



FCM Working Group

27 June 2022

European Commission; DG SANTE E.2

Agenda

- General points
- Revision
- Amendments to Regulation (EU) No 10/2011
- Bamboozling action
- Regulation (EU) No 284/2011
- new Recycling Regulation
- AoB

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



FCM TEAM

- Bastiaan Schupp
 - Team leader – Recycling, Revision (blue part), (Plastics)
- Jonathan Briggs
 - Revision, general coordination + risk assessment, major EFSA files, (R 284/2011)
- Greta Borg
 - Revision (sustainability); coordination other Commission files (e.g. environmental)
- Apostolos Kapsalis
 - Recycling (register + authorisation Decisions); Revision (procedures)
- Stella D'Amore (50%)
 - Implementation existing legislation (mainly substances under Regulation (EU) No 10/2011)
- Angele Aquilina
 - Organisation of meetings, administrative support to the team, handling of documents and mailings
- Isabella Wagner
 - Trainee (to leave at the end of July ☺)

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Present priorities

- Revision – IA to be completed in 2024
 - Public consultation
 - Start of study
- Recycling – ensure a smooth implementation
 - Register
 - Guideline
 - PET authorisations

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Main purpose of this meeting

- To discuss main agenda points
 - to provide you with an update on the Revision
 - to explain the updates to Regulation (EU) No 10/2011
 - to introduce our work on implementing the new recycling Regulation
- To prepare for the next meeting (provisionally 19/20 September)
 - substantial interaction on recycling
 - discussion on detailed approaches foreseen under revision
- We strongly encourage your physical presence in September

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Revision

Objectives, Approach, State of Play



FCM Evaluation

- Staff Working Document published 9 June 2022 (https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials/policy-initiatives/evaluation-eu-rules_en including summaries in FR and DE)
- Provides basis for the revision + political commitments given in Farm to Fork Strategy and Chemicals Strategy for Sustainability
- Overall the current FCM Regulation functions as expected to a certain extent, and partly fulfils its objectives, in particular for plastic FCMs for which specific EU rules apply.
- There is EU added value and it also remains relevant for all stakeholders

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



FCM Evaluation

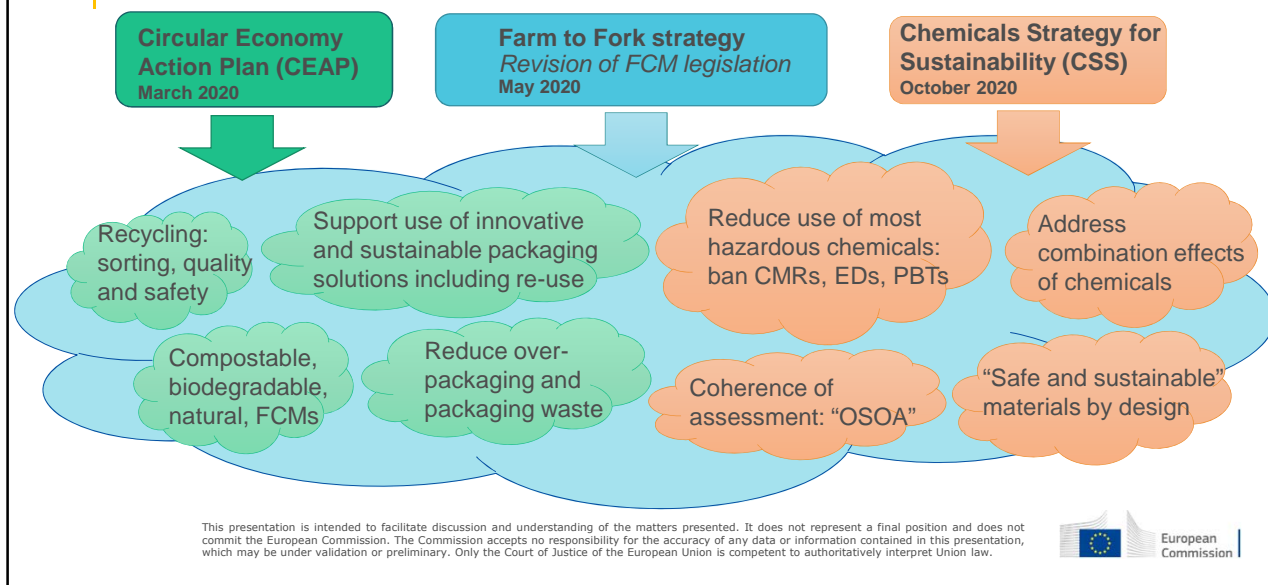
- Main problems identified:
 1. Rules for many materials remains poorly defined → uncertainty over safety and problems concerning functioning of EU market
 2. Issues with current approach –
 - Resource intensive and not optimally efficient
 - Has led to technically complex rules
 - Lack of prioritisation of hazardous substances and focus on safety of final article
 3. Rules geared only towards traditional chemistry e.g. manufacture of polymers rather than rules that also encourage sustainable alternatives;
 4. Exchange of compliance information poor, enforcement challenging and generally weak
 5. Lack of support for specifically SMEs
 6. Room for better coherence e.g. with REACH
 7. Lack of understanding and information to consumers



This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



European Commission's commitments



Relevant COM initiatives

- **'One Substance, One Assessment' (OSOA)** Mechanism for data generation, streamlining data flows on chemicals and increasing data sharing and re-use across legislation, better use of academic data
- **Safe and sustainable by design** Ensure the development, commercialisation, deployment and uptake of safe and sustainable-by-design substances, materials and products
- **Non-toxic material cycles** Decontamination of waste streams, increase safe recycling
- **Extension of GRA and essential use criteria** Operationalisation of ESU concept in legislation
- **Targeting of EDs – revision of CLP Regulation** To be banned in consumer products subject to essential use
- **Targeting of PFAS** General ban under REACH including FCM and packaging;
- **Combination effects ('mixtures')** Provisions to take account of the combination effects in FCM legislation
- **Revision of CLP ED identification and other new hazard classes**
- **Revision of REACH** Simplifying communication in the supply chains, extension of the GRA, control and enforcement
- **Implementation of requirements in Directive (EU) 2020/2184** Including a positive list of substances for materials in contact with drinking water

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.

FCM revision: Main policy themes and pillars

Safety and sustainability

A. Shifting focus onto final material

- Rules to better define level of safety required aimed at addressing the full characteristics of all final FCM articles
- Refocus on broader material types (e.g. synthetic, inorganic, natural fibres etc); include composite FCMs

B. Prioritisation of substances

- All substances to which consumers may be exposed regardless of origin, substance groups
- Tiered approach, with precedent given to certain hazard classes (CMRs, EDs, PBTs and vPvBs)
- EU regulation of other substances
- Self-assessment of more benign substances and/or those migrating in low amounts

C. Supporting safer and more sustainable alternatives

- Ensure safety and facilitate marketing of more sustainable FCMs
- Expand rules to prioritise and support all forms of safe re-use and recycling



Information exchange, compliance and enforcement

D. Improving quality and accessibility of supply chain information

- Clear and consistent rules on data requirements and information transfer throughout the supply chain, including a DoC for all FCMs
- Digitalisation to help businesses, including SMEs to ensure compliance and for Member States to enforce

E. System for verifying compliance

- Delegated bodies under Official Control Regulation 2017/625
- Notified Bodies tasked with conformity assessment
- Further development of test methods and technical standards as required

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



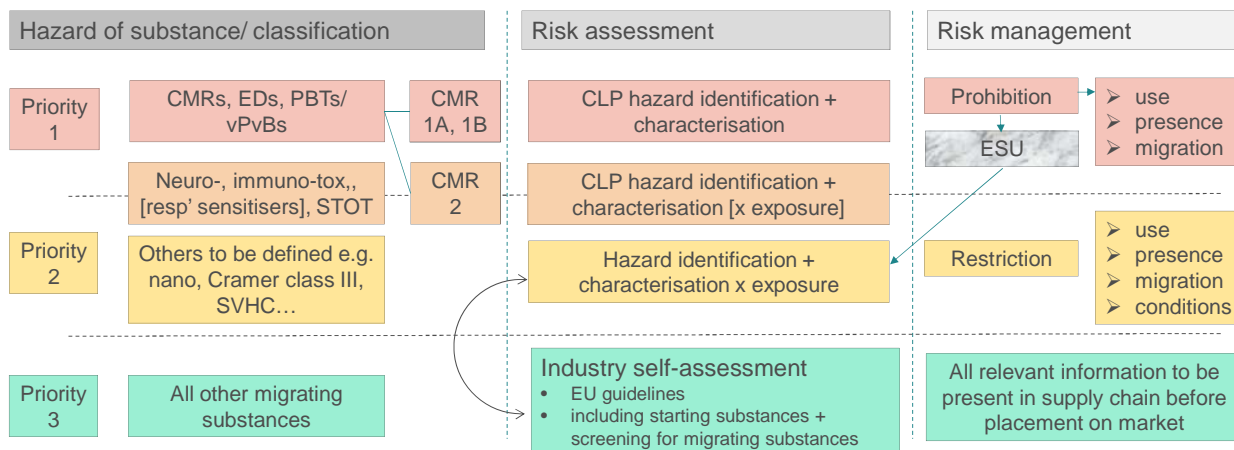
Considerations for prioritisation of substances

- All substances that may pose a risk to consumers, regardless of origin, including non-intentionally added substances (NIAS) and groups of substances
- Tiered approach, with precedence given to certain hazard classes (see next slide)
- Specific implementation to be elaborated
 - Role of EFSA, ECHA and national risk assessment bodies to be further clarified
 - Dependent on material type – e.g. different considerations needed for recycling, natural fibres
 - Point of risk management (use of substances, manufacturing process, final FCM article)
- Considerations for exposure
 - via FCM and via other sources
 - vulnerable populations and
 - combination effects
- Discussion started between COM and EFSA, tbc also with MSs

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Overview for prioritisation of substances



This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Possible options supporting more sustainable alternatives

Beyond ensuring their safety including recycling, we may additionally consider to:

- Prioritise the safety assessment of substances used in innovative sustainable materials and natural materials (e.g. plant or food-derived) over non-sustainable ones
- Increase safety and legal certainty of re-use systems (hygiene, quality control)
- Set incentives supporting the placing on the market of sustainable FCM (e.g. sustainability information on FCM, positive list of natural materials)
- Set requirements supporting the recycling and reuse of materials (e.g. reduce complexity)

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Next steps

- Publication of ToR for a **study to support objectives D and E** (July 2022)
 - Develop options for an **IT infrastructure required for information exchange**
 - Define the **roles of the various actors** (operators participating in the FCM production chain, food business operators, competent authorities in the EU and abroad, notified bodies, delegated bodies and consumers)
 - Define **analytical (laboratory) methods** that can support efficient verification of compliance and controls of final FCMs with the safety requirements
 - To be published shortly, duration 12 months
- **Policy options paper** to expand further on roadmap

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Next steps

- Publication of **Public Consultation** (July 2022)
 - Questions for citizens on scope of the legislation, the safety of FCMs, consumer information and labelling and aspects relating to re-use and sustainability
 - Questions for stakeholders (you, business associations, businesses, NGOs etc) on scope, including more focus on final articles, prioritization of substances, supporting safe and more sustainable FCMs and improving supply chain information, compliance and enforcement
 - To be published shortly, duration 12 weeks + (for summer break)
- Parallel/ follow-up work → **citizen engagement group** (run by Commission's JRC) (autumn)
- Further consultation work foreseen (targeted questionnaires, case studies, discussion in MSs' WG etc) (autumn and beyond)

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Call for experts under EMI RTD database

1. Unit E 2 will create a pool of experts (MSs, researchers etc.) in FCM (WG 07-08 Feb)
2. [Work as an expert \(europa.eu\)](https://ec.europa.eu/work-as-an-expert) & register their profile,
3. Experts teams will be established in order to to participate (a) preparation, (b) evaluation and (c) exchange of experience in FCM
 - Once sign in, pls use the following keyword in the domain /area of interest:
 - FCM (Food Contact Materials)
4. Additional questions use SANTE-fcm@ec.europa.eu & DG SANTE (webpage) https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials/policy-initiatives/revision-eu-rules_en#call-for-experts

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Upcoming amendments to Regulation (EU) No 10/2011

16th, 17th, 18th, future



16th amendment

- Delayed again (originally planned for June PAFF)
 - our present priorities did not allow for finalising the text
 - firmly planned for 30 September PAFF, text will be circulated well in time
- Content (provisional):
 - deletion of FCM 96 (wood), and FCM 121 (salicylic acid)
 - new limits / group restrictions for the authorised phthalates (157, 159, 283, 728 and 729)
 - adjustment specification FCM 1059 (PHBH)
 - addition of 6 new substances
 - 1,2,4-tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate
 - (triethanolamine-perchlorate, sodium salt) dimer
 - N, N-bis(2-hydroxyethyl)stearylamine partially esterified with saturated C16/C18 fatty acids
 - Phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate
 - Benzophenone-3,3',4,4'-tetracarboxylic dianhydride
 - Extension of use from PET to PEF of
 - FCM 1007, diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl] phosphonate
 - at 0,1 % w/w (polymer)
 - Underlines the need for a Revision of the legislation

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



17th amendment

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



17th Amendment + change to GMP Regulation

- To align with new recycling Regulation
 - too complex as part of the recycling Regulation
- Planning (shortest)
 - detailed discussion during next WG, first draft planned for early September
 - final Legal check after WG
 - feedback period in October
 - vote 24 November
- before revision we foresee no further change to text or Annex III – V
 - i.e. apart from substances, the 17th would be the last amendment

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



17th – possible amendments to R 10/2011

- a link to the new Regulation on recycled plastics
 - either add line in Article 4... or take recycled plastic out of scope (Article 2(2))
- enhanced purity requirements
 - avoid that contaminants can be present in listed substances manufactured from waste;
 - maximum dimer and trimer content, no heavier oligomers
- rules on the composition of plastic reprocessed from scraps and off-cuts;
 - link to GMP; 'by-product' under waste framework; meet chapter II
 - cause exceedance of migration limits
 - not been in contact with food, printed, coated (including with adhesives), lubricants
 - Article 10

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



17th – possible amendments to R 10/2011

- We may consider to clarify the multi-layer concept in Article 14
 - **introduction of migration testing requirement** for multi-material multi-multilayer materials
 - only if the outer layer is plastic
 - ensure that recycled plastics are subject to migration testing if covered by primary plastic
- would be a significant change to present practices
 - also applies to non-recycled plastics
 - consideration of the consequences
- Re-word some references to 'plastic-layers' (e.g. Article 5, 6)

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



17th – possible amendments to R 10/2011

- Other matters foreseen once under 16th amendment:
 - Labelling of permitted conditions of use Annex I (partial alignment with recycling)
 - New assignments for cheeses (table 2 of Annex III)
- Provide more clarity in view of bamboo and coffee parchment discussions
 - clarify difference between starting substances and additives
 - starting substances are not particles, if only particle surface reacts → additive
 - EFSA opinion on glass fibres provides the basis
 - requirements on natural substances (Article 9, a bit similar to substances in nanoform)
 - clarify between purified substances from natural origin, and unpurified natural materials
 - authorisation to be at species level, to take account of effect on matrix
 - EFSA opinion on wood to provide the basis

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



17th – possible amendments to GMP regulation

- 17th amendment also to amend the Annex to Regulation (EC) No 2023/2006
- Amendment to point B (concerning recycled plastics)
 - some small matters under point 2
 - addition of point 3 'quality assessment stages'
- Addition of point C
handling of off-cuts and scraps intended for reprocessing under R 10/2011
 - separate collection at point of manufacture (i.e. the cutting/scraping operation)
 - prevent contamination during further handling and transport and remain under GMP
 - declaration of compliance

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



17th amendment

- Anything on the previous slides will be subject to further
 - discussion with Member States and Stakeholders
 - legal scrutiny
 - analysis by Commission services
- It is therefore subject to potential significant change and re-consideration
- before the next WG a first draft text should normally be available

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



18th amendment

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



18th amendment to Regulation (EU) No 10/2011

- To introduce limit for styrene
 - based on pre-cautionary principle
- To introduce limit on TiO₂
 - to reflect that it should not migrate
- Timing – Aim for vote in September or November
 - (note 16th, 17th and 18th amendment likely to swap order)

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



State of play

- September 2019: IARC classifies styrene as *probably carcinogenic to humans* (Group 2A), based mainly on inhalation risks
- Commission notes there is no limit on styrene under R 10/2011, asks EFSA for evaluation of the findings by IARC
- September 2020: EFSA concludes that a concern for genotoxicity associated with oral exposure to styrene cannot be excluded
- Commission services prepare limit (10 ppb, pre-cautionary)
 - Industry notes significant difficulties with migration testing, could be orders of magnitude higher
- Commission services organise a survey to identify problems

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



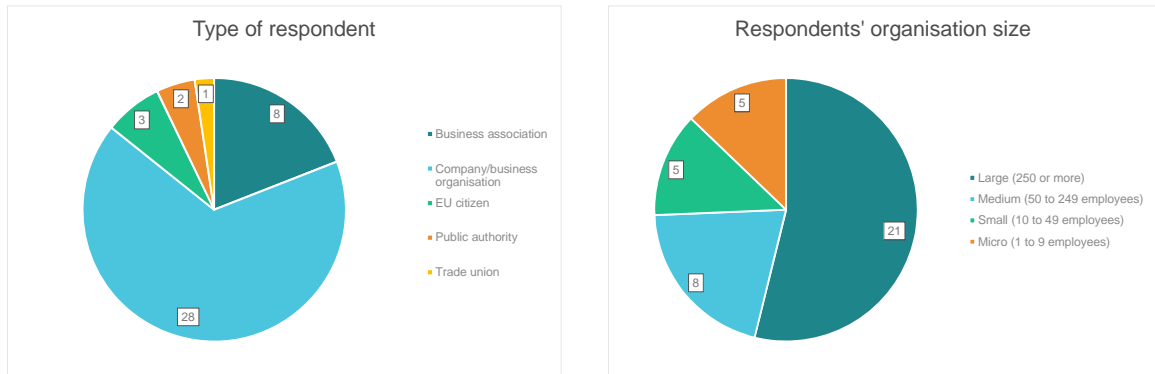
Respondents overview I

- 42 responses, mostly from large business operators (BOs)
- More than 25% of responses from Germany
- Small sample size -> not representative
- Two public authorities took part: a regional agency and a national authority

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Respondents overview II

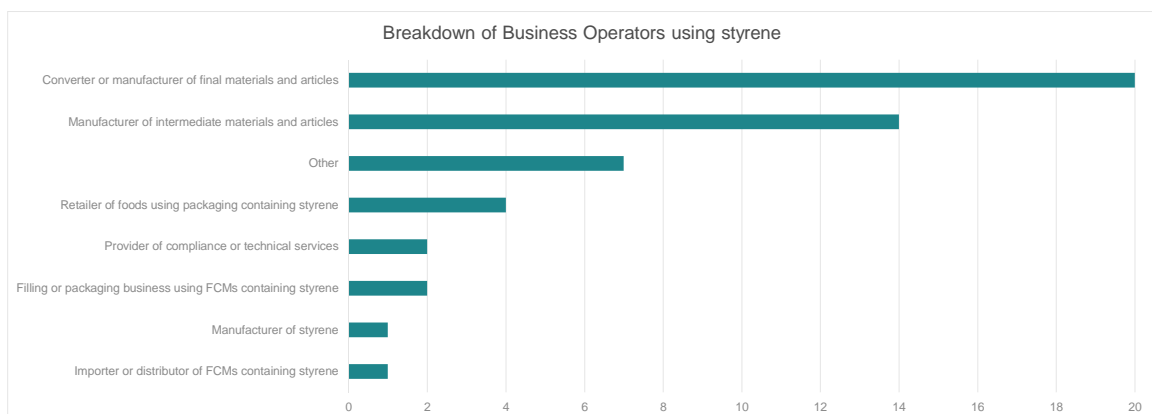


excluding the individual EU citizens that responded to the survey

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Respondents overview III



This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



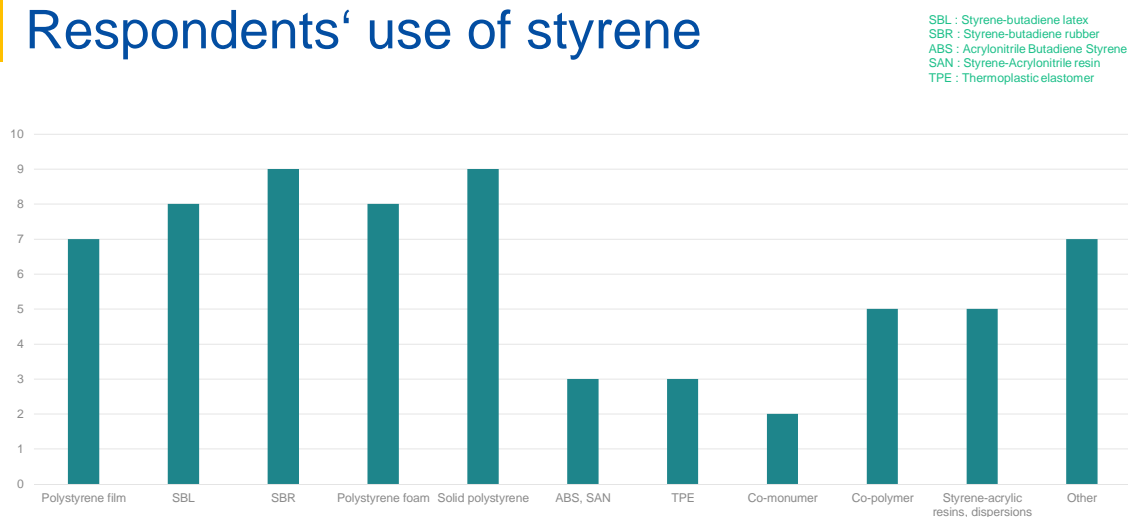
National legislation

- Respondents have to follow national legislation regarding styrene:
 - DE: BfR recommendations on food contact materials (XIV, XXI and XXXVI)
 - IT: Decreto Ministeriale 21/03/73 about Materials in contact with foodstuffs
 - NL: Warenwetregeling verpakkingen en gebruiksartikelen - 2014 - Chapter III
 - FR: Arrêté du 5 août 2020 relatif aux matériaux et objets en caoutchouc destinés à entrer en contact avec des denrées alimentaires
 - BE: KB 25/9/2016 Royal Decree on varnishes and coatings intended to be brought into contact with foodstuffs
 - CH: Swiss Ordinance on Materials and Articles (SR 817.023.21)
 - Outside Europe: legislation of the US and China

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Respondents' use of styrene



This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.

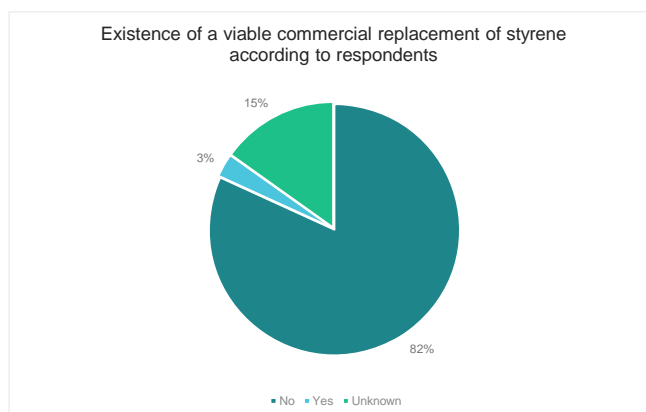


Alternatives to styrene

Most respondents highlighted that although research is being carried out, for specific applications of styrene no feasible alternatives were found, as no other material can fulfil all requirements.

Some respondents did not have any information on whether there are replacements for styrene in their application.

One operator mentioned that PET could be a replacement for polystyrene film.



This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Example I: Alternatives to Polystyrene

- Mostly PE and PP, but also PET, PLA, PA, glass and paper-based alternatives were suggested as a replacement for PS in the packaging sector.
- Alternatives to PS have unfavourable properties:
 - Increased weight
 - Reduced mechanical strength
 - Reduced design freedom and processability
 - Poorer UV resistance
 - Unsuitable for the production of “snappable” packaging
 - Reduced circularity and environmental footprint
- As a result, for example in the dairy industry, it is not possible to replace PS, also because of hygienic properties of the material.

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Example II: Alternatives to EPS

EPS : Expanded Polystyrene
 EPP : Expanded Polypropylene
 EPE : Expanded Polyethylene
 PUR: Polyurethane

- EPP, EPE, bio-based foams, coated cardboard, PUR, pulp and wood were suggested as a replacement for polystyrene foam in the packaging sector.
- Alternatives to PS have unfavourable properties:
 - Less durability
 - Lower impact resistance - risk of damage to items
 - Poorer insulative properties
 - Lower moisture resistance
 - Hygienic issues
 - Increased costs
 - Difficulties with recycling

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law, legislation, but should not in any way be seen as giving a final interpretation of existing legislation or a proposal of new legislation.



Verification of Compliance I

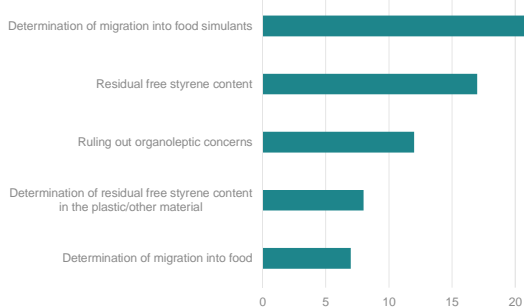
- Respondents mentioned the following ways of ensuring compliance:
 - Most respondents verify compliance by determining the Overall Migration Limit (OML) according to EU regulation 10/2011.
 - Since there is no SML for styrene mentioned, no migration tests on styrene specifically are carried out.
 - Production under GMP requirements and following BfR recommendations.
 - Some respondents rely on the supplier documentation (e.g. DoC).
 - Respecting positive lists of national and EU legislation.

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law, legislation, but should not in any way be seen as giving a final interpretation of existing legislation or a proposal of new legislation.

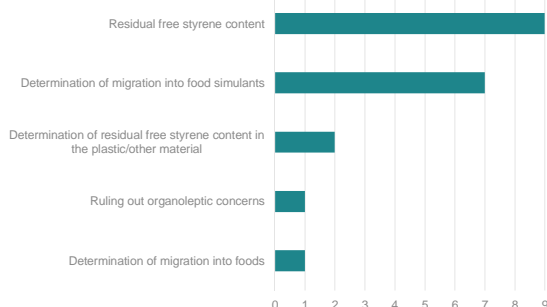


Verification of Compliance II

Respondents' way of testing for compliance



Specifications received by suppliers of respondents



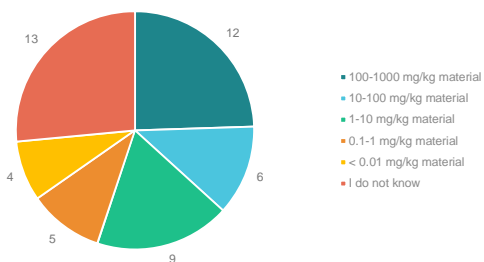
According to some respondents, the migration into food is 10 to over 100 times smaller than in the food simulants.

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.

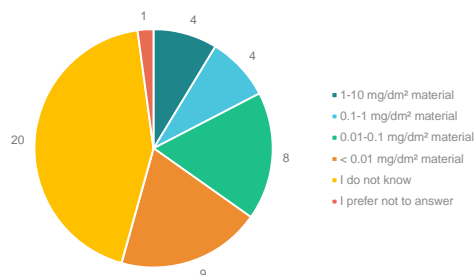


Residual styrene and styrene migration

Residual free styrene concentration in the materials



Migration under typical testing conditions



This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Additional information provided by stakeholders I

- Presence of free styrene monomer can be above 500 mg/kg polystyrene, which leads to a theoretical maximum amount of migratable styrene above the regulatory limit.
- There can be a high variability between laboratories when measuring the free styrene content of the same sample with the same method.
- Migration into the food is usually at least of a factor of 10^4 less than the presence of free styrene monomer in the material.
- Testing the migration into food is possible but very challenging, especially since there are no defined standards.

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Additional information provided by stakeholders II

- Migration of styrene into food was analysed for following product categories:
 - Dairy products (migration from PS below 10 ppb – 30 ppb, from ABS around 100 ppb, from SAN below 10 ppb)
 - Fish and meat (migration from EPS below 10 ppb – 30 ppb)
 - Oil (migration from ABS around 200 ppb, from SAN below 20 ppb)
- Migration into food simulant is up to 100 times higher than into food, depending on the testing conditions (e.g. type of food simulant).
- It was highlighted that in some food, styrene occurs naturally and could influence the results of the analysis.

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Precautionary measures

Styrene authorised under Regulation (EU) No 10/2011 without a migration limit (FCM 193).

EFSA Opinion adopted 9 September 2020 (*EFSA Journal* 2020;18(10):6247) re-evaluating the safety of styrene based on IARC opinion => Inconclusive but could not exclude the potential toxicity of styrene.

Because safety uncertainties and no migration limit means it may theoretically migrate up to the overall migration limit of 60 mg/kg food the Commission is considering to take a **precautionary measure** :

- **Set a temporary limit of 10ppb in food**

(preparation of Mandate for EFSA for full Styrene evaluation underway)

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Precautionary measures

Results from the call for data :

The results data show a range of migration of styrene into food from 10µg/k g to 200 µg/kg depending on the product and the plastic analysed.

Free styrene concentration in styrene based plastics may exceed 500 mg/kg, which explains why in a food or food simulant a high migration may occur, even if the food simulant is only mildly aggressive on the plastic.

EFSA conclusion that in many foods 10 ppb is in practice not exceed partially confirmed in survey

- **Specific testing rules :**

In order to take into consideration overestimation/underestimation in current testing, **testing with simulant will not be allowed**, the quantity of the free styrene in the plastic will need to be determined by extraction and shall not exceed 10 ppb in the food, assuming 100% migration.

When feasible, testing in food will be possible subject directly to the limit of 10 ppb.

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Resulting draft amendment to FCM 193

- To Introduce 10 ppb migration limit
 - based on ALARA, not toxicology
- To lay down two testing approaches:
 - Test in the food (10 ppb limit directly applies – note point 1.4 of Annex V)
 - Extract from the plastic, account for amount of food in contact, 10 ppb limit assuming 100% migration

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Titanium dioxide

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



State of play

EFSA recently published an opinion on TiO_2 as a food additive (EFSA Journal 2021; 19(5):6585).

Presently TiO_2 is authorised under Regulation (EU) No 10/2011, as FCM 610 and banned as a food additive. However, historically TiO_2 was authorised in plastic on the basis of authorisation as a food additive.

April 2020, EFSA opinion on prioritization of the re-evaluation of the already authorized substances from Annex I to Regulation (EU) No 10/2011

→ EFSA considered the prioritisation of the establishment of SMLs for substances authorised without an SML under Regulation 10/2011, **TiO_2 has been assigned a low priority based on the assumption that it does not migrate (EFSA Journal 2020; 18(6):6124, p 22). However this did not take the later opinion on its use as an additive into account.**

Non-negligible risk that this substance may migrate from poorly manufactured or soft plastics, it is appropriate to introduce the requirement that it shall not be detectable in a migration test.

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Precautionary measures

Non-negligible risk that this substance may migrate from poorly manufactured or soft plastics, therefore appropriate to introduce the requirement that it shall not be detectable in a migration test.

In practice :

Lay down a **ND limit on Ti in Annex II**, as testing for TiO_2 is difficult.

Other authorised species containing Ti are similar to TiO_2 and authorised also on the basis of the assumption that they should not migrate

Appropriate detection limit to be verified with the EURL – FCM

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Bamboozling



“BAMBOO-ZLING”

EU Enforcement Action on plastic Food Contact Materials made of bamboo ‘powder’

Results



TI
m
ce
fo
w
ti

state discussion and understanding of the present a final position **Directorate General for Health and Food Safety** the Commission accepts no responsibility for the information contained in this presentation, preliminary. Only the Court of Justice of the European Union has the authority to authoritatively interpret Union law.

Unit G4

Food hygiene and fraud

27.06.2022

Communication European Commission

Meeting with BEUC

SANTE

Bamboo-zling

EU Enforcement Action on plastic Food Contact Materials (FCM) made of bamboo 'powder'

Between 2019 and May 2021, 77 notifications about FCM containing bamboo fibers were reported in the Rapid Alert System for Food and Feed (RASFF). In the same period, 20 requests for cooperation were created by Member States in the Administrative Assistance and Cooperation System (AAC). The non-compliance that were notified mostly related to the unauthorised use of bamboo additive as a filler and/or the mislabeling of products falsely declared as made of 100% bamboo.

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.

European Commission

Successful cooperation with Customs through DG TAXUD

European Commission | CRMS 2 Customs Risk Management System

RIF > RIF003/EU/2022

Details

RIF type: Single Irregularity

Issuing office: EU 01

Main issue of the RIF: Bamboo action for detecting illegal additives in food contact materials

Description: Since 2019, there has been a significant number of notifications (65) about plastic Food Contact Materials (FCM) containing illegal bamboo powder, reported in the Rapid Alert System for Food and Feed (RASFF). Migration of melamine and formaldehyde has been found considerably above the Specific Migration Limits (SMLs), potentially presenting a health risk. Food contact material (FCM) containing additives like bamboo, cellulose, maize, rice, starch, hemp, etc.) are illegal, because these vegetable substances are not listed in Annex I to Reg. (EU) n. 10/2011. They are not allowed to be used in FCM production. In addition, those substances, when used as fillers in plastics, influence the migration properties of the plastic, causing premature deterioration. Furthermore, the phenomenon tends to worsen with prolonged use over time.

The Commission has launched on 6th of May an EU enforcement action (see attached document), involving Member States' health authorities and customs authorities to control unauthorised additives (bamboo, cellulose, maize, rice, starch, hemp, etc.) potentially dangerous and misdeclared to avoid health checks and duties.

The profile will be valid until 30 June 2022

1. Health risks: Since 2019, there has been a significant number of notifications (65) about plastic Food Contact Materials (FCM) containing illegal bamboo powder, reported in the Rapid Alert System for Food and Feed (RASFF). Migration of melamine and formaldehyde has been found considerably above the Specific Migration Limits (SMLs), potentially presenting a public health risk. Food contact material (FCM) containing additives like bamboo, cellulose, maize, rice, starch, hemp, etc.) are illegal, because these vegetable substances are not listed as additives in Annex I to Reg. (EU) n. 10/2011. They are not allowed to be used in FCM production. In addition, those substances, when used as fillers in plastics, influence the migration properties of the plastic, causing premature deterioration. Furthermore, the phenomenon tends to worsen with prolonged use over time.

2. Possible misdeclaration: Some plastic FCM made of bamboo powder have been falsely misdeclared under the code 441919. Recently, TAXUD dealt with the classification of one particular product consisting partly of grounded bamboo and partly of melamine plastics, intended for contact with food, named "Bamboo caps (bamboo beakers)". TAXUD is of the opinion that the above-mentioned "bamboo cup" manufactured from a composite material made up of plant lignocellulose fibres and a melamine resin binding substance, are to be classified within the code 3924100011 (Tableware and kitchenware containing polyamide or melamine, consigned from CNHK), or 3924100019 (Tableware and kitchenware containing polyamide or melamine, other), or 3924100020 and 3924100090 (Tableware and kitchenware of plastics other). Please, note that products declared within 441919 pay 0.0%, while those declared within 392410 pay 6.5%. For the risk related to misclassification of bamboo products with the legally authorized additive, please consider this RIF as covering FRC 5.2 and FRC 5.3

No laboratory analysis is required to reject the import of the illegal products (chemical analysis on possible migration are only optional).

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.

European Commission

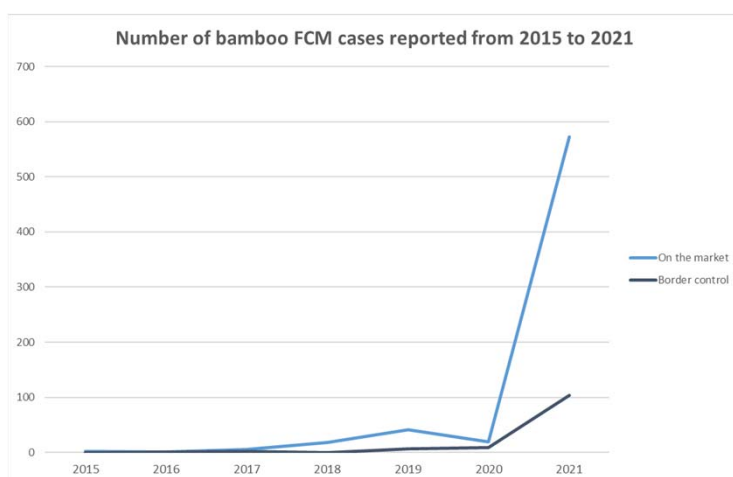
Overview of notifications

- 21 countries participated.
- In total 716 cases of food contact material containing unauthorised bamboo powder were notified
- Of these 716 cases, 612 were related to products found on the market, while 104 were out goods rejected at the border
- A total of 551 cases presented an e-commerce aspect, meaning the product was also or exclusively traded online by e-traders or e-platforms.
- In most e-commerce cases (548), the goods were found on the market; only three times the concerned food contact materials were rejected at the border.
- Other plant based additives: wheat, including wheat straw (22 notifications), rice husks, maize, vegetable fibres and plant parts.
- 35 cases were notified, of which 20 were e-commerce-related.

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Number of FCM cases reported



This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



FCM containing Bamboo / other plant-based additives

FCM containing bamboo and other plant-based additives (May 2021 - April 2022)						
Notifying country	Bamboo			Other plant additives		
	Notification basis			Notification basis		
	On the market	Border control		On the market	Border control	
AT	27	-		-	-	
BE	24	2		1	-	
CZ	7	-		-	-	
DE	168	-		-	-	
DK	35	-		3	-	
EE	27	-		1	-	
ES	62	52		9	1	
FI	38	-		-	1	
FR	38	-		7	-	
GR	-	-		-	2	
HU	99	-		-	-	
IE	-	5		-	3	
IT	1	-		-	-	
LT	1	-		-	-	
LU	19	-		3	-	
NL	-	40		-	-	
NO	3	-		-	-	
MT	-	3		-	-	
PL	23	1		3	1	
PT	-	1		-	-	
SI	40	-		-	-	
Total	612	104		27	8	
	716			35		

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Possible health risk case - Example

- The laboratory analysis of a sample of the product in question, 4800 pieces of coffee cups with bamboo fibres manufactured in China, detected both a migration of melamine (8.6 mg/kg; maximum permitted level: 2.5 mg/kg) and a migration of formaldehyde (373.1 mg/kg; maximum permitted level: 15 mg/kg).
- Due to a decision of the company, in 2018 the goods were removed from sale and kept in their warehouse.
- Nonetheless, information for the customers was posted in the company's branches.



This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.





Thank you for making the
action a success !



SANTE-BAMBOO-ENFORCEMENT-ACTION@ec.europa.eu



https://ec.europa.eu/food/safety/food-fraud/coord-act_en



Regulation (EU) No 284/2011

Summary of official controls on consignments of plastic kitchenware from
China and Hong Kong: Update June 2022

Results 2020 – 2021

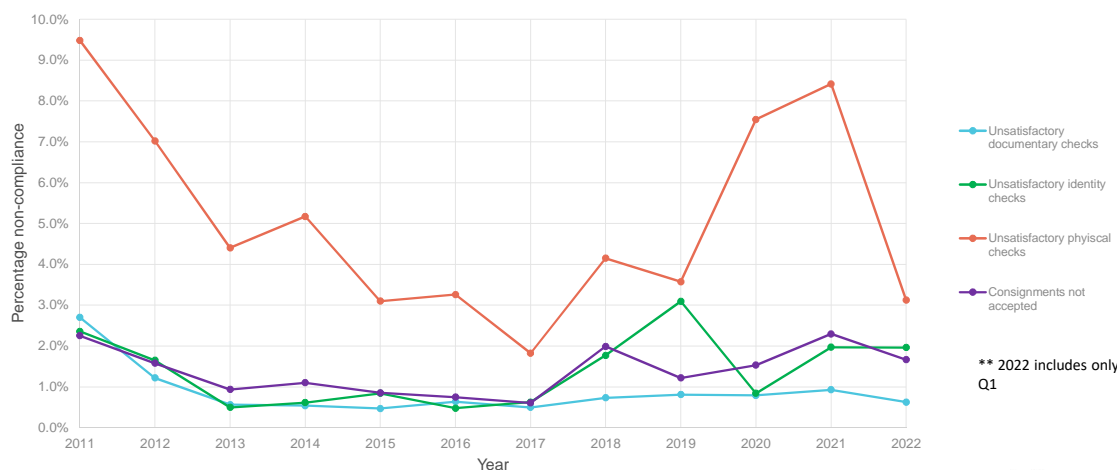
- Number of imports of consignments of melamine or polyamide over last 2 years
 - 2020 = 2152 (15 MSs + Norway)
 - 2021 = 1589 (12 MSs + Norway)
 - 2022 (Q1) = 325 (11 MSs + Norway)
- Average of approximately 4300 consignments per year for period 2012 – 2019
- Documentary checks performed on 100% of consignments; identity and physical checks performed on around 10% (as required)

59

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Non-compliance and non-acceptance rate



60

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Physical checks: Type of hazard

- 2020: Total physical check failures = 16/212 (7.5%)
 - Melamine = 3
 - Polyamide = 9
 - Mixed consignments = 2
- 2021: Total physical check failures = 15/166 (9.0%)
 - Melamine = 9
 - Polyamide = 6
- 2022 (Q1): Total physical check failures = 4/119 (3.4%)
 - Melamine = 1
 - Polyamide = 3

61

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Reminder: Summary of results from controls under Commission Recommendation 2019/794

- **2019** → 5381 samples → 184 samples non-compliant (3.4%)*
- **2020** → 4762 samples → 80 samples non-compliant (1.7%)*
- Main non-compliances → Melamine/ formaldehyde (122 samples) and metals (67 samples)

62

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Discussion on Regulation 284/2011

- Views from the Member States on this Regulation

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



New Recycling Regulation

State-of-Play; tasks and responsibilities; Commission Guidance



Discussion today

- State of play
 - PRAC expires on 12 August – objection/extension is possible
 - Adoption foreseen in September – depends on work peak after holidays
 - Entry into force foreseen in October (!)
- Discussion is intended to
 - prepare you for the entry into force of the new Regulation
 - prepare you for a much more substantial discussion in September
 - take account of your observations/questions towards the entry into force
 - remind of the authorisation decisions
- Topics
 - introduction to remind you of main aspects of the Regulation
 - **tasks for competent authorities, operators, and timing thereof**
 - contents of guidance – short discussion only

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



the new Regulation

A short reminder to introduce the discussions

*COMMISSION REGULATION (EU) ...
of **XXX**
on recycled plastic materials and articles intended to come into contact with foods, and
repealing Regulation (EC) No 282/2008
(Text with EEA relevance)*

*THE EUROPEAN COMMISSION,
Having regard to the Treaty on the Functioning of the European Union,
Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the*

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



1: scope and purpose

- The new Regulation replaces Regulation (EC) No 282/2008
 - Regulation (EC) No 282/2008 is the present Regulation, **it ceases to exist**
 - the new Regulation sets out transitional provisions
- The new Regulation requires that:
 - **All** recycled plastic **content...**
 - in materials and articles that **foreseeably** come in contact with food...
 - is manufactured with a **suitable recycling technology!**
- There are two exceptions:
 - manufacture of **pure** substances listed in Annex I to Regulation (EU) No 10/2011
 - manufacture of recycled content **with a novel technology**

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Definitions

- Definitions related to →
 - technology
 - process
 - installation
- recycling
- decontamination
- To note:
 - definitions in Article 2(3) apply only in the scope of this Regulation
 - facilitate the functioning of this Regulation

- (1) → 'recycling technology' means a specific combination of physical and chemical concepts, principles, and practices to recycle a waste stream of a certain type and collected in a certain way into recycled plastic materials and articles of a specific type and with a specific intended use, and includes a decontamination technology;¶
- (2) → 'decontamination technology' means a specific combination of physical and chemical concepts, principles, and practices part of a recycling technology which have as primary purpose to remove contamination;¶
- (3) → 'recycling process' means a sequence of unit operations that is intended to manufacture recycled plastic materials and articles through pre-processing, a decontamination process, and post-processing, and which is based on a specific recycling technology;¶
- (8) → 'decontamination process' means a specific sequence of unit operations which together have as primary purpose to remove contamination from plastic input in order to make it suitable for contact with food, using a specific decontamination technology;¶
- (11) → 'recycling installation' means the equipment operating at least a part of a recycling process;¶
- (12) → 'decontamination installation' means specific equipment operating a decontamination process;¶

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



2: Technologies, Processes and Installations

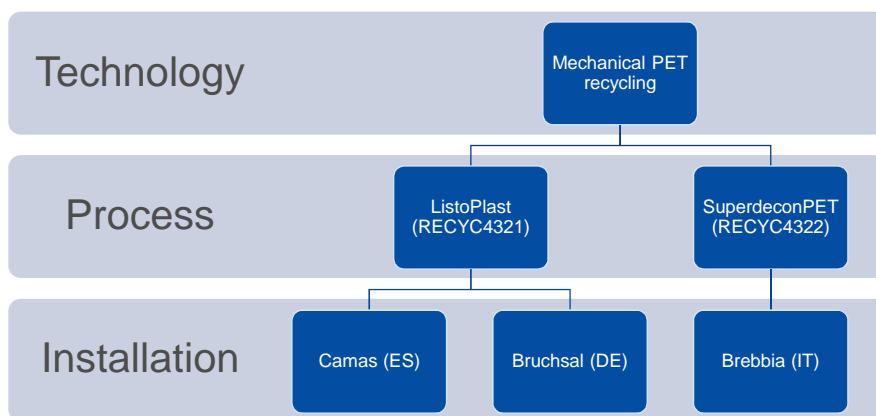
- **Recycling Technology**
 - generic concepts, principles and practices to recycle a defined input into a defined output
- **Recycling Process**
 - well described specific sequential operations based on a recycling technology
- **Recycling Installation**
 - **hardware** that actually recycles the plastic using a process

- **Three associated procedures to establish safety**
 - 'establish' suitable recycling technologies (EFSA + COM)
 - 'authorise' recycling processes (EFSA + COM)
 - 'control' recycling installations (audits) MS Competent Authorities

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



example



any correspondence to reality is purely a coincidence

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



3: Focus on decontamination

- Under New Regulation a recycling process has **always three parts**
 - **pre-processing** → **decontamination** → **post-processing**
 - subject to specific rules
- The **required amount of decontamination** depends on pre- and post-processing
 - residual contamination in final plastic material sufficiently low so that no harm can occur



This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



4: Establishment of suitable technologies

- Suitable technologies are established on basis of novel technologies
 1. **publication of safety report** showing the technology results in safe plastic
 2. placing on the market and **monitoring of contaminants** (publication of reports)
 3. **EFSA evaluation** (this will be very strict → take note under 1. and 2.)
 4. if favourable, **technology established** in Annex I to the Regulation (for anyone to use)
- Any technology is defined by input, decontamination principles, use of output
 - if technology so requires, individual recycling processes shall be authorised and/or use schemes
- The new Regulation already establishes two suitable technologies:
 - mechanical PET recycling, max 5% non-food consumer waste, **authorisation of processes**
 - recycling from closed and controlled chain, no authorisation of processes, use of scheme

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



5: Authorisation of Processes

- For now, only mechanical PET processes require authorisation
- The 230+ processes that applied for authorisation will be authorised
 - authorisations to follow quickly after entry into force of new Regulation
 - only small changes to regime under Regulation (EU) No 282/2008
- Slightly different regime for future applications, only by developers
- Recycling installations to be registered and audited
 - registration shall be **immediately after entry into force** of the new Regulation
 - Compliance Monitoring Summary Sheet to be agreed with competent authorities
 - **batch based** declarations of compliance

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



6: Entry into force

- Entry into force foreseen early Q4
 - The present Regulation, Regulation (EC) No 282/2008 immediately repealed
- Transitional provisions
 - registration after 2 months minus 30 working days, i.e. within 3 weeks after entry into force
 - processes that apply up to 9 months after entry into force may remain on the market until decision on their authorisation
 - applied for authorisation, but not a suitable technology? application deemed terminated
 - plastic content not manufactured with suitable technology? no longer legal after 9 months, **or** novel technology
 - special provisions for novel technologies including use of plastic behind a functional barrier
- We are preparing a note for guidance to help you in implementation
- Communications to recyclers under preparation

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



7: the Annex

- Annex I – suitable technologies
 - two for now:
 - mechanical PET recycling (no recycling scheme, process authorisation)
 - recycling from a closed and controlled chain (recycling scheme, no process authorisation)
 - Restrictions
- Annex II – Compliance Monitoring Summary Sheet
 - to be agreed with Competent Authority 1 year after registration of installation
- Annex III – declarations of compliance
 - one for recyclers, one for converters
 - template based, batch based

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Annex I, table 1, laying down *suitable* technologies

(1) Recycling technology number	(2) Technology name	(3) Polymer type (detailed specification in Table 2)	(4) Short description of the recycling technology (detailed specification in Table 3)	(5) Specification of input	(6) Specification of output	(7) Subject to the authorisation of individual processes	(8) Specifications and requirements (reference to table 4)	(9) Derogations (reference to table 5)	(10) Recycling scheme applies
1	Post-consumer mechanical PET recycling	PET (2.1)	Mechanical recycling (3.1)	Only PET PCW containing maximum 5% materials and articles not used in contact with food.	Decontaminated PET; additional specifications may apply to output from individual processes	Yes	-	-	
2	Recycling from a closed and controlled chain	All polymers manufactured as primary materials in compliance with Regulation (EU) No 10/2011	Basic washing and microbiological decontamination during remoulding (3.2)	Chemically uncontaminated used materials and articles solely obtained from a closed loop; polymers not collected in mixed form, and/or from consumers	Materials and articles remoulded into the same materials and articles as those originating from the recycling scheme from which the plastic input was obtained	No	4.1		Yes

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



ANNEX II

Template for the Compliance Monitoring Summary Sheet in accordance with Article 26 of Regulation (EU) .../...

The template shall be completed taking account of the definitions set out in Regulation (EC) No 2023/2006 on good manufacturing practices, and Annex B thereof.

Abbreviations used in this document in accordance with Regulation (EC) No 2023/2006:

QA: Quality Assessment
 SOP: Standard Operating Procedure
 SOP code: a SOP code is comprised of two numbers, the number of the SOP and the number of the document in which it is described in the format SOPNr – DocNr; the document number shall correspond to the document number listed in section 2.3, the SOP number to the numbering system of the recycler.

1. SECTION 1: IDENTIFICATION

The numbers (RIN, RFN, RON, RAN, NTN) referred to in this section shall correspond to the numbers in the Union Register laid down in accordance with Article 24 of Regulation (EU) .../...

1.1 Identification of the recycling installation

Installation name	
Applied recycling technology in accordance with Annex I	
EU Register number (recycling installation number, 'RIN')	
Facility Address	
Recycling Facility Number ('RFN')	
Contact details	
Position/Role of contact persons	
Relevant national register numbers, if any	
Notification date (Article 25(1)(a))	

1.2. Identification of the recycler

Company Name	
EU Register number (Recycler Operator Number, 'RON')	
Address of the head office	
Contact details	

ANNEX III

Templates for declaration of compliance

Part A: Declaration of compliance to be used by recyclers

RECYCLERS DECLARATION OF COMPLIANCE with REGULATION (EU) 2022/XXX

I, the undersigned, declare in name of [ADD NAME OF RECYCLER] as identified in section 1.1, that the recycled plastic material identified in section 1.2 was produced in accordance with [Regulation (EU) .../.../PO please add reference to this Regulation]. The recycled material to which this declaration applies is suitable for use in contact with food, provided it is used in accordance with the restrictions set out section 3 of this declaration, and with the instructions in this declaration and with the labelling on the product.

Hereby I declare that the contents of this declaration is correct to the best of my knowledge and in compliance with [Regulation (EU) .../.../PO please add reference to this Regulation].

Section 1: Identification

1.1 Recycler	1.2 Recycled product	1.3 Competent authority
1.1.1 Name	1.2.1 Tradename / designation	1.3.1 Name
1.1.2 FCM-RON*	1.2.2 Batch No.	1.3.2 Address
1.1.3 Country	1.2.3 FCM-RIN*	1.3.3 Country/region
1.1.4 FCM-RFN*	1.2.4 Other information	1.3.4 assigned Registration Number

Section 2: Compliance

2.1 Basis for authorisation or permission to operate (tick one box only)

2.1.1 <input type="checkbox"/>	Authorisation Decision	RAN*
2.1.2 <input type="checkbox"/>	Recycling scheme	RSN*
2.1.3 <input type="checkbox"/>	No authorisation or recycling scheme required	
2.1.4 <input type="checkbox"/>	Novel technology	NTN*


2.2 Results of compliance assessment as listed in the compulsory quality assessment stages in table 3.1 of Annex II, compulsory only if 2.1.1 ticked
 Important: Fields 2.2.2 to 2.2.4 may be left blank, provided field 2.2.5 is ticked

Stage**	Decision criteria and outcomes)	Batch Number(s)
2.2.1 Exit		
2.2.2 Entry		
2.2.3 Input		
2.2.4 Output		

2.2.5 The undersigned confirms that the information required in fields 2.2.2 to 2.2.4 will be made available to competent authority upon its request, within 3 working days.

Section 3: Instructions and information to users of the product

3.1 Instructions to converters		
3.1.1	Maximum recycled content (w/w%)	%
3.1.2	Percent recycled content (w/w%)	%
3.1.3	Restrictions of use***	



tasks and responsibilities

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



(partial) overview

- **Actors (in no particular order)**
 - Member State Central Authorities
 - **Competent Authorities in territory**
 - EFSA
 - EURL-FCM / JRC
 - **Recyclers** (under our definition)
 - Other actors in the recycling industry
 - waste-managers / developers / FBOs
 - developers of technology/processes
 - recycling scheme managers
 - **European Commission**
- **Communication tasks (between actors)**
 - Notify
 - **installation**, company, technology, developer, scheme
 - concerns (over safety)
 - changes/transfer of ownership
 - Submit
 - compliance monitoring summary sheet
 - application
 - Register marking used in scheme
 - Communicate
 - instructions (to users and consumers)
 - information on functional barriers

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



After entry into force

- 0 months
 - Regulation (EC) No 282/2008 is repealed
 - note this changes basis, e.g. applications to EFSA
 - many obligations placed on recyclers
- 2 months
 - starting date of existing installations
 - (8 months for installations using NT)
- 6 months publish report on NT
 - + submit study on functional barrier to CA
- **9 months**
 - deadline for submission of application for PET process, to stay on market
 - deadline to stay on market for technologies not established suitable or registered as novel
- 24 months
 - Certification of waste collection + proficiency tests monitoring methods

timing (not complete)

Prior to / after something else

- 1 month
 - after start date of installation recycler to submit CMSS to CA (to be agreed in 1 year)
- 6 months
 - prior to start of first installation developer to notify competent authority and Commission of novel technology (then within 5 months the CA must act)
 - every six months provide monitoring data (recycler to developer)
 - every six months publish a report (developer)
 - Opinion (EFSA after receiving application)

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Objective for discussion

- to highlight some particularly important tasks
 - increase awareness
 - see what questions there are
 - allow you to start preparing
- Discussed today already in more detail
 - Registration of recycling installations + CMSS
 - Registration of novel technologies
 - Authorisations
- Detailed discussion + overview in September
 - together with draft guidance

Article 4

Requirements for recycled plastic materials and articles

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.

6. The Union register established in Article 24 includes the following information regarding the manufacture of the recycled plastic:
- (a) the decontamination installation where the recycled plastic was manufactured, the address of the recycling facility, and the identity of the recycler operating it;
 - (b) the applied authorised recycling process, if the applied suitable recycling technology requires the authorisation of recycling processes;
 - (c) the name of the recycling scheme used, the identity of the entity managing it, and the applied markings, if the applied recycling technology requires the use of a recycling scheme;
 - (d) the name of the novel technology, if the manufacture of the recycled plastic uses a novel recycling technology.

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Registration of installations

- recyclers to register 30 working days prior to start date of installation
 - note: for existing installations this is about **3 weeks** after entry into force
 - notify the installation and address and other information to CA and Commission
- Commission to update Register – status ‘newly registered’
- Establish compliance monitoring summary sheet to CA
 - recycler needs to have this at the start date of the installation
 - and submit it within one month from start date (wording in Article 25(1)(c) and 26(2))
- Competent authority to verify correctness
 - notify the reception of the CMSS to Commission upon submission; status to become ‘*being established*’
 - verify the information and perform ‘a control’ (i.e. audit) in accordance with Article 27
 - inform the Commission that compliance is established within one year
 - status to become ‘*active*’ (or ‘*suspended*’)
- It is important that recyclers know to which CA they shall notify
 - Use list on our website? Are they to register more locally?
- SANTE-FCM-RECYCLING-REGISTER@ec.europa.eu

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Recycling Schemes

- 15 days prior to the start of the scheme its manager must inform us
 - for the purpose of the registration of the scheme in the register
 - considered very light, no further delay
- Registration of recycling process as for PET, but no CMSS
 - but these processes, even if they do little, must register!
- Enforcement to focus at food business operators
 - If FBO uses packaging with label, they should be following the rules of the scheme
 - enforcement at the scheme manager/recyclers is of course possible

Article 9

Requirements for the operation of recycling schemes

1. A single legal entity shall act as the manager of a recycling scheme, and shall be responsible for the overall functioning of the recycling scheme.
At least 15 working days prior to the start of the operation of a recycling scheme the manager of the recycling scheme shall inform the competent authority in the territory where it is established and the Commission for the purpose of its registration in the Union register established in accordance with Article 24.
The manager shall provide its name, address, contact persons, the name of the scheme, a summary of the scheme not exceeding 300 words, the marking referred to in paragraph 5, a list of Member States where business operators participating in the schemes are located, and references to any decontamination installations used by the scheme. Thereafter, the manager shall ensure this information is kept up to date.
2. A compliance monitoring summary sheet shall not be established, and Article 25(1)(c), and Article 26 shall not apply when recyclers notify the production of recycled plastic as part of a recycling scheme, unless column 8 of Table 1 of Annex I requires to establish it. In case Article 25(1)(c), and Article 26 do not apply, the registration status in accordance with paragraph 2, point (g) of Article 24, as referred to in Article 25(2), shall be 'active'.
3. The manager of the recycling scheme shall provide a single document to all participating business operators and other participating organisations. This document shall set out the objectives of the scheme, explain how it functions, provide instructions, and set out the detailed obligations it places on the participants. The explanation shall include a description of the recycling operations.
4. Recycling schemes shall be set up in accordance with the specific requirements applicable to the applied suitable recycling technology as laid down in table 1 in

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Novel Technology (in general)

- 6 months before the start of the operation developer to notify competent authority (Article 10(2))
 - to include the information referred to in Article 10(3)
- Competent Authority to check compliance with requirements in Article 10 within 5 months
 - See Article 10(8) (which has an annoying mistake)
 - CA may delay the start of the first recycling installation
 - CA shall inform the Commission of serious concerns
- Transition for **existing** technologies:
 - time-limit in Article 10(2) applies (6 months before the start of the operation)
 - but, 6 months after entry into force developer to comply with Article 10(3) and 10(4)
 - the start of the operation is 8 months after entry into force
 - i.e. to developer to notify novel technology before 8-6=2 months after entry into force (but additional 4 months for Article 10(3) and (4))
 - **recyclers** to notify **installations** 8 months – 30 working days= about 6.5 months
 - 5 months after CA received info under 10(3) to check compliance (i.e. 11 months after entry into force)
 - start of installations cannot be delayed (they are on the market already)

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Functional barriers

- Novel technology, previous slide applies
- However:
 - Special provisions for who can become developer
 - Report under 10(3) to include migration test or other means to show that the barrier works still to be submitted after 6 months
 - Slightly lower monitoring requirement

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Authorisation Decisions

- About 270 EFSA applications
 - some still on-going, others not for PET, others withdrawn or other issues
 - present count approximately 210 authorisation decisions, will increase
- The new Regulation provides basis for authorisation
 - we will strive to authorise all processes quickly after entry into force
 - notification at the same time, as much as possible
- Detail of decisions to be discussed in September
 - you have seen them in the past; they will be nearly the same
- Note some provisions in Regulation apply only to authorised processes
 - particularly in relation to the register

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Contents of Guidance

- explain the main parts and procedures of the Regulation
 - provide in accessible terminology the main approach and obligations
- provide guidance for specific actors, setting out the main requirements particularly for:
 - authorisation holders and recyclers
 - developers and operators of novel technology (special attention to the goals they should achieve)
 - enforcement authorities
- lay down the procedures concerning the register (Article 24)
- provide guidance on analytical techniques
 - Chapter IV and Article 32
- include a non-binding template to report monitoring results
 - following the model provided by Austria
- provide non-binding guidance on Annex II
 - this was already provided in December 2021

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Other matters

- Detailed discussion to follow in September
 - discuss the work in detail, some other procedures and enforcement as well
- Potential issue with the entry into force – some provisions hard to comply with
 - Article 4(6) and Article 29 require info that may not yet be available at entry into force
 - It is intended to be fast – we will check again the rationale
- Mistake in Article 10(8) which refers to itself
- Please let us know any problems with language versions
 - please send TRACK CHANGEs version by 5 July
- Please let us know where operators should notify/inform
 - Central Authorities (list already on our website) or locally (should we provide list?)

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Any Other Business



AoB

- Update on the status of BPA, with view to the adaptation of our control plan (PT)
- High aluminium migration from metallic FCM (PT)
- FCM 93, 94, 95 related to contam discussion (BE)
- Lignocellulose (EE)

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



Thank you

Happy to receive questions/discuss...

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not represent a final position and does not commit the European Commission. The Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.

