill targets for packaging**, where reuse is most effective
3. Phase out of unnecessary or avoidable packaging

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## The Packaging and Packaging Waste Directive (PPWR)

### Direct implications for FCM area

#### Articles :

- Article 5: Requirements for substances in packaging
- Article 6: Recyclable packaging
- Article 7: Minimum recycled content in plastic packaging
- Article 8: Compostable packaging
- Articles 10 and 26: requirements to reuse FCM
- Article 13: requirements for documentation
- Article 22 and annex V: Obligations of manufacturers
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## The Packaging and Packaging Waste Directive (PPWR)

### Direct implications for FCM area

#### Articles :

- Article 5: Requirements for substances in packaging
  - Restrictions on substances of concern that negatively affect the re-use and recycling of materials
- Article 6: Recyclable packaging
  - All packaging must be recyclable
  - Specific conditions to be fulfilled : **designed for material recycling**, recycled at scale and **effectively and efficiently separately** collected, **sorted into defined waste streams** without affecting the recyclability of other waste streams, **recycled** so that the resulting secondary raw materials are of sufficient quality compared to the original material and used to **substitute the primary raw materials** for packaging.

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## The Packaging and Packaging Waste Directive (PPWR)

### Direct implications for FCM area

#### Articles :

- Article 7: requirements for recycled content of plastic packaging (PET and other)
  - Set minimum percentage of recycled content recovered from post-consumer plastic waste (for PET and other type of packaging).
- Article 8: Compostable packaging
- Articles 10 and 26: Reusable packaging – reuse and refill targets
  - Packaging in the market should fulfil the conditions set in the article. Standardisation of the packaging.
  - Set minimum percentage of reusable packaging in the market.

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## The Packaging and Packaging Waste Directive (PPWR)

### Direct implications for FCM area

#### Articles :

- Article 13: Obligations of manufacturers
  - Requirements for labelling and technical documentation (QR code, digital data carrier)
- Article 22 and annex V: Restrictions on use of certain packaging formats
  - After 3 years after entry into force of this Regulation operators shall not place on the market packaging in the formats and for the purposes listed in Annex V

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## The Packaging and Packaging Waste Directive (PPWR)

- The revision of the FCM regulation pursues similar goals and consistency will be ensured
- The file is currently **in the first reading step at the European Parliament**, the proposal has been referred to the Committee on Environment, Public Health and Food Safety (ENVI)

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# Amendments to Regulation (EU) 10/2011

## ‘Quality Amendment’

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## Overview

- 16<sup>th</sup> amendment (substances):
  - PRAC finalised, should have been adopted, administrative delay  
→ **adoption expected next week**
- Quality amendment:
  - being drafted – recitals – very limited progress
  - discussion on approach to impurities
- Authorisation of DEHCH (part of 18<sup>th</sup> amendment)
  - bis(2-ethylhexyl)cyclohexane-1,4-dicarboxylate (CAS No. 84731-70-4, FCM No 1079)
  - presented in PAFF on Monday, written procedure
- Styrene (foreseen 40 ppb limit)
  - preparations on-going

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## Background quality 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
- Other amendments / clarifications
  - Aging: clarification of 'Stability rule' + provision on aging
  - Retailers to receive a DoC
  - minor changes to testing requirements, derogation in Article 17(2)(a) to go, assignment cheeses

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## Article 8(5)

- A = 50 ppb
  - this follows EFSA Guidance
- B = 0.15 ppb
  - (TTC, 0.00015 mg/kg)
- There appears limited opportunity to lay down significantly higher/other cut-offs
- i.e. limited assessment of all migratable NIAS to be required between 50 and 0.15 ppb
- There are a number of practicable problems that business operators will experience – these are real problems
  - analytical limits, availability for testing, number of substances, variation of substances
- On the other hand we need clear guidance
- How to approach?

5. For the purpose of paragraph 2, 3 and 4 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 non-intentionally added substances 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 migration into the food; or,
- (iv) are unknown or unassessed, 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 the food.

by derogation from point (iii) and (iv), where the plastic is used to pack:

- dry unpeeled fruit or vegetables that must be peeled or washed,
  - other dry non-fatty foods when the packaging is in contact with less than 10% of the food surface and is open to the atmosphere,
  - fully wrapped in a material without absolute barrier properties, provided this material is not in contact with the plastic for a time exceeding 4 hours or when the contact exceeds 10% of its surface, and the plastic packaging is open to the atmosphere, or,
  - as secondary packaging foods packed in sealed metal or glass packaging.
- 10% migration instead of full migration into the food may be assumed.

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## Approach NIAS presently under consideration

- Substances (i.e. NIAS) migrating above 50 ppb require full risk assessment in accordance with Article 19
- Substances migrating between 0.15 ppb and 50 ppb require a limited toxicological assessment that at least excludes genotoxicity
  - **unless:** All suppliers exclude genotoxic substances are present
  - at each production stage good understanding of chemistry will be required
    - reaction products, degeneration products, introduction / presence of impurities
    - i.e. a comprehensive analysis of NIAS, with subsequent reflection on potential genotoxicity
    - would the substance be in a free form, i.e. is migration likely
    - inventory of substances
  - **aim:** to do the assessment at most appropriate stage in supply chain
- Below 0.15 ppb obviously no action

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## Enforcement of NIAS approach

- It should be possible to enforce these (potential) provisions with relative ease
    - risk that some business operators otherwise feel insufficient urgency
  - Studies done by business operators need to be easily available to CA
    - registration?
  - Appropriate transition periods needed
    - complex, large number of substances → does that mean very long?
  - Need to strengthen GMP requirements?
    - aimed at controlling and limiting the presence of impurities
- We will be addressing the question marks

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# Work on plasticisers

Agenda item 5: EFSA update on re-evaluation of phthalates, structurally similar substances and replacement substances from FCMs

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## Follow-up for Member States and stakeholders

- Data is needed to support exposure estimates and therefore ultimately the risk from the presence of these substances from FCM
- Relevant substances for which data is made available will be assessed by EFSA in the second part of the work (pending mandate from the Commission)
- Possible risk management depending on outcome of assessment
- Insufficient or no data → no adequate assessment → unable to confirm safety → authorisation of substance(s) can no longer be supported at EU level
- Experience will be used to inform on practices for new FCM rules e.g. inter-Agency cooperation, 'one substance, one assessment', grouping of substances and possible combination effects

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# Morning Discussion 06/07

CEPI

Recycling

AoB



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# CEPI presentation

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# Progress Implementation Regulation (EU) 2022/1616

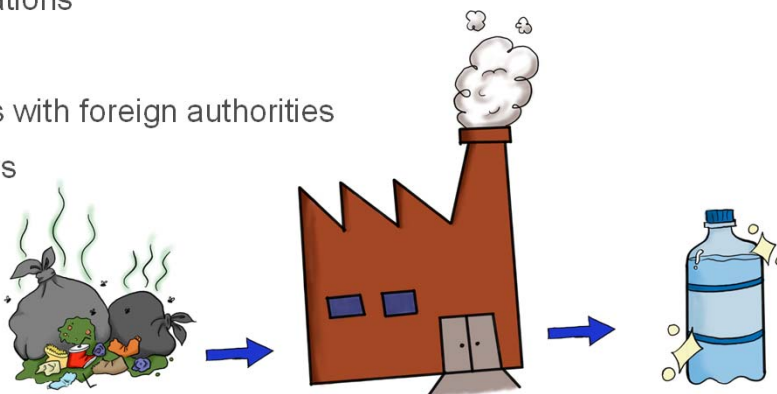
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## Discussion Recycling

- Register and Authorisations
- Amendments
- Feedback on meetings with foreign authorities
- Questions and Answers



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## Part 1: Register and Registration

- Consultation and evaluation of Forms: COM & CAs in EU Level
  1. Two different periods of consultation took place: May & June ← **WG 27<sup>th</sup> & 28<sup>th</sup> of April**
  2. Number of cases needed additional investigation in order to be ready to upload in the Register List
  3. A number of entries have excluded since additional work needed in order to complete all the missing gaps
- Ongoing work: Register Lists (received till 31<sup>st</sup> of December 2022) upload in FCM SANTE website – 1<sup>st</sup> of June 2023 ← **May to June**
- Next Step: Register Lists (forms received from 1<sup>st</sup> of January till 30<sup>th</sup> of June 2023) will be uploaded in FCM SANTE website – **1<sup>st</sup> to 2<sup>nd</sup> week of July 2023** ← **July to August**

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## Part 1: Register and Registration -

### • [Resources for plastic recyclers \(europa.eu\)](https://europa.eu)

PAGE CONTENTS

- 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

scheme, the installation, the facility and the operator). Please see the example provided ([completed registration form for recycling schemes](#) <sup>(EN|\*\*\*)</sup>).

- **Form 5 - Novel technologies:** [accessible on this link](#)  
Register your Novel Technology

**Section 1 - Year 2022:  
Forms received by 31<sup>st</sup>  
December**

#### 2. The Union Register

##### i. EU Union register of technologies, recyclers, recycling processes, recycling schemes, and decontamination installation

This draft list contains installations, facilities and companies located in the EU registered before 31 December 2022. The current lists of the Register (established in accordance with Article 24 of Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with foods) will be updated in regular basis.

- **List 1:** [Register of Recycling Installations in the EU](#) <sup>(EN|\*\*\*)</sup>
- **List 2:** [Register of Recycling Facilities in the EU](#) <sup>(EN|\*\*\*)</sup>
- **List 3:** [Register of Recycling Companies in the EU](#) <sup>(EN|\*\*\*)</sup>

**EU Member States**

##### ii. EU Union register for countries located outside EU of technologies, recyclers, recycling processes, recycling schemes, and decontamination installation

This draft lists contains installations, facilities and companies located outside EU registered before 31 December 2022. The current lists will be updated in regular basis.

- **List 1:** [Register of Recycling Installations outside of the EU](#) <sup>(EN|\*\*\*)</sup>
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**Non EU Member States**



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- **List 3:** [Register of Recycling Companies outside of the EU](#) <sup>(EN)</sup>\*\*\*

**Section 2 - Year 2023:  
Forms received from 01<sup>st</sup>  
January to 30<sup>th</sup> June**

**EU Member States**

**Non EU Member States**

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# Part 1: Register and Registration

- Art 24 describes of 2022/1616 the general rules to be included in the Register:
  - 3.The Register shall assign the following entities with unique numbers:
- recyclers are assigned a recycler operator number ('RON');
- decontamination installations are assigned a recycling installation number ('RIN');
- recycling facilities are assigned a recycling facility number ('RFN');
- recycling schemes are assigned a recycling scheme number ('RSN');
- authorised recycling processes are assigned a recycling authorisation number ('RAN');
- novel recycling technologies are assigned a novel technology number ('NTN').

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## Part 1: Register and Registration

- The Register Lists are not yet complete, Article 24(2) requires further data
  - Further fields will be made available progressively
  - Particular focus on registration status, Article 24(2)(c)
- Data to be revised and renewed in regular basis (once per quarter) in order to be up to date & facilitate the control and audit process
- Ongoing work with IT department, in order to build up an IT system to facilitate all the information received in the Register.
- For the time-being we are taking incremental steps

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## Part 2: Authorisation of recycling process

- COM invited the applicants (from 2008 till today) with a valid dossier (EFSA opinion & RECYC Number) to revise their personal data
  1. June & September 2022
  2. 175 replies received
- Batch separated in order to facilitate the process
  1. Batch 1: 175 Authorisations Decisions
  2. Batch 2: The other ongoing & to be finalised dossiers
- Under evaluation of the Authorisations Decisions, MSs will be informed about the process to be followed soon

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## WG 27<sup>th</sup> & 28<sup>th</sup> of April

# Authorisation of recycling process

- Under evaluation: COM & MSs
  1. All EFSA opinions evaluated and separated in categories ← WG 10<sup>th</sup> February
  2. Categories selected due to their similarities, recommendations & conclusions
  3. Draft templates to be finalised & kick off the process
- Ongoing work: Consultation Process - COM ← WG 27<sup>th</sup> & 28<sup>th</sup> of April
  - Process started beginning of April
    - SANTE internal consultation
    - COM internal services
- Final step: Finalising & Voting the Authorisation Decisions ← May
  - MSs to be informed about the Authorisation decisions templates
  - Process to be explained to MSs: September to October

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## Part 3: Where to find (1) Register EU Survey forms & (2) Register Lists

1. Register Forms:
  - **EU Survey: All forms under one**
    - 1, 2, 3 & 4 Forms merged in one
    - <https://ec.europa.eu/eusurvey/runner/123RECYCForms>
  - Novel Technology form available
    - <https://ec.europa.eu/eusurvey/runner/5RECYCLNovelTechnology>
2. Register Lists:
  - [Resources for plastic recyclers \(europa.eu\)](https://ec.europa.eu/eusurvey/runner/5RECYCLNovelTechnology)

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## Amendments

- First Amendment
  - previously correction of Article 5(2) – will now address more matters
- Second Amendment
  - Certification under Article 6(3)
- (perhaps better naming – ‘first amendment’ and ‘certification amendment’)

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## First amendment

- Change to Article 5(2)
 

*‘Recycled plastic, recycled plastic materials and articles, and products in which those materials or articles are contained, shall be accompanied by a declaration of compliance in accordance with Article 29’*
- This causes a need to clarify what is required by operators downstream of converters
- Article 29 to become
 

*‘requirements for declarations of compliance applicable to specific operators’*
- Simplified declaration required from
  - food business operators
  - manufacturers of appliances, kitchenware, etc.
  - distributors and importers

5. The simplified declaration of compliance referred to in paragraph 4 shall at least:

- (1) identify the business operator issuing the declaration;
- (2) identify the food product or other product, to which the declaration applies;
- (3) confirm that the recycled plastic materials and articles used in the product comply with this Regulation;
- (4) set out the amounts of recycled content in the plastic materials or articles that the product contains; this amount shall be in accordance with the information indicated in field 2.1.4 of the declaration of compliance supplied by the converter under paragraph 3; and,
- (5) provide any relevant instructions to the users of the product.

This declaration may be provided in a separate document, or as part of the labelling of the food product. The issuer of a simplified declaration of compliance shall provide all declarations of compliance on which basis the simplified declaration is issued to the competent authorities of the Member States if they so request.

6. By derogation to paragraph 4,
  - (a) distributors that do not modify the composition of a product, may pass on the declaration of compliance they received from their suppliers to the next operator in the supply chain without issuing their own; and,
  - (b) retailers may omit issuing a declaration of compliance provided relevant instructions set out in the declaration of compliance received from their supplier are provided to the users of the product by other means.’

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## First Amendment other than DoC

- Small change to Article 10 (4):
  - in the first line of paragraph 4 of Article 10 the word ‘recycler’ replaced with the word ‘developer’
- Additional transitional provision (subject to legal verification)
  - ‘By derogation to Article 26(4) the status of the registration of a decontamination installation shall not be changed to ‘suspended’ before 10 October 2024.’
- First draft text nearly ready, expected directly following the summer

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## Certification Amendment

- Revised waste framework will not address quality of input materials
  - We need to have stronger provisions on certification under Article 6
- Initially foreseen approach
  - certification needs to be done by notified bodies
  - notified bodies require accreditation
  - accreditation requires a standard, which can be the Regulation
  - certification possibly part of or in parallel with ISO 14001 (or 9001) certification
- Far from certain, only initial analysis has been done
  - Discussions foreseen with Commission services in autumn

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## Feed-back on meetings with non-EU CAs

- Recyclers need to register installations with competent authority in territory
  - agreement within one year on CMSS, there after no more placing on the market
- This places an obligation to audit on the CA, outside of the EU this is difficult
  - there may be no 'suitable' competent authority
  - the authority is not competent for doing an audit
  - Official Control Regulation applies
- Discussions with FDA, and Australian authorities
- Event in Bangkok: [Seminars \(eu-asia-sps.com\)](http://Seminars(eu-asia-sps.com))
  - To discuss and create awareness on FCM legislation
  - 26-27 June



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## Basic message (you may consider the 40-slide presentation interesting...)

Why is there specific legislation on plastic recycling for food contact?



- High level of trust needed – health protection – consumer trust - uptake

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Two main elements of the EU approach

- Recycling processes must prove their decontamination capability **on paper**
  - EFSA assessments – Commission authorisation – ‘regulatory approval’
- Recyclers must show that they operate the process correctly **in practice**
  - Good Manufacturing Practices (‘GMP’) – Competent Authorities – Audits
- The second point is often overlooked
  - the focus of many is on approval – not on continuous application of GMP
  - role for the competent authorities

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## Questions and Answers

- We did not ask you in particular to prepare any questions
- But we will try to answer to our best abilities

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## AoB

- Notification of lead migration from ceramics via RASFF
- Coatings on food (HU, NL)
  - When is it an FCM → if it is not edible, hence if it will not foreseeably be consumed
  - When is it a plastic FCM → if it is a final plastic before in contact with the food
    - i.e. if it is liquid when being applied, it is not a plastic

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# Thank you

Happy to receive questions...

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