Understanding the requirements of EU food contact legislation

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The content of this lecture does not necessarily represent the position of the European Commission
Overview

Legislative overview

Current legal framework for non-harmonised materials

- EU – Framework Regulation and GMP
- National

Roadmap – not yet harmonised materials
General requirements for all FCM + Mandate for specific measures


SPECIFIC MEASURES

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

Substances
- Vinyl chloride monomer
- Nitrosamines
- BADGE, BFDGE & NOGE
**What are food contact materials – FCM?**

- Already in contact with food
- Intended to come into contact with food
- Reasonably expected to come into contact with food

- Food packaging
- Food processing machinery
- Kitchenware, tableware

*Framework Regulation (EC) 1935/2004*
Rules applicable to all FCM

- Do not endanger human health
- Do not change composition of the food in unacceptable way
- Do not mislead the consumer
- Be manufactured according to GMP
- Traceability
- Labelling

Rules applicable to all FCM

Quality assurance system
- Suitability of the starting materials
- Processes design and operation
- Premises and equipment
- Qualification of staff

Documentation

Quality control

At all manufacturing stages except starting materials

Regulation on Good Manufacturing Practice (EC) 2032/2006
Control of constituents

**Quality assurance system**

• **Processes design and operation**

  **Starting materials**
  – Impurities
  – Under control by the manufacturer
  – Positive listing in national legislation

  **Operation parameters**
  – Reaction products
  – Degradation products
  – Under control by the manufacturer
  – Positive listing in national legislation

**Regulation on Good Manufacturing Practice (EC) 2032/2006**
Control of constituents

National Material specific legislation

- List of authorised substances
- Based on Risk assessment or not
- Migration limits
- Residual content
- Substance Specifications
- Use specifications

National legislation?

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Control of constituents

by Manufacturer

• Risk assessment
  substances not subject to positive listing
  Impurities
  reaction products
  degradation products

• Availability of EFSA opinion

• Availability of other general accepted risk assessment

Manufacturers obligations

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Documentation

Good manufacturing practice

• paper or electronic format
• Available to enforcement on request
• Substance specifications, composition formulae, process design, toxicological information, hazard identification, exposure assessment
• Compliance with national legislation or own risk assessment
• Records of the quality control system

Regulation on Good Manufacturing Practice (EC) 2032/2006

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Future developments and challenges

Not yet harmonised materials

• Prioritisation of other materials
• What needs to be regulated?
• How should it be regulated?

Parameters to consider

• What is the administrative burden for authorities, industry?
• What is the economic impact?
Roadmap

1. Context – Problem definition
2. Objectives
3. Options
4. Initial assessment of impacts
5. Evidence base, planning, consultation
6. Website
Problem definition

- Safety of materials on the market
  - Limitations on national risk assessment
  - Limitations on enforceability
  - Limitations on enforcement
  - Limitations on GMP and risk assessment at industry level
- Incomplete functioning of internal market
Affected parties

- **Member States**
  - national legislation
  - enforcement of FCM legislation
- **FCM manufacturing Industry**
  - starting materials,
  - intermediates
  - final materials
- **Food industry using FCM**
- **Importers**
- **Manufacturers in third countries**
- **risk assessment bodies**
  - **EFSA**
  - national
- **Testing institutes**
Objectives

- Ensure that safe FCM are placed on the EU market
  - Improve risk assessment performed on food contact materials
  - Improve the self-control of manufacturers by increasing the knowledge and transparency throughout the productions chain of FCM on substances used.
  - Improve the enforcability of the safety requirements of FCM.
- Improve the functioning of the internal market
  - Minimise the burden to industry created by diverging national rules or other certification and accreditation system
  - Introduce a level playing field for goods from EU and third countries
Options

- No action at EU level leaving Member States to set up specific requirements at national level
- Establishment of lists of substances, materials or processes used together with migration limits;
- Negative lists of substances not to be used in FCM;
- Setting out obligations and criteria for risk assessment of substances and/or materials;
- Setting out obligations and criteria for information exchange throughout the manufacturing chain via declaration of compliance and supporting documentation;
- Setting out detailed material specific rules on good manufacturing practice
- Combinations of the above
Assessing the impact

- Identify specific options for addressing specific problems in production chains
- Contribution of the option to solve the problem;
- Impact of the options to the different actors
  - Economic
  - Social
- Administrative burden
- Enforceability
Information we need from you

- Current practice
  - What safety information is available at which stage?
  - How and to which extent is safety information exchanged
  - Management tools to ensure safety
- Structure of and actors in existing production chains
- Market shares
  - Share of large, SME and microbusiness (number and volume based)
  - Share of EU vs Third Country
  - Distribution within the production chain
WEBSITES ON FOOD CONTACT MATERIALS

**EU legislation**
http://ec.europa.eu/comm/food/food/chemicalsafety/foodcontact/index_en.htm

**Risk assessment**
http://www.efsa.europa.eu/

**Migration testing**
http://ihcp.jrc.ec.europa.eu/our_labs/eurl_food_c_m

**FCM Roadmap**