



EU policy on FCM

Ensuring safe recycled plastic FCM

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European Commission; DG SANTE E.2

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Ensuring safe recycled plastic FCM

- Recycled content in plastic food contact materials is becoming increasingly important
- Topics
 - Short intro on FCM
 - What are Safe Food Contact Materials?
 - How do we ensure the safety
 - of plastic FCMs?
 - of recycled plastic FCMs?
 - Some considerations on policy and legislation
 - Regulation (EU) 2022/1616
 - 17th amendment to Regulation (EU) No 10/2011 (upcoming)
 - Not a complete overview – target of discussion is recycled plastic
 - simplify some issues

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EU legislation on FCMs



- **'Framework' Regulation (EC) No 1935/2004**
 1. Ensure a high level of protection of human health and the interests of consumers
 2. Ensure the effective functioning of the internal market
- Applicable to all FCMs: already in contact with food (e.g. packaging), intended to be in contact (kitchenware, food processing equipment) or likely to transfer constituents
- General rules and procedures for FCMs including safety and role of EFSA, definitions, labelling, traceability, inspection and control
- Basis for specific measures e.g.
 - Regulation (EU) No 10/2011 on plastic FCM authorising substances with restrictions e.g. SMLs
 - Regulation (EU) 2022/1616 on recycling of plastic

What are safe FCM?

- Regulation (EC) No 1935/2004 (Article 3):

FCMs are to be manufactured such that they do not transfer their constituents to food in quantities which could endanger human health

- FCMs must be (chemically) safe... they may not endanger health
- but... FCMs not necessarily to be free of (hazardous) substances!

Ensuring the safety of plastic FCMs - impurities

- Plastic FCMs to comply with Regulation (EU) No 10/2011
 - Lays down rules on composition
- Only authorised substances may be used to manufacture plastics
 - EFSA assesses all starting substances (monomers) and additives
 - they are authorised subject to restrictions (e.g. permitted use, limits,...)
 - by derogation some substances are permitted without authorisation (including impurities)
- What about those ‘permitted’ impurities?
 - ‘non intentionally added substances (NIAS)
 - originating from the manufacturing process
 - individual impurities must be risk assessed (Article 19) → they **must be identifiable**

Article 19

Assessment of substances not included in the Union list

Compliance with Article 3 of Regulation (EC) No 1935/2004 of substances referred to in Articles 6(1), 6(2), 6(4), 6(5) and 14(2) of this Regulation which are not covered by an inclusion in Annex I to this Regulation shall be assessed in accordance with internationally recognised scientific principles on risk assessment.

Ensuring the safety of recycled plastic FCMs - contaminants

- With respect to the used plastic that is being recycled:
 - it must comply with Regulation (EU) 10/2011
- However used plastic is contaminated, with substances originating from:
 - its use (e.g. constituents of food), and potential misuse (e.g. paint residue)
 - from contamination in waste collection systems
 - from non-food plastics
 - ...
- Those contaminants are not necessarily identifiable, their presence is random
→ Safety requires a fundamentally different approach than we take to known impurities

Ensuring the safety of recycled plastic FCMs - approach

1. Understand which kind of substances may be present in the collected waste
 - can we exclude certain substances? E.g. genotoxic substances?
 - characterisation of the plastic input (types of substances, amounts) is required
 2. Understand at what levels the worst substances expected in the input may be present in the final plastic without endangering human health
 3. Calculate the required cleaning efficiency of the recycling technology
- new Regulation (EU) 2022/1616 implements this approach
 - to decontaminate a well defined plastic input to ensure the output is safe when used as intended
 - independent scientific verification by EFSA

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New recycling Regulation (EU) 2022/1616

- The new Regulation requires that:
 - **All** recycled plastic **content**...
 - in materials and articles that **foreseeably** come in contact with food...
 - is manufactured with a **suitable recycling technology!**
- One exception:
 - manufacture of **pure** substances listed in Annex I to Regulation (EU) No 10/2011
 - 17th amendment to address what it means for those substances to be pure

decontamination

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



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Technologies, Processes and Installations

- Recycling **Technology**
 - generic concepts, principles and practices to recycle a defined input into a defined output
- Recycling **Process**
 - well described specific sequential operations based on a recycling technology
- Recycling **Installation**
 - **hardware** that actually recycles the plastic using a process
- Three associated procedures to establish safety
 - ‘establish’ suitable recycling technologies (EFSA + COM)
 - ‘authorise’ recycling processes (EFSA + COM)
 - ‘control’ recycling installations (audits) MS Competent Authorities

Establishment of suitable technologies – novel technologies

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

'Chemical Recycling'

- Chemical recycling is subject to Regulation (EU) 2022/1616
 - plastics may be recycled with suitable recycling technologies, they may be chemical
 - however, Regulation (EC) 2022/1616 allows the production of plastic from substances manufactured from waste that are authorised under Regulation (EU) No 10/2011 – (e.g. monomers) – to be used in accordance with that Regulation
 - 'Chemical Recycling' is not an official term
- Regulation (EU) No 10/2011 sets out substances should be of a high degree of purity and should be suitable (but not much more)
 - 17th amendment is to clarify the purity requirement – including regarding unidentified substances – this would result in a practical limit for the presence of unidentified NIAS
 - 17th amendment also to set rules for the processing of off-cuts and scraps

Thank you

Happy to receive questions/discuss...

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