



Food Contact Materials – gaps to be addressed – the roadmap exercise

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

Overview

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 - 2. National legislative framework**
 - 3. CoE initiatives**
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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

- Nitrosamines
- BADGE, BFDGE & NOGE

National legislation

Lists of substances

Authorised
Risk assessed
inventory

Limits & restrictions

Content
Migration
purity

Others

GMP
DoC
Registration of
businesses
Conditions of use
Prohibition of use
Hygiene

NL
DE
IT
CZ
SK
FR
ES
CoE

Paper & board
Coatings
Adhesives
Printing inks
Rubber

NL
DE
IT
CZ
SK
FR
CoE

Paper & board
Coatings
Adhesives
Printing inks
Rubber
Metal & alloy
Glass
Ceramic

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/ReferencesEurNatLeg_20091026.pdf



National legislation

- *Not all MS have national legislation in place*
- *More than half of the MS legislation only cover up to 3 materials*
- *National ongoing initiatives*
 - **Germany: mineral oils, printing inks**
 - **Netherlands: update of Warenwet**
 - **FR, BE, SV, DK: Bisphenol A**
 - **Belgium – CoE: Substances database**



Council of Europe Resolutions

- *CoE can be active where EU is not acting*
- *Resolutions with inventory lists and testing recommendations*
 - **Need updating**
 - **Cover: paper&board, coatings, colorants, silicone, cork, rubber, ion-exchange, printing inks**
 - **New 2013: metals & alloys**

http://www.coe.int/t/e/social_cohesion/soc-sp/public_health/food_contact/COE%27s%20policy%20statements%20food%20contact.asp#TopOfPage



EFSA ESCO WG

- *Risk assessment in MS*
- *collect the information present in MS*
- *to anticipate emergency situations*
- *ESCO inventory list*
 - **2800 entries (paper&board, printing inks, coatings, rubber, colorants, wood and cork)**
 - **230 risk assessed to SCF Guidelines FCM (1991)**
- *Strategies for prioritization of evaluations*
- *Strategies for preliminary advice in crisis situation*
- *Network of experts in crisis situation*

<http://www.efsa.europa.eu/en/supporting/pub/139e.htm>



Other relevant legislation

- *Link to REACH*
- *Link to Biocides Regulation*

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 I*
 - **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*
- *Consumers*

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*

Instruments

- *EU regulation*
- *National regulation*
- *EU guidance*
- *National guidance*
- *Industry self-regulation*

Initial assessment of impacts

- *No actions*
 - **Status quo remains**
- *EU measure*
 - **Harmonised rules**
 - **Level playing field**
 - **Cost**
 - **Administrative burden**
- *Industry self-regulation*
 - **Cost**
 - **Administrative burden**
 - **Divergent rules**
 - **Enforceability**

Evidence base, planning, consultation

- *Impact assessment steering group*
- *Questionnaire to MS and Industry associations*
- *External study (2014)*
- *Focussing of objectives*
- *Open public consultation*
- *SME test*



Website

http://ec.europa.eu/governance/impact/planned_ia/roadmaps_2012_en.htm