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## Agenda

### 11 September, afternoon

1. Welcome, AoB points
2. Short update on
  - revision of FCM EU rules
  - amendments to Regulation (EU) No 10/2011
  - a measure restricting the use of BPA
3. Progress implementation of Regulation (EU) 2022/1616  
Register/Authorisations/Amendment/Q&A
4. AoB points
  - BTSF

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# Revision of FCM Legislation

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## FCM revision approach

- |  |  |
|--|--|
| 1. Define main policy themes and broad initial solutions           | 2022   |
| <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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## 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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## On-going work

- Draft of document outlining the possible future of FCM legislation on-going
  - target: publicly available in November
- 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')*

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# Sustainability study

## Scope and Objectives :

- Preparatory study to support the development of the full policy options for the revision (Pillar C)
- This requires **defining sustainability when applied to FCMs, to analyse the current FCM market** by providing a mapping of the products currently available in the market, **to determine the regulatory gaps existing between the current regulations** in order to **characterise policy measures** that would help placing sustainable FCMs on the market.

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# Sustainability study

45 WEEKS

## Tasks:



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# Amendments to Regulation (EU) 10/2011

## ‘Quality Amendment’

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## Overview

- 16<sup>th</sup> amendment (substances):
  - Commission Regulation (EU) 2023/1442  
→ Published 12 July 2023
- Authorisation of DEHCH
  - bis(2-ethylhexyl)cyclohexane-1,4-dicarboxylate (CAS No. 84731-70-4, FCM No 1079)
  - Commission Regulation (EU) 2023/1627  
→ Published 10 August 2023
- Quality Amendment: drafting on-going

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## Background quality amendment

- Process
  - Internal EC discussion draft
  - Further discussion WG 17 November 2023; intention to vote in PAFF first half 2024
- Alignment with recycling regulation
  - Manufacture of substances from waste (Article 1(3) R 2022/1616, 'chemical recycling')
  - Revision of 'layer approach'
  - GMP requirements (amendment of Annex to Regulation No (EU) 2023/2006)
  - Declaration of compliance – introduction of recycled content
- Natural materials
  - Purity of substances + use of authorised natural materials
- Biocides
  - Separate Commission decision removing biocides of the provisional list
  - removal of the provisional list + derogation for substances authorised under BPR
- Other amendments / clarifications
  - Aging: clarification of 'Stability rule' + provision on aging
  - Retailers to receive a DoC
  - Changes to testing requirements,, assignment cheeses

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## Bisphenol A (BPA)

Brief update/ some issues to discuss today

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## Reminder

- 19 April: EFSA opinion published – SML 20,000 times lower than before
- 23 May: Commission announced the initiative on bisphenol A (BPA)
- 5 – 6 July: Initial discussion in Expert Working Group
- 18 July: Webinar for stakeholders + follow-up Q&A (in Commission's FCM document library)
- 15 September: First deadline for initial request from businesses for extended transitional period beyond 18 months

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## Topics to briefly reflect on today

- Industrial-scale coated applications
- BADGE
- BPA as contaminant in e.g. recycled paper and action levels
- BPA based FCMs with trace migration levels in membrane applications used for purification e.g. polysulphones
  - Polysulfone resins are synthesized by condensation of the disodium salt of BPA with 4,4-dichlorodiphenyl sulphone (EC No 201-247-9, CAS No 80-07-9) (EFSA CEF Panel, 2015)
  - Purification of water, dairy processing, clarification and concentration of fruit juices, de-alcoholisation of wine and beer, purification of sugar.

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## Topics to briefly reflect on today

### Industrial-scale applications

- Current storage for cereal, oilseed and protein based food is estimated above 300 million tons for the EU
- No development so far for alternatives – technology used for can coatings not applicable
- No data available on typical migration levels of BPA

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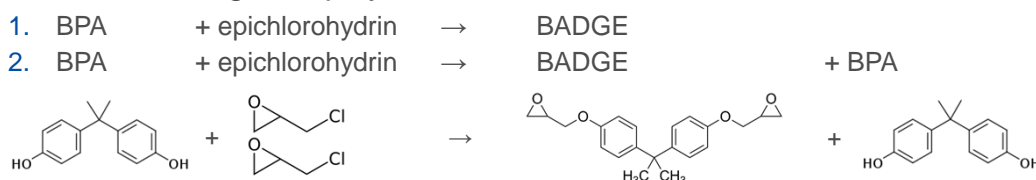


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## Topics to briefly reflect on today

### BADGE

- Cured epoxy resins = **epoxy resin** + hardener to produce a thermoset polymer
- Traditional coatings are polymer chains of:



- Thermally cured with co-reactive resin (e.g. phenolic resin + reactive groups)
- Residual BPA?

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## Topics to briefly reflect on today

### BPA as contaminant in e.g. recycled paper and action levels

- RASFF AA23.4517 → BPA and BPS in paper napkins
- BPA → 157 µg/kg (Reg 1935/2004 legal limit: 50 µg/kg); BPS 82.5 µg/kg
- Cold water extract according to EN 645 (more similar to migration than acetonitrile extract)
- Also migration test: 10% ethanol used (simulant A of Reg 10/2011) in a migration cell → migration lower 137 µg/kg

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## Upcoming action points (autumn – winter 2023)

- Measure currently being drafted
- Discussion and written comments from MSs
- Four-week feedback from stakeholders
- Vote PAFF

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# Progress Implementation Regulation (EU) 2022/1616

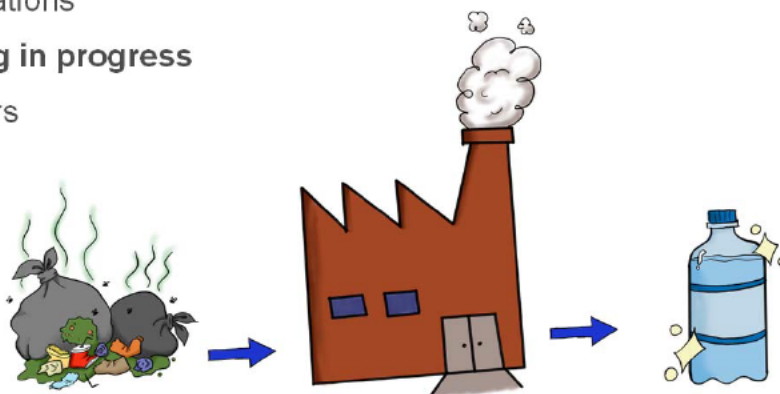
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## Discussion Recycling

- Register and Authorisations
- Amendment – **drafting in progress**
- Questions and Answers



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WG 06<sup>th</sup> of July

## 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  
18<sup>th</sup> July

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## Part 1: Register and Registration -

### 2. The Union Register

**Section A: Year 2022 (Forms received until 31 December 2022)**

**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](#) (EN)\*\*\*
- List 2: [Register of Recycling Facilities in the EU](#) (EN)\*\*\*
- List 3: [Register of Recycling Companies in the EU](#) (EN)\*\*\*

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

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](#) (EN)\*\*\*
- List 2: [Register of Recycling Facilities outside of the EU](#) (EN)\*\*\*
- List 3: [Register of Recycling Companies outside of the EU](#) (EN)\*\*\*

Non EU Member States

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## Part 1: Register and Registration -

### Section B: Year 2023 (Forms received from 1 January until 18 July 2023)

#### 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 from 1 January to 18 July. 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> <sup>\*\*\*</sup>
- **List 2:** [Register of Recycling Facilities in the EU](#) <sup>(EN)</sup> <sup>\*\*\*</sup>
- **List 3:** [Register of Recycling Companies in the EU](#) <sup>(EN)</sup> <sup>\*\*\*</sup>

#### 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 from 1 January to 18 July. The current lists will be updated in regular basis.

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

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**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 Novel Technology

- Novel recycling technologies are assigned a novel technology number ('NTN').
- 26 Novel recycling technologies dossier received till today
  - Majority from EU MSs
  - Novel Technology
    - Close Loop
    - ABA
    - Chemical recycling
- Process to be followed as described in Art 10,11 & 14, Com Regulation (EU) 2022/1616
- Evaluation of the dossiers, guidance & Timeline : MSs CAs & COM

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## Part 1: Register and Registration

- The Register Lists contains limited information's, as described in 2022/1616, COM could provide information's missing from the CAs,
- 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.

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European Commission > Food > Food and Feed Information Portal

Search Search all domains

**Feed Additives**  
The Commission has established the European Union Register of Feed Additives, which is regularly updated, and it makes reference/links to the relevant authorisation Regulations. Those Regulations include the specific requirements for placing the additives on the EU and EEA market.  
[Search for Additives](#)  
[Disclaimer](#)  
[Download Register in Excel format](#)  
[Latest updates to the Register](#)

**Food Additives**  
This database is a searchable tool informing about the food additives approved for use in food in the EU and their conditions of use. It is based on the Union list of approved food additives laid down in Annex II to Regulation (EC) No 1333/2008.  
[Search for Additives](#)  
[Browse by categories](#)  
[European Legislation on Food Additives](#)  
[Information documents](#)  
[Disclaimer](#)

**Food Flavouring**  
This database is a searchable tool informing about the flavouring substances approved for use in food in the EU and their conditions of use. It is based on the Union list of approved flavourings and source materials laid down in Annex I to Regulation (EC) No 1334/2008.  
[Search for food flavouring](#)  
[Browse by categories](#)  
[European Legislation on Food flavourings](#)  
[Disclaimer](#)

**Health Claims**  
The search tool only allows searches for health claims, and not nutrition claims.  
[EU Register of Health Claims](#)  
[Some health claims subject to the individual authorisation procedure](#)  
[Download Register in Excel format](#)

**Food Contact Materials**  
[Search for Additives](#)  
[Disclaimer](#)  
[Download Register in Excel format](#)  
[Latest updates to the Register](#)

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TRAINING  
European Commission

English Search Search

European Commission > Food > Food and Feed Information Portal > Food Contact Materials-Recycling Data > Search FCM-Recycling Data

**Search FCM-Recycling Data**

Plastic FCM Recycling data (941 matching records)

| Data Type                    | Assigned ID | Name |
|------------------------------|-------------|------|
| Decontamination Installation |             |      |
| Decontamination Installation |             |      |
| Decontamination Installation |             |      |
| Decontamination Installation |             |      |
| Decontamination Installation |             |      |
| Decontamination Installation |             |      |
| Decontamination Installation |             |      |
| Decontamination Installation |             |      |
| Decontamination Installation |             |      |

hidden  
info considered of commercial relevance

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## Part 1: Register and Registration

- FFSPM- Food and Feed Information Portal Database
  - Access to all the parties involved (COM & CAs, Companies & Public)
  - Register Lists production
  - Documents in the portal
    - Forms
    - Guidance documents
    - Legislation
  - Ability to revise the data in real time
    - COM & CAs
    - Applicants


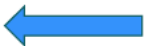


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## Authorisation of recycling process

WG 06<sup>th</sup> of July

- 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**  **September to October**
  - MSs to be informed about the Authorisation decisions templates
  - Process to be explained to MSs:

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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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## 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: Better Training for Safer Food

Ongoing and forthcoming courses on FCMs

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## Auditing of plastic recycling processes for FCM

| SESSION | START DATE | END DATE   | CITY    | COUNTRY |
|---------|------------|------------|---------|---------|
| 1       | 04/02/2020 | 07/02/2020 | Leipzig | Germany |
| 2       | 09/05/2023 | 12/05/2023 | Leipzig | Germany |
| 3       | 20/06/2023 | 23/06/2023 | Vienna  | Austria |
| 4       | 10/10/2023 | 13/10/2023 | Treviso | Italy   |
| 5       | 14/11/2023 | 17/11/2023 | Vienna  | Austria |
| 6       | 20/02/2024 | 23/02/2024 | Treviso | Italy   |

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## FCM - Control, marketing & use

| SESSION | START DATE | END DATE   | CITY       | COUNTRY  |
|---------|------------|------------|------------|----------|
| 11      | 25/09/2023 | 28/09/2023 | Valencia   | Spain    |
| 12      | 16/10/2023 | 19/10/2023 | Porto      | Portugal |
| 13      | 20/11/2023 | 23/11/2023 | Bratislava | Slovakia |
| 14      | 22/01/2024 | 25/01/2024 | Bologna    | Italy    |
| 15      | 04/03/2024 | 07/03/2024 | Valencia   | Spain    |
| 16      | 15/04/2024 | 18/04/2024 | Bratislava | Slovakia |
| 17      | 27/05/2024 | 30/05/2024 | Bologna    | Italy    |
| 18      | 08/07/2024 | 11/07/2024 | Bratislava | Slovakia |
| 19      | 09/09/2024 | 12/09/2024 | Porto      | Portugal |
| 20      | 21/10/2024 | 24/10/2024 | Valencia   | Spain    |

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## Further information

- <https://better-training-for-safer-food.ec.europa.eu/training/course/index.php?categoryid=52>
- Please contact your national BTSF contact point to participate!  
<https://better-training-for-safer-food.ec.europa.eu/training/mod/data/view.php?id=43>
- E-Learning online resource: <https://better-training-for-safer-food.ec.europa.eu/training/course/info.php?id=220>

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# Thank you

Happy to receive questions...

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