



# **DG SANTE activities: Update on EC food contact materials baseline study**

**FIP scientific network for the cooperation and  
harmonisation of risk assessment of food contact materials  
3<sup>rd</sup> meeting, 24-26 May 2016**

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**The views expressed are purely those of the presenter and may not in any circumstances be regarded as stating an official position of the European Commission.**

# EU Framework legislation:

## Regulation (EC) No 1935/2004

### Food contact materials must not:

- Endanger human health
- Bring about an unacceptable change in the composition of the food
- Bring about a deterioration in the organoleptic characteristics

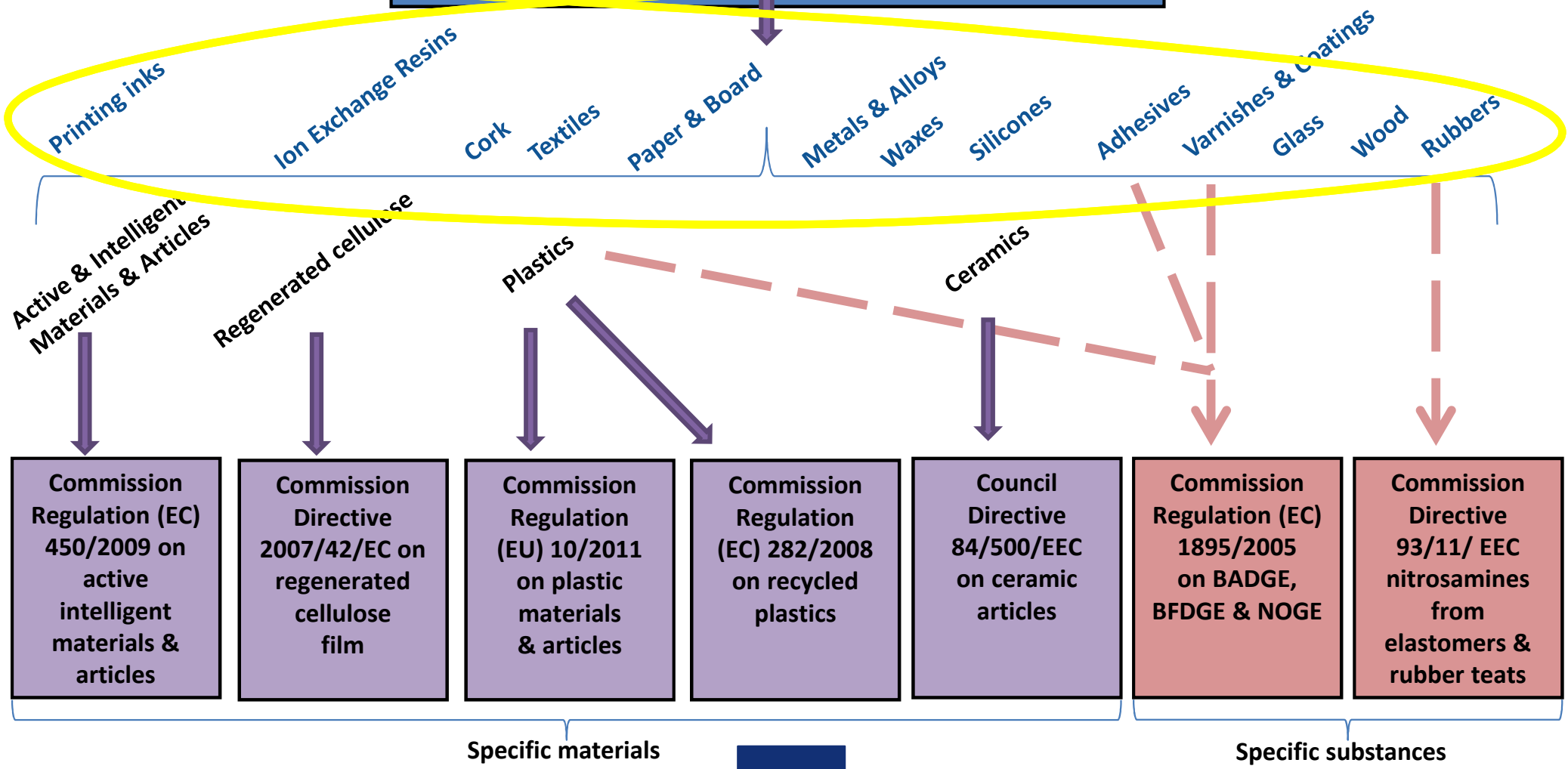


**Specific measures possible for 17 types of material** as well as..

Definitions, role of EFSA and authorisation procedure, labelling, traceability, declaration of compliance (DoC)

# Framework Regulation (EC) No 1935/2004

## GMP Regulation (EC) No 2023/2006





# JRC "baseline" study

**To support DG SANTE in the mapping of the situation in the EU concerning non-harmonised FCM**

Intended to allow the European Commission to assess the efficiency and effectiveness of the current situation, including the benefits as well as the administrative burdens and costs of the existing situation on businesses.

# Specific tasks

## ➤ **Workpackage 1 – Existing measures:**

- ✓ Regulatory frameworks at national & supranational level
  - *Individual materials, combinations of materials, substances*
  - *GMP, DoC requirements*
  - *Registration for businesses*
- ✓ Industry guidance and self-regulation
  - *Which sectors, what is available?*
  - *Type of self-regulation*
  - *To what extent it is applied*
- ✓ Risk assessment approaches
  - *Which ones are available*
  - *What do they use? Who are they available to?*

# Specific tasks

## ➤ **Workpackage 2 – market overview:**

- ✓ Information on the supply chain
  - *Who are the actors upstream and downstream?*
  - *Differences between sectors*
- ✓ Trade information from difference sectors
  - *Organisations and members*
  - *Distribution of SMEs*
- ✓ Market data
  - *Values*
  - *Volumes*

# Specific tasks

- **Workpackage 3 – Information tabulation:**
  - ✓ Gathering of information from WP1 and WP2
  - ✓ Integrated into tables and spreadsheets
    - *Flexible and retrievable information*

# Specific tasks

- **Workpackage 4 – Analysis of the baseline:**
  - ✓ Efficiency and effectiveness of the measures
    - *Are the tools sufficient to demonstrate safety and compliance?*
    - *To what extent are they followed and enforced?*
    - *Gaps, overlaps and inconsistencies*
    - *Perceived or real barriers to trade*
  - ✓ Cost effectiveness
    - *Costs and impacts of current measures*
    - *Administrative burden and costs for MSs*
    - *Administrative burden and costs for industry*



# Approach: on what?

- **Adhesives**
  - **Ceramics**
  - **Cork and wood**
  - **Glass**
  - **Ion exchange resins**
  - **Metals and alloys**
  - **Multimaterials**
  - **Paper and board**
  - **Printing inks**
  - **Rubber**
  - **Silicones**
  - **Varnishes and coating**
- 
- *Plastics considered as benchmark since EU regulated*
  - *Ceramics considered for aspects beyond EU regulated*
  - *Kitchenware and processing equipment also considered separately*

# Approach: Regulatory frameworks

## ➤ Mapping of regulatory frameworks

- ✓ Compilation of National legislations EU – beyond EU
- ✓ Compilation of Standards
- ✓ CoE, GMP, industry guidance and self-regulations
- ✓ Review of replies from Q2012-roadmap poll (MS and Ind.)
- ✓ Comparisons of existing measures

## ➤ How?

- ✓ Public access – national websites
- ✓ Repositories (Decernis)
- ✓ Validation and completion by direct queries with MS CA
- ✓ Same for industry and GMP

# Approach: market/sectorial data

## ➤ Supply chain and market data

- ✓ Supply chain compositions and sectorial associations
- ✓ Market data
  - *trade data- volume values- units-*
  - *Distributions of SMEs*

## ➤ How?

- ✓ Public access – professional associations websites
- ✓ From the sectors themselves
- ✓ From external sources (Euromonitor, Pira)
- ✓ Completion by additional direct queries with Industry associations (2 different questionnaires)

# Approach: Safety and official controls

## ➤ Safety indicators

- ✓ FVO reports
- ✓ RASFF data (with caution!)
- ✓ Queries with MSCA and NRLs on campaign and monitoring data over the years 2005-2014
- ✓ Statistics on the effectiveness of measure on imports
- ✓ Monitoring and scoping study on harmonised campaigns on controls for FCM

**Confidential information**



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## Next steps

- **Finalise Baseline study and publish**
- **Generation of master lists as reference data**
- **EN translations for main national legislations (non-official)**
- **DG SANTE to consider report and what if any further steps needs to be taken at EU level**