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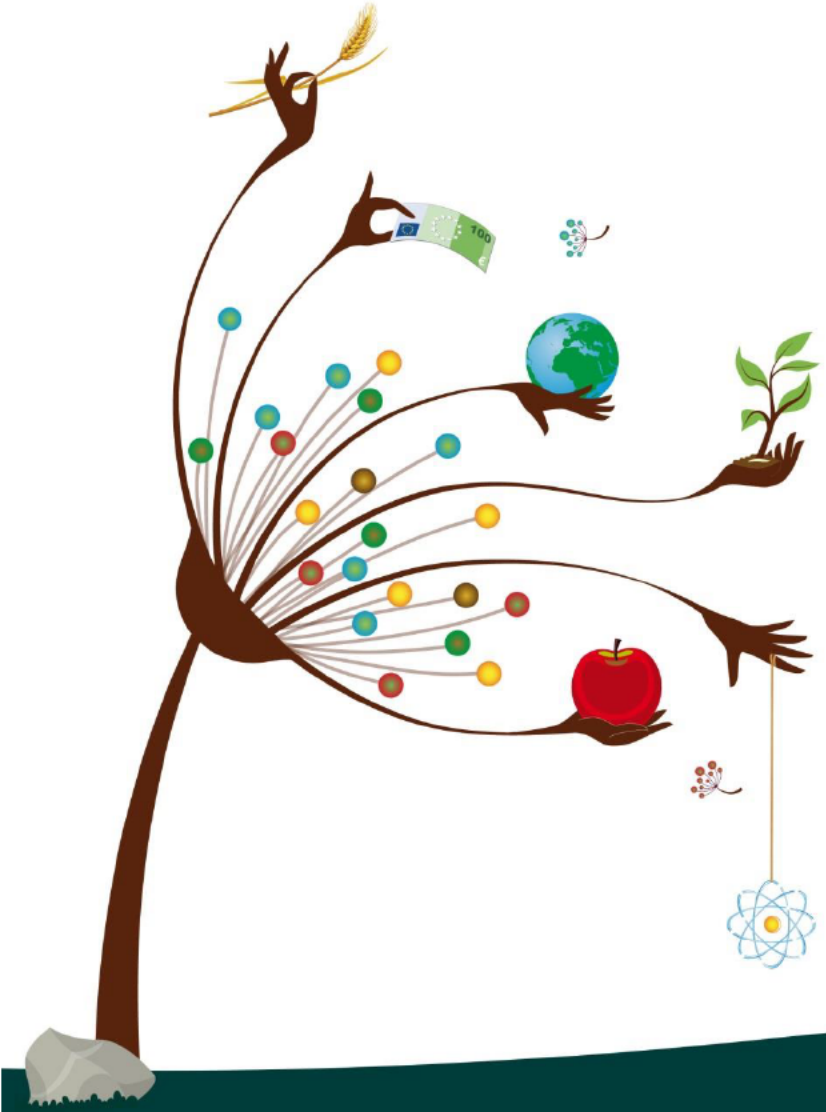

FCM Baseline study

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European Commission

Context

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

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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

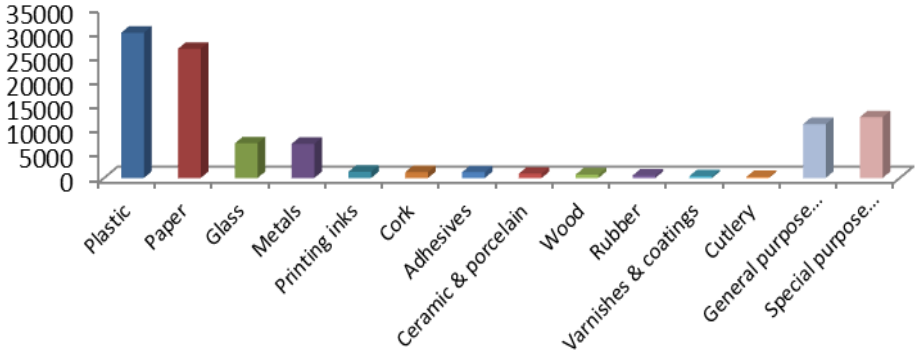
- **Towards**
  - ✓ Risk assessment, risk management and enforceability of controls
  - ✓ Effectiveness: convergence of national rules, safety indicators
  - ✓ Efficiency: burden or trade-related issues

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

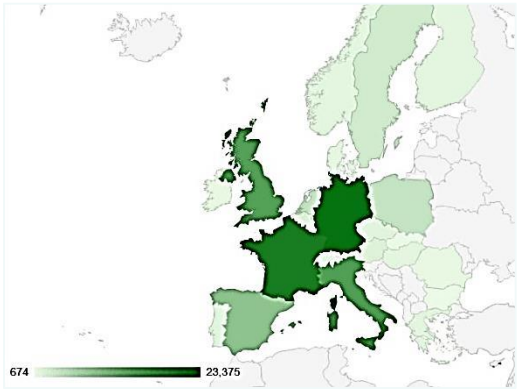
  - ✓ *Materials (packaging), but also considering kitchenware and processing equipment*
  - ✓ *Plastics considered as benchmark since EU regulated*
  - ✓ *Ceramics considered for aspects beyond EU regulated*

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)

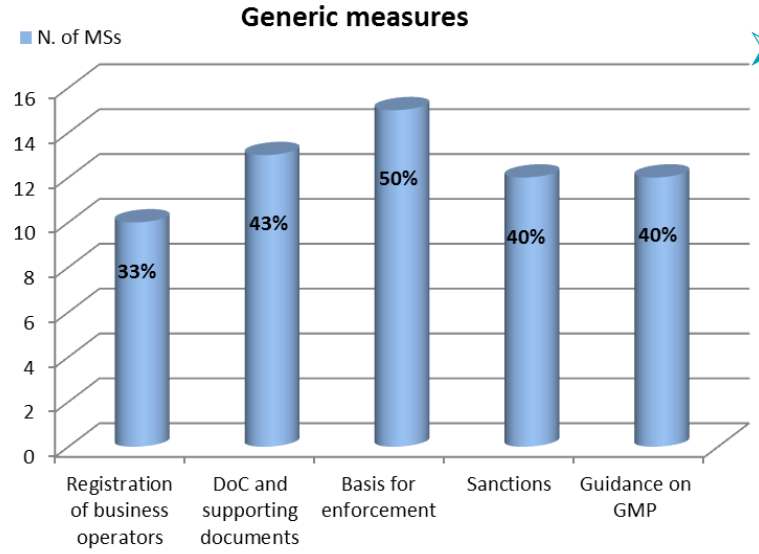
- **Existence and access to industry schemes**
  - ✓ Stated to be based on EFSA
  - ✓ Available but not very much detailed
  - ✓ Are they or can they be used also by SMEs?

- **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**

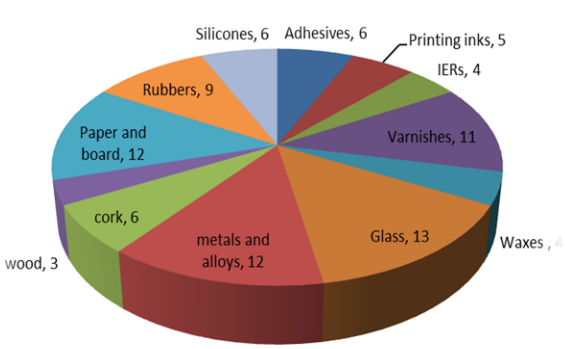
↓

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, coatings, P&B)
  - ✓ some only by a few (wood).



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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

Examples

Varnishes and coatings
Large number of MSs (more than 10)
>1700 substances
5% in common for several MSs
Standards, guides, convergence with plastics reg.

Waxes
Lack of information
lack of guides and controls
Undefined No of substances
Small market size: small concern?

Rubber
Complexity in definitions
> 1000 substances
18% in common by several MSs
60% of restrictions are different
Lack of convergence on rules
Lack of guidelines

Silicone
2 compositional definitions
Lack of standards
>300 substances
11% in common by several MSs
General sector guidance
Testing methods is an issue

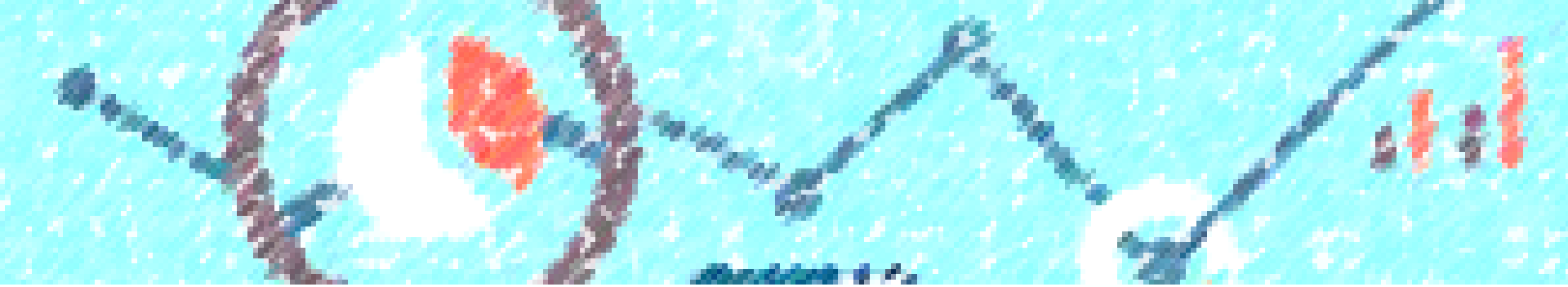
Adhesives
Many end uses
1323 substances
<1% in common by several MSs
Lack of standards
industry guides

Printing inks
>5000 substances
1(2) complete national legislation (CH, *DE*)
<1% regulated by more MSs

Ion exchange resins
Ca. 400 substances
Few but relevant measures
Some standards
Lack of industrial guidelines

Cork and wood
Regulated by few MSs
Sectorial guidance
Ca. 170 substances
11% in common by several MSs

Paper and board
9% in common by several MSs
>1700 substances
Presence of standards, sector guides (GMP and on compliance)



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

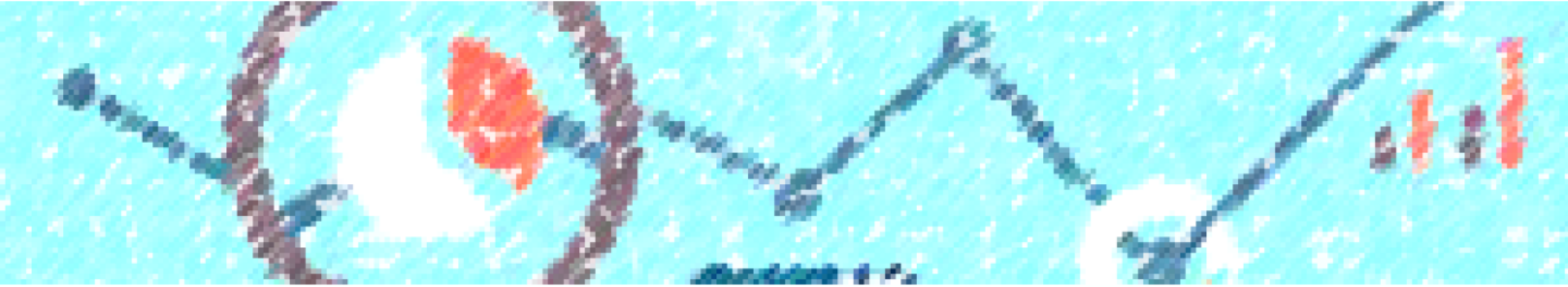
→ **Lack of understanding of others' rules**

→ **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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