



European Commission update on Food Contact Materials (FCMs)

**FIP scientific network for the cooperation and harmonisation
of risk assessment of FCM, the 'EFSA FCM Network' meeting
6 – 7 November 2019**

Jonathan Briggs

Policy officer

European Commission

DG SANTE, Unit E2 – Food Processing Technologies and Novel Foods

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.

Evaluation of EU FCM legislation

Examining the **effectiveness, efficiency, coherence, relevance** and **EU added value** of the legislation in achieving its principle objectives (securing a high level of protection of human health and consumer interests and; ensuring the functioning of the internal [EU] market)

Basic FCM legislation is 43 years old (originally Directive 76/893/EEC, now Regulation 1935/2004) and has **never been systematically evaluated**

2018 – 2019 targeted stakeholder consultation to support and external study – interviews, surveys, case studies, focus groups, workshops and 12-week open public consultation

Supporting existing study + information



Staff Working Document
Q1 2020



Next steps....?

Evaluation of EU FCM legislation

Stakeholder feedback on current EU risk assessment and management

- Role of EFSA is widely and positively recognised among stakeholders, contributing to the credibility of the positive list approach
- Together with the risk management at the EU level, this is considered to contribute strongly to **EU added value**
- The approach is **effective** for protecting human health from possible risk of main starting substances but has several limitations:
 - Focus has been on starting substances and not substances migrating from final FCM.
 - Uncertainty as regards risk assessment of NIAS: How should this be done? Who is responsible? Where is the information in the supply chain?
 - Exemptions for certain substances (e.g. colourants)
 - High number of regulated substances contributes to poor rate of controls by MSs
 - In addition, most substances for which a migration limit is set have no accredited methods of analysis

Evaluation of EU FCM legislation

- Questions over **efficiency**:
 - The current approach is tailored only to specific material types (plastics)
 - It is generally quite slow and can be costly. In reality, the approach cannot realistically be continued for all materials individually due to resources
- Questions over **relevance**:
 - Lack of a systematic review: Is the science up to date? Reliance on notifications of new information under Article 11(5)
 - Do we need to review all of the substances – are all of the substances on the list still in use?
- Question over **coherence**:
 - Process is often criticised and considered to be incoherent compared with other EU legislation (e.g. REACH) but also differences exist between EU and national level

Ongoing work: Regulation (EU) 10/2011 on plastic FCM

Ongoing (14th) amendment

- Addition of 3 authorized substances with restrictions
- New restrictions for certain metals such as arsenic (As), cadmium (Cd), chromium (Cr), lead (Pb), and mercury (Hg)
- New detection level of 0.002 mg / kg in food or in food simulants for primary aromatic amines (PAA)
- Changes to compliance testing for entire appliances/food processing equipment
- Changes to test requirements for repeated use
- Changes to some test conditions for overall migration
- Adequate information to strengthen the Declaration of Compliance to facilitate, for example, the requirements of new metals and PAAs

Entry into force first half 2020

Ongoing work: Regulation (EC) No. 282/2008 on recycled plastic FCM

1. Amendment of the Regulation

- Transition after the adoption of the authorisation Decisions (PET processes for which an application has not been received; PET processes for which an application has been received but which have been modified; other non-PET plastics)
- Clarification of the role of the authorization holder and recyclers
- Obligations of the authorization holder and recyclers
- Compliance monitoring summary sheet
- Definition of non-compliance
- Procedures for implementation

2. Implementation

- Initial authorisation Decisions voted on (~130), foreseen 2020
- First control activities
- Continuous monitoring and application



Ongoing work: Regulation (EC) No. 282/2008 on recycled plastic FCM

At a later stage .. all other types of plastic and recycling processes

- Focus on **all recycled plastics**, including those in a closed loop and polyolefins including HDPE
- Increasingly important to the circular economy and recycling targets of the EU (June 2019). FCM plastics are a very significant part of the total plastic use
- Different approach required for these plastics– (1) EFSA sets the criteria (2) EFSA evaluates the process and publishes the opinion
- Include **all forms of chemical recycling**

Just Sorting

...

Mechanical Recycling

...

Super Critical Extraction

...

Dissolution

...

Hydrolysis

...

Feed Stock Recycling

Chemical recycling

CEFIC: 'next big thing'

- but presently out of scope
- subject to Regulation (EU) no 10/2011 – new plastics

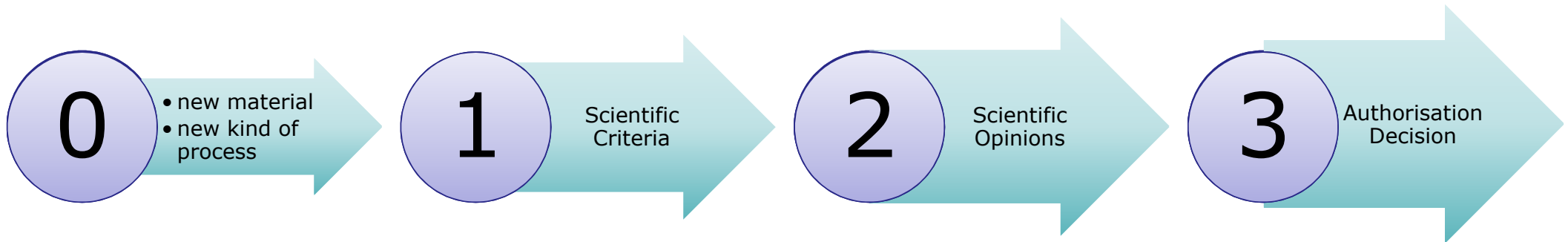
Missing:

- definition
- criteria for ensuring safety

Approach being considered

- all chemical recycling processes in scope
- authorisation
- except for feed stock recycling

Potential two step scientific approach for Non-PET



Consortium(?) would apply to establish scientific evaluation criteria for a new type of recycling process

1. EFSA establishes scientific evaluation criteria (as done for PET in 2011)

Individual applicants apply for authorisation based on established criteria

2. EFSA publishes opinion on the safety of the process

EFSA may decide no individual Authorisations may be necessary

- for a kind of process
- step 2 and 3 omitted

Procedure defined in legislation to ensure legal certainty

Ongoing work: Update on heavy metals from ceramic and vitreous FCMs



Background

- Significant reductions needed to 1984 limits for lead and cadmium, as indicated by previous EFSA opinions
- JRC work undertaken 2013 – 2017 to ensure analytical capabilities

Discussions have recommenced

- Inception Impact Assessment published June 2019, setting out problem definition and potential ways forwards
- Consider inclusion of other metals (e.g. cobalt, chrome, nickel, aluminum)
- Consider inclusion of vitreous materials (glass, enamelled metals)

Impact Assessment now being drafted

- Key focus on possible mitigation measures for certain businesses, such as labelling and communication to consumers allowing higher limits, transitional periods and specific testing rules to prevent unnecessary compliance work

Other specific issues at EU level:

- **FCM No. 1068 'Glymo'** [3-(2,3-epoxypropoxy)propyl]trimethoxy silane: Potentially genotoxic and is used in several FCMs – Commission plans to regulate epoxysilanes
- **Plastic-bamboo FCMs:** Question over use of bamboo as an additive (filler) in melamine. Also labelling issues. Member States are currently controlling. See discussion note via website
- **Mineral Oil Hydrocarbons (MOHs):** Member States collecting data. new information and possible update to 2012 opinion. Afterwards Commission may consider possible regulatory measures if appropriate and feasible
- **Commission Recommendation 2019/794 on coordinated controls:** MSs testing to determine prevalence of certain substances migrating from FCM. Results 2020 – then follow up discussion also taking into account results from Regulation 284/2011
- **Ongoing EFSA mandates:** Includes prioritisation of substances authorised in plastic FCMs without an SML, wood flour and fibres, styrene, bisphenol A and bisphenol S
 - Possibly for the future: Prioritisation of other substances which have an SML but for which new scientific information is available which may affect the authorisation;: Business Operator responsibility to notify under Article 11(5)

Contact and further information

European Commission webpages on FCMs
http://ec.europa.eu/food/food/chemicalsafETY/foodcontact/index_en.htm

Contact us: SANTE-FCM@ec.europa.eu

