



# FCM Working Group

26-27 April 2021

## Instructions

- Please put the country code in front of your name
  - example: *XX – your name*; where XX is AT, BE, BG, ....
  - if not, **please log out**, correct the name where WebEx asks you, **and log-in again**
- Always **turn off you camera** – unless presenting
- Always ensure your **microphone is muted** when your are not speaking
- Please **use the chat to raise questions**
  - no 'hand raising' as we might not see

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.



# agenda

## 11 February – Afternoon

- EU action on melamine-bamboo
- Changes to Regulation No 282/2008
- Regulation 10/2011
  - 16<sup>th</sup> amendment
  - Transitional provisions (15<sup>th</sup> + 16<sup>th</sup>)
- AoB points (d-g)
  - beeswax wrapping (DE)
  - virtual workshop on GMP
  - lignocellulose (EE)
  - active coffee filters (DE)

## 12 February - morning

- New e-submission system EFSA applications
- Update ceramics and FCM evaluation
- Migration of cyclo-di-BADGE
- AoB points (a-c)
  - EFSA information request
  - EURL update on guidelines
  - Coordinated control plan

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 FCM activities

- Implementation existing legislation
    - Recycling
      - update legislation (until summer 2021)
      - authorisations (Autumn 2021)
    - Plastics
      - 16th amendment (finish before summer)
      - substances (on-going – minor)
      - DoC (also relevant for recycling, if it can be achieved by the summer)
      - Styrene (Autumn)
      - EFSA Mandates – if achievable
  - Ceramics Impact Assessment
    - Resulting in new Regulation (IA end of year)
  - Review FCM legislation
    - Finalisation of the Evaluation (by summer)
    - Review + development of new policy options (from autumn)
- Focus on FCM revision
- Aka. Implementation activities largely to stop after summer (authorisations continue)

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 Recycling + 16<sup>th</sup> amendment

- Nearly stable texts following last WG
- Near finalised state triggered new comments (some significant)
  - texts no longer stable
  - not possible to finalise texts ahead of this meeting
  - no detailed discussion therefore
- Likely extra WG late May / early June
  - Recycling first

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.



## 15<sup>th</sup> + 16<sup>th</sup> amendment

to Regulation (EU) No 10/2011



## 16<sup>th</sup> Amendment main issues

- Transition procedure
  - general transition procedure (next slides)
  - specific transition procedure to allow for revocation needs change
- Phthalates – allocation factors
- Different objectives
- Other matters
  - recitals – different structure
  - several smaller issues / comments

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.



## 15<sup>th</sup> amendment

(b) 'placing on the market': the holding of materials and articles for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves.

- Transition period is raising questions:

*'Plastic materials and articles complying with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation, and which were first placed on the market before 23 March 2021 may continue to be placed on the market until 23 September 2022 and remain on the market until the exhaustion of stocks.'*

- Significant problems over 'first placed on the market'



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.



## 'first placed on the market'

- Interpretation 15<sup>th</sup> amendment:
  - the expression 'first placed on the market' in Article 2 of the Amendment refers to all materials and articles which were initially placed on the market before 23 March 2021, i.e. those that:
    - were already placed on the market at the time of the entry into force of the Amendment
    - have a different composition or characteristics as those materials and which were **initially** placed on the market before 23 March 2021.
  - therefore, all plastic materials and articles not compliant with the Plastics Regulation as amended, but lawfully placed on the market before 23 March 2021 may remain on the market;
  - materials and articles with the same composition and characteristics as such products, even if manufactured after that date, may continue to be placed on the market, until 23 September 2022; they may remain on the market until exhaustion of stocks thereafter
  - After 23 March 2021, all materials and articles with a composition or characteristics other than those of materials and articles already on the Union market at that date must comply with the Plastics Regulation as amended.
- Concurs with the drafting intention for the 15<sup>th</sup> amendment
- No need to change this provision (significantly) under the 16<sup>th</sup> amendment.
  - No definition of first placed on the market based on issuing of DoC (problematic in several ways)
  - Simple wording, but still taking care of the other issue related to the supply chain (intermediate and final products)

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



## clarification of the text

- clarify Article 3 and 3a (conditions for operating a recycling process)
- rethink the modification, suspension and revocation mechanisms
- split a number of long Articles
- re-work the transitional provisions
  - particular attention to applications we will not yet be authorising
- several other smaller issues

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.



## Recast

- Clarification + Splitting of Articles not possible as 'amendment'
    - replacement of (nearly) entire body of Regulation 282/2008 would result
- Recast, i.e. new Regulation that repeals Regulation 282/2008
- The content stays – subject to smaller changes and simplification – the same
  - Other advantages
    - significant simplification of the recitals
    - fine tuning of the scope
    - easier transitional provisions

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.



## Scope- three possibilities

- Reduce the scope to mechanical PET recycling only
- Same scope as R 282/2008
- Cover all plastic recycling, but no detailed rules

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.



## Latest version of text

- draft Regulation is being assembled
- consultation with you as soon as stable version is there
- likely a dedicated WG later in May

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.



# AoB points

Beeswax

Enforcement of GMP

Lignocellulose

Active Coffee filters



## Beeswax

- BfR FAQ published 6 April 2021
- [https://www.bfr.bund.de/en/beeswax\\_cloths\\_what\\_should\\_you\\_look\\_out\\_for\\_-271075.html](https://www.bfr.bund.de/en/beeswax_cloths_what_should_you_look_out_for_-271075.html) (EN)

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.





# Enforcement of GMP

- Online workshop organised by CVUA Stuttgart, EURL FCM and Kantons in Switzerland, September 2021
- Aimed at food safety enforcement authorities to:
  1. Learn about the most recent developments in the area of GMP enforcement
  2. Participate in the development of joint tools for checking compliance documentation
  3. Put gained knowledge into action by testing the new tools from your office.
- Expressions of interest to [REDACTED]. Include:
  - Who you are
  - what function you have
  - What training you have
  - What you'd expect from the suggested workshop
  - What experience you have in enforcement of FCM 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.



# Lignocellulose

REF	SYNONYM	FUNCTION	AMBIENT STATE	YES	NO	NO			
595	19510	0011132-73-3	lignocellulose	no	yes	no			

- Can lignocellulose obtained from sawdust consisting of mainly lignin and cellulose be considered authorised?
  - Regulation doesn't define lignocellulose
  - Old application, no detailed EFSA opinion / dossier available
  - Internet: lignocellulose is cellulose + hemicellulose and lignin (makes wood woody)
- Easy confusion with lignocellulosic biomass (wood chips, possibly ground Bamboo)
- However, only authorised as a starting substance, not as an additive!
  - Article 8 applies; it shall be suitable for this purpose
  - both cellulose and lignin can be crosslinked, so, can be starting substances
  - lignocellulosic biomass cannot be suitable for this purpose → too many other substances, NIAS, risk assessment impossible
- Given potential relevance for 'new' plastic materials we will follow up on definition
  - some of these products may not be called 'plastic', but for instance, 'paper'

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.



# Active Coffee Filters

- Germany: can coffee filters that provide taste to the food be legally used?
- Framework Regulation →
  - A FCM cannot **deteriorate** organoleptic properties of the food
  - Active materials only to extent shelf-life of packaged food
  - R 450/2009 uses similar wording
- Coffee filters are not packaging
- So, no one cannot use those filters...?
  - does 'deteriorate' mean to change the inherent properties of the food?
  - discussion

(a) 'active food contact materials and articles' (hereinafter referred to as active materials and articles) means materials and articles that are intended to extend the shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food;

1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

(c) bring about a deterioration in the organoleptic characteristics thereof.

## Article 4

### Special requirements for active and intelligent materials and articles

1. In the application of Article 3(1)(b) and 3(1)(c), active materials and articles may bring about changes in the composition or organoleptic characteristics of food on condition that the changes comply with the Community provisions applicable to food, such as the provisions of Directive 89/107/EEC on food additives and related implementing measures, or, if no Community provisions exist, with the national provisions applicable to food.

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.

