Introduction to EY workshop on study in support of the revision of FCM legislation

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European Commission

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EU legislation on Food Contact Materials (FCMs)

- Applicable to **all FCMs**
  - already in contact with food (e.g. food packaging)
  - intended to be brought into contact (kitchenware, food processing equipment)
  - that can reasonably be expected to be brought into contact with food or transfer constituents to food under normal or foreseeable conditions of use

- Size of the industry is considerable = €100 billion

Plastics €30 bn	Paper €25 bn	Glass €20 bn	Other €18 bn	Metal €7 bn

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Legislation on FCMs

- FCM legislation is in place since 1976
- Current basic act: **Regulation (EC) No 1935/2004**
  - It is to ensure
    - **a high level of protection of human health**
    - the effective functioning of the internal market
  - Provides for general rules and procedures
    - Defines the role of EFSA, definitions, labelling, traceability, inspection and control
    - allows for specific measure on materials
- Specific measures
  - Regulation (EU) No 10/2011
  - Regulation (on plastic FCM authorising substances with restrictions e.g. SMLsEU) 2022/1616 on recycling of plastic
  - Most other materials subject to specific National Legislation

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Fundamental problems with the Regulation

The FCM legislation was subject to evaluation, this concluded that:

- Absence of specific EU harmonised rules for FCMs other than plastics
- Focus on authorisation of starting substances
- Lack of prioritisation in the risk assessment of substances
- Rules geared towards traditional chemistry, instead of sustainable alternatives
- Lack of complete information for consumers

→ FCM legislation needs to be revised

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Revision: working objectives and principles

- Objectives
  - Achieve full harmonisation; prioritise risk assessment; simplify the legislation
  - High level of transparency over migratable substances
  - Refocus on final materials and articles; producers responsible
    - (materials and articles likely to become two different concepts)
  - Increase sustainability of materials
- Principles
  - FCMs to be inert; migration to be allowed, only by derogation, and only if safe & transparent
    - implementation: it is to become much simpler to place inherently safer FCMs on the market
  - Implicit requirement on supply chain: no information, no market

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EU FCM revision: Main policy themes and pillars

Safety and sustainability of food contact materials (FCMs)

A + B together to become the core of the future risk management approach + new material categories to apply that approach

A. Redress focus onto final material

- Better define the level of safety required, addressing the full characteristics of all final FCM articles and migrating substances, including NIAS
- Cluster into broader material types (synthetic, natural, inorganic; recycled, composite, active)

B. Prioritisation of substances

- Define rules for the risk assessment of all substances that migrate from FCMs
- Tiered approach:
  - Tier 1: generic risk (hazard) based (CMRs, EDs, PBTs and vPvBs)
  - Tier 2: risk assessment by public authorities
  - Tier 3: Self-assessment by business operators of more benign substances

C. Supporting more sustainable alternatives

- Ensure fewer hazardous chemicals
- Prioritise more sustainable use of FCMs
- Coherence and support to other EU rules on sustainability, including packaging and food

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A: Rebalance focus: final material

- **all substances that may migrate should be known to the producer of the final material or article**
  - the maximum migratable quantity is known and under control of GMP
  - substances have been risk assessed – exposure below resulting limit
  - no difference between NIAS and IAS (or the transfer of any constituents)
- **the information is (largely) to be provided by the supply chain**
  - high level of transparency required
- **expertise on chemistry needed with final producer**
  - (or with their consultants)

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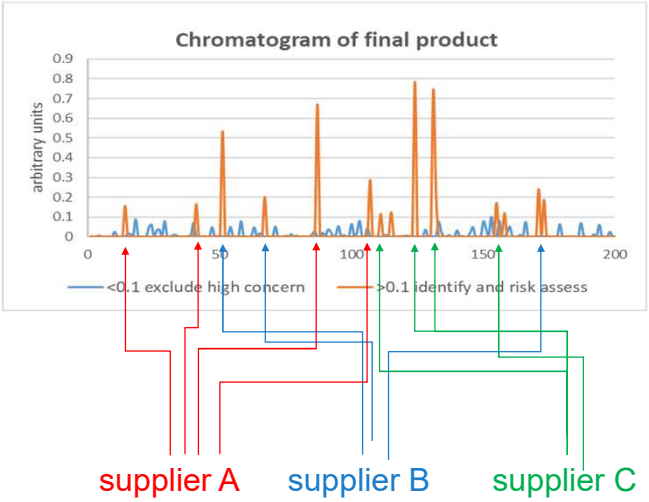
A: In practice

- **If** the **final** producer were to make a 'forest of peaks' style chromatogram:
- They would need to be able to explain all peaks give rise to safe migration level
- Information can't come from (present) analytical techniques **(→F)**
- Information to come from suppliers as shown on right→



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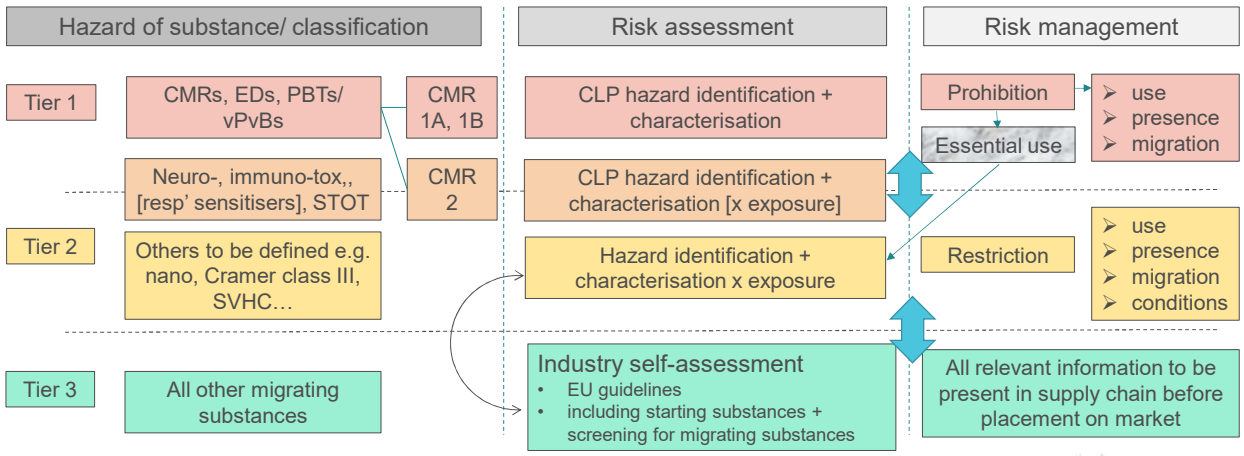
B: Prioritisation of substances

A basic tiered system…



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B: Prioritisation of substances

Where should the information come from – particularly for TIER 3?

- Supply chain/ business operators
  - Information on starting substances and other migrating substances via screening
  - Toxicological information, migration data, risk assessments
- EFSA (existing data and risk assessments)
- ECHA
  - Information on substances registered under REACH, substances under evaluation and those of concern, risk assessments on drinking water materials etc
  - Common data platform under development
- Member States
  - National lists and existing risk assessments
- One Substance One Assessment principle should apply
  - transparency and access to data

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Resulting information needs

- Risk assessment
  - transparent risk assessment TIER 3
  - one substance one Assessment
- Information in the supply chain
  - migratable substances
  - migration assessment
- Enforcement
  - data on risk assessment
  - presence of migratable substances

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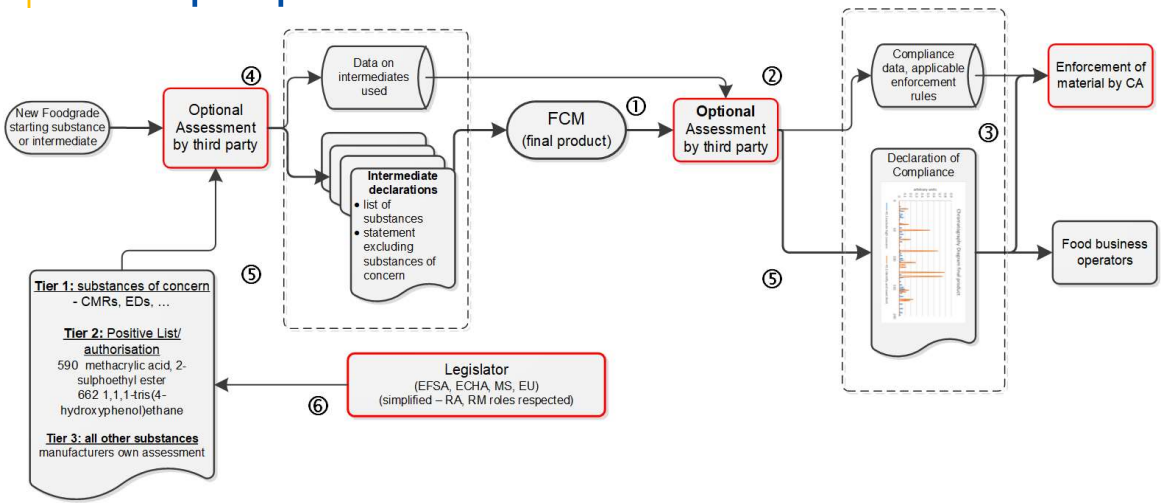
Example provided in Terms of Reference



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Information exchange, compliance and enforcement of FCMs

To verify safety, sustainability and ensure smooth functioning of the internal market

D. Improving quality and accessibility of supply chain information

- Clear and consistent rules on data requirements and information transfer throughout the supply chain, including a DoC for all FCMs
- Digitalisation to help businesses, including SMEs to ensure compliance and for Member States to enforce

E. System for verifying compliance and undertaking of official controls

- Delegated bodies under Official Control Regulation 2017/625
- Notified Bodies tasked with conformity assessment

F. Analytical methods

- Migration testing rules
- Analytical methods (i.e. for official controls)
- Further development of test methods and technical standards as required

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Organisation of the work on the Revision

- Most of the work done in house
  - Policy paper (delayed due to present implementation workload)
  - Specific working groups → define policy + provisions (delayed due to missing paper)
    - each group independent chairing expert + stakeholders

  → Refined policy paper which serves as basis for impact assessment and proposal
- Studies by contractors
  - Consumer perception (finished)
  - **Study on information exchange, compliance and enforcement**
  - Study on sustainability (starting)
  - Overall impact assessment

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Background of the study on information exchange, compliance and enforcement

- Study to develop options and to assess impact thereof:
  - to support IT infrastructure for information exchange
  - to verify compliance, controls, and the roles of different actors

    → develop options for under pillars D + E of the evaluation
- IT infrastructure for information exchange needed to facilitate
  - self-assessment of the risk of 'tier 3' substances
  - full knowledge on the identity and amount of all substances present in final FCMs
  - enforcement authorities to quickly understand the safety of FCMs

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Main objectives of the study – Terms of Reference

- Three options to be developed for an IT infrastructure, including how verification of compliance and controls can be carried out and the roles of the relevant actors
- Options to include are the following (modifications + sub-options possible)
  1. a centralised system – EU body principally responsible
  2. de-centralised system – MS responsible
  3. de-centralised system – businesses responsible
  - sub-options to investigate the use of supporting bodies (EU agency, MS CAs, notified bodies)
- Study to develop and describe the overall architecture
- Additional elements
  - consider feasibility, funding, and implementation pathways
  - compare feasibility and impacts
  - consider practical and efficient use (including security, intellectual properties, enforcement)
  - describe process of verification of compliance + roles and responsibilities
  - assess impact of information requirements on FCM operators, particularly SMEs

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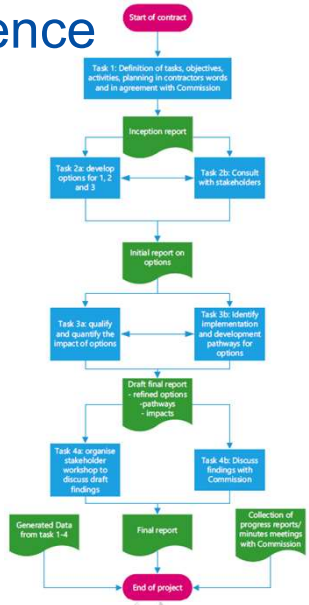
Tasks and reports – Terms of Reference

- Inception report, based on:
  - Task 1: definitions of tasks, objectives, activities and planning
- Initial report on options based on:
  - Task 2a: develop options
  - Task 2b: consult with stakeholders
- Draft final report (refined options, pathways, impacts), based on:
  - Task 3a: qualify and quantify the impact
  - Task 3b: Identify implementation and development pathways
- Final report, based on:
  - **Task 4a: stakeholder workshop to discuss draft findings**
  - Task 4b: discuss findings with Commission



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Validation workshop – todays activity

- This workshop is not a Commission workshop – it is organised by EY
  - to discuss findings of their study with participants
- Your views are important to the Commission
  - on the EY study
  - on the project as a whole
- At closure today we will discuss our intended follow-up

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closing session

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Conclusions

- Conclusions
  - Policy option 1 voted first: the industry asks the Commission to keep their data
  - We do now better understand the criteria by which to look at IT systems
  - However, we do not yet have concrete elements for a system
    - the 'system' is still very abstract
  - We do not really understand the impacts of the policy options
  - We do not really understand the role of enforcement
  - However, the 'system' is not necessarily considered 'science fiction'
- Limitations
  - Full future policy context not fully known columns A, B, C and F
  - Impact assessment cannot be fully achieved at this phase

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Organisation of the Revision

- Presently we are still in a preparatory phase
- Step 1: Real start of the work expected by the summer
  - publication of **policy paper** detailing elements for future FCM policy
  - most follow-up to be done in-house by Commission services
  - separate study on sustainable FCMs
- Step 2: work continues in working groups of experts to refine policy paper
  - chaired by independent experts
  - each working on specific topic – largely following the structure of the pillars
- Step 3: impact assessment based on refined policy paper
- Step 4: drafting of new Legal act based on the impact assessment

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Thank you

Happy to receive questions…

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