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 harmonised**
  - 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)
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](image)
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
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 guidance: 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).
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 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

➢ What is not clear:
  ✓ Lack of data on implementation of mutual recognition: need monitoring
  ✓ Limited national transposition of CoE resolutions
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.

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

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

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

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

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

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

Examples

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

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

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

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

**Affect export**
- Lower safety

**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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