



# 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*

## Framework Regulation (EC) No 1935/2004

General requirements for all FCM + Mandate for specific measures

## GMP Regulation (EC) No 2023/2006



## 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

Framework Regulation (EC) 1935/2004



# 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?

10.09.2013

MOCRINIS, Bologna



# 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**



# 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**

# 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?**

## Challenges

# 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](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\\_cm](http://ihcp.jrc.ec.europa.eu/our_labs/eurl_food_cm)

## **FCM Roadmap**

[http://ec.europa.eu/governance/impact/planned\\_ia/docs/2014\\_sanco\\_005\\_fcm\\_specific\\_provisions\\_for\\_materials\\_other\\_than\\_plastics\\_en.pdf](http://ec.europa.eu/governance/impact/planned_ia/docs/2014_sanco_005_fcm_specific_provisions_for_materials_other_than_plastics_en.pdf)