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

Advisory Group
Friday 25 November 2016

Bastiaan Schupp

European Commission
DG SANTE, Unit E2 – Food Processing Technologies and Novel Foods
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
General requirements for all FCM + Mandate for specific measures

requirements for Good Manufacturing Practices
Applicable to all FCM

SPECIFIC MEASURES

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

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

• 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
• **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

- 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
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)
**Activities in 2017**

*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
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
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