



# FCM Working Group

29 June 2021

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# agenda

- State of play
  - FCM Revision
  - 16<sup>th</sup> amendment R 10/2011
- Ceramic materials and Articles
- Discussion way forward recycling
- Enforcement action Bamboo
  - General state of play and objectives
  - Misleading labelling
- AoB
- BTSF workshop on controls 4-6<sup>th</sup> October

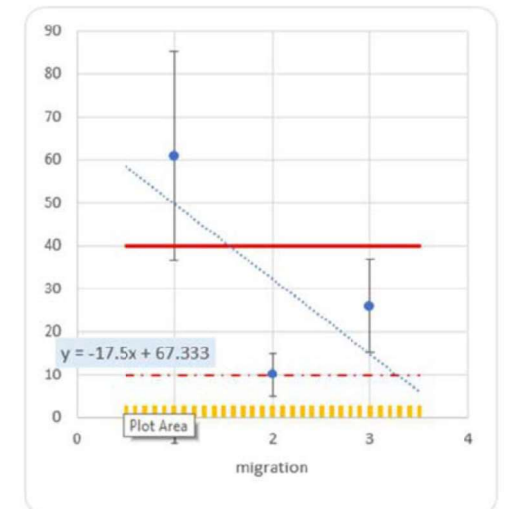
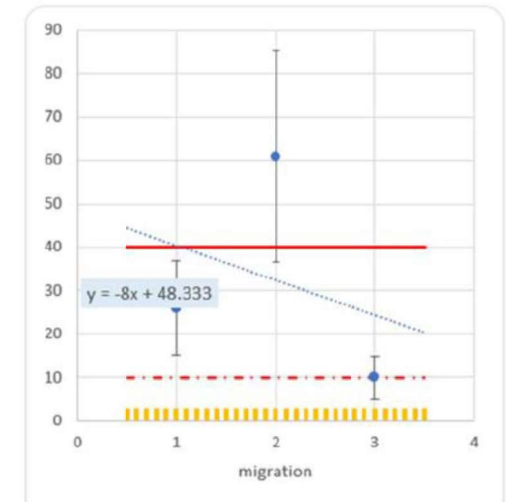
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# 15<sup>th</sup> + 16<sup>th</sup> amendment

to Regulation (EU) No 10/2011

# 15<sup>th</sup> Amendment – repeat testing

- Repeat SML testing
  - Before the 15<sup>th</sup> amendment 3 consecutive tests, last test used for SML
- After 15<sup>th</sup>, same 3 consecutive tests, result must not increase, last test for SML
  - Why? → To check for an indication of long term stability in *achievable* lab test
  - What if  $M2 > M1$ , but  $M3 < M2$  (or even  $M3 < M1$ ) → not stable → fail
  - Examples on the right are non-compliant, SML=40, LoQ=10
- Consultation on-going NRLs, organised by EURL
  - **Main focus:** measurement uncertainty, simplified, when is:  $M1 = M2$  or  $M2 = M3$ ?
  - minor discussion (for time being) what is a suitable method? } *discretion CA/OCL as per OCR*
  - What if LoQ industry lab  $\gg$  LoQ enforcement lab? } *'suitability of method' Art. 34(2)*
  - What if  $M3 > M1$  but  $M3 \ll SML$  when  $LoQ \ll SML$ ? → non-compliant
- (NRLs asked for comments and concrete proposals to EURL by 5 July)



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# State 16<sup>th</sup> amendment

- Nearly stable texts beginning of the year – or so we thought
  - in May we concluded no longer stable text
  - limited follow-up so-far
  - substances to move separately
- Dead-line just after summer
  - reduce in ambition (or cancel all together, but needed for recycling)

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# reminder 16<sup>th</sup> amendment

## provisional content subject to likely change

### Main text

- Microbial fermentation in some cases allowed without specific authorisation (also changes to Annex)
- Off-cuts and scraps (Article 10(1))
- Labelling of restrictions (Article 10(3))
  - related to column 10 of table 1 of Annex I

### Annex

- Wood flour, salicylic acid and lauric acid, vinyl ester to be deleted – time for new application
- German language BPA correction
- Update to Phthalates (may be made applicable to rubber as well)
- Update to PHBH (FCM 1059)
- new substances 1078, 1080 (also affecting 793, 822)
- new Cheese assignments in table 2 of Annex III
- DoC template
- OM0 in coverage OM8 and OM9 (clarification); OM6 also worst case for D1 (correction)

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# Ceramic and vitreous FCMs

Impact assessment and recast of Directive 84/500/EEC



**ANNEX I**  
**SPECIFIC MIGRATION LIMITS**

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

# Recast of Directive 84/500/EEC

- No change to discussions in 2017
  - Lower SMLs for Pb and Cd
  - Addition of SMLs for Al, As, Ba, Co, Cr and Ni
  - Ceramics and glass (incl. Vitreous coatings i.e. enamels & crystalware).
- No discussion on the SMLs or scope → Only scope for adjustment = « mitigating provisions »

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# Increased quality control in the supply chain

## **Objective = Reduce the need to test**

→ GMP Annex to R2023/2006 to select and control raw materials, control production and contamination

→ Requirements in legislation for suppliers to know the composition and origin of their materials and provide information to MS CA upon request (control) and to downstream manufacturers where metal content  $> 0,1\%$  (?)

# Increased quality control in the supply chain

→ Additional requirements for suppliers targetting artisans and hobbyists to provide:

- 1) Summary of EU legislation and obligations as FCM producer including text for leaflet to final consumer
- 2) Adequate manufacturing instructions if for food contact
- 3) Labelling material

# Traditional producers

- Where cannot meet new SMLs → Apply for derogation to continue market at factor 10x above SMLs.
  - Legislation will set conditions for applying to MS CA
    - Manufacturing process used before 1918 or decoration techniques used before 1850 or local/regional/national cultural value since 1968 and only produced (former: sold) within that geographic area
- AND
- Need to change those to comply with new SMLs
- AND
- Major steps of manufacturing and/or decoration processes is done manually, with each item handled in that step by physical person
- AND
- Limits on volume and turnover

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# Traditional producers

- MS CA assess applications made:
  - Either for process or product or all articles from an individual manufacturer or group of manufacturers using a specific process
  - Burden on applicant to substantiate their application meets the criteria and why they cannot meet the new SMLs
  - Time limit to apply – Traditional cannot be new
  - Imports also subject to same rules. Third countries will need to setup similar systems and apply for recognition to an EU MS.
- Labelling and information provided to end-user + DoC

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# Artisanal producers

- Where cannot meet new SMLs → Enable to continue market at factor 5x above SMLs.
- Legislation will set criteria defining what is considered artisanal
  - Micro-entreprise
  - No automation
  - No formal division of labour, 33% of staff must be able to manufacture from A to Z
- No application but low volume and size
- Labelling and information to end-users

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# Tailored transition plans

- Address structural problems and avoid disrupting supply chains and market
- Time limit to apply and on duration of the transition
- Clear milestones, conditions and monitoring towards compliance
- Burden on business to demonstrate

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# Control & Enforcement

- Through DoC and SD - also on importers
- Of mitigating provisions
  - Register of traditional products/producers to which derogation is granted
  - Register and monitoring of tailored transition plans
  - Controls including of BO supplying to artisans/hobbyists, market and import controls

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# Impact assessment

- No change in policy options
- Only leeway is on way to reduce impact on industry
- Not only study, also:
  - OPC – Autumn/Winter 2021
  - Webinar – Autumn 2021
  - SWD – End 2021 /Beginning 2022

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# Support study

- Duration 7 months from January to August 2021
- Objective = Support the impact assessment
- Tasks = Collect data on impacts, costs and ways to mitigate them
- → Focus on administrative burden and better regulation
- → Significant impact on industry → Gather views and data on mitigating provisions
- → Update evidence base

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# Recycling

# state-of-play recycling

- Quicker move forward was anticipated in May – no stable text yet
- Two main issues
  - Transition – equal & fair treatment of all recyclers
  - Detailed technical matters
- Result: we are replacing the Regulation
  - It will cover all recycling processes by the same set of rules
  - It will use updated terminology  
(but you'll still be able to recognise major parts of it)

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# Latest version of text

- Regulation is being drafted
  - consultation with you as soon as stable version is there
  - target to finish by the summer
- Objectives:
  - Ensure recycled plastic is safe for food contact
  - Regulate all recycling processes – require that plastic is decontaminated during recycling
  - Ensure clear terminology
  - Keep matters simple, including enforcement and evaluation
- Anything on next slides subject to potential change

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# Scope

- The Regulation is to apply to:
  - the placing on the market of recycled plastic and the use thereof
  - the development and operation of recycling processes to manufacture that plastic
- It is not apply to:
  - the manufacture of substances listed in table 1 of Annex I to Regulation from waste
  - scraps and off-cuts (where they are not waste under the waste legislation)
- Regulation (EU) No 10/2011 remains applicable to recycled plastics

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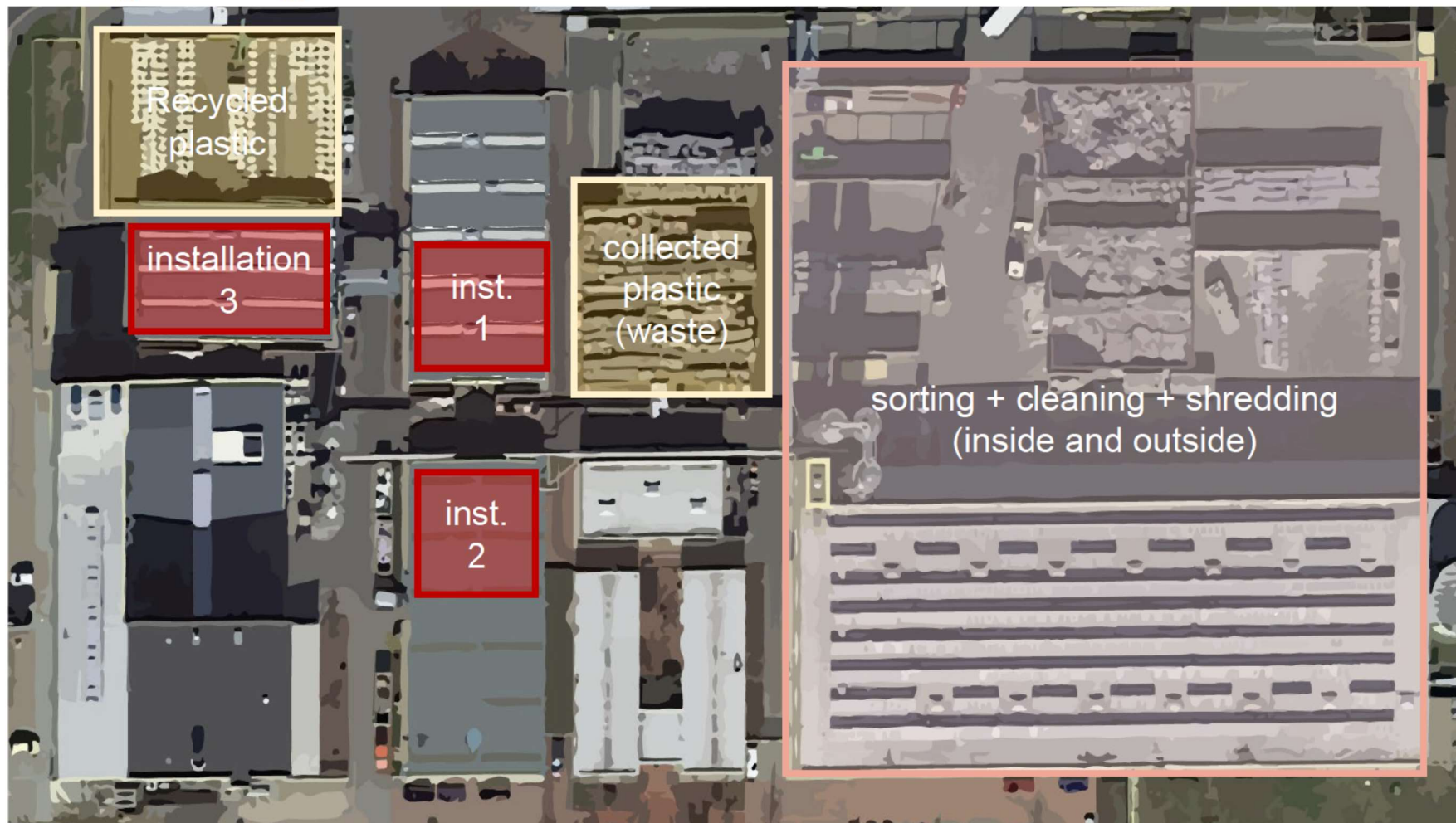
# Main Requirements

- Recycled plastic placed on the market for food contact
  - must be recycled with a recycling process that includes a decontamination step
  - the decontamination step is to ensure Article 3 of R 1935/2004 is met
  - the recycling process is to be authorised
  - the process must also be operated subject to generic rules
- Derogations
  - no decontamination requirement for closed loop processes
  - recycled plastic may be placed on the market for process development purposes

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# Recycling Site

illustration based on actual site, modified



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# New Terminology

- Recycling process has three parts
  - pre-processing, decontamination, post-processing
- There are to be three layers (which in loose terminology got called ‘processes’)
  - Recycling Technology – e.g. ‘mechanical PET recycling’
  - Recycling Processes – applying a technology (EFSA assessed >170 mechanical PET processes)
  - Recycling Installations – equipment installed a facility based on a process (previous slide)
- Equivalent terminology only applied to decontamination
  - decontamination technology, process, installation

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# Draft definitions

- ‘*recycling process*’: the sequence of operations which include pre-processing, a decontamination step and post-processing, and which aim to manufacture recycled plastic for use in recycled plastic materials and articles
- ‘pre-processing’: all operations carried out to sort, shred, wash, mix, or otherwise process plastic waste in order to produce plastic input
- ‘*decontamination step*’: all operations of which the primary purpose is to remove contamination from plastic input
- ‘*recycled plastic*’: originates from the decontamination step of a recycling process and from subsequent intermediate stages of manufacturing in post-processing
- ‘*post-processing*’: all intermediate stages by which the output of a decontamination step is further processed into recycled plastic materials and articles
- ‘*recycled plastic materials and articles*’: materials and articles in their finished state that contain recycled plastic;
- ‘*recycling installation*’: the equipment operating a recycling process and which includes a decontamination installation;
- ‘*recycler*’: any natural or legal person who applies a recycling process, or one or more stages thereof, except if only post-processing;

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# Focus on decontamination

- Main point of evaluation and enforcement is to be the decontamination step
  - It has a defined input: e.g. washed and shredded post-consumer waste max 5% non-food
  - the recycled plastic must be used in accordance with specifications
- The decontamination step must be shown to clean adequately
  - defined configuration of the process; operating conditions
- The decontamination installation must be installed and operated accordingly
  - at a single location;
  - pre-processed waste can originate from everywhere; recycled plastic converted everywhere
- Fully compatible with EFSA's work

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# Development of Technology

- EFSA would only evaluate processes that apply a technology listed in Annex I (new)
- However, operators may place plastic on the market for the purpose of technology development
- subject to strict requirements;
  - they must be able to state it is safe; frequent monitoring; same general rules
  - time limited
- EFSA will be asked to develop evaluation criteria
  - technology added to Annex I
  - processes can be evaluated as part of authorisation procedure
- De-facto this follows the same approach as for mechanical PET recycling
  - in a much shorter timespan, and with monitoring

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# Other parts of the text

- Application procedure for authorisations of processes roughly similar;
  - it is to restrict who can apply (and who will become authorisation holder)
  - additional information to be required to facilitate risk management and enforcement
- Other mechanism still in place
  - registers,
  - compliance Monitoring Summary Sheet
  - official control (specification of control techniques, but simplified procedures)
  - compliance documentation
- Closed-loop use ('closed-loop recycling scheme'); to be subject to two sets of rules
  - for participation in a scheme,
  - for recycling material originating from such a scheme
- Transitional provisions
  - Processes applied for before a date after entry into force may stay on the market until termination of the application procedure
  - Processes applying other technologies must register as 'under-development' to continue

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# AoB points