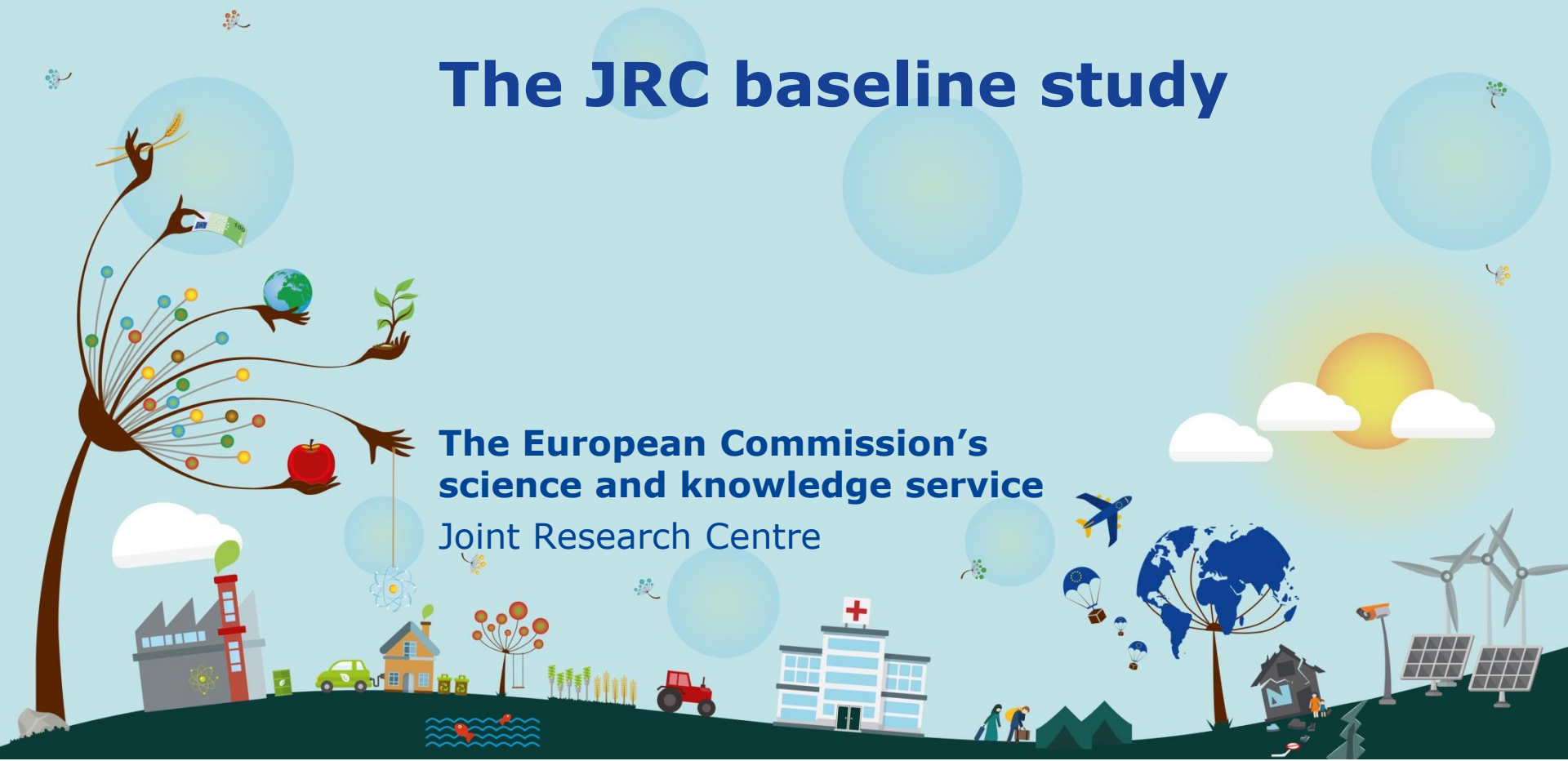
The JRC baseline study



The European Commission's science and knowledge service

Joint Research Centre

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)

BTSF, Better Training for Safer Food
HFAA, Health and Food Audits and Analysis
RASFF, Rapid Alert System for Food and Feed

Approach (2) Analysis of data

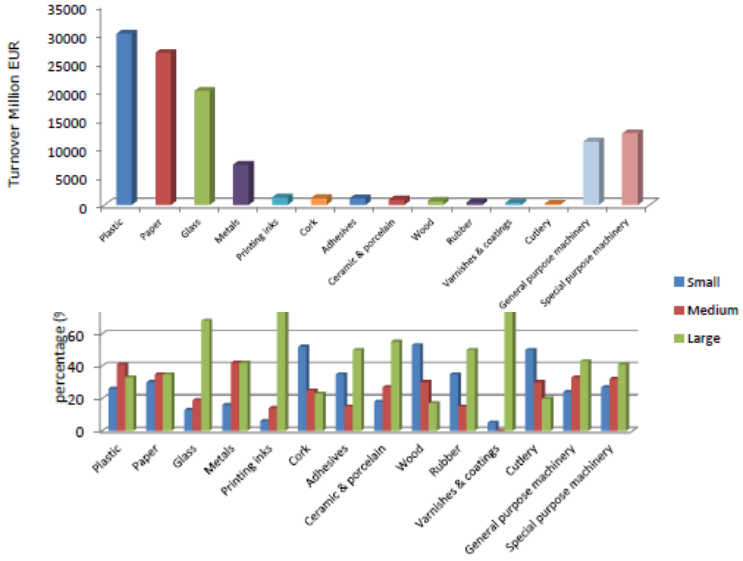
- **Towards**
  - ✓ Risk assessment, risk management and enforceability of controls
  - ✓ Effectiveness: convergence of national rules, safety indicators
  - ✓ Efficiency: burden or trade-related issues

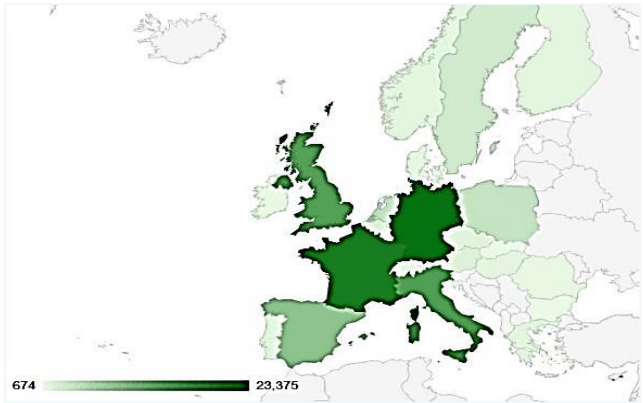
- **Scope**
  - ✓ Adhesives
  - ✓ Ceramics
  - ✓ Cork and wood
  - ✓ Glass
  - ✓ Ion exchange resins
  - ✓ Metals and alloys
  - ✓ Multi-materials
  - ✓ Paper and board
  - ✓ Printing inks
  - ✓ Rubber
  - ✓ Silicones
  - ✓ Varnishes and coating

  - ✓ *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





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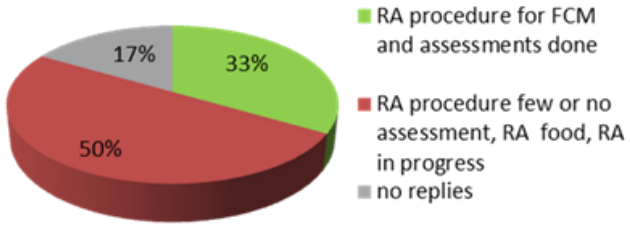
Risk assessment (1)

- 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

→ Role of EFSA's FIP Network?

- 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)

→ Significant expertise required



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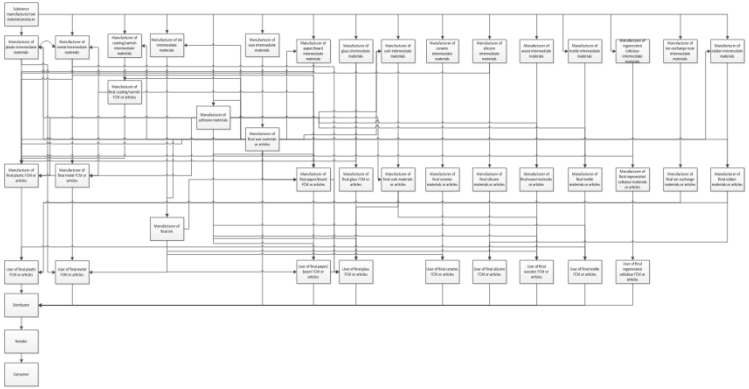
Risk assessment (2)

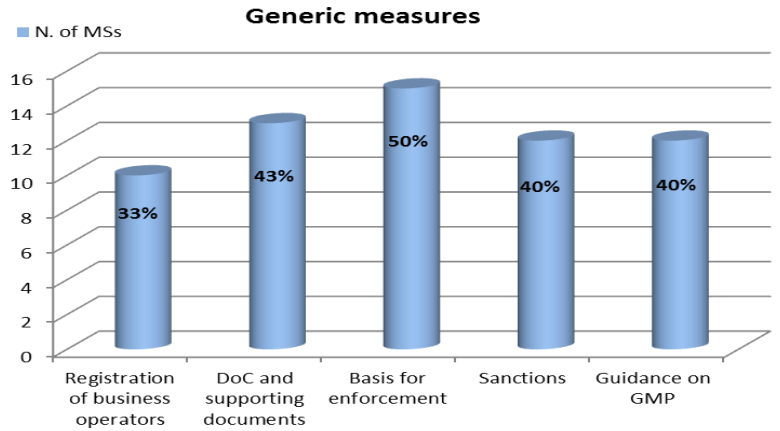


- Existence and access to industry schemes
  - ✓ Stated to be based on EFSA
  - ✓ Available but not very much detailed (enough?)
  - ✓ Used by or usable for SMEs?
- Hurdles in supply chain
  - ✓ Lack of transfer of safety related information in the manufacturing chain
  - ✓ Lack of communication
    - 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



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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

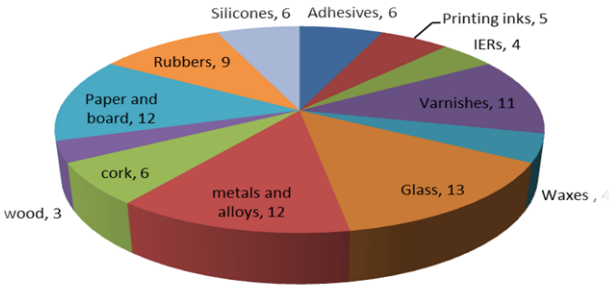
↓

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



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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.

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

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

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

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

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

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

Hurdles

- **multiple or lack of national legislation:**

✓ Different languages	→ Lack of understanding of others' rules
✓ Difficult access and complex frameworks	→ Industry: Need for expert advice, multiple testing = extra costs
✓ Diverging (types of restrictions, limits, requirements, etc.)	→ Controls: Uneven quality of results in official controls or in compliance in DoC/SD
	→ Different testing, different results?
✓ No clear-cut references stated by MSs	→ Affect safety?

Hurdles

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

→ Need of ad-hoc development:
- ✓ Extra costs
- ✓ Extra labour 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

- **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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