The European Commission’s science and knowledge service
Joint Research Centre
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
- Multi-materials
- 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
- Significant presence of SMEs for most materials
  - except glass, inks, varnishes and coatings
- In general, DE, FR, IT, UK, ES and PL leading suppliers
  - PT for cork
Risk assessment (1)

- At MS level
  - Lack of common guidelines and transparency in risk assessment (RA) across MSs
  - Often different protocols for the authorisation of substances between MSs and compared to that of EFSA

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

Role of EFSA's FIP Network?

Significant expertise required
Risk assessment (2)

- Existence and access to industry schemes
  - Stated to be based on EFSA
  - Available but not very much detailed (enough?)
  - Used by or usable for SMEs?

- Hurdles in supply chain
  - Lack of transfer of safety related information in the manufacturing chain
  - Lack of communication
    - Esp. on composition and toxicological characterisation of substances and intermediates
  - MSs requirements for substance evaluation and authorisation
    - Deviating from EFSA
    - 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
  - Lack of monitoring or controls plans
    - Inconsistent drivers for monitoring?
    - Limitations of the RASFF system to assess safety issues
GMP frameworks

- **At MS level**
  - Few comprehensive guidelines
  - 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 Competent Authorities (CA) 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 8000 substances were found.
  - Implementation tools: different types of limits used (SML, QM, compositional)

- **Differences between sectors**
  - Regulation by only few MSs (wood) to more than 10 MSs (metal, glass)
  - Most regulated: metals/alloys, varnishes/coatings, paper&board, glass
Material-specific national measures (2)

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

- Hurdles in implementation:
  - Wide array of substances regulated (100-5000+)
  - Limited percentage of substances in common for one material
  - 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 measures of other MSs

- What MSs report:
  - Case-by-case basis
  - Few specific references to BfR, CoE, NL
  - Specific cases: CH for inks, DE for P&B, FR and DE for silicones
  - Lack of data on implementation of mutual recognition: better monitoring needed
  - 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.

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

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

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

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

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

**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

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

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

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

**Testing methods is an issue**
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?
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 labour for Off controls
- If by third labs: proprietary not shared

Affect export
Lower safety

Risk of court cases: extra costs
Conclusions

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 access to national markets is affected
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