



1

Agenda

Thursday 13:30 – 17:30 hrs

1. Welcome, AoB points
2. Progress implementation (EU) 2022/1616
3. Amendments to Regulation (EU) No 10/2011
4. EFSA opinion BPA (15:30)
 - EFSA presentation + Q&A

Friday 09:30 – 12:30 hrs


5. Revision FCM rules
 - public consultation
 - consumer studies (presentations Kantar, BEUC)
 - progress on other pillars
6. AoB

AoB:

- a) PFAS Restriction Proposal (COM)
- b) FCM made from wood (DE)
- c) Packaging material from pectin (DK)
- d) Grocery Bags (LU)
- e) Compliance to R 10/2011 (FR)
- f) certification under 6(3) of R 2022/1616 (SE)

other points to be determined

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



1

2

Progress Recycling Regulation

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



3

WG 10th February

Part 1: Register and MSs contribution

- We would like your attention in the following fields:
 - A number of installations, facilities and companies could be distributed in more than one Member State, as a result pls double check information's related to the MSs (fields 1.2., 2.2. and 3.2.)
 - A number of entries could be misleading due to:
 - Duplication
 - Naming of the data received
 - Information missing
 - Fields with «0» , indicates that the current information missing
 - Miscellaneous (end of the table) part, concerns facilities and companies not linked directly with decontamination installation

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



2

4

WG 10th February

Register and MSs contribution

- Data entered (name for recycling installation or facility) proved to be misleading, in such a case please provide us with the correct one. Please ensure that naming for installation or facility:
 - is unique for each installation at a facility and sufficiently descriptive
 - avoids using the name of the manufacturer of the installation, such as 'Starlinger' or 'Erema'.
 - should not necessarily repeat the company name, or the address where it is located (which is very common in the present list), unless possibly if you have several facilities

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



5

WG 27th & 28th of April

Register and MSs contribution

- Cooperation with the **MSs Authorities** the last few months, gave us the opportunity to finalise the first draft version of the Register:
 - 1. Register Lists for:
 - RIN
 - RFN
 - RON
 - 2. Next steps in the Register List process:
 1. Consulting CAs (bilateral) additionally for a few cases:
 - Duplication
 - Naming of the data received
 - Information missing
 - Fields with «0»
 2. Finalising the Lists received till 31st of December 2022
 3. Preparing and consulting the application received in the first quarter of 2023
- Comments and questions to be forward [SANTE-FCM-RECYCLING-REGISTER](#)

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



3

6

WG 27th & 28th of April

Register and Registration

- Register lists:
 - **EU Survey: All forms under one**
 - 1, 2, 3 & 4 Forms merged in one
 - <https://ec.europa.eu/eusurvey/runner/123RECYCForms>
 - Novel Technology form available
 - <https://ec.europa.eu/eusurvey/runner/5RECYCLNovelTechnology>

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



7

WG 10th February

Part 2: Authorisation of recycling process

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

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



4

8

Authorisation of recycling process

WG 27th & 28th of April

- Under evaluation: COM & MSs
 1. All EFSA opinions evaluated and separated in categories
 2. Categories selected due to their similarities, recommendations & conclusions
 3. Draft templates to be finalised & kick off the process
- Ongoing work: Consultation Process - COM
 - Process started beginning of April
 - SANTE internal consultation
 - COM internal services
- Final step: Finalising & Voting the Authorisation Decisions
 - MSs to be informed about the Authorisation decisions templates
 - Process to be explained to MSs: next few weeks

WG 10th February

WG 27th & 28th of April

May to June

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



9

Numbering system

- Entities to be numbered:
 - installations, facilities, operators, schemes, novel technologies, authorisations
- System established under Regulation 282/2008: RECYCXXX
 - XXX consecutive number assigned during application for authorisation
- Problems with consecutive system:
 - risk to assign same number / risk for unexplained gaps → administrative difficulties
 - large number of entities, not as clear processes as only authorisations
 - confusion, also for competent authorities, which number belongs to which line?
- Other problems:
 - operators may assign a value to their place in the sequence
 - increase risk for fraud / misuse – it are very simple numbers
 - number does not give any information on the entity it numbers
 - no inherent check whether the number is correct

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



5

10

Advantages / Disadvantages

- More robustness
 - ensures unique entity names
 - number independent of assignment order
- Number provides information
 - less risk for mistakes
 - competent authorities can check whether entity may fall in their territory
- More complex – requires computer
 - look-up table for postcodes (NUTS) is huge (thanks to the Netherlands ☺)
- Does not cover locations outside the EU – no NUTS regions
 - look-up for UK cannot be (easily) handled by excel – too large
 - manual approach

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



13

Activities

- Numbering will be part of the register – publication imminent
- Numbering also used for the authorisations
- Available information
 - Document will be provided (rather technical description)
 - Excel verification tool will be made available
 - NUTS: [Background - NUTS - Nomenclature of territorial units for statistics - Eurostat \(europa.eu\)](https://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&language=en&code=sdg_11_6_10)

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



14

Amendments to R 2022/1616

- On-going work
 - Clarification of Article 5(2) – DoC
 - Other clarification to the DoC
 - Article 10(4) reference should be to developer, not recycler
- Are there other matters?

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



15

Amendments to Regulation (EU) 10/2011

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



16

8

Overview

- 16th amendment (substances):
 - PRAC finalised, should have been adopted, administrative delay
- Quality amendment (was 17th amendment):
 - being drafted – recitals take some time
 - main outstanding issues:
 - 0.15 ppb value, next slide;
 - aging being seriously considered
- Authorisation of DEHCH (part of 18th amendment)
 - bis(2-ethylhexyl)cyclohexane-1,4-dicarboxylate (CAS No. 84731-70-4, FCM No 1079)
 - presented in PAFF on Monday, written procedure
- Styrene (foreseen 40 ppb limit)
 - Text + mandate to EFSA in internal procedures

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



17

Article 8(5)

- A = 50 ppb or 90 ppb (or 100 ppb)
 - To be discussed with EFSA
 - (0.05 or 0.09 mg/kg) (or 0.1 mg/kg)
- B to be 0.15 ppb
 - (TTC, 0.00015 mg/kg)
 - No clear argument to justify a higher value
- But 0.15 ppb is an issue:
 - detected substances not identifiable
 - NIAS not available for tox testing
 - other practicable difficulties
- Solution is being analysed

5. For the purpose of paragraph 2, 3 and 4 a high degree of purity shall mean that any substance used in the manufacture of plastic materials and articles in accordance with Article 5 or 6 contains only non-intentionally added substances that individually either:

- (i) are in accordance with specifications or restrictions specified in the authorisation of the substance in table 1 of Annex I, if any; or,
- (ii) have been subject to an individual risk assessment in accordance with Article 19; or,
- (iii) have been subject to a limited toxicological assessment that at least rules out genotoxicity, and are present at a level that cannot give rise to an individual migration from the final plastic material or Article exceeding **A** mg/kg food, assuming their full migration into the food; or,
- (iv) are unknown or unassessed, but are present at a level that cannot give rise to an individual migration from the final plastic material or Article exceeding **B** mg/kg food, assuming their full migration into to the food.

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

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

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



9

18

Article 8

1. Any substance used in the manufacture of plastic materials and articles in accordance with Article 5 shall correspond to the identification and specification of that substance in Table 1 of Annex I by means of its name and where applicable its CAS number, and any additional specifications.
2. The following shall apply to the purity of substances originating from a natural origin:
 - (i) if the substance is identified by a chemical name, it shall be of a high degree of purity, or,
 - (ii) if the substance name refers to the name of a natural multi constituent material, that material may be used as obtained from nature, provided it has been separated in its entirety from other natural matter and parts of the plant or other natural source from which it was obtained that are not identified by the substance name.

Any additional specifications or requirements applicable to a substance or material from a natural origin set out in Table 1 of Annex I, applicable to the substance or material, shall apply.
3. Substances used in the manufacture of plastic materials and articles in accordance with Article 5 or 6 shall be of a technical quality and suitable for the intended and foreseeable use of the materials or articles, and shall be of a high degree of purity.
4. Substances recovered from waste in accordance with Directive 2008/98/EC² may only be used in the manufacture of plastic materials and articles in accordance with Article 1(3) of Regulation (EU) No 2022/1616. These substances shall be of high degree of purity.

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



19

EFSA opinion BPA

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



20

10

EFSA opinion on BPA

- Presentation by EFSA
- Q&A
- Preliminary discussion of possible risk management

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



21

Current state of play: use of BPA

- BPA is used to manufacture epoxy resins for coatings to line food and drink cans, metal lids and some large-scale storage tanks for the food industry.
- Also employed in the manufacture of hard, durable plastic including polycarbonate
 - this use is limited in food contact applications to articles such as water dispensers and moulding equipment.
- Other more limited uses include its possible use in some adhesives and inks
- Outside the scope of FCM, its use in plastic is more important; construction, automotive, medical and healthcare industries as well as in consumer products, such as electronic goods and household appliances.

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



11

22

Current state of play: FCM legislation on BPA

- BPA (FCM 151) is authorised as a monomer in plastic FCM according to Commission Regulation (EU) No 10/2011 (as amended)
 - SML is 0.05 mg/kg
 - Not to be used for the manufacture of polycarbonate infant feeding bottles. Not to be used for the manufacture of polycarbonate drinking cups or bottles which, due to their spill proof characteristics, are intended for infants and young children
- An SML of 0.05 mg/kg also applies to varnished and coated FCMs (Commission Regulation (EU) 2018/213)
 - no migration of BPA permitted from varnished or coated FCM specifically intended to come into contact with infant or milk-based drinks and similar products specifically intended for young children

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



23

Issues to consider

- EFSA opinion
 - TDI of 0.2 ng/kg bw is very low – exposure is above this
 - Identification of a number of effects in addition to those on the immune system; reproductive and developmental effects as well as metabolic effects
- BPA is classified as reprotoxic under the CLP Regulation (Repr. 1B) and as an endocrine disruptor (human health and environment) in accordance with the REACH Regulation (SVHC)
- Restrictions in place and planned under REACH Regulation

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



12

24

Issues to consider

- Outcome of EFSA opinion → limited choices for risk management in FCM
- Risk management considerations
 - Scope of restrictions
 - Transitional period(s)
 - Effect on supply chain and food safety
 - Alternatives
 - intentional use / unintentional use (including contamination and BPA in food)
- Coated metal packaging industry have anticipated the situation and considered the potential impacts

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



25

Revision of FCM Legislation

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



13

26

FCM revision approach

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

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

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



27

FCM revision: Main policy themes and pillars

Safety and sustainability

A. Shifting focus onto final material

- Better define level of safety addressing the full characteristics of all final FCM articles including NIAS
- Cluster into broader material types (synthetic, inorganic, natural; recycled, composite, active)

B. Prioritisation of substances

- Define rules for the risk assessment of all (migratable) substances
- Tiered approach:
 - Tier 1: hazard based rules (CMRs, EDs, PBTs and vPvBs)
 - Tier 2: risk assessment by public authorities
 - Tier 3: Self-assessment by operators of more benign substances

C. Supporting safer and more sustainable alternatives

- Ensure fewer hazardous chemicals
- Prioritise more sustainable use of FCM
- Coherence and support to other EU rules on sustainability

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

F. Analytical methods

- Migration testing rules
- Analytical Methods (i.e. OCR methods)
- 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 necessarily represent a final position and does not commit the European Commission. The European Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary assessment. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.



14

28

Activities in pillars

- Pillar A&B – preparation of documents on-going
- Pillar C – sustainable use of FCM: definition of ToR ongoing
 - present focus on policy options for sustainable FCM
 - how can FCM legislation best contribute
- Pillar D&E – we are working with the contractor to fully define the work
- Pillar F – waiting for definition of work programme
 - first discussion with EURL

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



29

discussion today

- Presentation results stakeholder consultation
- Presentation on consumer perceptions
 - Kantar (our contractor)
 - BEUC (European consumer association – did a similar survey independently)

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



30

15

Main results of the public consultation

Working group 28-04-23

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

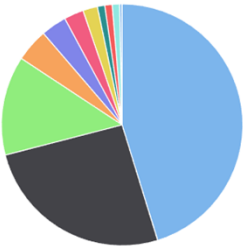


Responses


- The process was launched by the European Commission on the Europa website on 05/10/22, and open until 11/01/2023, generating a total of 610 valid responses.
- Most replies were submitted by EU citizens (45%), followed by Company and Business (26%) and Business associations (13%).

By category of respondent

Category	Count	Percentage
EU citizen	276	45.25%
Company/business	157	25.74%
Business association	81	13.28%
Public authority	27	4.43%
Non-governmental organisation (NGO)	21	3.44%
Academic/research Institution	16	2.62%
Other	12	1.97%
Environmental organisation	6	0.98%
Non-EU citizen	6	0.98%
Consumer organisation	6	0.98%
Trade union	2	0.33%



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



Key responses:

Consumers

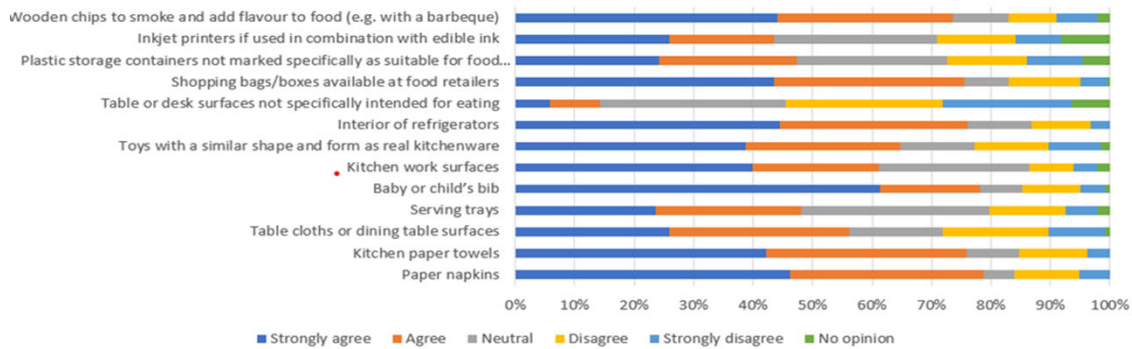
This presentation is intended to facilitate discussion and understanding of the matters presented. It does not necessarily represent a final position and does not commit the European Commission. The European Commission accepts no responsibility for the accuracy of any data or information contained in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



33

Scope and safety of FCMs and articles

To what extent do you agree that the following should be considered a FCM or article subject to safety rules



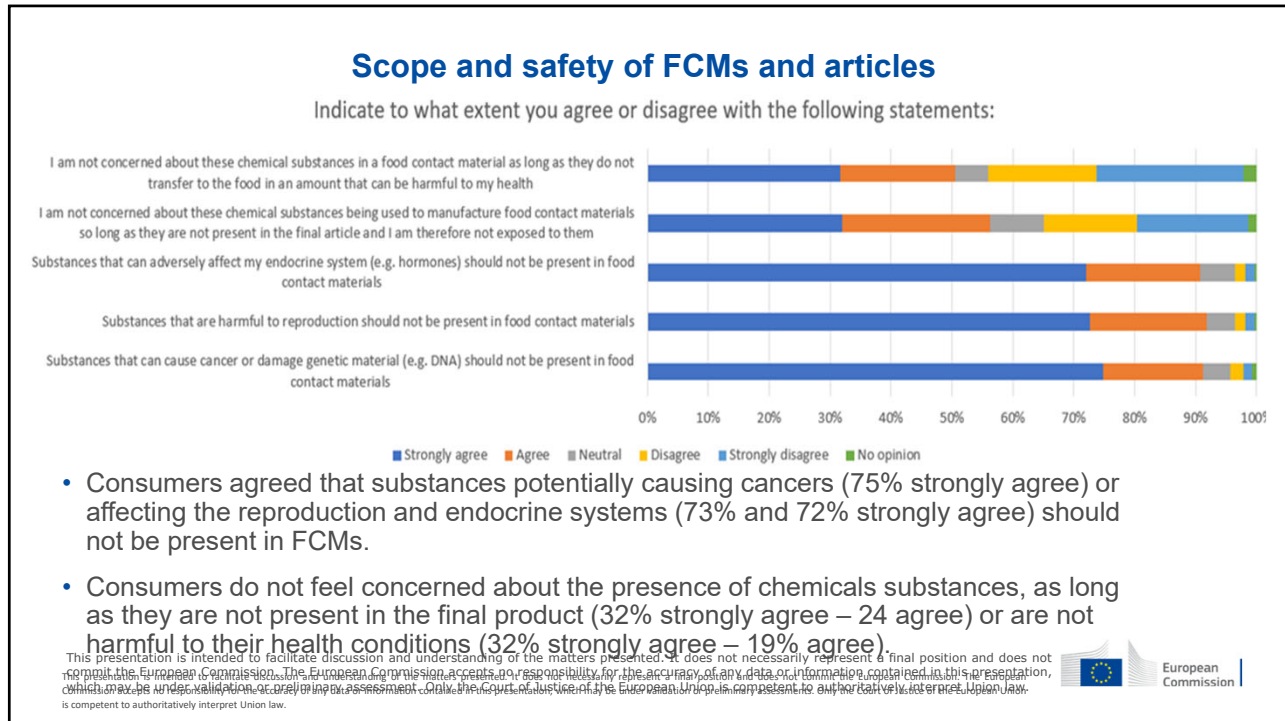
- Some articles are easily associated with FCMs, i.e. baby or child's bibs (46% strongly agree – 33% agree), kitchen papers towels (42% strongly agree – 33% agree), shopping bags available at food retailers (44% strongly agree – 32% agree), etc.
- Consumers considered less as FCMs and FCMs articles items i.e. tablecloths and dining table surfaces (26% strongly agree – 30% agree), tables and desks not intended for eating (26% disagree – 22% strongly disagree).

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

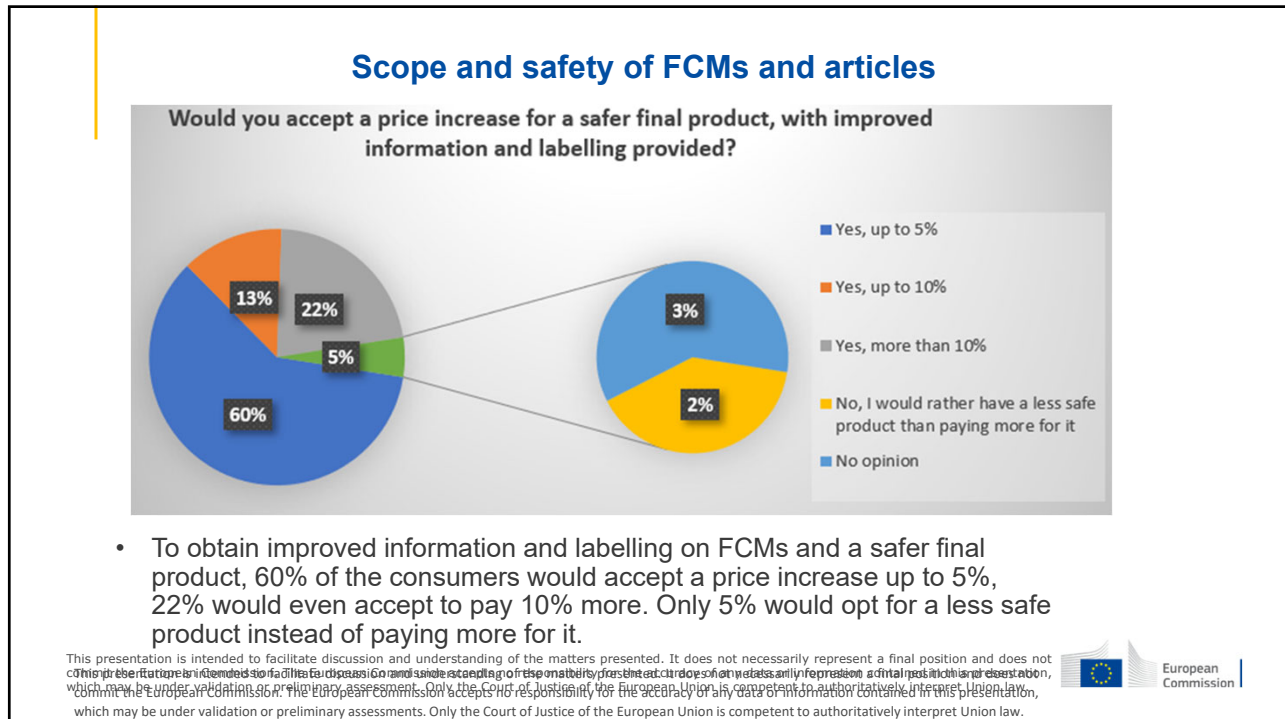


34

17



35



36

Practicality and utility of FCMs information and labelling

- For 44% of the consumers the current wine glass and fork symbol is insufficient to provide safety information on FCMs, the other 46% believes it is enough.
- They are in general in favour of the introduction of a range of symbols to warn on the restrictions of use of the food contact article (66%).
- Another favourable opinion (66%) was expressed on the creation of a guidance text or instructions on the product (as leaflets) and the spreading of awareness campaigns on FCMs (59%).

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



37

Sustainability and re-use of FCMs and articles

- Consumers agree that food safety is more important than the recyclability or reusability of food packaging (72%).
- Environmental legislation and the framework for sustainable food systems (FSFS) should achieve sustainable use of FCMs, and not the FCM legislation (74%).

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

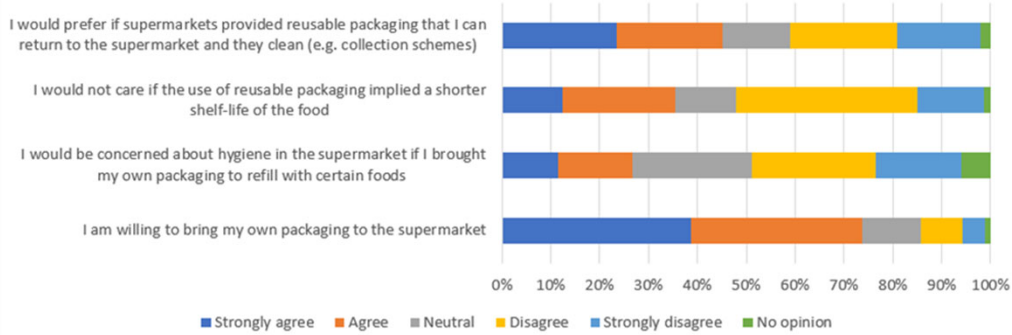


19

38

Sustainability: Consumer habits

Indicate to what extent you agree or disagree with the following statements:



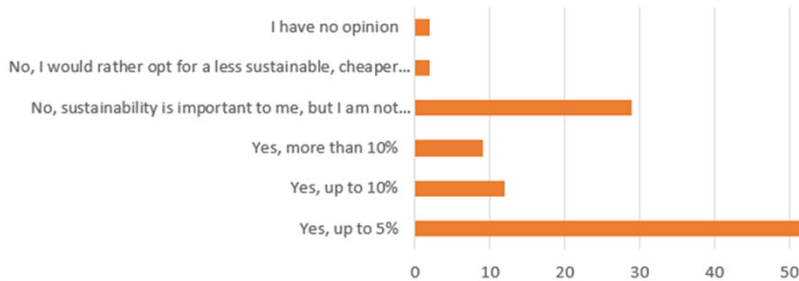
- However, consumers prefer reusable articles over recycle single-use ones and tend to reuse food packaging when possible. Moreover, they are willing to bring their own packaging at supermarkets.

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



Sustainability: Consumer habits

Are you willing to pay a higher price for products that are more sustainable (eg. easily biodegradable, recyclable or reusable)?



- In some circumstances consumers would not be willing or able to pay an increase price for more sustainable options (29%), but the majority (57%) would accept an increase in price up to 5%.

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



Key responses:

Stakeholders

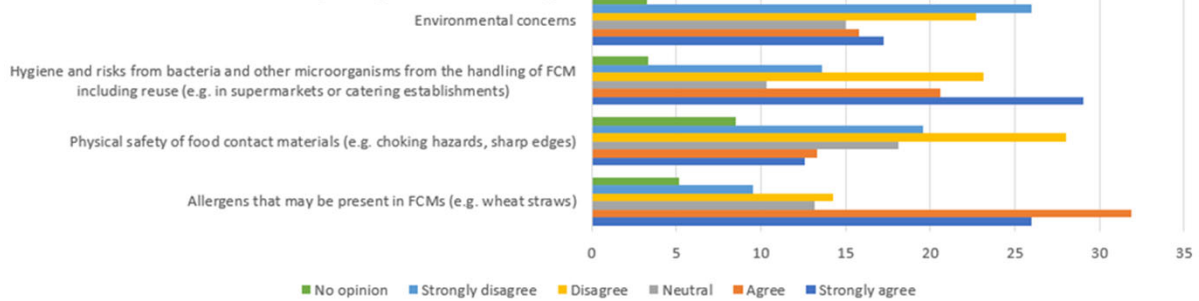
This presentation is intended to facilitate discussion and understanding of the matters presented. It does not necessarily represent a final position and does not commit the European Commission. The European Commission accepts no responsibility for the accuracy of any data or information contained in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



41

FCMs – scope of safety

To what extent do you agree that FCM legislation should address the following:



- NGOs agree the FCMs legislation should primarily address environmental concerns (41% strongly agree - 53% agree) and FCMs allergens (83% strongly agree).
- Public authorities would rather focus on allergens (65% agree).
- Business associations disagree on including physical safety in FCMs legislation (33% disagree and 30% strongly disagree) and, together with business organizations, disagree on addressing environmental concerns (respectively 25% disagree and 27% strongly disagree).

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

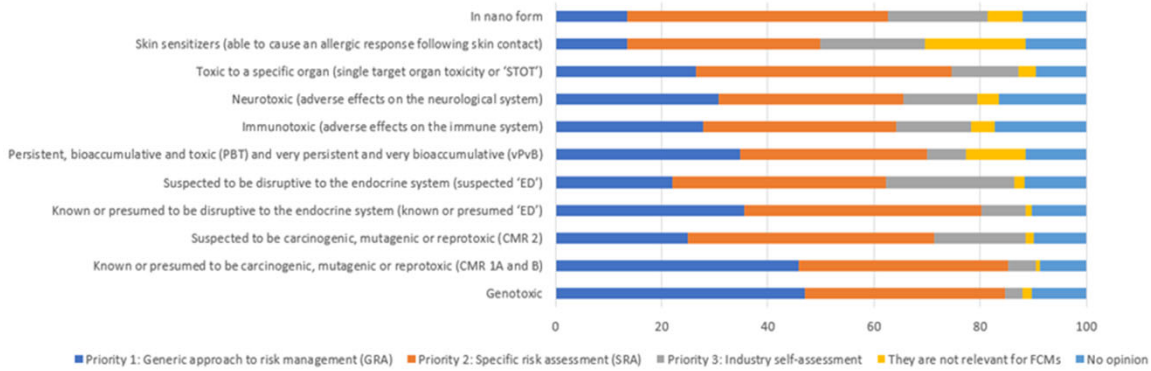


21

42

Safety – basis for risk management

On what basis should the following FCM substances be risk-managed:



- For substances as genotoxic, CMR 1A and B, CMR 2, ED, PBT, vPvB, STOT, immunotoxic and neurotoxic substances, public authorities and NGOs would prioritize a generic risk assessment, whilst business organisations and associations would opt for a specific risk assessment.
- A general consensus exists concerning skin sensitizers and nanoforms, which shall be specifically risked assessed.

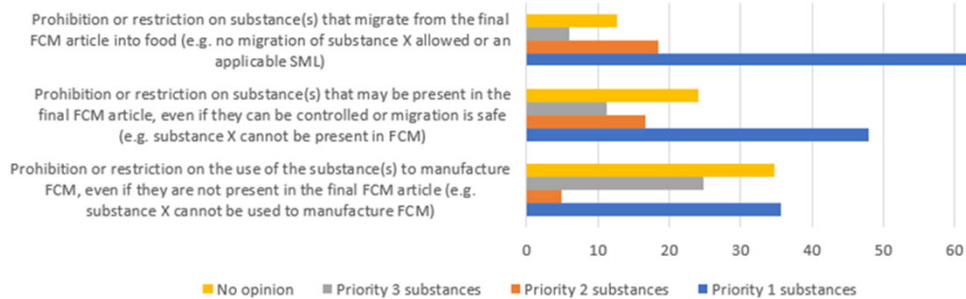
This presentation is intended to facilitate discussion and understanding of the matters presented. It does not necessarily represent a final position and does not commit the European Commission. The European Commission accepts no responsibility for the accuracy of any data or information contained in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



43

Regulatory intervention

For the different priority groups, indicate at what point you consider intervention most appropriate:



- Business organizations and associations expressed mainly no opinion about how to appropriately intervene in the supply chain.
- NGOs and public authorities would respectively support prohibition or restriction on the use of the substance(s) to manufacture FCM and on substance(s) that migrate from the final FCM article into food.

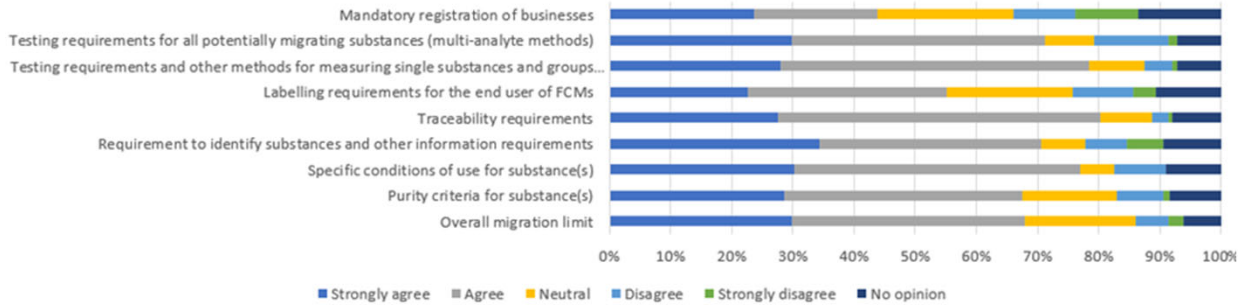
This presentation is intended to facilitate discussion and understanding of the matters presented. It does not necessarily represent a final position and does not commit the European Commission. The European Commission accepts no responsibility for the accuracy of any data or information contained in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



44

Risk assessment

To what extent do you agree that the following tools are appropriate for the risk management of FCM substances:

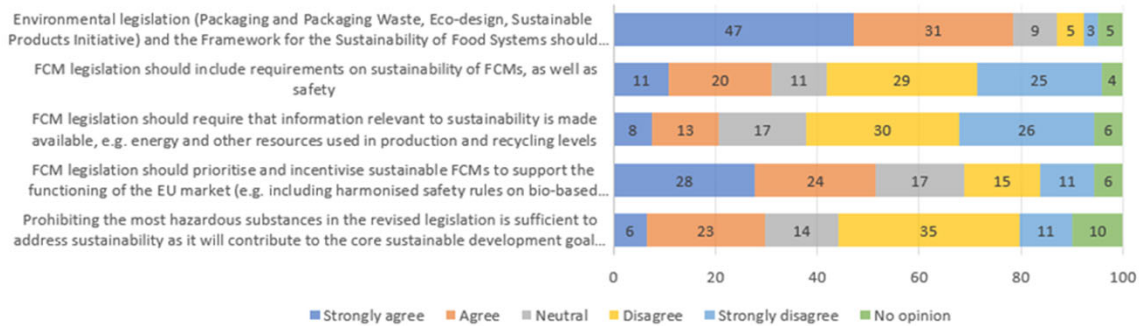


- Requirements to identify substances, together with traceability, labelling and testing requirements, also received a wide support among the different stakeholders.
- These options are particularly endorsed by NGOs and public authorities (more than 80% favourable responses).
- Mandatory registration of business is also identified as an appropriate tool, but it is less supported by business associations and organizations compared to NGOs and public authorities (17% and 22% agree vs 83% and 46% strongly agree).

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

Sustainability of FCMs

TO WHAT EXTENT DO YOU AGREE WITH THE FOLLOWING:



- According to business associations and organizations and public authorities, prohibiting the most hazardous substances in the revised legislation is not sufficient to address sustainability. This point is not shared by NGOs (74% strongly agree).
- Stakeholders agree that FCM legislation should prioritise and incentivise sustainable FCMs to support the functioning of the EU market (between 32% and 52%), even though numerous NGOs expressed a neutral positioning on this topic (47%).

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

Sustainability of FCMs

Business associations and organizations showed a prompt disagreement on the idea that FCM legislation should make available information relevant to sustainability (33% and 28% strongly disagree, 33% and 31% disagree), while this option is positively assessed by NGOs (59% strongly agree) and relatively by public authorities (31% agree).

Public authorities, and even more businesses organizations and associations, believe that environmental legislation should address the sustainable use of FCMs, and not the FCMs one. NGOs would rather underpin a FCM legislation which takes into consideration also sustainable concerns and needs.

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



47

Improve quality and accessibility of FCM production chain information

- The current declaration of compliance (DoC) and requirements for information passed in the supply chain are overall satisfactory for business associations and organization and public authorities, but not for NGOs. A DoC should be mandatory for all FCMs, with a fixed format.
- Some disagreements are visible on the introduction of an approval step of the final FCM article. Business organizations and associations do not think that this would improve compliance and safety along the supply chain nor bringing marketing and commercial benefits for businesses.
- The least preferred option for business associations and organizations would be the application of a QR code or equivalent to give information to users of FCMs. Positive feedback was received by business associations and public authorities about clarifying, via FCM legislation, to which actors (i.e. manufacturers of starting substances, convertors, final FCM article producers, etc.) specific rules or information requirements apply.
- Business organizations mostly consider that notified Bodies should be used for the verification of compliance and would help businesses to ensure safety. For NGOs member States competent authorities should be supported by the use of delegated bodies as provided by Regulation (EU) 2017/625 for official controls.

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



24

48

Presentations on consumer perception

- Presentation BEUC
- Presentation Kantar

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



49

Any Other Business



50

25

- PFAS Restriction Proposal (COM)
- FCM made from wood (DE)
- Packaging material from pectin (DK)
- Grocery Bags (LU)
- Compliance to R 10/2011 (FR)

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



51

Restriction proposal on PFAS

Annex XV dossier of Regulation 1907/2006 (REACH Regulation)
Relevance to food contact materials (FCMs)

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



26

52

Summary

- Identification of per- and polyfluoroalkyl substances (PFASs) in accordance with Article 59 of Regulation 1907/2006 (REACH Regulation) with properties of particular concern
- Main concern for all PFASs and/or their degradation products that are in the scope of the restriction proposal is the **very high persistence**
- Annex XV report addresses the risks to the environment and human health and provides an assessment of the effectiveness, practicability, monitorability and socio-economic impacts of two restriction options
- Prepared by Germany, the Netherlands, Sweden, Denmark and Norway

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



53

Scope

- Any substance that contains **at least one fully fluorinated methyl (CF₃-) or methylene (-CF₂-) carbon atom** (without any H/Cl/Br/I attached to it)
- Grouping based on two aspects
 - Chemical structure (i.e. in line with OECD 2021 PFAS definition)
 - Persistence
- Ensures equivalent hazards and risks are covered, avoid regrettable substitution, prevention of future exposures of PFAS which are not currently in use
- A substance that only contains the following structural elements is **excluded from the scope** of the restriction: **CF₃-X or X-CF₂-X'**^{NB}

^{NB} where X = -OR or -NRR' and X' = methyl (-CH₃), methylene (-CH₂-), an aromatic group, a carbonyl group (-C(O)-), -OR'', -SR'' or -NR''R'''; and where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH₃), methylene (-CH₂-), an aromatic group or a carbonyl group (-C(O)-).

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



27

54

Restrictions

PFASs shall not be manufactured, used or placed on the market as substances on their own, and in:

- Another substance, as a constituent (impurity)
- A mixture
- An article (**including FCMs**)

In a concentration of or above:

- ≥ 25 ppb for any PFASs
- ≥ 250 ppb for sum of PFASs
- ≥ 50 ppm * for PFASs

* If total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs.

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



55

Derogations

- 5-years or 12-years (based on set criteria relating to alternatives)
 - Time-limited derogations are foreseen when limited alternatives are available (26 in total)
 - Potentially non-stick coatings in industrial bakeware (to be considered after the consultation)
- Time-unlimited derogations (specifically justified)
 - Few types of substances benefit from unlimited derogations: PPPs, BPs, human and veterinary medicinal products

If no derogation, transition period will be 18 months

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



28

56

Published information

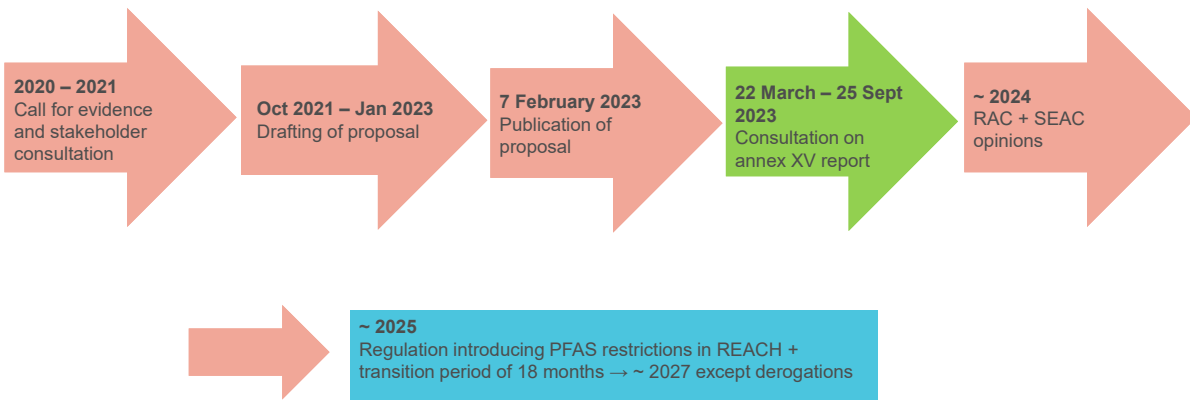
- [Annex XV Restriction Report](#)
 - Summary, problem identification, justification for restrictions, assessment of possible RM
 - Page 58 for baseline on use in FCMs
- Annexes to the report (relevant section on FCM and packaging in brackets)
 - [Annex A](#) (A.3.4 page 37): uses and applications inc. coated packaging, plastic films, cookware, processing and polymerisation aids, industrial food equipment
 - [Annex B](#) (B.9.4, page 241): Types of PFAS and potential exposure
 - [Annex E](#) (E.2.3, page 147): Assessment of potential impacts
- Consultation 22 March – 25 September 2023

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



57

Timeline



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



29

58

Further information

ECHA website

<https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term>

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



59

Existing proposal

Undecafluorohexanoic acid (PFHxA), its salts and related substances

- Shall not be manufactured or placed on the market as substances on their own from [date]. Shall not, from [date], be used in the production of, or placed on the market in:
 - (a) another substance, as a constituent;
 - (b) a mixture;
 - (c) **an article**, in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1000 ppb for the sum of PFHxA- related substances
- Includes FCM (see annex XV restriction report: 2.5.1.6, page 60)
- Call for evidence, consultation and RAC and SEAC opinions completed
- First discussion on legal proposal in June REACH Committee

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



30

60

FCMs made from wood (DE)

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



61

Organoleptic concerns of FCM made of wood

- Wood may leave colour or other effects on food
- To what extent would we tolerate that organoleptic effects occur?
- to note: separately we are discussing with EFSA on the safety of natural materials

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



62

31

FCMs made from pectin

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



63

FCM made from pectin

- Can pectine film for food contact be regarded as plastic and will it be compliant (provided GMP, adequate purification and that all other possible additives in the material are in compliance)?
- Can pectine film for food contact be regarded as food – provided it is correctly produced and labelled as food (hygiene, ingredients, allergens, expiration date, packaging material etc)?
- **Our view: It depends**
 - If not edible, it is a food contact material
 - Chemically modified → authorisation under R 10/2011 likely required
 - It is difficult to consider it under starch authorisation
 - if edible (and suitable for eating) → food → not a food

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



32

64

Grocery bags

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



65

Dealing with grocery bags

- Recurring question
- Pressure put on MS's authorities to be lenient on grocery bags
 - 'risk based approach'; 'pragmatic'; 'not FCM'
- Our reasoning: we should be pragmatic and not put unnecessary burden
- However
 - risk based approach assumes we understand the risk
 - pragmatic should still be fair – no arbitrary assumptions to R 1935/2004

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



66

33

Google

grocery bag

Q All Images Videos News Maps More Tools

plastic food paper reusable transparent

https://www.bing.com/images/search?q=grocery+bags&form=HDRSC4&first=1

grocery bags

Cambridge Dictionary Dictionary Translate Grammar

groceries

Meaning of groceries in English

groceries
phrase [plural]

the food that you buy in a grocer's shop or supermarket:

- *I was carrying three heavy bags of groceries.*
- *That's more than I spend on my weekly groceries.*

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

European Commission

67

Grocery bags – low risk?

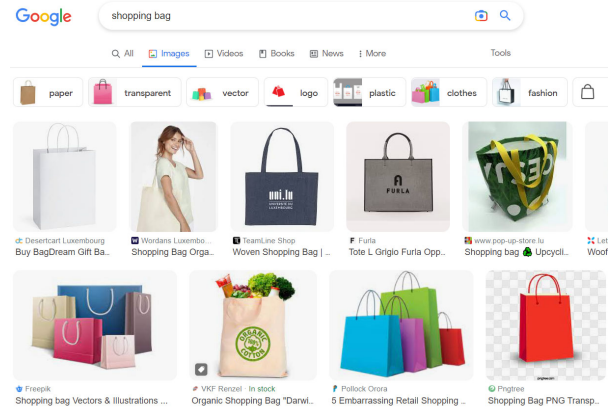
- A grocery bag is a food contact material
 - It may be used in direct contact with fresh food
 - Would there be a particularly low risk?
 - intended contact at ambient temperatures for several hours
 - foreseeable contact could be longer – consumer may store food in bag
 - conditions easily covered in Annex V to Regulation (EU) 10/2011 (not even the mildest)
 - Recycled content – if not an FCM it could come from anywhere
 - no control, significant risk
- grocery bags to be considered as FCM subject to existing rules

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

68

What about shopping bags?

- Grocery bag is a kind of shopping bag (or a specific use thereof)
 - Shopping bag is used for all kinds of items, including food
- Shopping bags are provided in supermarkets
 - that also sell unpackaged foods
 - foreseeable use as grocery bag



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



69

Possible pragmatic approach

- Shopping bags in general would not be considered to be FCM
- If bags are provided in shops that sell unpacked food:
 - they are FCM and should comply with the legislation, unless:
 - clearly labelled not to be used in contact with *unpacked* food
 - and organoleptically neutral (no strong smell)
- We could support the approach in legislation
 - both R 10/2011 and R 2022/1616 are being amended
 - if you see a need

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



70

35

Two questions on R 10/2011

- butanediol
- Annex V

France

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



71

Question on interpretation of R 10/2011

- Does the authorisation of butanediol also allow for R butanediol? Authorised as FCM 228 with CAS 107-88-0
 - it appears the CAS NR covers the racemic mixture, no specification, so 100% R butanediol would be covered
- Can business operators substitute simulants for economic reasons?
 - point 3.4.2: “if based on scientific evidence the substitute food simulants result in migration that is at least as severe as migration that would be obtained using the food simulants specified in Annex II”
 - section 3.2: “if it is not technically feasible to perform tests in simulant D2”
 - no clear answer – discussion with EURL

Butane-1,3-diol

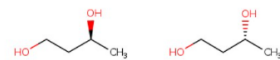
Regulatory process names 14 C

Substance identity

EC / List no.: 203-529-7

CAS no.: 107-88-0

Mol. formula:



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



36

72

Thank you

Happy to receive questions...

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

