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Agenda

1. Welcome and determination AoB
 - Three questions from DE
2. Regulation (EU) 2022/1616
3. Regulation (EU) 10/2011

- We postponed the discussion on Regulation (EC) No 284/2011

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Point 2: Recycling



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Introduction: present priorities

- Rapid growth foreseen of recycled plastic market
 - PPWR soon to be adopted, further targets for recycled content → novel technologies
- Staying on top of the administrative part
 - registration of installations, >760 installations today
 - novel technologies and schemes
 - authorisation Decisions
- 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

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Point 2: Recycling

- Discussion on topics relevant under Regulation (EU) 2022/1616
 - a) State of play register
 - b) Direct access for Member States CAs to the register
 - c) Suspension of installations in the registers
 - d) Overview of novel technologies
 - e) Authorisation Decisions

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Point 2 Recycling: a. State of play register

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Part 2a: State of play – The Register

The screenshot displays the 'Food and Feed Information Portal Database' website. The top navigation bar includes the European Commission logo, the language 'English', and a search box. The main content area is divided into sections for 'Food Additives' and 'Food Flavouring'. A yellow arrow points to the 'Recycling Companies' link under the 'Food Flavouring' section. The 'The Union Register' section is also visible, providing information on recycled plastic materials and novel technologies.

Food and Feed Information Portal Database

The Union Register

Commission Regulation (EU) 2022/1616 on recycled plastic materials and articles establishes through Article 24 a Union register of novel technologies, recyclers, recycling processes, recycling schemes, and decontamination installations, as well as a list of recycling facilities. The main purpose of this register is to provide information to the users of recycled plastic to allow them to verify compliance of plastic materials they have received, as well as for competent authorities to facilitate their work on official control.

The register is kept by the Commission and can be accessed using the [Food and Feed Information Portal](#).

The register provides registration numbers of the following entities:

- ROK, recycling operator number;
- RFL, recycling facility number;
- RRI, recycling installation number;
- (RAN), recycling scheme number;
- (RBN), recycling technology number;
- (NTN), novel technology number;
- ...

[Search for Allergens](#)

Food Flavouring

This database is a searchable tool informing about the flavouring substances approved for use in food 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
- APIs
- Disclaimer

<https://ec.europa.eu/food/food-feed-portal/screen/home>

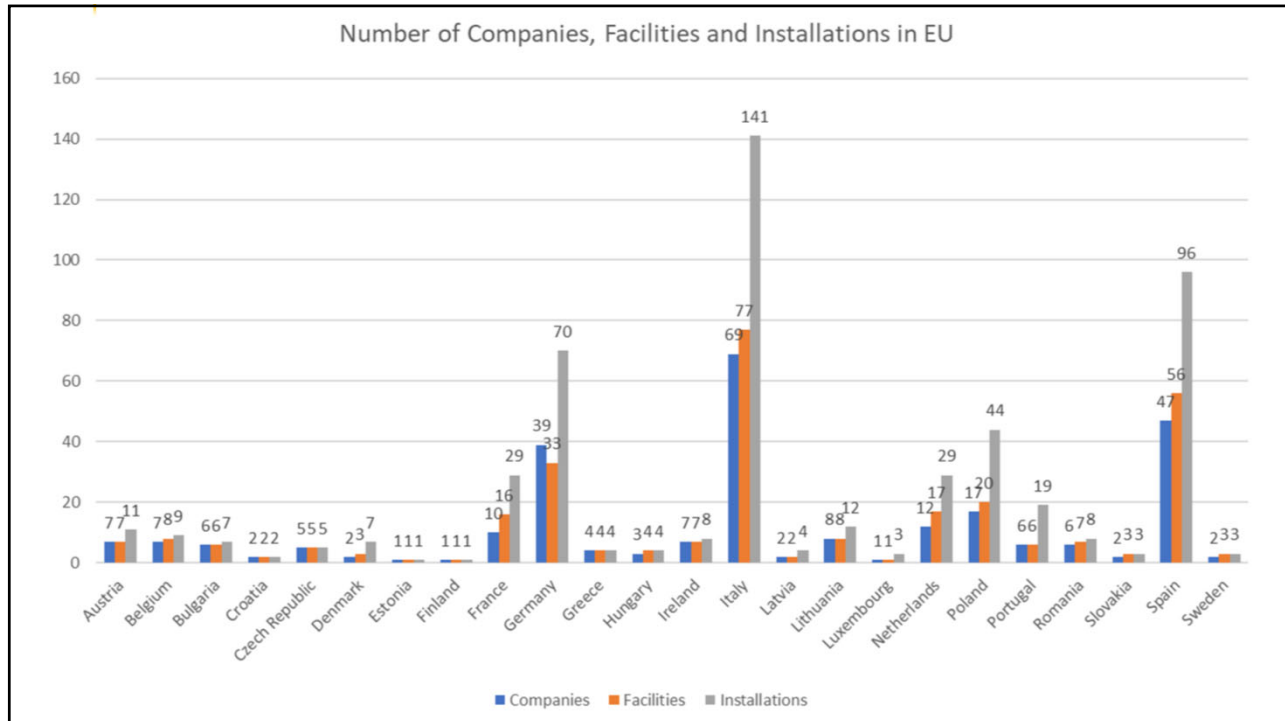
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Part 2a: State of play – The Register

- Number of Companies: 415
- Number of Facilities: 470
- Number of installations: 762
- Number of EU countries: 24
- Number of non EU countries: 38

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Part 2a: State of play – The Register

	In EU countries	global %
• Number of Companies: 415	→ 266	→ 64%
• Number of Facilities: 470	→ 297	→ 63%
• Number of installations: 762	→ 520	→ 68%

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Point 2 Recycling:

b. Direct access for Member States CAs to the register

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Point 2b: IT development for Recycling Registration

Year
2024

Main assets of the present website:

1. Access to all the parties involved (COM & CAs, Companies & Public) -Year 2024
2. Register Lists online on website
3. Documents on website
 1. Forms
 2. Guidance documents
 3. Legislation

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Point 2b: IT data for Recycling Registration

**Year
2025**

- FFSPM - Food and Feed Safety Policy Manager
(relatively new SANTE overall management system)

Step 1: **Read only access** for relevant parties (COM & CAs, Operators)

1. COM & CAs – January to February 2025
 1. Purpose: data evaluation and verification by MSs
 2. Cross checking of the audits already taken place in 2024 (status visible)
2. operators – under study

Step 2: **Full Access** (i.e. with the possibility to edit information directly)

1. for MS to be implemented in future, but timeline not yet confirmed
2. for business operators – under study, but not clear whether possible

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Point 2 Recycling: c. Suspension of installations in the registers

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Suspension of recycling installations

Article 4

Requirements for recycled plastic materials and articles

- 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

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'.

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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 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-115	HORIZON TECHNOLOGIES FZC - STARLINGER IV+	United Arab Emirates	AE9-1CK-1FN	AE9-1CK-1OJ
ANG-99C-018	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
AT1-3TS-017	Production Line SSP	Austria		
AT1-4PL-0IN	Production Line EX1			

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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Point 2 Recycling:

d. Overview of Novel Technologies

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Point 6c : Novel technologies

- Art 24 describes of 2022/1616 the general rules to be included in the Register:
 - 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');
 - authorised recycling processes are assigned a recycling authorisation number ('RAN');
- To be assigned
 - novel recycling technologies to be assigned a novel technology number ('NTN');
 - recycling schemes are assigned a recycling scheme number ('RSN');

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Actions taken: Novel Technology – July 2024

- Novel recycling technologies are assigned a novel technology number ('NTN').
- 36 (+ 5 since July 2024) Novel recycling technologies dossier received till today
 - Nine (10) EU MSs and four (04) non EU MSs
- Process to be followed as described in Art 10,11 & 14, Com Regulation (EU) 2022/1616
- Verification of the 36 Recycling Novel Technology dossier, COM will consult by e-mail MSs competent authorities in order to validate (second / third week of May):
 - Step 1: Whether they have the dossier mentioned in Annex II (if not, send us an email and we'll transfer the relevant documents).
 - Step 2: After the first check (Step 1), Annex I a & b must be completed in order to verify the evaluation of the forms and documents that were provided.
 - Step 3: Notify the Commission by e-mail about that the preliminary assessment and verification

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Actions to be taken

- Verification of the 36 (July) + 6 (new) Recycling Novel Technology dossiers
 - COM will consult by e-mail MSs competent authorities in order to validate
- verify with the MSs competent authorities
 - (a) need additional information's
 - (b) double check the information following the completion of Annex I (a-c)

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Annex I

a.

Please complete the following information	Information to be completed by competent authorities	
1. → Company name	<input type="checkbox"/>	<input type="checkbox"/>
2. → Address of the developer	<input type="checkbox"/>	<input type="checkbox"/>
3. → Contact persons	<input type="checkbox"/>	<input type="checkbox"/>
4. → Name of the novel technology	<input type="checkbox"/>	<input type="checkbox"/>

b.

Documents and data included in EU Survey form (as described under article 24)	Document provided	
	YES	NO
5. → Name of the contact	<input type="checkbox"/>	<input type="checkbox"/>
6. → Address of the installation	<input type="checkbox"/>	<input type="checkbox"/>
7. → Contact persons	<input type="checkbox"/>	<input type="checkbox"/>
8. → Name of the novel technology	<input type="checkbox"/>	<input type="checkbox"/>
9. → Summary of the novel technology not exceeding 300 words	<input type="checkbox"/>	<input type="checkbox"/>
10. → Uniform Resource Locator ('URL') locating the reports to be published in accordance with paragraph 4 and Article 13(4)	<input type="checkbox"/>	<input type="checkbox"/>
11. → Names and addresses or numbers of any recycling facilities at which the development of the technology is foreseen to take place; please attach or copy a list	<input type="checkbox"/>	<input type="checkbox"/>

c.

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË – Tel. +32 22991111
Office: B232 04/063 – Tel. direct line +32 229-67386

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Documents and data included in the application dossier (as described under Article 10(3))	Document provided		YES, but INSUFFICIENT
	YES	NO	
1. → Characterisation of the novel technology based on the properties of recycling technologies set out in Article 3(2);	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. → Explanation of any deviations from the requirements set out in Articles 6, 7 and 8, or whether the novel technology applies a recycling scheme;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. → Extensive reasoning, and scientific evidence and studies, compiled by the developer, demonstrating that the novel technology can manufacture recycled plastic materials and articles that comply with Article 3 of Regulation (EC) No 1935/2004 ensuring also their microbiological safety, including a characterisation of contaminant levels in the plastic input and in the recycled plastic, a determination of the decontamination efficiency, and of the transfer of these contaminants from the recycled plastic materials and articles to the food, and reasoning on why the applied concepts, principles, and practices are sufficient for meeting those requirements;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. → Description of one or more typical recycling processes using the technology, including a block diagram of the main manufacturing stages, and, if relevant, an explanation of the used recycling scheme and of the rules governing its functioning;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. → Explanation based on point (a) describing why the technology is to be considered different from existing technologies and is to be considered novel;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. → Summary proposing evaluation criteria to the Authority for its potential future evaluation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. → At the time of the notification, the recycler shall also publish a detailed initial report on its website using the URL provided in accordance with paragraph 2, concerning the safety of the manufactured plastic based on the information provided in paragraph 3. That report may omit details of recycling processes and installations that use the novel technology as far as these details are justifiably of commercial relevance, and shall provide a robust summary containing all information necessary to make an independent assessment of the technology without the need to consult the information contained in more detailed reports and studies;	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. → The developer shall adapt the template of the compliance monitoring summary sheet provided for in Annex II to the extent necessary to reflect the particularities of the novel technology. It shall provide this adapted template to compliance monitoring summary sheet to all recyclers using the novel technology.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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41 dossiers Novel Recycling Technologies

- novel recycling technologies are assigned a novel technology number ('NTN').

NTN	Austria	Belgium	Denmark	Germany	Italy	Lithuania	Netherlands	Poland	Spain	Sweden
EU	5 (+3)	6	1	6 (+1)	5 (+2)	1	1	1	1	1

NTN (Non-EU)	China	Switzerland	Taiwan	Turkey	UK
	1	1	1	1	7 (+1)

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Outlook

- 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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Point 2 Recycling:

e. PET Authorisation Decisions

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State of play

1. Adoption of the recycling authorisation decisions voted in October PAFF – in 1Q 2025
 - 51 Decisions to be adopted following the PAFF of October
2. Finalisation of the other authorisation decisions from batch one - in Q 1 and Q 2 of 2025
 - Batch 1 includes a total of 191 authorisation decisions
3. Kick of the next phase of recycling authorisation decisions (Batch 2) – Q 3 to Q 4 of 2025
 - Batch 1 (RECYC 001 - RECYC 260) – those not shared with the Member States yet
 - Batch 2 (RECYC 261 and above) – all the Decisions with RECYC 261 till today with a valid EFSA opinion

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Point 2 Recycling:

Other matters

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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*'

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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(b);
 - (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 minimise 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.

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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Possible amendments to the Regulation

- Amendments to Regulation (EU) 2022/1616 were discussed early 2024
 - priority to authorisation decisions, but to be re-started
 - a correcting and an amending Regulation were foreseen
- The correcting Regulation to Regulation (EU) 2022/1616 is being restarted
 - progress expected soon, please let us know without delay if you know of something requiring correction
 - most corrections relate to Chapter IV (novel technology procedure)
- 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.
- The amending Regulation will be re-validated internally
 - support to Article 6(3) + possible DoC for input material originating from pre-processing
 - clarification of applicability of DoC in post-processing stages
 - possible change to Annex 1 line 1 (PET), flame test
 - progress expected soon as well – discussion will take longer
 - (delay of deadlines)

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3- Discussion on R 10/2011

Discussion on Articles 11(4) and 17

Applications for authorisation of untreated wood

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

Untreated wood flour or fibres

1. FCM-2024-26631 not valid
2. FCM-2024-28710 not valid
3. FCM-2024-29050 not valid
4. FCM-2024-25810 RFI
5. FCM-2024-25811 RFI
6. FCM-2024-27410 RFI

Salicylic acid

7. FCM-2024-29748 RFI

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Time-line 'quality amendment'

- Feedback/Have your say: 13 March 2024 - 15 April 2024 (124 responses)
- Information event: 14 June 2024
- PAFF: 20 September 2024
- Scrutiny EP and Council: 30 October 2024 - 30 January 2025
- Expected publication Q1 2025

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Future amendments Plastics Regulation

EFSA opinions

<u>Safety demonstrated</u>	<u>Safety not adequately demonstrated</u>	<u>Upcoming</u>
<ul style="list-style-type: none"> -Nanosilver -Nano-precipitated-calcium-carbonate -Oligomeric-lactic-acid -Triphenyl-phosphite -Calcium-tert-butylphosphonate -Mixture-of-nonamethylenediamine-and-2-Methyl-1,8-octadecylamine-(NMDA-and-MODA) -Amines, di-C14-C20-alkyl, oxidised, from hydrogenated vegetable oil -Oxidised-rice-bran -Chopped-carbon-fibre -Waxes -Nickel (EFSA-CONTAM-opinion) 	<ul style="list-style-type: none"> -Fatty-acid-coated-nano-precipitated-calcium-carbonate -Bleached-cellulose-pulp PCOEE-and-cobalt-stearate 	<ul style="list-style-type: none"> -2,2'-oxydiethylamine-FCM-1094 -FCM-19 -FCM-20

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Article 11(4) of Plastics Regulation

Article 11

Specific migration limits

4. Where it is specified that no migration of a particular substance is permitted, compliance shall be established using appropriate migration test methods selected in accordance with Article 11 of Regulation (EC) No 882/2004 that can confirm the absence of migration above a specified limit of detection.

For the purposes of the first subparagraph, unless specific detection limits have been set for particular substances or groups of substances, a detection limit of 0,01 mg/kg shall apply.

- Detection limit is used if no migration is permitted
- 0,01 mg/kg applies unless a specific detection limit is set
- If migration is detected below the detection limit (e.g. because of progress in analytical methods), is the material or article compliant?

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Surface to volume ratio

In Article 17 paragraph 2 is replaced with the following: ¶

‘2. By derogation from paragraph 1, a surface to volume ratio equal or higher than 6 dm² per kg of food may be applied for the following materials and articles: ¶

- containers and other articles, containing or intended to contain a volume of less than 500 ml or more than 10 litres; ¶
- a material or article for which, due to its form, it is impracticable to estimate the relationship between its surface area and the quantity of food in contact therewith; ¶
- sheets and films that are not yet in contact with food; ¶
- for sheets and films containing a volume less than 500 ml, or more than 10 litres. ¶

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Surface to volume ratio

Including 'may' provision while keeping the current Article 17(2)'s phrasing

14 June 2024 version

Article 17(2) is replaced with the following: ¶

2. By derogation from paragraph 1 for: ¶

- (a) → containers and other articles of a volume of less than 100 ml, a surface to volume ratio of 12 dm² per kg of food may be applied, ¶
- (b) → a material or article for which, due to their form it is impracticable to estimate the relationship between the surface area of such materials or articles and the quantity of food in contact therewith, a surface to volume ratio of 12 dm² per kg of food may be applied, ¶
- (c) → sheets and films that are not yet in contact with food, a surface to volume ratio of 12 dm² per kg of food may be applied. ¶

This paragraph does not apply to plastic materials and articles intended to be brought into contact with or already in contact with food for infants and young children, as defined by Directives 2006/141/EC and 2006/125/EC. ¶

2 September 2024 version

In Article 17 paragraph 2 is replaced with the following: ¶

2. By derogation from paragraph 1, a surface to volume ratio equal or higher than 6 dm² per kg of food may be applied for the following materials and articles: ¶

- (a) → for containers and other articles, containing or intended to contain a volume of less than 500 ml or more than 10 litres, ¶
- (b) → for a material or article for which, due to its form, it is impracticable to estimate the relationship between its surface area and the quantity of food in contact therewith, ¶
- (c) → for sheets and films that are not yet in contact with food, ¶
- (d) → for sheets and films containing a volume less than 500 ml, or more than 10 litres. ¶

This paragraph does not apply to plastic materials and articles intended to be brought into contact with or already in contact with food for infants and young children, as defined by Directives 2006/141/EC and 2006/125/EC. ¶

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Next steps?

- Gathering new data on food packaging packages and their S/V ratio
- Whether using the current fixed S/V for small packages poses a risk for health may be demonstrated by the new data
- The redrafting of Article 17(2) should be based on the new data (for example, establishing a fixed S/V considering the risks)
- There appears to be a trend towards smaller packaging

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Next steps? (2)

- 2016 EFSA scientific opinion 'Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials
- The standard value of 6 dm²/kg is considered an appropriate conversion factor to represent the surface to mass ratio of packages food stuffs
- For special applications a different surface / mass ratio could be justified

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Next steps? (3)

- 2016 EFSA opinion based on data older than ten years
- Consider this task in relation to potential EFSA's work supporting revision process (e.g. updating/refining risk-assessment /exposure model, compliance (food simulants, FRF), aging/lifespan of FCMs etc)

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4 –Revision FCM legislation

State-of-play

Sustainability study – feedback on workshop of 5 Decemeber

Inventory of use of GMP under National systems



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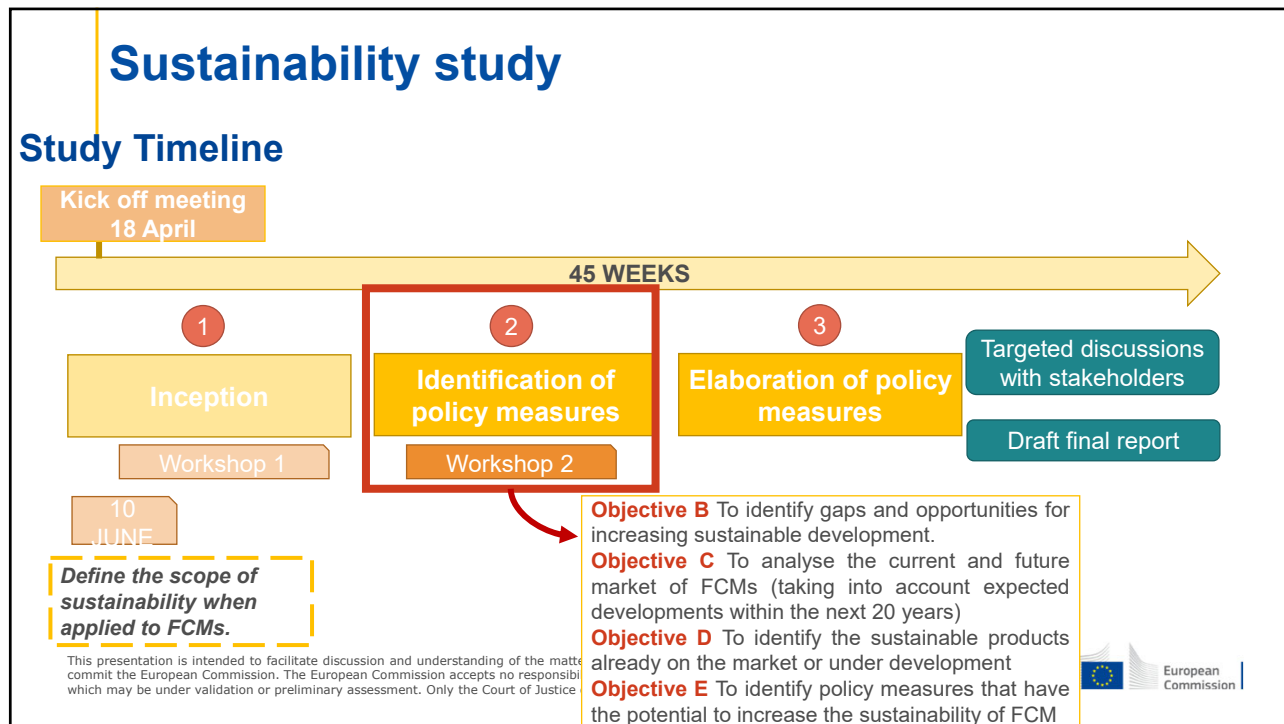
State-of-play Revision

- *Present Activities*
 - **Scoping paper** being prepared internally → internal discussion → external elaboration
 - external elaboration being prepared → elaboration by groups of independent experts
 - **Sustainability study** : Entering the last phase of the study (assessment of the short list of measures, targeted meetings with stakeholders)
 - Revalidation of the priorities with the new Commission
- *Foreseen timing*
 - Scoping paper 2024, policy paper late 2025, IA mid 2026, legislative proposal early 2027
 - validation by new Commission first step

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Sustainability study

Workshop of 5 December :

- Long list of 31 measures => **9** pre-selected measures to be discussed and ranked
- Around **30 participants/experts** from EC, NGOs, academia, business association and Member States divided in 5 groups.
- **5** roundtables dedicated to discuss 2 measures.

Each of the discussions aimed to receive the opinion from the participants on the legitimacy and feasibility of the proposed measures. The participants were provided with a documentation prior to the meeting in order to prepare for the discussion during the workshop.

Two ranking votes were carried out at the beginning and at the end of the workshop.

Even though the emphasise of the workshop is on increasing sustainability of FCMs, the primary objective remains the safety of the materials/article placed in the market.

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Sustainability study

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

- Meeting with ICF on 12 December:

Selection of the 4 measures to be 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

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Sustainability study

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

- Meeting with ICF on 12 December - **organisation of the next steps** :
 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)
 3. **Organisation of targeted meetings with stakeholders** : 5 meetings, same stakeholder group e.g one meeting with MS experts, 1 meeting with industry e4tc..

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GMP Study

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GMP implementation in Member States

- National and regional guidelines often significantly more developed and comprehensive than Regulation (EC) No 2023/2006.
- Problems identified during the Evaluation:
 1. Poor exchange of safety and compliance information in the supply chain.
 2. Rules do not sufficiently take into account the specificity of SMEs.
 3. Prevention of NIAS.
- What should be the future role of GMP in FCM legislation?

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EU legislation applicable to all FCMs

'GMP' Regulation (EC) No 2023/2006

Objectives:

1. Ensures that the manufacturing process is well controlled.
2. Establishes a quality assurance system (organised and documented arrangements made with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules).
3. Establishes a quality control system (monitoring of the implementation and achievement of GMP; specifically referring to measures that ensure compliance of starting materials and intermediate materials and articles with specification determined in QAS).

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QAS

Quality assurance system

1. The business operator shall establish, implement and ensure adherence to an effective and documented quality assurance system. That system shall:
 - (a) take account of the adequacy of personnel, their knowledge and skills, and the organisation of the premises and equipment such as is necessary to ensure that finished materials and articles comply with the rules applicable to them;
 - (b) be applied taking into account the size of the business run by the operator, so as not to be an excessive burden on the business.
2. Starting materials shall be selected and comply with pre-established specifications that shall ensure compliance of the material or article with the rules applicable to it.
3. The different operations shall be carried out in accordance with pre-established instructions and procedures.

- Personnel Training.
- Compliance with Legislation: Ensuring conformity to legal and regulatory requirements.
- Process Management: Managing processes effectively, including defining control points and setting criteria for end products.
- Corrective Actions: Establishing and implementing corrective actions as part of the quality assurance process.
- Monitoring and Inspection: Monitoring implementation of the QAS, including control points and inspection of the final product.

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QCS

Quality control system

1. The business operator shall establish and maintain an effective quality control system.
2. The quality control system shall include monitoring of the implementation and achievement of GMP and identify measures to correct any failure to achieve GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.

- Raw material.
- Storage of raw material.
- Customer requirements.
- Processing and production quality control system.
- Finished product. Verification of fulfilment of both legal and quality requirements.
- Storage of finished product.
- Traceability and recall of non-conforming products.
- Labelling.

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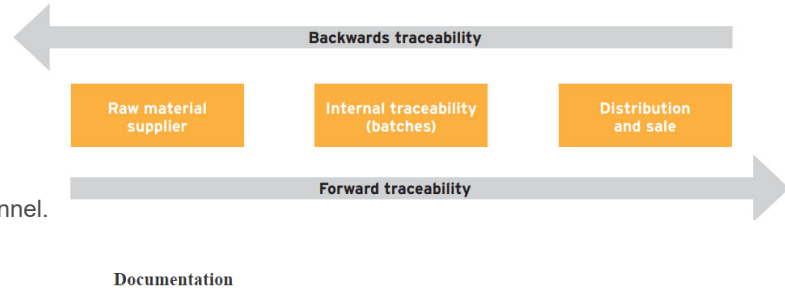


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Information exchange in the supply chain

Minimal required documentation:

- Selection of materials.
- Registration of production data.
- Production controls.
- Procedure for corrective actions.
- Controls on the finished product.
- Training and information of the personnel.
- Storage management.
- Distribution, shipment and transport.



1. The business operator shall establish and maintain appropriate documentation in paper or electronic format with respect to specifications, manufacturing formulae and processing which are relevant to compliance and safety of the finished material or article.
2. The business operator shall establish and maintain appropriate documentation in paper or electronic format with respect to records covering the various manufacturing operations performed which are relevant to compliance and safety of the finished material or article and with respect to the results of the quality control system.
3. The documentation shall be made available by the business operator to the competent authorities at their request.

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NIAS migration

- Impurities:
 1. The impurities and their concentrations are consistent with those of the substance tested.
 2. The impurities do not migrate more strongly into the food than the substance they accompany.
- Reaction products:
 1. Oligomers and low molecular weight cyclic compounds from polymers.
 2. Reaction products between different substances.
 3. Migratory substances from commodities produced from or with resins.
- Set-off and other technological effects.

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JRC report on Non-harmonised food contact materials in the EU: regulatory and market situation

Annex C - availability of GMP documentation for different materials at industry level under European umbrella organisations
GMP documentation containing different levels of GMP information for different materials at the level of European umbrella organisations

Material Category	Associations	Document	Material Category	Associations	Document
Adhesives	FEFCO (The Association of the European Adhesives and Sealants Industry)	Industrial adhesives on transparency of materials and articles for food contact prepared by a joint work of major FEFCO industry associations Guidelines for Good Manufacturing Practices in the Production of Adhesives and Sealants (Handbook for Food Contact Materials) 2005 Guidelines for Good Manufacturing Practices of Food Packaging Adhesives in Reference to Regulation (EC) No 1831/2003 (2014)	Labels	IFPC (European Federation of Conjugated Board Manufacturers)	International Good Manufacturing Practice Standard for Conjugated & Solid Board - Acquittance Conditions and Procedure for Certifying Bodies, second edition, January 2009 - (Note request: check the CEPI position)
Printing inks	ESPI (European Printing Ink Association - sector of CEFC)	Good Manufacturing Practice (GMP) Printing Inks for Food Contact Materials (2 nd revised version, March 2009 - September October 2009 version)	Rubber	ESMA (European Carbon Seals Association)	ESMA - Good Manufacturing Practice (GMP) - September 2011
Varnishes and coatings	CEFC (European Council of Adhes, Printing Inks and Amino Acids)	CEFC - Good Manufacturing Practices (GMP) Food Contact Coatings, 2010 update	Rubber Association	CEFC (Confederation Européenne des Lignes)	CEFC - Good Manufacturing Practices (GMP) - September 2011 Note: only highlights the fact that most of the products member associations produce are not articles or materials but raw materials and are thus excluded from the scope of Regulation (EC) 1831/2003
Discharge agents	SOFA (a member of CEFC)	CEFC - Code of good industrial practices on transparency of materials and articles for food contact, 2004	Silicones	CEFC (Confederation Européenne des Lignes)	CEFC - Good Manufacturing Practices for Organosilicon Materials Intended to Come into Contact with Food, 2000 Note: only highlights the fact that most of the products member associations produce are not articles or materials but raw materials and are thus excluded from the scope of Regulation (EC) 1831/2003
Resins	ESMA (European Seals Manufacturers Association)	ESMA - Guide to good manufacturing and hygiene practices for metal caps, packaging and closures for foodstuffs (May 2006)	Cork	APCO (Associação Portuguesa de Cortiça)	Code International des Pratiques Industrielles (CIPI) International Code of Cork Stopper Manufacturing Practices (ICCMF) 6.04 Edition, highlights the steps involved in the production of cork. Detailed information on the requirements of the CE and CE systems and areas, plus detailed information on the materials. A new technology for variable reduction on natural cork stoppers: INNOCOOP process
Waxes	FEVE (European Wax Federation)	FEVE - Guide to good manufacturing and hygiene practices for metal packaging in contact with food (May 2006)	Wood	FEFCO (European Federation of Conjugated Board and their Components)	FEFCO - Good Manufacturing Practices for the sector of Wooden Packaging and their Components Intended to come into Contact with Food (2005)
Textiles	CEFC (Confederation Européenne des Lignes)	CEFC - Code of good industrial practices on transparency of materials and articles for food contact, 2004	Glass	CEFC (Confederation Européenne des Lignes)	CEFC - Good Manufacturing Practices for the sector of Glass Packaging and their Components Intended to come into Contact with Food (2005)
Ceramics	MAPEI (Union Européenne de Fabricant et des Petites et Moyennes Entreprises)	MAPEI - Code of good industrial practices on transparency of materials and articles for food contact, 2004	Plastics	CEFC (Confederation Européenne des Lignes)	CEFC - Good Manufacturing Practices for the sector of Plastic Packaging and their Components Intended to come into Contact with Food (2005)
Coatings	CEFC (Confederation Européenne des Lignes)	CEFC - Code of good industrial practices on transparency of materials and articles for food contact, 2004	Recycled Plastics	CEFC (Confederation Européenne des Lignes)	CEFC - Good Manufacturing Practices for the sector of Recycled Plastics and their Components Intended to come into Contact with Food (2005)
Metals	CEFC (Confederation Européenne des Lignes)	CEFC - Code of good industrial practices on transparency of materials and articles for food contact, 2004	Recycled Plastics	CEFC (Confederation Européenne des Lignes)	CEFC - Good Manufacturing Practices for the sector of Recycled Plastics and their Components Intended to come into Contact with Food (2005)
Composites	CEFC (Confederation Européenne des Lignes)	CEFC - Code of good industrial practices on transparency of materials and articles for food contact, 2004	Recycled Plastics	CEFC (Confederation Européenne des Lignes)	CEFC - Good Manufacturing Practices for the sector of Recycled Plastics and their Components Intended to come into Contact with Food (2005)
Other	CEFC (Confederation Européenne des Lignes)	CEFC - Code of good industrial practices on transparency of materials and articles for food contact, 2004	Recycled Plastics	CEFC (Confederation Européenne des Lignes)	CEFC - Good Manufacturing Practices for the sector of Recycled Plastics and their Components Intended to come into Contact with Food (2005)

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Questions from Germany

- An electric appliance intended to manufacture a possible novel food
- Information to be contained on certain labels under Article 15 FCM
 - information needed on Registered offices
 - information requirements vs. the GPSR (general product safety)

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