Food Contact Materials: non-harmonised materials, information in the supply chain, and regulation of printed FCM

Advisory Group

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Food Contact Materials

What is a food contact material?

➢ Intended to be brought into contact with food

➢ Already in contact with food and intended for that purpose

➢ Can reasonably be expected to be brought into contact with food or to transfer constituents to food under normal or foreseeable conditions of use
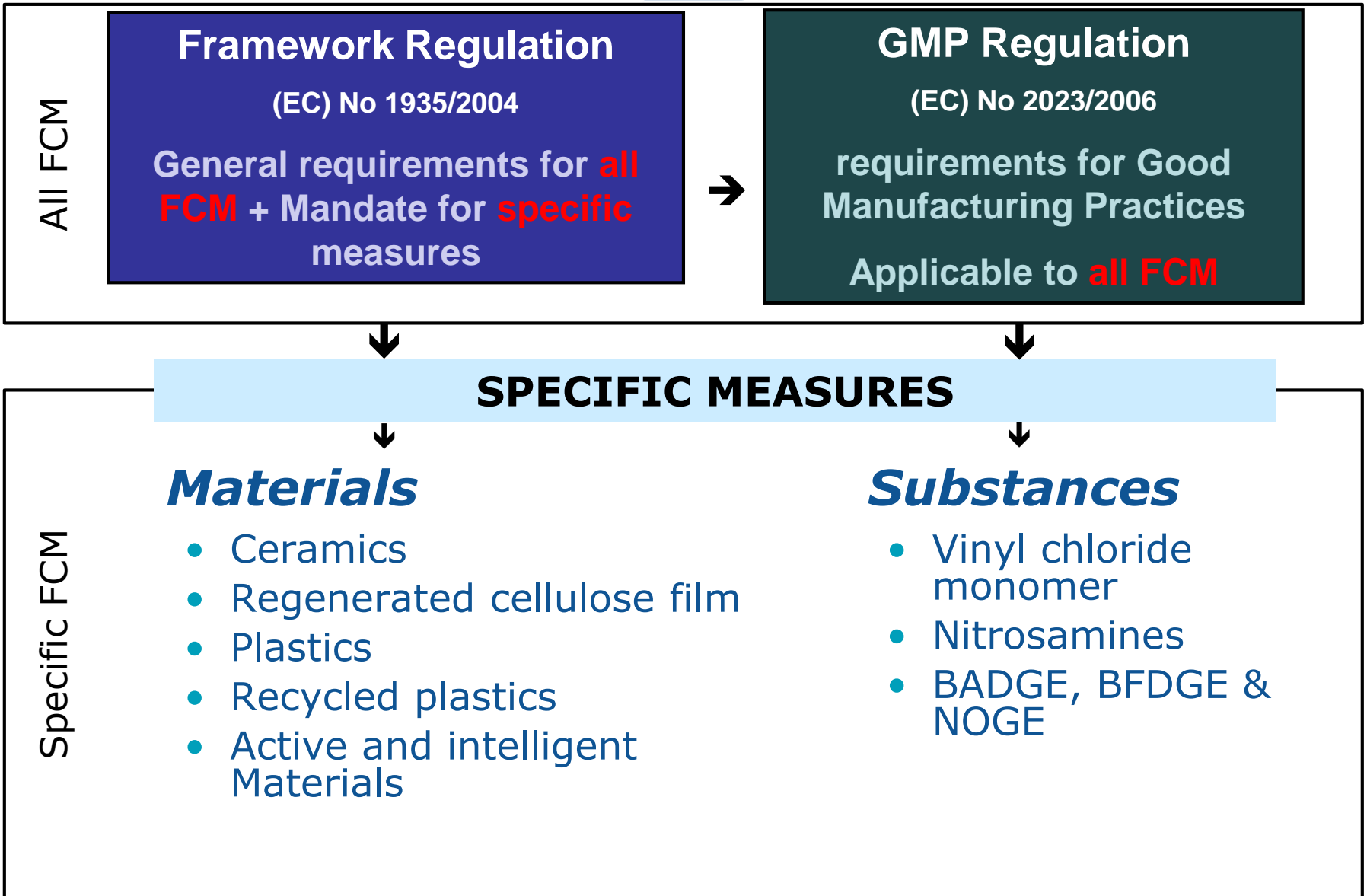
Current EU legislative framework

- Regulation 1935/2004 ⟹ harmonised legal framework
  - ➤ Must not endanger human health
  - ➤ Must not bring about unacceptable change in composition of food or organoleptic characteristics
  - ➤ Definitions, traceability and labelling requirements

- Regulation 1935/2004 ⟹
  - ➤ Empowers Commission to adopt specific measures on 17 materials
  - ➤ Member States may maintain or adopt national provisions if no EU specific measures

legislative overview

All FCM	**Framework Regulation** **(EC) No 1935/2004** **General requirements for all FCM + Mandate for specific measures** →	**GMP Regulation** **(EC) No 2023/2006** **requirements for Good Manufacturing Practices** **Applicable to all FCM**

SPECIFIC MEASURES

Specific FCM

Materials

- Ceramics
- Regenerated cellulose film
- Plastics
- Recycled plastics
- Active and intelligent Materials

Substances

- Vinyl chloride monomer
- Nitrosamines
- BADGE, BFDGE & NOGE

Plastics

- **Regulation (EU) No 10/2011 on plastics**

  and Regulation (EC) No 282/2008 on recycled plastics

- **Exclusive measures for plastics including plastics in multi-material multi-layers**

  authorised list of substances with restrictions e.g. specific migration limit (SML)

  rules on testing

  requirements on Declaration of Compliance (DoC) and Supporting Documentation

- **Regular amendments to add substances**

- **EU Guidance available on Regulation and also information in the supply chain and migration modelling**

  technical guidelines for compliance testing from EU-RL (JRC) to be published shortly

- **Regulation is technically complex and time consuming**

  an observation with consequences for harmonisation

non-harmonised

- **13/17 not subject to harmonised EU legislation**

- **Absence of EU measures**

  National provisions can be in place or developed
  mutual recognition is applicable

- **lack of harmonisation has consequences**

  reduced level of health protection
  barriers on the internal market

- **Requests from stakeholders for further harmonised measures**

  Member State Authorities
  European Professional Organisations
  European Parliament
  consumer groups and NGOs

JRC study

*Study to prepare possible further harmonisation*

- **Started in late 2014.**

Objective:

- **To support mapping situation in the EU on FCM policies for non-harmonised materials**

- **Mapping supply chains including actors involved, SMEs**

- **Collecting and organising data on measures in place**

  National risk assessments
  Industry guidance
  National specific measures on FCMs

- **Examine available indicators of**

  Effectiveness (towards general safety criteria)
  Efficiency (burden and perception of barriers to trade)

Market landscape

➢ Plastics and paper & board biggest markets

(million Euro)
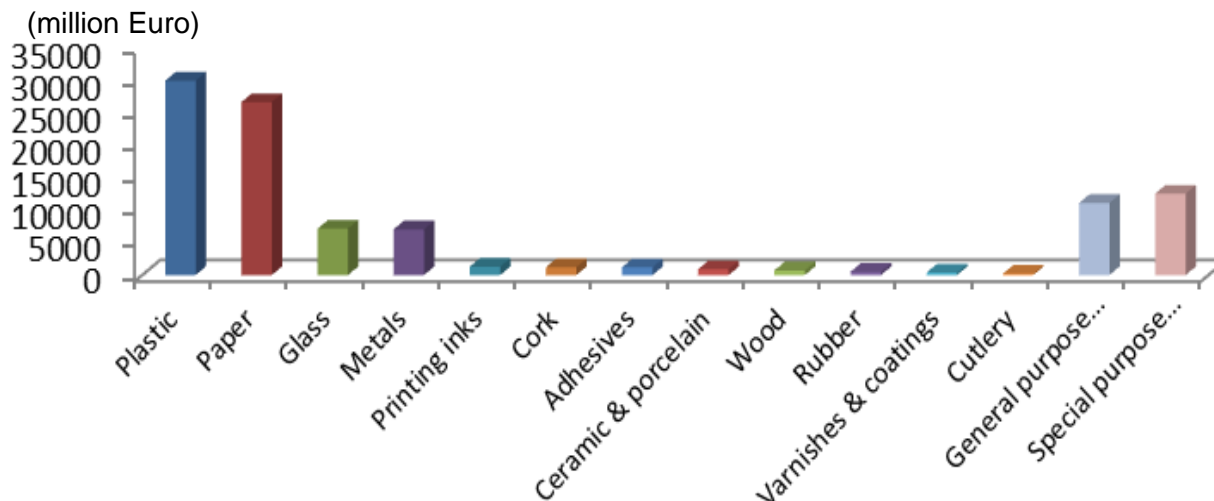
➢ Most materials except glass, inks and varnishes & coatings show significant presence of SMEs

➢ In general – Germany, France, Italy, UK, Spain and Poland leading suppliers

➢ FCM supply chains are generally complex and lengthy

Risk Assessment (RA) frameworks

- Not all **MSs** have a RA body or expertise in assessments
- Not all have RA specific to FCMs
- National RA schemes not publicly available
- Most common approach: EFSA principles (40%) but other approaches mentioned
- **Industry** schemes reported to be based on EFSA but lacking details
- Other tools available e.g. FACET but significant expertise needed
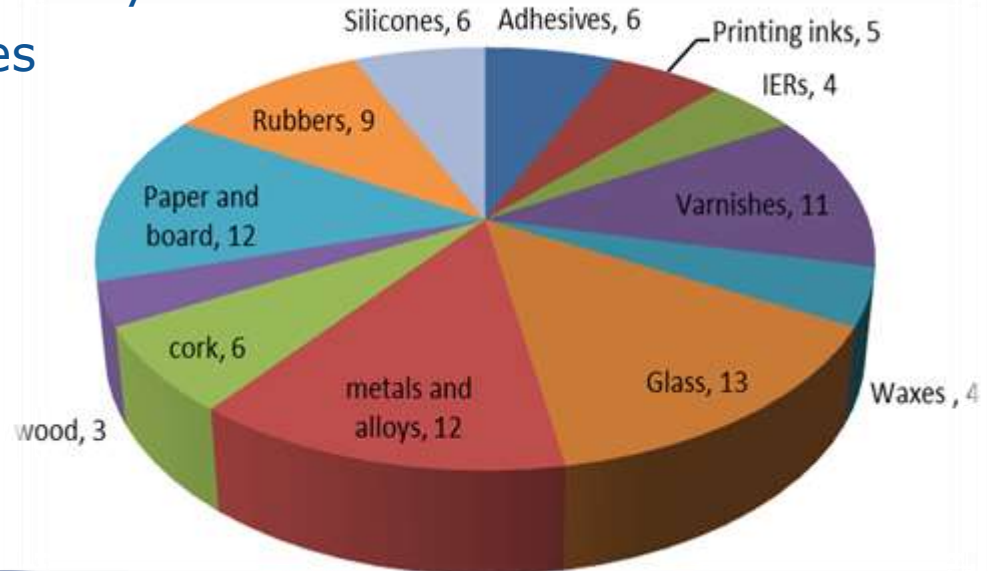
- **Hurdles in supply chain**
  - ✓ **Lack of transfer of safety related information in the supply chain**
  - ✓ **Lack of communication**
    - Esp. on composition and toxicological characterisation of substances and intermediates
  - ✓ **MSs requirements for substance evaluation and authorisation**
    - Varying from EFSA or in different formats and application templates

General measures on FCMs

➤ National frameworks include registration of businesses, Declaration of Compliance (DoC) & Supporting Documentation (SD) requirements, GMP, basis for enforcement and sanctions and certification systems

➤ General hurdles include difficulty in accessing national measures and language barriers

➤ Lack of implementation of DoC and SD

  • **Requirements and criteria for DoC and SD vary between MSs**

  • **Absence of link between quality of documentation such as DoC/ SD and sanctions**

➤ GMP frameworks exist at MS level but not described in detail; most are not material specific

➤ Industry GMP guidance on adhesives, inks, coatings and paper & board but lack of information on use and access by SMEs

Specific measures on FCMs

- ➢ No MS regulates all materials but 19 MSs regulate more than one
- ➢ Most regulated materials: metals & alloys; varnishes & coatings; paper & board; glass
- ➢ Most common approach: lists of authorised substances
- ➢ Implementation tools: limits – different types are used (SML, QM, compositional). Approach not always same
- ➢ Varying definitions, substances not always identifiable
- ➢ Many substances regulated that are not risk assessed
- ➢ Lack of commonality of substances regulated and with different SMLs
- ➢ CoE transposition limited

Silicones, 6; Adhesives, 6; Printing inks, 5; IERs, 4; Varnishes, 11; Rubbers, 9; Paper and board, 12; cork, 6; metals and alloys, 12; Glass, 13; Waxes, 4; wood, 3

Overview

Example for a selection of three materials with relevance

➢ **Paper and board**
- Largest market after plastics (turnover 26 billion € - plastics 30 billion €)
- Regulated in 12 MSs
- >1700 substances
- SMEs: about 2/3 of the market

➢ **Inks**
- At start of the chain: multiple uses, accountability
- >5200 substances (78% of all regulated substances)
- Micro and small-medium very relevant in number and half of turnover

➢ **Varnishes and coatings**
- At start of the chain: multiple uses, accountability
- Regulated in 11 MSs
- >1700 substances
- Predominance of large enterprises (number and turnover)

Demonstration of safety and barriers to trade

➤ Multiple and often diverging national legislation

- • Complex and diverging requirements
- • Difficulty in accessing measures and RA protocols
- • Multiple investments for industry for RA applications
- • Lack of standards and methods
  - – *Difficult to enforce, no systematic data on monitoring*
  - – *Difficult to demonstrate compliance*
  - – *DoC/SD and link to sanctions*

➤ Lack of accountability across manufacturing chains

➤ Issues with mutual recognition

➤ Access to national markets for SMEs more affected

➤ Lack of clarity in requirements for third countries (imports)

Tentative list

New activities

- **Ex-post evaluation of Regulation 1935/2004**

- **EU measure on printed food contact materials**

- **Study of information in the supply chain**

- **New series of SANTE.F fact finding missions on FCMs**

- **Recommendation on monitoring of mineral oils**

Existing work

- **Implementation of recycling processes**

- **Continuation of authorisations under Regulation 10/2011**

- **Continuation of Better Training for Safer Food (BTSF) for FCMs**

Printed FCM

Possible prioritisation – health concerns

- **German notification, scientific study**
- **adoption foreseen mid 2018**

Initial Scope

- **printed food contact materials**

= printing inks + food contact materials that are printed

Simplification

- **information in the supply chain and compliance**
- **possibly over 5000 substances involved**

Presently under preparation internally

supply chain

functioning of transfer of information in the supply chain

- **Declarations of Compliance + Supporting documentation**
- **our feeling is that the functioning of this mechanism could be improved**
- **we need to ensure that plastic materials are safe**
- **REFIT platform recommendation on Declarations of Compliance**

Objectives

- **to understand the functioning of the plastics Regulation**
- **to inform possible harmonised measures**

Method

- **survey directed at Member States and Business Operators**
- **we will ask for examples of documentation**

Useful links and contact

European Commission webpages on FCMs

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm

FCM online database

https://webgate.ec.europa.eu/sanco_foods/main/?event=display

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