



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

FCM WG 24-25 February

*this presentation was used to facilitate discussion and for consultation, and is not necessarily representative of any final position of the Commission*

**COMMISSION REGULATION (EU) No 10/2011**

**of 14 January 2011**

**on plastic materials and articles intended to come into contact with food**

(Text with EEA relevance)

(OJ L 12, 15.1.2011, p. 1)

Amended by:

Official Journal

		No	page	date
<b>M1</b>	Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011	L 87	1	2.4.2011
<b>M2</b>	Commission Regulation (EU) No 1282/2011 of 28 November 2011	L 328	22	10.12.2011
<b>M3</b>	Commission Regulation (EU) No 1183/2012 of 30 November 2012	L 338	41	12.12.2012
<b>M4</b>	Commission Regulation (EU) No 202/2014 of 3 March 2014	L 62	13	4.3.2014
<b>M5</b>	Commission Regulation (EU) No 865/2014 of 8 August 2014	L 238	1	9.8.2014
<b>M6</b>	Commission Regulation (EU) 2015/174 of 5 February 2015	L 30	2	6.2.2015
<b>M7</b>	Commission Regulation (EU) 2016/1416 of 24 August 2016	L 230	22	25.8.2016
<b>M8</b>	Commission Regulation (EU) 2017/752 of 28 April 2017	L 113	18	29.4.2017
<b>M9</b>	Commission Regulation (EU) 2018/79 of 18 January 2018	L 14	31	19.1.2018
<b>M10</b>	Commission Regulation (EU) 2018/213 of 12 February 2018	L 41	6	14.2.2018
<b>M11</b>	Commission Regulation (EU) 2018/830 of 5 June 2018	L 140	35	6.6.2018
<b>M12</b>	Commission Regulation (EU) 2019/37 of 10 January 2019	L 9	88	11.1.2019
<b>M13</b>	Commission Regulation (EU) 2019/988 of 17 June 2019	L 160	10	18.6.2019
<b>M14</b>	Commission Regulation (EU) 2019/1338 of 8 August 2019	L 209	5	9.8.2019

Corrected by:

**C1** Corrigendum, OJ L 349, 19.12.2012, p. 77 (1183/2012)

*Apologies for the numbering confusion*

ate discussion and understanding of existing and  
sting legislation or a proposal of new legislation.



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# 15<sup>th</sup> and 16<sup>th</sup> Amendments

## 15<sup>th</sup> voted positively on Friday

- A short discussion on some of its elements
- Focus on implementation

## 16<sup>th</sup> for next time (probably June SC)

- Plan: draft text next WG
- Focus on main policy elements

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# 15<sup>th</sup> Amendment

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# Updates to Annex I

- nothing really remarkable
- detection limit for FCM 236 in note 28 → 0.002 mg/kg
- change to antimony trioxide;
  - migration limit now clearly applies to all sources of antimony trioxide, not only its use as additive
- potential swelling issue regarding the treated TiO<sub>2</sub>

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# Re-work of Annex II

- Reasons
  - lanthanides → Opinion has similar structure as basis for Article 6(3)(a)
  - a **table is clearer** as list is becoming longer
  - LODs need to be addressed
  - to place restrictions on **heavy metals** that are **likely impurities** + antimony
- Table 1 of Annex II should not be considered a positive list ('Union List')
  - Clarified in second paragraph of point 1 of Annex II
  - However, Article 6(3)(a) is de-facto a hidden Union List
- Chromium: LOD applies unless hexavalent chromium in the material can be excluded
- PAAs:
  - new LOD of 2 ppb applies only to the REACH list
  - Article 19 + Sum ≤ 10ppb to all others not in Annex I → primary basis for controls are documents
  - EURL has method: contains 16 of the 22 PAA mentioned in REACH, 20 other PAAs

# LOD concept

- Two reasons to assign a 'ND' limit with a defined LOD
  1. on basis of Article 11(4) → no TDI/MoE established, high toxicity (origin: SCF list 4B)

list 4:

**Section A (for monomers)**

Substances for which an ADI or TDI could not be established, but which could be used if the substance migrating into foods or in food simulants is not detectable by an agreed sensitive method.

**Section B (only for monomers)**

Substances for which an ADI or TDI could not be established, but which could be used if the levels of monomer residues in materials and articles intended to come into contact with foodstuffs are reduced as much as possible.

2. SML can be set, but is well below (verified) analytical capability, typically heavy metals
- LOD traditionally fixed at 10 ppb
    - better methods may be available, but not necessarily suitable for enforcement
    - still, improved health protection needed → **10 ppb needs to be lowered where possible**
    - LOD defined via PT organised by EURL → eventual **accreditation** needs to be possible

# Communication on LODs

- We will strengthen our communication to industry and stakeholders
- Over the next few years LODs will be lowered where possible
  - to come close to levels which would be required for adequate health protection
- Requirements in the DoC are being strengthened via 15<sup>th</sup> amendment

## Message:

- Testing is only a backstop; low migration to be achieved via compliance work
  - Explain Article 3 of Regulation 1935/2004 in this context
  - 10 ppb (in Article 11(4)) is not a migration limit!
  - documentary controls based on composition and calculations to be used
  - → lowering of LODs not considered as a burden



# Testing of appliances and equipment

- Basis is simple, migration limit applies in the food prepared with appliance
  - it should facilitate enforcement → not need to look at parts
  - should also be easier for business operators
- Practice may not be so simple (as we noticed in drafting)
  - relatively easy to establish compliance, non-compliance more difficult
  - please use the provision in practice and provide your feedback
- Not applicable to OML
  - hard to trace back to offending part
  - Could still be used (perhaps) for screening in some cases

# Repeated use

- SML
  - initially intended  $M3 < M2 < M1$ , so decreasing like in OML testing
    - provision was changed to 'not exceed' → too complex because of uncertainty and ND
    - difficult to defend three times at same level, below SML would be non-compliant
  - Migration not stable, i.e. goes up? **Not compliant even if below SML**
    - Should increase safety of materials such as plastics containing Bamboo
  - However, **testing burden increases** → three analysis needed
- OML essentially unchanged
  - 1st paragraph updated, 2nd paragraph clarified, 3rd paragraph strengthened

# Transition

## Article 2

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 [enter date 6 months after the date of entry into force of this Regulation] may continue to be placed on the market until [enter date 24 months after the date of entry into force of this Regulation] and remain on the market until the exhaustion of stocks.

- New Concept
  - **first 24 months:** products placed legally on the market before entry into force continue
  - **first 6 months:** also new products still allowed to be on the market
- Time-line
  - June 2020: estimated entry into force; old rules (before amendment) can still be used
  - December 2020: stop placing new products on the market developed under old rules
  - June 2022: stop placing products on the market compliant with old rules
- Why? Reformulations may be required → avoid enforcement issues
- Preference was more staged approach applicable to different provisions
  - became overly complex
- 16<sup>th</sup> amendment same approach, but also June 2022 end of transition

# 16<sup>th</sup> amendment

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# Discussion

## Discussion on

- phthalates + wood
  - EFSA presentations
- biocides – possible approach
- DoC – change to template
- reprocessing of plastic
- cheese in table 3 to Annex III
  - suggestion from industry
- Wording/ DE translation FCM 151

## No specific discussion on:

- Regular Substances
  - 2 so far identified, likely more
    - relevant for phthalates discussion
- other suggestions received:
  - formatting of CAS Nos
  - FCM 3 and 13 inconsistent
- **However:** please submit other observations quickly or remind us of you earlier communications

# Wood

EFSA Presentation

Decision on Risk management policy

Bamboo

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# Risk Management

- **Present authorisation based on inertness cannot be maintained**
- Future: species must be evaluated on case-by-case basis
- Compatibility with the polymer shall be ensured
- This also applies to other plant materials

## EFSA:

*“Wood **cannot be considered inert** per se owing to the many low molecular weight substances it contains, and when migrating into food, the safety of these constituents must be assessed. Presently available information is **insufficient to support that the authorisation of wood flour and fibres, untreated**’ (FCM No 96) is in accordance with Regulation (EC) No 1935/2004. Given the chemical differences in composition of **wood species**, the safety of migrants from these materials **must be evaluated on a case-by-case basis**, considering beyond species also origin, processing, treatment for compatibilisation with the host polymer and assessment of the low molecular weight constituents migrating into food. **This applies to other plant materials as well.**”*

<https://doi.org/10.2903/j.efsa.2019.5902>

# Transition

- Entry into force of 16<sup>th</sup> amendment (t=0)
- t+6 months: business operators to register intention to apply
  - not registered? No continued marketing of product
- t+9 months: deadline for application to EFSA
  - registered, but not applied? No continued marketing of product
- Applied? Can stay on market, until:
  - Application not valid? 3 months for second attempt
  - EFSA states it is unsafe, or submitted data does not support conclusion on safety
  - either fixed time expired (3-4 years), or strict deadlines under stop-the-clock
  - **authorisation in Annex I (and may continue on the basis of that authorisation)**



# Options for bamboo (and corn) flour

## A. consider Bamboo flour is not legally on the market if used in plastic

- Why?
  - EFSA opinion clarifies wood requires narrower interpretation (by species)
  - Bamboo is a grass, not a wood; **wood scope** cannot be expanded, but **should be narrowed** on basis of EFSA opinion
- Transition does not apply, **marketing of plastics containing Bamboo ends**
- **Condition:** consistent enforcement throughout Union is agreed

## B. acknowledge situation on left, but continue allowing these products

- Why?
  - ubiquitous marketing
- **Bamboo remains under Transitional rules**
  - wood, bamboo, corn, and similar plant based flours remain under rules on previous slide
- Enforcement to take place on basis of:
  - SML/OML (Melamine + Formaldehyde)
  - Transition approach (i.e. registration + dossier, on-going evaluation)

# Phthalates

EFSA Presentation

Discussion on Risk management

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# Mandate to EFSA for re-evaluation

- Currently under discussion
- Will include:
  - Short exercise to establish which phthalates to include (in addition to those specifically authorised, if any) and which materials to cover
  - Protocols for inclusion of new scientific criteria for toxicological and exposure data to ensure transparency and consistency
    - Establishment of a common submission/data format specifically for the reporting of the occurrence of phthalates from FCMs
  - Re-evaluation of the risks to public health related to the presence of phthalates in foodstuffs from FCMs
    - All relevant endpoints
    - Co-exposure
    - Contribution of FCM compared with other sources

# Risk management of phthalates in plastic FCM

Name	TDI (mg/kg bw)	Allocation factor	SML (mg/kg)	Group SML(T) (mg/kg)
Dibutyl Phthalate (DBP) FCM 157	0,01	50%	0,3	60 mg/kg (sum of a number of substances)
Butylbenzylphthalate (BBP) FCM 159	0,5	None	30	60 mg/kg (sum of a number of substances)
Bis(2-ethylhexyl)phthalate (DEHP) FCM 283	0,05	50%	1,5	60 mg/kg (sum of a number of substances)
Di-isononylphthalate (DINP) FCM 728	0,15	None		9 (sum with DIDP) 60 mg/kg (sum of a number of substances)
Di-isodecylphthalate (DIDP) FCM 729	0,15	None		9 (sum with DINP) 60 mg/kg (sum of a number of substances)

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# Risk management of phthalates in plastic FCM

Name	Authorised uses
Dibutyl Phthalate (DBP) FCM 157	Only to be used as: (a) Plasticiser in repeated use FCM contacting non fatty-foods (b) Technical support agent in polyolefins in concentrations up to 0,05% in the final product
Butylbenzylphthalate (BBP) FCM 159	Only to be used as: (a) Plasticiser in repeated use FCM (b) Plasticiser in single-use FCM contacting non-fatty foods except for infant formulae and follow-on formulae
Bis(2-ethylhexyl)phthalate (DEHP) FCM 283	Only to be used as: (a) Plasticiser in repeated use FCM contacting non fatty-foods (b) Technical support agent in concentrations up to 0,1% in the final product
Di-isononylphthalate (DINP) FCM 728	Only to be used as: (a) Plasticiser in repeated use materials and articles; (b) Plasticiser in single-use FCM contacting non-fatty foods except for infant formulae and follow-on formulae (c) Technical support agent in concentrations up to 0,1 % in the final product.
Di-isodecylphthalate (DIDP) FCM 729	Only to be used as: (a) plasticiser in repeated use FCM; (b) plasticiser in single-use FCM contacting non-fatty foods except for infant formulae and follow-on formulae (c) technical support agent in concentrations up to 0,1 % in the final product

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# Considerations

1. Grouping of phthalates
2. Allocation factors
3. Risk management for other FCMs

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# Grouping of phthalates

Name	tTDI (mg/kg bw)	Allocation factor	SML (mg/kg)	Group SML(T) (mg/kg)
DBP	0,01	50%	0,3	60 mg/kg (sum of a number of substances)
BBP	0,5	None	30	60 mg/kg (sum of a number of substances)
DEHP	0,05	50%	1,5	60 mg/kg (sum of a number of substances)
DINP	0,15	None		9 (sum with DIDP) 60 mg/kg (sum of a number of substances)
DIDP	0,15	None		9 (sum with DINP) 60 mg/kg (sum of a number of substances)

- EFSA has set tTDI for 4 phthalates (individual tTDIs are the same)

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# Grouping of phthalates

- DINP is currently grouped together with DIDP as current analytical methodology for the purposes of consistent enforcement means these two substances are too difficult to distinguish without further validation
- According to information collected as part of SANTE's survey, DINP is not used together with low weight molecular phthalates (DBP, BBP, DEHP)
- Endpoints related to reproductive and developmental toxicity, including for DINP need to be revisited in light of possible new data

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# Allocation factors

Name	tTDI (mg/kg bw)	Allocation factor	SML (mg/kg)	Group SML(T) (mg/kg)
DBP	0,01	50%	0,3	60 mg/kg (sum of a number of substances)
BBP	0,5	None	30	60 mg/kg (sum of a number of substances)
DEHP	0,05	50%	1,5	60 mg/kg (sum of a number of substances)
DINP	0,15	None		9 (sum with DIDP) 60 mg/kg (sum of a number of substances)
DIDP	0,15	None		9 (sum with DINP) 60 mg/kg (sum of a number of substances)

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# Allocation factors

- Not possible for EFSA to quantify contribution from [plastic] FCM
- However, evidence on use of phthalates in other FCMs, consumer products and exposure via dust and air
- Possible contribution of DIBP which exerts comparable effects to DBP and to which consumers are also exposed (see Appendix C of EFSA opinion)
- Current allocation factors are inconsistent and not in line with possible contributions from other sources (see section 3.7 of EFSA opinion, ECHA 2017)

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# Risk management from other FCM

- DBP, BBP, DEHP, DINP, DIDP used as plasticisers in rubber although progressively phasing out those that are of a low molecular weight (DBP, BBP, DEHP)
- Also used as catalyst for polymerisation
- May also constitute a significant contribution from FCM
- National rules or standards already in place but only in some MSs (e.g. FR, IT, NL, DE)

# Possible outcome

Name	tTDI (mg/kg bw)	SML (mg/kg) no allocation factor	Allocation factor	SML (mg/kg) with allocation factor	Group SML(T) (mg/kg)
DBP	0,01	0,6	20%	<b>0,12 (0,3)*</b>	<b>0,6 mg/kg (sum of DEHP, DBP and BBP expressed as DEHP equivalents [DEHP*1 + DBP*5 + BBP*0.1])</b>  60 mg/kg (sum of a number of substances)  <b>1,8 (9)* (sum of with DIDP and DINP)</b>  60 mg/kg (sum of a number of substances)
BBP	0,5	30	20%	<b>6 (30)*</b>	
DEHP	0,05	3	20%	<b>0,6 (1,5)*</b>	
DINP	0,15	9 (sum of DIDP and DINP)	20%		
DIDP	0,15		20%		

\* present SML; new SML subject to confirmation by EURL

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# Biocides

Risk management

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# Biocides

(under Regulation 10/2011!)

- Present:
  - Not explicitly addressed (additive)
  - 1 or 2 listed in table 1 of Annex I
  - provisional list

## *Article 6*

### **Derogations for substances not included in the Union list**

1. By way of derogation from Article 5, substances other than those included in the Union list may be used as polymer production aids in the manufacture of plastic layers in plastic materials and articles subject to national law.

5. By derogation from Article 5, additives not included in the Union list may continue to be used subject to national law after 1 January 2010 until a decision is taken to include or not to include them in the Union list provided they are included in the provisional list referred to in Article 7.

- Possible future approach:

- **Derogation under Article 6**

“biocides may be used provided appropriately authorised for FCM under the BPR”

- Commission will consult EFSA over SML if SML would be needed

- SML for silver can be established

- suitability in polymer responsibility of business operator under Article 19

- **Provisional list removed**

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# Provisional list

## Article 7

### Establishment and management of the provisional list

1. The provisional list of additives that are under evaluation by the European Food Safety Authority (hereinafter referred to as the Authority) that was made public by the Commission in 2008 shall be regularly updated.
2. An additive shall be included in the provisional list:
  - (a) when it is included in the list set out in Annex I; or
  - (b) when a decision of the Commission is not to include it in the Union list; or
  - (c) if during the examination of the data, the Authority calls for supplementary information and that information is not submitted within the time limits specified by the Authority.

PM ref. nr.	Name of the substance	CAS number	EFSA Opinion
86430	20%w/w Silver chloride coated onto 80% (w/w) titanium dioxide	-	16 <sup>th</sup> list of substances for food contact materials
86432	Silver-containing glass (silver-magnesium-calcium-phosphate-borate)	-	4 <sup>th</sup> list of substances for food contact materials
86432/20	Silver containing glass (silver-magnesium-aluminium-phosphate-silicate), silver content less than 2%	-	12 <sup>th</sup> list of substances for food contact materials
93930	2,4,4'-Trichloro-2'-hydroxydiphenyl ether	-	12 <sup>th</sup> list of substances for food contact materials
86437	Silver-zinc- aluminium – boron – silicate glass, mixed with 5-20% barium sulphate, silver content 0,35 – 0,6 %	-	7 <sup>th</sup> list of substances for food contact materials
86438	Silver zinc zeolite A (silver zinc sodium aluminosilicate calcium metaphosphate), silver content 1 - 1,6 %	-	7 <sup>th</sup> list of substances for food contact materials
86438/50	Silver zinc zeolite A (silver-zinc sodium magnesium aluminosilicate calcium phosphate), silver content 0,34-0,54 %	-	7 <sup>th</sup> list of substances for food contact materials

Provisional List of Additives  
1<sup>st</sup> publication date: 10/04/2008  
11<sup>th</sup> update 28/10/2011

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PM ref. nr.	Name of the substance	CAS number	Opinion
93930	2,4,4'-Trichloro-2'-hydroxydiphenyl ether	-	list of substances for food contact materials (1)

(1) Following the judgement in the court case T-262/10, the Commission Decision 2010/169/EU as regards the provisional list of substances for food contact materials and articles intended to come into contact with food under Directive 2002/72/EC is annulled. The substance 2,4,4'-trichloro-2'-hydroxydiphenyl ether (Triclosan, surface biocide) in the Union list of additives for food contact materials under Directive 2002/72/EC is inserted in the provisional list.

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# Discussion

## Advantages

- simple
- resolves provisional list
- biocides are dealt with under BPR as originally intended
- no double authorisation approach
  - when not on BPR list: no awkward remaining listing under R 10/2011
- Triclosan removed (no application under BPR)

## Disadvantages

- an SML still needs to be established; likely via Commission mandate
- suitability in plastic not fully assessed by EFSA
- only use as additive in plastics covered



# Other matters

Template based DoC - Towards the Digital economy

Reprocessing of plastics

Change to the listing of Cheese in table 3 of Annex III

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# Template based approach

- First discussed for Glymo →
- Also for plastics and recycled plastics
- Annex IV describes what, not how
- Template will
  - precisely describe what is required
  - provide clear format for Competent Authorities
  - no more 'disclaimers'
  - allow for digital approach

**ANNEX 2**  
**Template for Declaration of Compliance**

DECLARATION of COMPLIANCE with REGULATION (EU) 2020/XXX

I, the undersigned in section 4 declare in name of [ADD NAME OF MANUFACTURER] as identified in section 1.1, that the product identified in section 1.2 contains an epoxy silane and is subject to Regulation (EU) 2020/XXX; I hereby declare on the basis of my analysis to which I keep supporting documentation available to competent authorities of the Member States and can be requested via the contact point mentioned in section 1.1.4, and the information provided in section 2 that this substance is used in full compliance with all provisions of Regulation (EU) 2020/XXX, provided it is used subject in accordance with section 3 of this declaration, to which purpose I provided adequate instructions and labelling on the product.

I claim full responsibility for the contents of this declaration and for ensuring the compliance with Regulation (EU) 2020/XXX, this declaration shall apply in full until the date set in section 5, or until a relevant amendment of Regulation (EU) 2020/XXX invalidates it, or until I recall this declaration.

**Section 1 Identification**

1.1 manufacturer		1.2 product		1.3 competent authority	
1.1.1 name		1.2.1 main name		1.3.1 name	
1.1.2 address		1.2.2 trade-names		1.3.2 address	
1.1.3 country		1.2.3 epoxy silane		1.3.3 country region	
1.1.4 contact		1.2.4 other info		1.3.4 reg. number	

**Section 2: Compliance**

**2.1 basis for authorisation (tick one box)**

2.1.1	<input type="checkbox"/>	Table 1.a of Annex I	Applicable SML	
2.1.2	<input type="checkbox"/>	Table 1.b of Annex I	Use No + step	
2.1.3	<input type="checkbox"/>	Transitional provisions	EFSA Q number	

**2.2 migration testing results (fill only if 2.1.1 is marked, or if 2.1.3 is marked, and a SML is applied)**

2.2.1 test results	
2.2.2 test conditions	
2.2.3 laboratory	(add name + address)

**2.3 statement on correct use (apply only when 2.1.2 is marked)**

2.3.1	Manufacturing stage (letter in accordance with column 5 of table 1.b):	N/A at stage (2.3.2 - 2.3.5):
2.3.2	Applied controls on manufacturing method	<input type="checkbox"/>

# Reprocessing of plastics

- Idea originates from discussion under Recycling
  - This is an established practice, but trade is difficult, **and is not recycling**
- *Drafting Example, e.g. include in Article 4 of Regulation 10/2011:*  
*“Plastic off-cuts and other scraps originating from moulding or extrusion can be re-grinded and placed on the market as intermediate materials provided:*
  - *The plastic has not been printed and has not come into contact with food or other substances;*
  - *no detectable degeneration of the plastic has occurred;*
  - *and scientific evidence shows that the off-cut or scrapped plastic is still compliant to the Regulation when moulded or extruded for at least three consecutive extrusions under real and foreseeable manufacturing conditions.”*
- We may set out additional rules under GMP regulation (‘Annex C’)
  - appropriate collection in manufacturing facilities
- Consultation with industry on precise rules/terminology

## Regulation (EC) No 282/2008:

2. This Regulation shall not apply to the following recycled plastic materials and articles, provided that they have been manufactured according to good manufacturing practice, as laid down in Regulation (EC) No 2023/2006:

(a) recycled plastic materials and articles made with monomers and starting substances, derived from chemical depolymerization of plastic materials and articles;

(b) recycled plastic materials and articles made from unused plastic production offcuts and/or process scraps in compliance with Directive 2002/72/EC, that are recycled within the manufacturing site or are used at another site;

(c) recycled plastic materials and articles in which the recycled plastic is used behind a plastic functional barrier, as specified in Directive 2002/72/EC.

# Re-wording of line 07.04 in table 3 of Annex III

- Suggestion from Industry:

- The term “processed cheese” in item C has a specific meaning that does not match the examples given, but instead processed cheese is identical to “melting cheese” in item B. This is common knowledge and common usage, see for example [https://en.wikipedia.org/wiki/Types\\_of\\_cheese#Processed](https://en.wikipedia.org/wiki/Types_of_cheese#Processed)
- The term “soft cheese” in item C is being misinterpreted to mean any cheese which is not hard – I have an example of an enforcement authority classifying Brie as a soft cheese even though logic would say it is close enough to Camembert given as example in item B. I believe the term “soft cheese” as used next to cottage cheese is meant to mean fromage frais, quark, cream cheese etc.
- The terms and examples in items B and C need to be re-distributed to cover three distinct types of cheese: fresh uncured cheese, ripened cheese and processed cheese. The first two of those are not currently identifiable in the above table.

- This suggestion appears to make sense

(1) Reference number	(2) Description of food	(3) Food simulants					
		A	B	C	D1	D2	E
		07.04	Cheeses: A. Whole, with not edible rind B. Natural cheese without rind or with edible rind (gouda, camembert, and the like) and melting cheese C. Processed cheese (soft cheese, cottage cheese and similar) D. Preserved cheese: I. In an oily medium II. In an aqueous medium (feta, mozzarella, and similar)				

# Suggested approach

- A. Whole cheese with not edible rind – simulant E.
- B. Fresh uncured cheese e.g. cottage cheese, quark, ricotta, cream cheese, fromage frais etc. – simulants B(\*) and D1.
- C. Ripened soft, firm or hard cheese without rind or with edible rind (natural rind, washed rind, bloomy or mould) e.g. gouda, camembert, stilton, gruyère, parmesan etc. – simulant D2/3.
- D. Processed melting cheese e.g. wedges, spreads and slices – simulant D2/3.
- E. Brined or fresh cheese in a liquid medium e.g. feta, mozzarella etc. :
  - in an oily medium – simulant D2.
  - in an aqueous medium – simulant B(\*) and D1.

(1) Reference number	(2) Description of food	(3) Food simulants					
		A	B	C	D1	D2	E
07.04	Cheeses:						
	A. Whole, with not edible rind						X
	B. Natural cheese without rind or with edible rind (gouda, camembert, and the like) and melting cheese					X/3(**)	
	C. Processed cheese (soft cheese, cottage cheese and similar)		X(*)		X		
	D. Preserved cheese:						
	I. In an oily medium	X					X
II. In an aqueous medium (feta, mozzarella, and similar)		X(*)		X			

this presentation was used to facilitate discussion and for consultation, and is not necessarily representative of any final position of the Commission

# Wording/ DE translation FCM 151

151	13480	0000080-05-7	2,2-bis(4-hydroxyphenyl)propane	no	yes	no	0,05		<p>Not to be used for the manufacture of polycarbonate infant (6) feeding bottles (7).                  Not to be used for the manufacture of polycarbonate drinking cups or bottles which, due to their spill proof characteristics, are intended for infants (9) and young children (10).</p>
	13607								
151	13480	0000080-05-7	2,2-Bis(4-hydroxyphenyl)propan	nein	ja	nein	0,05		<p>Nicht zu verwenden bei der Herstellung von Säuglingsflaschen (6) aus Polycarbonat (7). Nicht zu verwenden bei der Herstellung von Trinkgefäßen und Flaschen, die aufgrund ihrer auslaufsicheren Ausführung für Säuglinge (9) und Kleinkinder (10) bestimmt sind.</p>
	13607								

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# Many Thanks!

The SANTE.E.2 FCM team

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This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion and understanding of existing and potential new legislation, but should not in anyway be seen as giving a final interpretation of existing legislation or a proposal of new legislation.

