The European Commission's science and knowledge service

Joint Research Centre

FCM Baseline study

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Context

- ✓ **Food safety: release of chemicals from FCM into foods**
- ✓ **Framework regulation establishes principles of safety assessment and management**
- ✓ **Not all harmonsied**
  - Some materials have EU wide approach
  - Others => national rules (13/17)
  - Use mutual recognition (4)
- ✓ **Can inconsistencies affect safety or trade?**

Approach (1) collection of data

- ✓ **Market / sectorial data**
  - Supply chain compositions and sectorial associations
  - Trade data- volume values- distributions of SMEs

- ✓ **Regulatory frameworks**
  - Examine risk assessment approaches
  - Comparisons of National measures (Generic + material-specific)
    - *EU – beyond EU CoE Norden, Standards (CEN, ISO, national)*
    - *Industry self-regulations (GMP, compliance documents, practices)*

- ✓ **Enforcement- safety / official controls**
  - Including HFAA audits, BTSF actions, RASFF, MSs data

- ✓ **Costs / burden, perception of barrier to trade** (MSs + associations)

Approach (2) Analysis of data

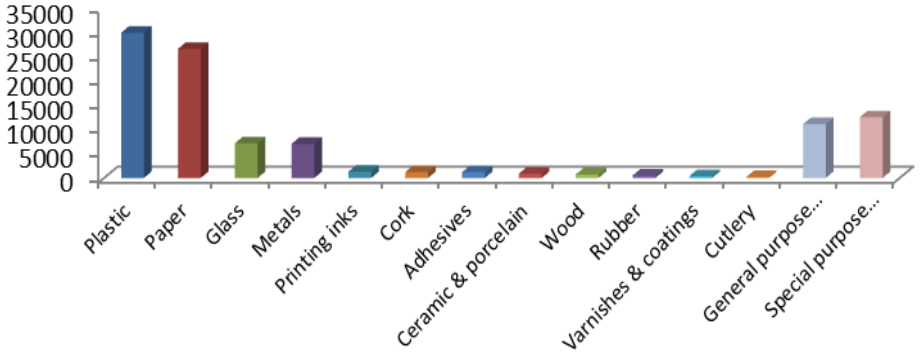
- **Towards**
  - ✓ Risk assessment, risk management and enforceability of controls
  - ✓ Effectiveness: convergence of national rules, safety indicators
  - ✓ Efficiency: burden or trade-related issues

- **Scope**
  - ✓ Adhesives
  - ✓ Ceramics
  - ✓ Cork and wood
  - ✓ Glass
  - ✓ Ion exchange resins
  - ✓ Metals and alloys
  - ✓ Multimaterials
  - ✓ Paper and board
  - ✓ Printing inks
  - ✓ Rubber
  - ✓ Silicones
  - ✓ Varnishes and coating

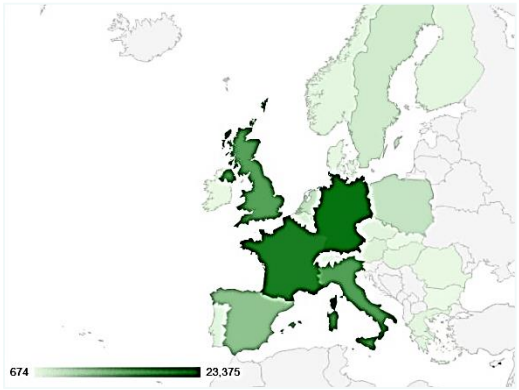
  - ✓ *Materials (packaging), but also considering kitchenware and processing equipment*
  - ✓ *Plastics considered as benchmark since EU regulated*
  - ✓ *Ceramics considered for aspects beyond EU regulated*

Market landscape

- 100 bn € annual turnover
- Plastic and P&B: biggest markets



- Some materials mostly larger enterprises (glass, inks, coatings)
- All other sectors show significant presence of SMEs (number, sometimes also in turnover)



- In general, DE, FR, IT, UK, ES and PL: leading suppliers (Portugal for cork)

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Risk assessment (1)

- **At MS level**
  - ✓ There is a lack of common guidelines and transparency in undertaking risk assessment (RA) work across MSs.
  - ✓ Protocols for the authorisation of substances often differ between MSs and differ from that of the European Food Safety Agency (EFSA).

- **Existence of RA tools but not fully exploited:**
  - ✓ Belgian-CoE FCM database (hazard characterisation)
  - ✓ FACET (exposure assessment)
  - ✓ Matrix (RA of non-listed substances)

→ **Significant expertise required**

Risk assessment (2)

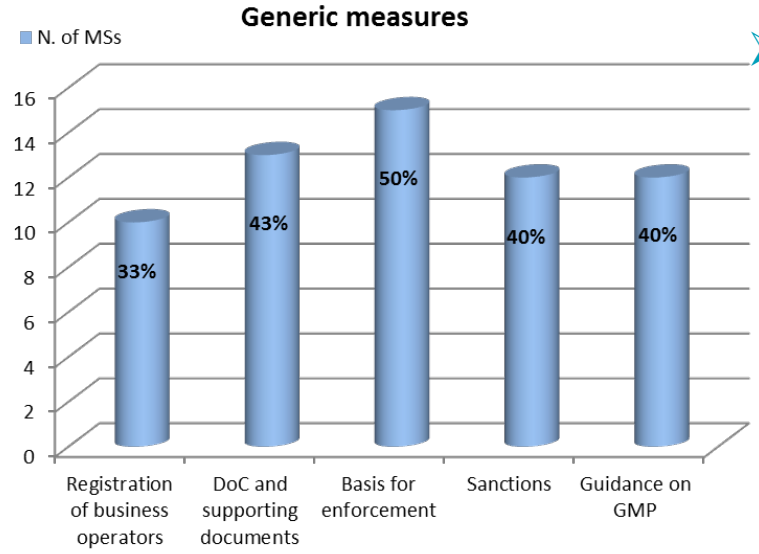
- **Existence and access to industry schemes**
  - ✓ Stated to be based on EFSA
  - ✓ Available but not very much detailed
  - ✓ Are they or can they be used also by SMEs?

- **Hurdles in supply chain**
  - ✓ **Lack of transfer of safety related information in the manufacturing chain / communication**
    - Esp. on composition and toxicological characterisation of substances and intermediates
  - ✓ **MSs requirements for substance evaluation and authorisation**
    - Varying from EFSA, or
    - Implemented in different formats and application templates

Generic national measures to FCMs

General hurdles:

- ✓ Difficult access to measures + Language barriers
- ✓ Need standards on food safety requirements common to all FCMs



Enforcement hurdles:

- ✓ **Gaps in DoC and GMP implementation**
  - Limited detailed requirements and guidance in national measures
  - Absence of link between quality of documentation (DoC/SD) and sanctions

- Inconsistent drivers for monitoring

- Limitations of RASFF to assess of safety issues

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GMP frameworks

- ✓ **At MS level**
  - Described in limited details
  - Most are not material-specific (except Italy)

- ✓ **At sectorial level**
  - Strong guidance on: adhesives, inks, coatings, and P&B
  - from detailed additions to Reg.2023/2006- to generic descriptions
  - Most guidelines describe certification systems on raw materials, QA, QC, but application extent is not known

➢ **Hurdles in GMP and guidelines:**

- ✓ MS and/or industry **g**uidance: aspects not equally covered, deviations
- ✓ For MS: Difficult for CAs to integrate the controls (DoC and GMP) into their structure (spread of supply chain)

➡ **Insufficient implementation**

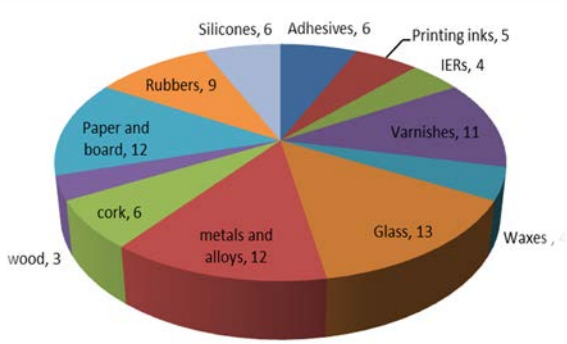
↓

Relevant EU investments (BTSF) to support to CAs and controls

Material-specific national measures (1)

- **General**
  - ✓ prevalently based on lists of authorised substances and restrictions.
  - ✓ Close to 8 000 substances were found.
  - ✓ Implementation tools: different types of limits used (SML, QM, compositional)

- **Differences between sectors**
  - ✓ Some materials are regulated by more than 10 MSs (metal, glass) and some only by a few (wood).
  - ✓ Most regulated: metals/alloys; varnishes/coatings; P&B; glass



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Material-specific national measures (2)

- ***Note: "regulated" taken in broadest sense***

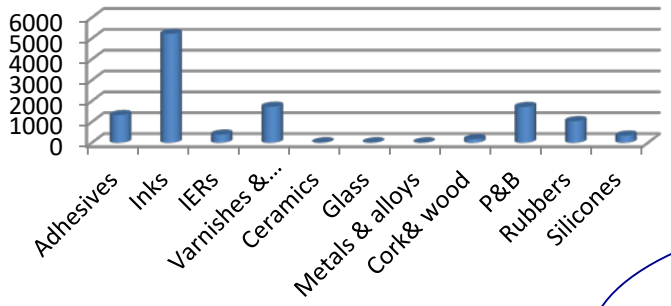
- **Hurdles from "positive list" approach:**
  - ✓ Varying **definitions** and fields of application
  - ✓ Substances not univocally **identified** (generic/cumulative descriptions)
  - ✓ Discrepancy regulated vs. risk assessed?

- **Hurdles in implementation:**
  - ✓ Wide array of substances regulated (100-5000+)
  - ✓ Substances differing across MSs for one material (limited % substances in common)
  - ✓ For same substance, differences across MSs on:
    - types of limits (QM/SML) for same material
    - numerical values across MSs for one material
  - ✓ Limitations of transpositions of CoE lists
  - ✓ Same substance, same MSs: different limit for different materials

Practices: references to national measures

- **What MSs report:**
  - ✓ Case-by-case basis
  - ✓ Few specific references (BfR, CoE, NL)
  - ✓ Specific cases: CH for inks, DE for P&B, FR and DE for silicones
- **What is not clear:**
  - ✓ Lack of data on implementation of mutual recognition: need monitoring
  - ✓ Limited national transposition of CoE resolutions
- **What industry reports:**
  - ✓ Specific mention of national rules in sector guidelines
  - ✓ Most common reference MSs: NL, DE, IT, ES and CH (+ CoE or Norden)
  - ✓ Not clear if small and micro-businesses are aware of national legislation and self-regulation

N. of regulated substances per material across national measures in the EU



Waxes

Lack of information

lack of guides and controls

Small market size: small concern?

Varnishes and coatings

Large number of MSs (more than 10)

5% in common for several MSs

Standards, guides, convergence with plastics reg.

Rubber

Complexity in chemical definitions

18% in common by several MSs

60% of restrictions are different

Lack of convergence on national rules

Lack of guidelines

Adhesives

Many end uses

<1% in common by several MSs

Lack of standards

Well-established industry guides

Silicone

2 compositional definitions

Lack of standards

18% in common by several MSs

General sector guidance

Testing methods is an issue

Printing inks

1(2) complete national legislation (CH, *DE*)

<1% regulated by more MSs

Ion exchange resins

Few but relevant measures

Some standards

Lack of industrial guidelines

Cork and wood

Regulated by few MSs

Sectorial guidance

11% in common by several MSs

Paper and board

9% in common by several MSs

Presence of standards, sector guides (GMP and on compliance)

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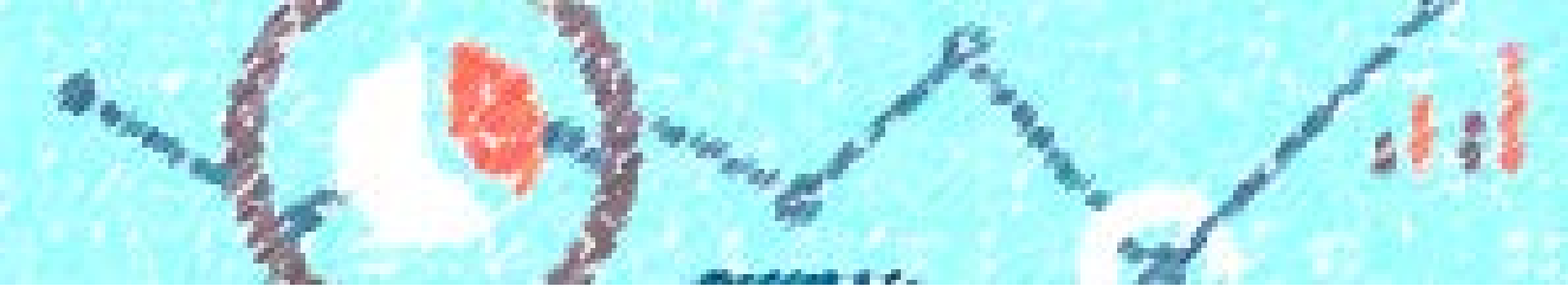


Summary of hurdles

- **multiple or lack of national legislation:**
  - ✓ Different languages
  - ✓ Difficult access and complex frameworks
  - ✓ Diverging (types of restrictions, limits, requirements, etc.)
  - ✓ No clear-cut references stated by MSs

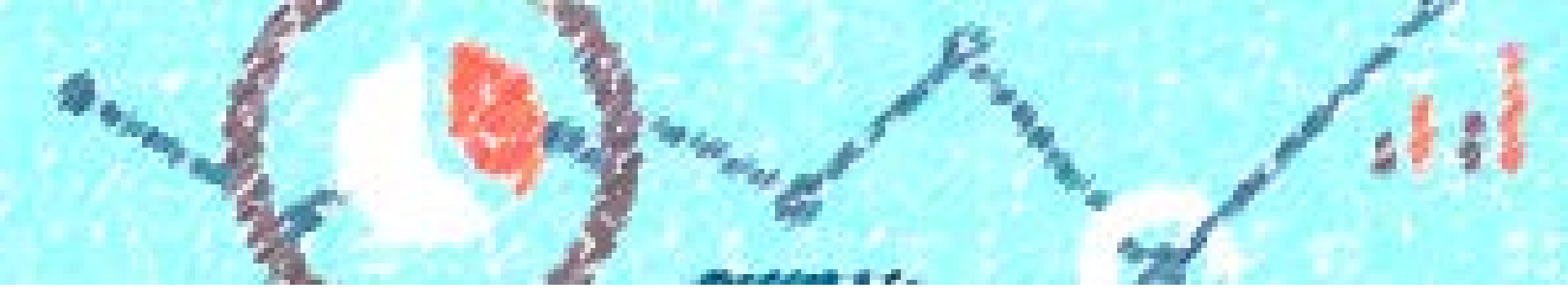
→ **Lack of understanding of others' rules**

→ **Industry: Need for expert advice, multiple testing = extra costs**

→ **Controls: Uneven quality of results in official controls or in compliance in DoC/SD**

→ **Different testing different results?**

→ **Affect safety?**



Summary of hurdles

- **Lack of standards and methods:**
  - ✓ Difficulty to show compliance
  - ✓ Difficulty to enforce

→ **Need of ad-hoc development:**
- ✓ **Extra costs**
- ✓ **Extra labor for Off controls**
- ✓ **If by third labs: proprietary not shared**

- **Absence of EU harmonised requirements:**
  - ✓ Third countries might develop their own rules
  - ✓ Importers might see less requirements

⇒ **Affect export**
Lower safety

- **Issues with mutual recognition:**
  - ✓ Difficult to understand
  - ✓ Not fully applied by some MSs

→ **Risk of court cases: extra costs**

Conclusions for the non-harmonised sectors

- **On effectiveness:**
  - ✓ **Safety less guaranteed due to:**
    - Different risk assessment and authorisation processes
    - Problematic enforcement
      - *DoC/SD and link to sanctions*
      - *No systematic data on monitoring, lack of strategic forum at MSCA?*
    - Lack of accountability across manufacturing chains
    - Lack of clarity in requirements for third countries (imports)

- **On efficiency:**
  - ✓ **Extra burden due to:**
    - Multiple and diverging legislation
    - Issues with mutual recognition
    - Extra EU investment to support enforcement (e.g. HFAA, BTSF)
    - Multiple investments of industry for different applications of RA concept
  - ✓ **SMEs (relevant for most FCMs) access to national markets is affected**

thank you!

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