WORKING GROUP ON FOOD CONTACT MATERIALS

16-17 November 2023

DG SANTE
European Commission

Agenda & Objectives

Agenda

Today

- Revision
  - State-of-play (short)
  - Ceramics
- BPA
- Quality amendment
  - Decision + amending act
  - Substances and MOAH (short)
- AoB

Tomorrow

- Implementation Recycling Regulation
  - state of play
  - correcting act (short)
  - amending act
  - Certification under Article 6(3)
- Authorisations
- Register
- Q&A + AoB

AoB

- Planned
  - Use of starting substances without a DoC
  - Identification of substances after sensory analysis (organoleptic problems)
  - Hot fill and Oven conditions
  - CHED-N
- Recycling
  - Feedback on BTSF
  - Feedback on collaboration on environmental legislation
- Anything else

Acts under preparation

act	State
• 250 authorisation Decisions	• Template nearly completed – preparation procedures to start still in November
• BPA	• First draft ready, internal procedures to start in November
• quality Amendment	• First draft ready, internal procedures on their way
• Decision provisional list	• same – no consultation no vote
• recycling Amendment	• First draft ready, internal procedures start after BPA
• recycling Correction	• Frist draft ready, internal procedures start after BPA

Authorisations written vote; BPA + quality amendment, feedback then vote (27/02); recycling acts vote (27/02)

Main objectives

- Prepare you for upcoming written consultations
  - what to expect
- Inform you on our thinking on the main provisions, their background, potential issues, etc.
  - this will give you the opportunity for questions during or shortly after the meeting
  - where possible we will take these into account still in the draft texts
- Exchange views

Revision state of play

State of play Revision

- Drafting of discussion document in progress
  - delayed because of high workload on implementation
  - it will provide the basis for discussions in dedicated expert groups
  - Organisation of expert groups being started
- On-going studies
  - EY study on pillar D and E has been extended to April
  - ToR for study on sustainability finalised – procedure for the call is starting
- Questions over Ceramic materials (next presentation)

Ceramic and vitreous FCMs

Recap and way forwards

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Recap

- 2011 – 2012: Post EFSA opinions – clear that present limits (from 1985) are too high and cannot be maintained
- Lower limits would burden groups of business operators
  - However, questions over analytical methods
- 2013 – 2017: JRC worked extensively and clarified methods
- 2019 – 2021: Impact Assessment (IA) work
  - Inception impact assessment published
  - Scope included also vitreous materials
  - Study performed by contractor → delivered end 2021

Main issues

- Imports and some EU traditional and artisanal food contact articles → significant non-compliance with proposed limits
- Uncertainty over impact (closures of businesses, replacement articles, impacts on sales, consumers)
- Where replacements are possible, articles then lose their value and ‘sales pitch’ and cannot compete with cheaper imports

Proposed SMLs

- Lower SMLs for lead (Pb) and cadmium (Cd)
- Addition of SMLs for aluminium (Al), arsenic (As), barium (Ba), colbalt (Co), chromium (Cr) and nickel (Ni)
- Covers ceramics and glass (incl. vitreous coatings i.e. enamels & crystalware)

Discussion on regulation of metals also relevant for FCM revision (i.e. also in metals and alloys)

Substance or substance group name	Expressed as	SML Cat. I (µg/dm²)	SML Cat. II (µg/l)	SML Cat. III (µg/l)	Additional restrictions, specifications and tests
Substances containing Lead	Lead (Pb)	2	10	3,3	
Substances containing Cadmium	Cadmium (Cd)	0,4	2,0	0,7	
Substances containing Aluminium	Aluminium (Al)	200	1000	333	
Substances containing Arsenic	Arsenic (As)	0,4	2,0	0,7	
Substances containing Barium	Barium (Ba)	240	1200	400	
Substances containing Cobalt	Cobalt (Co)	4	20	7	
Substances containing Chromium	Total chromium (Cr)	720	3600	1200	This limit may be used for total chromium species provided the presence of CrVI can be excluded.
Substances containing Chromate, hexavalent chromium, Cr(VI)	Chromium VI (CrVI)	Banned	Banned	Banned	Not be used intentionally to manufacture ceramic or vitreous materials and articles, and not to unintentionally form from Cr(III) using oxidising conditions during the manufacture of ceramic or vitreous materials and articles.
Substances containing Nickel	Nickel (Ni)	4	20	7	

Main issues from study work

- Low response rate to consultation. Majority were ceramic producers, mainly EU associations and larger industries.
- Focus on proposed SMLs and testing requirements (cost, third migration) – limited input and low interest in mitigating provisions
- Difficult to reach artisanal businesses – individual/micro businesses including hobbyists lack engagement at EU level and rely on national level rules
- They trust supply chain to deliver compliant raw materials (not just FCM)
- Similar concerns from other small and microbusinesses (e.g. small woodworkers), which is therefore relevant for the FCM revision
- Also concerns are over fair treatment with imports and labelling

Conclusions

- Very difficult to obtain data, in particular quantitative data on costs and impacts
- Most producers rejected any reduction/new SMLs as cannot meet them regardless of any mitigating provisions
- None of the mitigating provisions were acceptable or useful to industry
- Option 3/a defining stricter information and quality control requirements on the supply chain may help artisans and hobbyists
- Study recommends consulting again on possible solutions

Reminder: Mitigating measures

1. **Tailored transition plans** to address significant costs (e.g. replacement of raw materials and equipment such as ovens and where possible production methods in dialogue with national competent authorities tailored transition plans during which they can continue sell their articles while they make the necessary changes to comply. They would also need to label that their articles are under "transition" and inform customers on the adequate use and care needed.

Reminder: Mitigating measures

2. **Quality control through the supply chain** to control the quality of raw materials supplied and reduce their need to test final articles.
    - It may be more difficult for artisans to ensure the constant quality of their production and for some traditional and cultural articles to comply with the new limits because the value of their products depends directly on the use of those metals and/or production methods
    - Suppliers should be required to know and communicate the composition of their supplies (labelling, declaration of compliance) and to provide adequate instructions to artisanal producers and hobbyists on how to use those raw materials, the labels to put on final articles, and an explanation of legal requirements to produce and sell articles for food contact.

Reminder: Mitigating measures

3. **Conditional derogation for artisanal and traditional products**. This will enable artisans and producers of articles of traditional or cultural value to continue to produce and place on the market articles that comply with a higher limit under certain conditions:
   - mandatory labelling and adequate use and care instructions for end-users;
   - for traditional producers, mandatory application to the national competent authority…

Reminder 2018 explorative text

- Could still serve as a basis for parts of the discussion
- Particular the magenta part

Drafting table for consultation on a potential new Regulation of Ceramic and Vitreous food contact materials

Please note the following markings related to the core objectives of the text:

Text on a **white** background is the core text required to achieve a reduction of the limits for lead and cadmium in ceramic materials.

Text on a **coloured** background in the requirements and annex is **optional** and for discussion, the following sections are included:

- **Inclusion of glass and vitreous coatings:** These sections include glass and vitreous coatings into the scope of this measure.
  Why: The inclusion of these materials seems justified because of their high similarity to ceramic materials, and because of similar risk of metal migration and exposure.
- **Increased attention to production quality:** These sections shift the responsibility for compliance from migration testing to a shared responsibility throughout the supply chain.
  Why: The smallest operators have limited resources to invest in quality control and compliance. However also for larger operators it is difficult to ensure compliance to low limits without excessive testing obligations when the quality of their starting materials is not ensured.
- **The use of 'remediation plans':** Instead of setting out a long transition period, as might be needed by some business operators, these parts of the Regulation introduce a mechanism under which business operators can agree with competent authorities on a plan to ensure compliance is achieved after an agreed period of time. During this period higher limits can be agreed.
  Why: It is preferential to avoid a long transition period in particular where there is no concrete action plan in place that would follow to remedy the issue causing the non-compliance. It also provides knowledge on ongoing actions.
- **Artisanal and Traditional production:** This Regulation could allow for adjusting testing results for these producers.
  Why: Artisanal and Traditional producers are expected to have great difficulties to comply with low limits. If higher limits are allowed for this group, there should be suitable conditions and rules to mitigate the additional risk.
- **Metals other than lead and cadmium:** This Regulation could add limits for metals other than lead and cadmium.
  Why: These metals also cause health risks, and not adding them but measuring them causes compliance issues.

Regulation (EU) 2023/2411 on the protection of geographical indications for craft and industrial products

- allow locally renowned non-food products including glass and porcelain to be registered in the EU as geographical indications (‘non-food GI’)
- two-step registration procedure, starting at national level followed by an examination of the application by EUIPO
  - Member States can choose whether to set up a national registration authority or let EUIPO handle the whole process.
- verification procedures for the protection of GIs based on self-declaration to be the default procedure, MSs to reinforce with controls.
- entered into force 16 November 2023; applicable 1 December 2025
- needs further reflection on relevance for FCM measure

Going forwards

- Continue on the basis of the information and work done so far
- **Aim: introduce lower limits as well as support measures for the industry, including mitigating measures in particular for artisanal producers and those that use traditional techniques**
- Open to discussions on alternative solutions but solutions must be protective of health and implementable in practice – support impact assessment
- Also need to reflect on common themes affecting micro businesses and SMEs (not just artisanal)
  - resources, knowledge, leverage against suppliers, access to information, or access to the internal market, GMP, testing burden, documentation

Going forwards

- Support needed in particular to *reach affected businesses*: role for MSs to complement information we already have
  - clearly define criteria for artisanal and traditional producers and identify them – necessary in particular for labelling and separate limits
  - national campaigns aimed at increasing dialogue with artisanal and traditional producers to better understand impacts and how they can be mitigated with the current proposals and where practical and feasible, other possible mitigating measures
  - identify raw material suppliers and open dialogue with them on how compliance of raw materials for ceramic FCM can be improved and how testing requirements can be placed on them
  - Support vis-à-vis research and development into better methodologies and supply of raw materials as well as GMP
  - Estimates of costs needed!

Going forwards

- Commission to guide but **volunteers from Member States needed** to also coordinate work
- Delivery needed together with the revision of FCM rules
- Questions and thoughts?

Bisphenol A (BPA) in FCM

Outline of the draft measure

European Commission

Scope of the measure

- The use of BPA in the manufacture of plastic, varnishes and coatings, printing inks, adhesives, ion-exchange resins and rubber FCM
- The use of BPA to synthesise BADGE for the production of heavy-duty food contact coatings
- The use of other bisphenols in the manufacture of FCM
- The monitoring of BPA in recycled paper and board FCM and in BADGE

Commission Regulation (EU) No 10/2011 is amended; Regulation 2018/213 is repealed

Rules set out in the measure

- The use of BPA in the manufacture of plastic, varnishes and coatings, printing inks, adhesives, ion-exchange resins and rubber FCM is prohibited
- Except in the synthesis of BADGE and derivatives for the production of heavy-duty food contact coatings
  - BADGE to be obtained in separate identifiable batches
  - Must not be present with ND (TBC)
  - Must not lead to reaction (e.g. hydrolysis) which liberates or generates BPA

Rules set out in the measure continued

- Bisphenols classified as category 1A or 1B ‘mutagenic’, ‘carcinogenic’, ‘toxic to reproduction’ or category 1 ‘endocrine disrupting’ for human health in accordance with the criteria set out in sections 3.5, 3.6, 3.7 and 3.11 respectively of Annex I to Regulation (EC) No 1272/2008 may only be used in the manufacture of materials and articles if explicitly authorised in accordance with Articles 8 – 12 of Regulation (EC) 1935/2004 and used in accordance with any given restrictions and specifications or the following conditions have been fulfilled
- Applications for an assessment and authorisation within 9 months of the measure or classification; thereafter may be placed on the market until decision by Commission based on EFSA opinion

Transitional provisions

- In general, 18 months after application of the draft measure for final food contact articles except for the following:
  - final food contact articles intended to be filled with processed fruits and vegetables and processed fish (36 months)
  - final articles on which a varnish or coating has been applied specifically to the exterior metal surface, applicable only to that exterior material (36 months)
  - repeat-use final articles used as fixed components in professional food production equipment (e.g. moulding equipment, membrane filtration units, hoses, tubes, pumps, valves, closures, flanges, seals, gauges and sight glasses) (48 months)
  - if needed, containers and (transport) vessels with an S/V<1 (> about 200L) (48 months)
- Manufacturers of intermediate FCM to notify 9 months in advance in DoC
- Final food contact articles to be deployed for intended use within 12 months after transitional period

Monitoring, compliance and reporting

- Mandatory monitoring for
  - BPA in heavy-duty BADGE-based varnishes and coatings
  - presence in or migration from recycled paper and board FCM
  - discussion on other categories (e.g. food production equipment)
- Frequency of 5% of batches, selected at random
- Follow up when BPA detected to ascertain source, taking into account possible presence from source(s) other than FCM
- Reporting of results to Member States every year including action taken to reduce levels where appropriate
  - Member States to report levels to Commission
  - Discussion on (need for) action level
- DoC to identity operator, FCM, etc and confirmation that it complies with the rules – absence of BPA or SML and conditions of use for transitional products

Testing methods

- As per Regulation 10/2011 for organic synthetic materials
- CEN/TS 17497:2020 ‘Pulp, paper and paperboard. Determination of bisphenol A in extracts from paper and paperboard’ for recycled paper and board FCM
- Presence of BPA in BADGE/ heavy-duty BADGE-based varnishes and coatings TBD

Issues to discuss today

- Scope of the measure
- Scope, frequencies and approach on monitoring including responsibilities
- Paper and board:
  - Testing methods. Also migration test: 10% ethanol used (simulant A of Reg 10/2011) in a migration cell → migration lower 137 µg/kg
  - Follow up action if BPA detected e.g. RASFF AA23.4517 → BPA and BPS in paper napkins
- Transitional measures
  - Lengths
  - Niche applications e.g. polysulphone-based filtration membranes

Next steps

- Discussion now and informal written comments from MSs on approach by Friday 1 December
- Draft measure undergoing internal consultation procedures
- Comments from MSs on draft text + four-week feedback from stakeholders
- Vote PAFF Q1 2024

- We are considering to amend point A of the Annex to Regulation (EC) No 2023/2006 – more general approach to prevent off-set transfer and other forms of cross contamination for all FCMs

Amendments to Regulation (EU) No 10/2011 on plastic FCM and Regulation (EC) No 2023/2006 on GMP

European Commission

Overview of amendments

- By means of a Commission Regulation amending:
  - Article 3, 4, 5, 6, 7, 8, 9, 10 and 14 and Annex III, IV and V to Plastics Regulation (Regulation (EU) No 10/2011), and
  - Annex B to GMP Regulation (Regulation (EC) No 2023/2006)
    - introducing also a new Annex C
- By means of a Commission decision updating the provisional list
  - all 11 substances

Time-line

- Presently foreseen time-line
  - WG FCM 16-17 November 2023: explanation of provisions in the amendments
  - Have your say: December 2022-January 2023
  - PAFF February 2024
  - Adoption July 2024

- To note: delay may appear because of the need to align the process of the draft Commission decision and draft Commission regulation

Background amendments

- 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
  - GMP requirements (amendment of Annex to Regulation No (EU) 2023/2006)
  - DoC – introduction of recycled content
- Reprocessing of plastics
- Natural materials
  - purity of substances + use of authorised natural materials
- Substances with a biocidal function
- Updating reporting requirements
- Specifying the concept of high purity

Alignment recycling - layer issue

- The Recycling regulation does not refer to plastic layers; however, the Plastics regulation refers to it
- E.g. Article 5 says:

  "Only the substances included in the Union list of authorised substances […] set out in Annex I may be intentionally used in the manufacture ***of plastic layers in plastic materials and articles****."*
  - Also Article 6 and 8 refer to layers in this way
  - the Regulation doesn't say that layers need to be flat
- Many plastic materials and articles do not take the form of a layer; the Plastics regulation does not say that a layer needs to be flat
- However…the amendment should consider printed or coated plastics
  - Objective: to keep approach that the OML and SML applies to layers with printed or coated plastics, but compositional requirements regulated by national measures

Alignment recycling - layer issue

- To remove references to ‘plastic layers’ in Chapter II (Articles 5, 6, 8 and 9)
- And include a specific provision for determining SML and OML for printing inks and coatings in Article 6

Removing reference to layers

-Paragraph 1 of Article 5 is replaced with the following:

'Only the substances included in the Union list of authorised substances (hereinafter referred to as the Union list) set out in Annex I may be intentionally used in the manufacture of plastic materials and articles.'

-In paragraphs 1, 2 and 4 of Article 6 the phrase plastic layers is deleted

-Paragraph 1 of Article 8 is replaced with the following

> *'A substance used in the manufacture of plastic materials and articles in accordance with Article 5 shall correspond strictly to the name in Table 1 of Annex I, supplemented, where applicable, by the specified CAS number, and by additional specifications, if any. In case of doubt over the resulting designation of a substance a Member State or the Commission may consult the Authority, a business operator shall consult the competent authority of a Member State.'*

-In paragraph 1 of Article 9 the phrase plastic layers is deleted

Including provision for inks and coatings

-A paragraph 6 is added to Article 6 to make clear that national legislation applies for compositional requirements

> *'By way of derogation from Article 5, any substance may be used in the manufacture of adhesives, coatings and printing inks and applied on or incorporated in plastic materials and articles, if that use is in accordance with both Article 3 of Regulation (EC) No 1935/2004 and, where applicable, with specific measures and national law applicable to adhesives, coatings and printing inks.'*

Alignment recycling

- Ensure that plastics in scope of Regulation (EU) 2022/1616 are used in accordance with Recycling regulation:

(2) Point (e) of Article 4 is replaced with the following:

'(e) comply with the compositional and declaration requirements set out in Chapters II, III and IV of this Regulation; and

(f) comply with Regulation (EU) 2022/1616 on recycled plastic materials and articles if they are in the scope of that Regulation'

- And updating Annex IV (DoP) to Plastics Regulation and Annex to GMP Regulation

Reprocessing of plastics (off-cuts and scraps

-Adding a definition of re-processing in paragraph 20 of Article 3

> *'(20) re-processing of plastic' means the return of plastic materials resulting as a by-product from an intermediate or final manufacturing stage either to that stage itself or to an earlier stage in the manufacturing chain where it is remelted, mixed, reacted or otherwise combined with material originating from earlier manufacturing stages, or used in place thereof, to use it again in the manufacture of plastic materials and articles.'*

-And updating Annex IV (DoP) to Plastics Regulation and Annex to GMP Regulation

Reprocessing of plastics

-Specifying in paragraph 1 of Article 10 the conditions for using reprocessed plastics

Plastic materials and articles may contain reprocessed plastic if the reprocessed plastic meets the following conditions:

(a) it is collected in accordance with point B and C of the Annex to Regulation (EC) No 2023/2006;

(b) it originates only from off-cuts and scraps from plastic materials and articles referred to in Article 2(1)(a) that meet the compositional requirements set out in chapter II of this Regulation, and which are considered to be a by-product in accordance with Article 5 of Directive 2008/98/EC;

(c) it does not contain substances in an amount which could:

(i) exceed migration limits applicable to the plastic materials and articles to which the reprocessed plastic is added; or,

(ii) cause any other non-compliance of those plastic materials and articles with Article 3 of Regulation (EC) No 1935/2004;

(d) it does not contain constituents originating from:

(i) food;

(ii) printing, coating, or adhesives;

(iii) substances used for processing the plastic from which the off-cuts and scraps originate, such as lubricants or cutting fluids;

unless the constituents together contain only a limited number of well identified substances, of which the compliance with the conditions referred to in point (c) is demonstrated on the basis of an assessment in accordance with Article 19.

Substances with biocidal properties

Regulation 10/2011 authorisation of biocidal substances in plastic FCM

- Substances with an explicit biocidal function are not included in Annex I
- Article 7: provisional list substances are subject to national legislation
- Triclosan + 10 silver-based substances, for which EFSA has published positive opinions

Regulation 528/2012 concerning approval of biocidal substances and authorisation of biocidal products (the 'BPR')

- Includes treated articles
- Product-type 4 (food and feed area) covers FCMs
- Approval of biocidal substances used and subsequently authorisation of the biocidal product

Article 7

Establishment and management of the provisional list

1. The provisional list of additives that are under evaluation by the European Food Safety Authority (hereinafter referred to as the Authority) that was made public by the Commission in 2008 shall be regularly updated.

2. An additive shall be removed from the provisional list:

(a) when it is included in the Union list set out in Annex I; or

(b) when a decision is taken by the Commission not to include it in the Union list; or

(c) if during the examination of the data, the Authority calls for supplementary information and that information is not submitted within the time limits specified by the Authority.

Substances on provisional list

- None of the Substances on the provisional list is approved for PT4 under BPR
  - either no application submitted or non-approval (in progress)
- Draft Commission decision
  - to not include the 11 substances in Annex I of Plastics regulation
  - in accordance with Article 7(2)(b)
- Exhausting of stocks allowed

Subject to compliance with Regulation (EU) No 528/2012, plastic materials and articles treated with or incorporating substances listed in Article 1 and complying with Regulation (EU) No 10/2011, containing additives in accordance with Article 6(5) thereof used in accordance with national law may remain on the market until the exhaustion of stocks.¶

¶

Substances with biocidal properties in FCMs: Way forwards

- Since no new substances can be included on the provisional list, the provisional list will be withdrawn and Article 7 deleted
- FCM substances providing a biocidal function as an additive in plastic FCM will be subject to Article 6 (i.e. a derogation subject to the BPR)

> By way of derogation from Article 5, substance(s) allowed to be placed or made available on the Union market in accordance with Regulation (EU) No 528/2012 for product-type n°4 for use that covers incorporation into plastic materials and articles which may enter into contact with food, may be used as additives in the manufacturing of plastic materials and articles. The substance shall be used in compliance with any applicable terms and conditions, restrictions and specifications set out under that Regulation.

Why amending Article 8? Ensuring the safety of plastic FCMs - **impurities**

- Only authorised substances may be used to manufacture plastics
  - EFSA assesses all starting substances (monomers) and additives (+ related impurities)
  - they are authorised subject to restrictions (e.g. permitted use, limits,…)
  - impurities are permitted without authorisation ('NIAS'), but subject to risk assessment

- What about those 'permitted' impurities?
  - originating from the manufacturing process
  - individual impurities must be risk assessed
    → they **must be identifiable**
  - contaminants (from use) ≠ impurities (from manufacture)!

Article 19

Assessment of substances not included in the Union list

Compliance with Article 3 of Regulation (EC) No 1935/2004 of substances referred to in Articles 6(1), 6(2), 6(4), 6(5) and 14(2) of this Regulation which are not covered by an inclusion in Annex I to this Regulation shall be assessed in accordance with internationally recognised scientific principles on risk assessment.

Article 8 - purity

Article 8

General requirement on substances

Substances used in the manufacture of plastic layers in plastic materials and articles shall be of a technical quality and a purity suitable for the intended and foreseeable use of the materials or articles. The composition shall be known to the manufacturer of the substance and made available to the competent authorities on request.

- The purity requirement is amended
- Article 1(3) of R 2022/1616 states:
  - This Regulation shall not apply to the use of waste to manufacture substances included in the Union list of authorised substances in accordance with Article 5 of Regulation (EU) No 10/2011 [...], when intended for subsequent use **in accordance with that Regulation**
- Recyclers need legal certainty
  - Main issue is level of contaminants – when is the 'purity suitable'?

Update of Article 8; specifying a high degree of purity

Reasons

- **Recycled plastics**
- natural substances
- NIAS

- New structure of Article 8
  1. Only use of a substance corresponding to its identification and specification in table 1 of Annex I
  2. Substance shall be of a high degree of purity and a technical quality suitable for the intended and foreseeable use of the materials or articles
  3. Purity of substances originating from a natural origin
  4. Substances recovered from waste in accordance with Directive 2008/98/EC shall be of high degree of purity.

- So, what is a high degree of purity?

What is a high degree of purity?

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 contaminants, or individual impurities, decomposition, degeneration or reaction products that 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 a risk assessment in accordance with Article 19; or,

(iii) → have been subject to a limited toxicological assessment that at least rules out genotoxicity in accordance with the relevant guidance adopted by the authority and are present at a level that cannot give rise to an individual migration from the final plastic material or article exceeding 0.05 mg/kg food, assuming their full migrating into the food; or,

(iv) → are unknown and/or have been not subject to an assessment specified in (ii) or (iii), but are present at a level that cannot give rise to an individual migration from the final plastic material or article exceeding 0.0015 mg/kg food, assuming their full migration into the food.

Group assessment allowed for genotoxicity for similar substances

for the purpose of point (iii) the individual assessment may be substituted with a group assessment of genotoxicity if the assessed substances are chemically related and have the same or similar functional groups that could give rise of toxicity, or if the substances are obtained as a mixture representative for migration into food and the mixture is assessed as a whole using appropriate methods.¶

A lower migration may be assumed for certain packed products

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

- → dry unpeeled fruit or vegetables that must be peeled or washed, or,¶
- → 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, or,¶
- → as secondary packaging foods packed in sealed metal or glass packaging,

10% migration instead of full migration into the food may be assumed.¶

High purity – supporting information and controls

- Supporting information should show compliance with requirements of high purity

5.→Documentation·showing·compliance·with·paragraphs·1-4·shall·be·part·of·the·documentation·referred·to·in·Article·16.¶

- Samples can be taken at manufacturers

6.→Manufacturers·of·plastic·materials·and·articles,·and·of·products·from·intermediate·stages·of·their·manufacturing,·shall·ensure·that·it·is·possible·for·competent·authorities·to·verify·the·degree·of·purity·and·composition·of·substances·by·taking·samples.'¶

Specifying that only substances can be used in plastics corresponding strictly to the identity in Table 1 of Annex I

First paragraph of Article 8

A substance used in the manufacture of plastic materials and articles in accordance with Article 5 shall correspond strictly to the name in Table 1 of Annex I, supplemented, where applicable, by the specified CAS number, and by additional specifications, if any. In case of doubt over the resulting designation of a substance a Member State or the Commission may consult the Authority, a business operator shall consult the competent authority of a Member State.

Specific provision for natural substances

- Article 8(3) to include the following:
  - The substance shall be of a high degree of purity if the substance is identified by a chemical name (for example, lignocellulose ≠ random plant material that happens to have a high lignocellulose content)
  - However, where the substance name includes the name of the natural material, that material may be used as obtained from nature provided it has been separated from other natural matter not identified by the substance name. In this case, it may contain all substances that are naturally present in the natural matter identified by the name of the substance (for example, cotton fibres (FCM 24) do not need to be purified to contain only one substance, but cannot contain other parts of the cotton plant)

Specific provision for natural substances

- Article 8(3) to include the following:

3. The following shall apply to the purity of substances originating from a natural origin:

(i) if the substance is identified by a chemical name, it shall be of a high degree of purity, or,

(ii) if the substance name refers to the name of a natural multi constituent material, that material may be used as obtained from its biological origin, provided it has been separated in its entirety from other natural matter and parts of the plant or the other natural source from which it was obtained and that are not identified by the substance name.

Any additional specifications or requirements applicable to a substance or material from a natural origin set out in Table 1 of Annex I, applicable to the substance or material, shall apply.

Additional provision Article 8, Article 9

6. Documentation showing compliance with paragraph 1-4 shall be part of the documentation referred to in Article 16.

7. Manufacturers of plastic materials and articles, and of products from intermediate stages of their manufacturing shall ensure that it is possible for competent authorities to verify the degree of purity and composition of substances by taking samples at the manufacturing stage where the substance is first used.'

(9) The following paragraph 3 is added to Article 9:

'3. Substances meeting the definition of 'additive' which are in the form of solid particles or fibres of which only the surface is covalently bound to the polymers contained in the plastic shall be considered additives.'

Filler materials – additives

- Certain filler materials are covalently bound to the polymer chains
  - Glass fibres bound to plastic using Glymo (FCM 1068)

  → organic materials may be bound in a similar way
  - Does that chemical link make them starting substances?
  - No, they remain additives, as the bulk (most of the polymers contained in them) does not react
- To add to Article 9 the following:

‘3. → Substances meeting the definition of ‘additive’ which are in the form of solid particles or fibres of which only the surface is covalently bound to the polymers contained in the plastic shall be considered additives.’¶

Repeat use

- Stability rule
  - stability rule is not a requirement on composition
  - it is a testing requirement
- Specific provision on aging in Article 10(3)

3. → Where intended for repeat use in contact with food, the composition of plastic materials and articles shall be such that plastic materials and articles do not have an unacceptable deterioration during their foreseeable lifespan. Any increase in the migration of constituents of the material or article when subjected to subsequent use cycles shall be considered as unacceptable deterioration.¶

→ The maximum expected life span of the material and article shall be provided to its users by means of labelling or instructions, including instructions designed to slow down deterioration, as well as a description of observable changes that indicate end of life of the article or material based on the above elements.¶

The documentation required in accordance with Article 16 shall include a report on the assessment of the maximum foreseeable lifespan of the material or article.¶

Updating technical details of compliance testing

- Included general section on compliance testing in Annex V
- Many thanks to the EURL-FCM

COMPLIANCE·TESTING¶

For·testing·compliance·of·migration·from·plastic·food·contact·materials·and·articles,·an·analytical·method·in·accordance·with·the·requirements·of·Article·34·of·Regulation·(EU)·2017/625·shall·be·selected,·applying·the·following·specific·performance·criteria:·¶

– → For· the· purpose· of· enforcement· the· calibration· range· of· analytical· methods·shall·be·at·least·R_L·(relative·lower·calibration·range·threshold)·*·LL·(legal·limit)·to·R_U·(relative·upper·calibration·range·threshold)·*·LL,·using· a· minimum· of· 5· calibration· points· equally· distributed· in· this· range.·The·LL·shall·be:¶

  – → LL=SML·for·the·verification·of·compliance·with·a·SML,·or¶

  – → LL=FRF*SML· for· verification· of· compliance· with· a· SML· with·food·simulant·D1·or·D2·in·case·the·fat·reduction·factor·(FRF)·applies,·or¶

  – → LL=OML·for·verification·of·compliance·with·the·OML.¶

Unless·otherwise·specified·in·table·1·or·2·of·Annex·I·for·the·substance·of·which·the·LL·is·being·verified,·R_L·shall·be·0.2,·and·R_U·shall·be·2;¶

– → The· relative· standard· measurement· uncertainty· is· calculated· as· the· reproducibility· coefficient· of· variation· (CV_R)· using· the· following· formula's:¶

CV_R·=·0.22·(22·%) → for → m·≤··0.12·mg/kg,·and¶

CV_R·=·$2^{(1-½\log(m))}/100$ → for → ·0.12·mg/kg·<·m·<·138·g/kg¶

Where· m· is· the· measured· concentration· of· a· substance· that· is· to· be· evaluated· against· the· legislative· limit,· and· the· uncertainty· of· the· measured· concentration· of· a· substance,· u(m),· shall· be· determined· as· follows:·u(m)·=·CV_R·*·m.¶

In·addition,·the·rules·in·Chapter·1·-·4·of·this·Annex·shall·apply.'¶

Technical details on repeat use in points 2.1.6 and 3.3.2 of Chapter 2 of Annex V

'If the material or article is intended to come into repeated contact with foods, the migration test(s) shall be carried out three times on a single sample using another portion of food simulant on each occasion. Compliance of the material or article shall then be verified on the basis of the level of the migration found in the third test and on the basis of the stability of the material or article i.e. the specific migration in the second test shall not exceed the level observed in the first test, and the specific migration in the third test shall not exceed the level observed in the second test. ¶

To the purpose of the first paragraph, the sample shall be considered non-compliant if:¶

$m_3 > SML$, or,¶

$m_1 < m_2$, or,¶

$m_2 < m_3$, or,¶

$m_1 < m_3$,¶

where m_1, m_2, and m_3 are respectively the measured concentration in the first, the second and the third migration test carried out in accordance with the first subparagraph.¶

The compliance shall be evaluated applying the following specific performance criteria:¶

- → IF $(m_3 - SML)/[u(m_3)] > 1.64$ → → THEN $m_3 > SML$,
- → IF $(m_2 - m_1)/[u(m_2) + u(m_1)] > 1.64$ → THEN $m_1 < m_2$¶
- → IF $(m_3 - m_2)/[u(m_3) + u(m_2)] > 1.64$ → THEN $m_2 < m_3$¶
- → IF $(m_3 - m_1)/[u(m_3) + u(m_1)] > 1.64$ → THEN $m_1 < m_3$¶

where the uncertainty of the measured concentration of a substance $u(m)$, shall be determined as follows: $u(m) = CV_R * m$.¶

In case a measured concentration $m < R_L$ (relative lower calibration range threshold) * SML, the measured concentration m shall be considered equal to R_L * SML. This concentration shall be used for determining the corresponding uncertainty of the measured concentration and the concentration R_L * SML and the corresponding determined uncertainty shall be used for evaluating the compliance by the performance criteria set out in this point. ¶

However, if there is conclusive scientific proof that the level of the migration decreases in the second and third migration tests and if the migration limit is not exceeded in the first migration test, the material or article is considered compliant.¶

Irrespective of the above rules, a material or article shall never be considered to comply with this Regulation if in any of the migration tests a substance that is prohibited from migrating or from being released in detectable quantities as under Article 11(4) of this Regulation is detected.'¶

Technical details on repeat use in points 2.1.6 and 3.3.2 of Chapter 2 of Annex V

‘The applicable overall migration test shall be carried out three times or single sample using another portion of food simulant on each occasion. T migration shall be determined using an analytical method in accordance w the requirements of Article 34 of Regulation (EU) 2017/625 of the Europe Parliament and of the Council. Compliance with the overall migration lir shall be verified on the basis of the level of the overall migration found in t third test and on the basis of the stability of the material or article i.e. t overall migration in the second test shall not exceed the level observed in t first test, and the overall migration in the third test shall not exceed the le observed in the second test.

If it is not technically feasible to test the same sample three times, such when testing in vegetable oil, the overall migration test can be carried out testing different samples for three different periods of time lasting one, t and three times the applicable contact test time. The first migration, t difference between the second and the first migration and the differer between the third and the second test results shall be considered to repres the three successive overall migrations.’

However, if there is conclusive scientific proof that the level of the migrati decreases in the second and third migration tests and if the migration limit not exceeded in the first migration test, the material or article is consider compliant’.

Labelling provisions

- Article 10(4)

Plastic·materials·and·articles·that·are·intended·to·be·brought·into·contact·with·food·but·are·not·yet·in·contact·with·food·when·sold·or·supplied·to·consumers,·and·which·are·manufactured·with·substances·included·in·the·Union·list·for·which·column·10·of·table·1·of·Annex·I·sets·out·restrictions·related·to·one·or·more·of·the·following·conditions·of·use·of·the·final·material·or·article,·age·or·other·population·subgroups,¶

– → specific·foods·or·groups·of·foods,¶

– → contact·time·and/or·temperature,·and/or,¶

– → to·heating·conditions·such·as·oven·and·microwave·use,¶

shall·only·be·placed·on·the·market·if·labelled·with·instructions·of·use·directed·at·the·final·user·of·that·material·or·article,·and·in·accordance·with·Article·15·of·Regulation·(EC)·No·1935/2004,·ensuring·that·the·user·is·provided·with·adequate·information·to·prevent·using·the·material·or·article·under·conditions·exceeding·the·applicable·limitations.¶

If·such·a·material·or·article·is·intended·for·repeated·use,·and·by·derogation·to·Article·15(7)·of·Regulation·(EU)·No·1935/2004,·such·labelling·shall·be·indelibly·affixed·to·the·material·or·article·by·techniques·such·as·printing·or·embossing,·and·a·minimum·font·size·of·3·mm·(9·pt.)·shall·apply,·unless·for·technical·reasons,·that·information·cannot·be·affixed·with·such·techniques·to·the·material·or·article,·in·which·case·the·information·shall·displayed·in·accordance·with·Article·15(7)·thereof.'¶

Article 14

- Article 14 to specify migration testing in multi-material multi-layer materials and articles
- Objective is to further ensure safety in a changing market, particular in view of recycled materials

‘4. → By derogation from paragraph 1, Articles 11 and 12 of this Regulation apply only to multi-material multi-layer materials and articles when the surface layer that is in contact with food or the food simulant during tests used to verify compliance in accordance with Article 18 Regulation is made of a material in the scope of this Regulation.’ ¶

‘6. → In a multi-material multi-layer material or article, specific and overall migration limits for plastic layers and for the final material or article may be established by national law for multi-material multi-layer materials and articles to which the derogation provided for in paragraph 4 applies.’ ¶

Annex III

- Update of Cheese assignments

(1) → In table 2 of Annex III, the descriptions and simulant assignments for cheeses with reference number 07.04 is replaced in its entirety by the following:

'07.04	Cheeses:							
	A. Whole cheese with inedible rind						X	
	B. Unripened soft cheese (fresh cheese), e.g. cottage cheese, quark, ricotta, cream cheese, fromage frais, and similar cheeses		X(*)		X			
	C. Sliced ripened soft, firm or hard cheese or whole with edible rind, e.g. gouda, cheddar, gruyère, parmesan, stilton, tallegio, beaufort, tomino, brie, camembert, and similar cheeses					X/3		
	D. Processed cheese, e.g. wedges, spreads and slices					X/3		
	E. Brined or fresh cheese in a liquid medium e.g. feta and mozzarella:							
		I. in an oily medium					X	
		II. in an aqueous medium		X(*)		X		

Annex IV DoC)

- Update of point 6 on DoC in relation to ‘impurities’

‘6. →

adequate information relative to the substances used, including impurities in the substances used, reaction intermediates formed during the production process, decomposition or reaction products, in particular for which restrictions and/or specifications are set out in Annex I and II to the Regulation to allow the downstream business operators to ensure compliance with the Regulation.

At intermediate stages, this information shall include the identification and amount of the substances referred to in subparagraph 1 present in the intermediate material,

— that are subject to restrictions and/or specifications in Annex I and/or Annex II, or

— for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate material and which could be present in an amount that foreseeably gives rise to a migration from the final material exceeding 0,00015 mg/kg food or food simulant;’;

Annex IV (DoC)

- Point 9 is replaced to add points 10 and 11 on reprocessing and recycled plastics

'9. when a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of this Regulation;

10. when the plastic material is a batch of material intended for reprocessing the confirmation that it complies with Article 10(1) of this Regulation and that it has been collected in accordance with point C of Regulation (EC) No 2023/2006, and, as appropriate, a specification of its composition and instructions for reprocessing;

11. when the plastic material has been manufactured with one or more substances included in the Union list of authorised substances in accordance with Article 5 that have been recovered from waste materials in accordance with Article 1(3) of Regulation (EU) 2022/1616, the written declaration shall include the following:

(a) a confirmation that the level of individual contaminants is compliant with point (4)-of Article 8 of this Regulation; and,

(b) an indication of the total content of recovered substances in the plastic material or article calculated as weight of recovered substances per weight of the total material or article and expressed as percent.'

Point B (recycled plastics) of the Annex to Regulation 2023/2006

(4) → The title of section B and point 1 is replaced with the following:¶

'B. Minimum requirements for a quality assurance system to be operated at recycling facilities where recycled plastic in manufactured in accordance with Regulation (EU) 2022/1616¶

1. The quality assurance system implemented by the recycler must give adequate confidence in the capability of all recycling operations taking place at the facility to ensure the recycled plastic meets all applicable requirements set out in Regulation (EU) 2022/1616, including those set out in Annex I thereof.'¶

(5) → The following paragraph 3 is added to the end of section B: ¶

'3. → The quality assurance system implemented by the recycler shall include specific operations in the recycling process, 'Quality Assessment Stages', at which the recycler shall assess the quality of each batch of material directly originating from a manufacturing stage.¶

This assessment shall verify the quality of that material by verifying:¶

– → whether the applicable critical limits referred to in point 2(c) have been met at each unit operation that is part of the manufacturing stage; and,¶

– → whether the quality of the resulting material meets pre-defined criteria, using the tests, protocols and evidence referred to in point 2(e) applicable to the manufacturing stage.¶

→ The assessment shall result in a decision on whether the quality of the batch is considered conform and suitable for further processing, or whether its quality requires correction before further processing or, alternatively, whether it is discarded or used for non-food applications, in accordance with point 2(d).'¶

Point C (reprocessing) of the Annex to Regulation 2023/2006

'C. → Reprocessing of plastics in the scope of Regulation (EU) No 10/2011¶

1.→Plastic offcuts, scraps, and similar by-products of plastic manufacturing processes and intended to be reprocessed in accordance with Article 10(1) of Regulation (EU) No 10/2011 ('materials intended for reprocessing') shall be collected separately from waste as close to their point of first production as technically achievable, i.e. the point at which they are cut, scrapped or originate from a similar operation.¶

2.→Materials intended for reprocessing shall be collected either using a closed piping or belt system only intended for that purpose, or in clean bins, bags, or other containers designated to this purpose and which can easily be recognised as being intended only for this purpose. Those containers shall be closed as soon as they are fully filled. Up to the point of reinsertion in the plastic production process the applied containers shall be designed to prevent any contamination of the plastic material.¶

3.→Such bins, bags or containers may be transferred to reprocessing individually or be grouped in secondary packaging. The resulting unit shall be considered as a batch of material intended for reprocessing. The definition of 'batch' as defined in Article 2(20) of Regulation (EU) 2022/1616 shall apply.¶

4.→At any stage of production or reprocessing operations, operators shall ensure that the quality assurance system prevents that materials intended for reprocessing are mixed with batches of plastic of another composition, other materials, or with waste materials.'¶

.¶

Transitional measures

- Present text uses standard transition – provisions will apply after 18 months
- However, we are open to discussion with stakeholders if they provide a good justification
  - the justification should explain specifically why the period should be longer, what actions will be taken during that period, how long these take, etc.
  - they should provide quantitative data
  - only accepted for specific provisions

EFSA assessment of mineral oil hydrocarbons in food

European Commission

Previous EFSA CONTAM opinion 2012

MOSH

The CONTAM Panel considered the calculated MOEs to be a possible concern for human health, both for the background exposure levels and for the high exposure scenarios

MOAH

Insufficient data were available to perform a robust exposure assessment

Because of the potential carcinogenic risk, the CONTAM panel considered the exposure to MOAH through food to be of potential concern

EFSA CONTAM opinion 2023

MOSH

Taking into account the identified uncertainties, it is likely to very likely (with 65-95% certainty) that exposure levels do not raise health concern in ether mean or high-consumers

MOAH

Overall the presence of **3- or more ring MOAH would raise health concerns**; insufficient data were available to perform a robust exposure assessment

The CONTAM Panel concluded that, in the absence of reliable toxicity data, the **dietary exposure to 1-2 ring MOAH might raise a concern**

Recommendations EFSA CONTAM opinion 2023

MOSH

Generation of additional data for the refinement of the risk assessment of MOSH in food

MOAH

Generation of additional data for the refinement of the risk assesment of MOSH in food

Technical specifications of white mineral oils and waxes should be updated with detailed information about the MOAH content and composition

Way forward?

1. Update technical specifications of white mineral oils and waxes in Annex I of Plastics regulation (FCM substances 93, 94 and 95)
2. To reduce the presence of MOAH and MOSH from FCM in food.
   - include specific provisions for preventing MO(A)H contamination under point A of the Annex to the GMP regulation (part of the amendment discussed under BPA)

AoB

AoB

- Use of starting substances without a DoC
- Identification of substances after sensory analysis (organoleptic problems)
  - Q: Would we need to identify which substance is causing an organoleptic problem
  - A: Not according to any FCM legislation? What are the general practices in other MS?
- Hot fill and Oven conditions
  - Q: Can hot-fill conditions (based on EFSA opinion) be extended to oven conditions
  - A: No, they cannot hot-fill means no external heating and cool-down; they are set and validated on the basis of modelling that is different from oven use. Microwave use is even entirely different because that does not have a defined temperature.
- CHED-N

Recycling

European Commission

Agenda

Yesterday

- Revision
  - State-of-play (short)
  - Ceramics
- BPA
- Quality amendment
  - Decision + amending act
  - Substances amendment (short)
- AoB

Today

- Implementation Recycling Regulation
  - state of play
  - correcting act (short)
  - amending act
  - Certification under Article 6(3) (short)
- Authorisations
- Register
- Q&A + AoB

Recycling State of Play

- Registration
  - New iteration of the registers published
  - Schemes and novel technologies being analysed and added
  - IT development making progress
- Authorisations
  - Template nearly finalised → Decisions will be finding their way to you for a check soon
- Amendments
  - drafts for correction + amendment mostly ready – internal consultation to start after BPA
  - certification (Article 6(3)) to follow next year
- Guidance update on hold

Amendments to Regulation (EU) 2022/1616

Correction and amendments to R 2022/1616

- There will be two independent texts, the Amending act and the Correcting act
- The correction is to address (thus far) only issues in chapter IV:
  - Article 10(4) states: ‘At the time of the notification, the **recycler** shall also publish a detailed initial report on…’; this should refer to ‘the developer’ instead of to ‘the recycler’
  - Article 14(6) states: ‘… the Authority [EFSA] may request the developers of the novel technologies under assessment to supplement the information available to it with information compiled in accordance with **Articles 10** and 12, ...’; the reference to Article 10 should only be to 10(3)-(5). The rest is not about information, or about information to competent authorities
  - Article 14(8) refers to Article12(1)(b) and (e); this should be to 12(1)(a) and (c)

amendments presently being considered

- five amendments actively considered – subject to discussion:
  - clarification that DoC needs to go up to retail
  - explicit requirement for supporting documentation
  - prolongation of first audit period to October
  - temporary de-activation of recycling installations by recyclers
  - introduction of a 66% maximum recycled content limit for all mechanically recycled PET
- In addition – if need is confirmed
  - requirement in line 1 of Annex I that plastic input shall be ‘washed and dried’
  - explicit permission to use one physical installation for more than one process
- Subject to discussion with Member States, stakeholders, legal scrutiny

1: DoC clarification

- As intended (see Article 29(3)), but not clear from Article 5(2):
  - DoC needs to be provided also with recycled plastic materials and Articles
  - Otherwise traceability would break
- Reworded provision:

> '2. Recycled plastic, recycled plastic materials and articles, and other products in which those materials or articles are contained, shall be accompanied by a declaration of compliance in accordance with Article 29.

1a: also to retail?

- Following internal discussion, and further analysis, DoC also to be provided to retailers → traceability
- to avoid burden, simplified DoC will be permitted at certain stages

‘4. When placing products on the EU market,

– food business operators using recycled plastic materials and articles to pack food,

– business operators manufacturing kitchenware, appliances and processing equipment that contain recycled plastic or recycled plastic materials and articles, and,

– distributers and importers of those products

may issue a simplified declaration of compliance based on declarations of compliance in accordance with Annex III received from their suppliers.

1b: specification of simplified DoC (either in Article 29 or Annex III)

'4. When placing products on the EU market,

- food business operators using recycled plastic materials and articles to pack food,
- business operators manufacturing kitchenware, appliances and processing equipment that contain recycled plastic or recycled plastic materials and articles, and,
- distributers and importers of those products

may issue a simplified declaration of compliance based on declarations of compliance in accordance with Annex III received from their suppliers.

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 amount 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.

1c: specification of simplified DoC (either in Article 29 or Annex III)

6. By derogation to paragraph 4,

(a) distributers 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 on the basis of information received from their supplier are provided to the users of the product by other means.'

7. In case an operator referred to in paragraph 4 does not issue a simplified declaration in accordance with paragraph 4 and 5, and the derogations in paragraph 6 do not apply, it shall issue a declaration of compliance using the template set out in Part B of Annex III.

2: Requirement for supporting documentation

- We consider the requirement should become more explicit:

in Article 5, paragraph 2 is replaced by the following:

'2. Recycled plastic, recycled plastic materials and articles, and other products in which those materials or articles are contained, shall be accompanied by a declaration of compliance in accordance with Article 29.

Appropriate documentation to demonstrate that the recycled plastic or the recycled plastic materials and articles as well as products containing it comply with the requirements of this Regulation shall be available. It shall be made available without delay to the national competent authorities on their request. In case of recycled plastic, this shall include all relevant records kept in accordance with Article 7(4).';

3: prolongation DL under Article 26

- Given the complexity of the transition, certain audits in accordance with Article 26 will not be completed by 10 December 2023 – legal uncertainty
- Fully functional Register also delayed

  (our IT people are making good progress, though)
- Postponement to 2 years after entry into force, i.e. 10 October 2024
- Precise drafting to be clarified, possibly as extension to Article 31:

> the following paragraph 7 is added to Article 31:
>
> '7. 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.';

4: temporary de-activation of an installation

- Recyclers indicate that sometimes a recycling installation may not be needed for longer period
  - seasonal production
  - poor market
- Difficult to maintain such a non-active installation in accordance with the Regulation
  - risk for unnecessary controls
- It should be possible to have an 'inactive' status
  - for 6 - 20 months
  - (4 months seasonal production + 1-year poor market conditions)

The following paragraph 5 is added to Article 25:

'5. The recycler may notify to the Commission and the Member States that a recycling installation is not used for a minimum period of 6 months. During that period, it shall not be used to manufacture recycled plastics in accordance with this Regulation, and it shall not be subject to official controls. The registration status in accordance with paragraph 2, point (g), of Article 24 shall be 'inactive'.

At any time after expiry of the 6 months, the recycler may take the recycling installation into active use again by using it to manufacture recycled plastic in accordance with this Regulation. This shall be notified without delay to the Commission and the Member States.

After such re-activation, the registration status in accordance with paragraph 2, point (g), of Article 24 shall be:

– the same as the status before the de-activation, provided the inactive period lasted for less than 20 months, or;

– if the inactive period lasted for 20 months or more, the status shall become 're-activated', and the procedure in Article 26 shall apply. For the purpose of Article 26(4) the start date shall be the day of re-activation.'

5: limit on recycled content

- Certain operators presently market plastic with 100% recycled content
  - This is considered ‘green’
- We consider to limit recycled content to 66% in all mechanical recycled PET
  - EFSA assessment does not consider plastic input with high recycled content
  - Collection < 100%; other operators to meet 25%
    → import of material that does not meet Article 6
  - No data on safety, No proper controls in place on imports
- Limit considered temporary, but will not be drafted as temporary
- Probably added in line 1, column 6 (‘*output*’) of table 1, Annex I to the Regulation
  - clarification in individual authorisations that 66% applies, even if authorised for 100%

other potential amendments

- All input to mechanical PET recycling to be ‘washed and dried’
  - requirement should be added to all authorisation decisions
  - possibly added instead to line 1, column 5 (‘*input*’) of table 1, Annex I to the Regulation
  - primarily internal drafting matter; however, implication is that it will limit technology 1

- There are installations that can be used for more than 1 process
  - technical configuration the same, processing conditions different
  - in other words that makes perfect sense
- Regulation (EU) 2022/1616 does not explicitly prevent or support it
  - should we clarify that the same physical installation may be used for several processes?
  - i.e. one or more RIN numbers assigned to same installation
  - difference in operating conditions clarified in the respective CMSS

to conclude

- You will be asked for your feedback on these amendments
- It is equally important to let us know if there is anything else which would need in your present experience amending or correcting
- To come (but not under this amendment) certification under Article 6(3)

Recycling Point 8 & 9: Register and Authorisation Decisions

FCM inspections in Brussels…

Point 9a: Registration of mechanical PET installations

1. Consultation and evaluation of Forms: COM & CAs in EU Level

& preparation of the Register Lists (received till 31st of December 2022) upload in FCM SANTE website – 1st of June 2023

April to June

2. Register Lists (forms received from 1st of January till 30th of June 2023) uploaded in FCM SANTE website

18th of July

3. Publication of the next Vers of Register Lists (forms received from 1st of January till 27th of October 2023) in FCM SANTE website

27th October

Last vers:
27th of October

2. The Union Register

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

Section 1 - Year 2022: Forms received by 31st December

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 | •••

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

resent a final position and does not
ation contained in this presentation,
thoritatively interpret Union law.

European Commission

Section 1 - Year 2022: Forms received by 31st December

Please note the following:

1. Registers Lists presented in an alphabetical order per country & installation.
2. Recyclers present in the current list, may use the online forms in order to update their data (please include all the information's needed in the current forms) by **completing the online forms (1,2,3 and 4)**.
3. Recyclers that already revised their forms using those online forms, should use the codes (RIN/RFN & RON) presented in the 2023 (Section B) Register Lists for their Installation /Facility and Company. The new information has in that case superseded the 2022 information.
4. The current Register Lists of year 2022 will not be revised again.
5. In case a Register number is lacking (RIN/RFN & RON) to provide them to the CAs (Competent Authority) please present the PDF receipt of the Registration in EU Survey and indicate that codes are pending.
6. The online form has been developed to allow applicants submit their applications through the online web interface. As a result, a unique number is created once the registration completed in order to be used in future communication (Commission & Competent Authorities). Applicants kindly invited not to forward their online PDF forms to the Commission (only if requested).

Last vers:
27th of October

European Commission

Section 2 - Year 2023: Forms received from 01st January to 27th October

Section B: Year 2023 (Forms received from 1 January until 27 October 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 27 October. 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).

EU Member States

- **List 1**: Register of Recycling installations in the EU
- **List 2**: Register of Recycling Facilities in the EU
- **List 3**: Register of Recycling Companies in the EU

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 27 October.

Non EU Member States

- **List 1**: Register of Recycling installations outside of the EU
- **List 2**: Register of Recycling Facilities outside of the EU
- **List 3**: Register of Recycling Companies outside of the EU

Section 2 - Year 2023: Forms received from 01st January to 27th October

Please note the following:

1. Registers Lists presented in an alphabetical order per country & installation.
2. Please note the following Register numbers, RIN/RFN & RON, are linked to the name of the Installation /Facility and Company. If the name changes the Register numbers changes accordingly.
3. The Register Lists are revised once per quarter.
4. In case a Register number is lacking (RIN/RFN & RON) to provide them to the CAs (Competent Authority) please present the PDF receipt of the Registration in EU Survey and indicate that codes are pending.
5. The online form has been developed to allow applicants submit their applications through the online web interface. As a result, a unique number is created once the registration completed in order to be used in future communication (Commission & Competent Authorities). Applicants kindly invited not to forward their online PDF forms to the Commission (only if requested)

Last vers:
27th of October

European Commission

EU countries Year 2023: Forms received from 01st January to 27th October

	RIN	RFN	RON		RIN	RFN	RON
Austria	5	5	5	Italy	79	80	78
Belgium	3	3	4	Latvia	4	4	4
Bulgaria	3	3	3	Lithuania	11	11	11
Czech Republic	2	2	2	Netherlands	12	12	11
Denmark	1	0	3	Poland	27	27	27
France	14	14	14	Portugal	7	7	7
Germany	27	26	26	Romania	4	4	4
Greece	5	5	5	Slovakia	1	1	1
Hungary	3	3	3	Spain	49	49	48
Ireland	5	5	5	Sweden	1	1	1

Non EU countries Year 2023: Forms received from 01st January to 27th October

	RIN	RFN	RON		RIN	RFN	RON
Angola	1	1	1	Peru	1	1	1
Australia	2	2	2	Saudi-Arabia	1	1	1
China	13	13	13	Singapore	1	1	1
Colombia	1	1	1	South Africa	2	2	2
Ecuador	1	1	1	South Korea	5	6	6
Egypt	3	3	3	Switzerland	2	2	2
India	7	7	11	Taiwan	2	2	2
Indonesia	1	1	1	Thailand	3	3	1
Israel	3	3	3	Turkey	8	8	7
Japan	4	4	4	UAE	1	1	1
Malaysia	2	2	2	UK	14	11	13
Mexico	1	1	1	Myanmar	1	1	1
Oman	2	2	2	Serbia	1	1	1
Pakistan	1	1	1				

Point 9b : Recycling schemes

- 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’).

- recycling schemes are assigned a recycling scheme number ('RSN');

	Belgium	Bulgaria	Czech Republic	Denmark	France	Germany	Greece	Hungary	Netherlands
RSN	4	2	2	4	7	5	2	2	2
	Ireland	**Italy**	**Latvia**	**Lithuania**	**Slovenia**	**Poland**	**Portugal**	**Romania**	**Luxembourg**
RSN	3	11	1	1	1	3	4	2	2
	Slovakia	**Spain**	**Sweden**	**Estonia**	**Finland**	**Croatia**	**Cyprus**	**Malta**	**Austria**
RSN	2	9	2	1	3	2	1	1	2
	Mexico	**Morocco**	**Norway**	**Oman**	**South Korea**	**Switzerland**	**UK**	**Vietnam**	
RSN (Non-EU)	1	1	2	1	1	1	4	1	

Point 9b : Novel technologies

- 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’).

Point 9b: 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

26 dossiers Novel Recycling Technologies

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

	Belgium	Denmark	Germany	Spain	Italy	Lithuania	Sweden
NTN	6	1	5	1	3	1	1

	China	Turkey	UK
NTN (Non-EU)	1	1	6

Point 9a: IT development for Recycling Registration

- FFSPM- Food and Feed Information Portal Database

  - Access to all the parties involved (COM & CAs, Companies & Public) -Year 2024
  - Register Lists online
  - Documents in the portal
    - Forms
    - Guidance documents
    - Legislation
  - Ability to revise the data in real time
    - COM & CAs
    - Applicants

European Commission

EN English

Search

Search

Food and Feed Information Portal Database

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

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 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

Food Contact Materials

- Search for Additives
- Disclaimer
- Download Register in Excel format
- Latest updates to the Register

Part 8: Recycling authorisation decisions

- 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’).

WG 11th of September

- Under evaluation: COM & MSs
  1. All EFSA opinions evaluated and separated in categories
  2. Categories selected due to their similarities, recommendations & conclusions
  3. Draft templates to be finalised & kick off the process

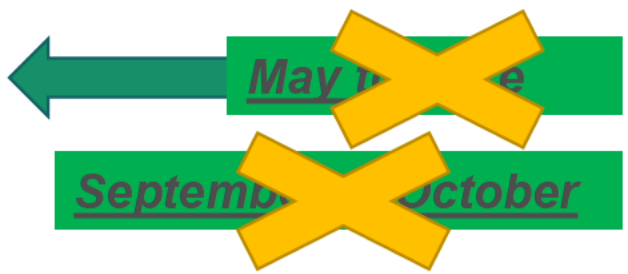
WG 10th February

- Ongoing work: Consultation Process - COM
  - Process started beginning of April
    - SANTE internal consultation
    - COM internal services

WG 27th & 28th of April

- Final step: Finalising & Voting the Authorisation Decisions
  - MSs to be informed about the Authorisation decisions templates
  - Process to be explained to MSs:

November & December 2023



European Commission

Part 8: Recycling authorisation decisions

- WG Documents to be shared with MSs
  - 1. MSs Authorisation Decision distribution
  - 2. MSs Authorisation Decision distribution + RECYC Number per MSs
  - 3. Evaluation Categories
  - 4. ex. of Recycling Efsa Opinion RECYC001
  - 5. ex. of Recycling Authorisation Decisions for RECYC001

❖Comments and questions to be forward SANTE-FCM-RECYCLING-REGISTER@ec.europa.eu

-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)

Thank you