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Food contact materials Policy

These slides accompany the explanation of the acquis to Albania and North Macedonia and can only be used for that purpose. Their content is subject to further development of the acquis and interpretation by the Court of Justice of the European Union

DG SANTE, Unit E2

What is a Food Contact Material ('FCM')?

- *Any material:*
  - **intended to be brought into contact with food**
  - **already in contact with food and intended for that purpose**
  - **can reasonably be expected to be brought into contact with food or to transfer constituents to food under normal or foreseeable conditions of use**
  - **not only packaging**

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EU legislation - objectives

- *Food Safety: FCMs must not*
  - **endanger human health**
  - **bring about an unacceptable change in the composition of the food**
  - **bring about a deterioration in the organoleptic characteristics**
- *Internal market: effective functioning*
  - **no barriers to trade**

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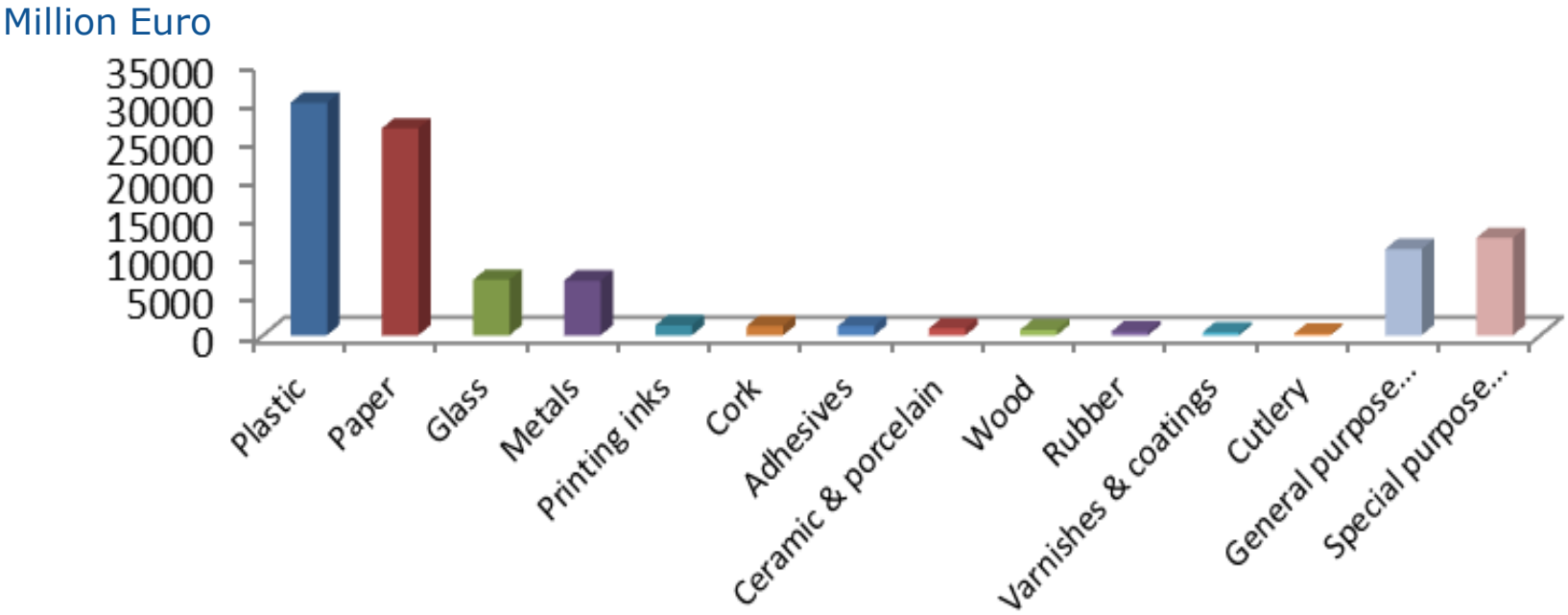
EU FCM market size is significant



- *~ 100 billion Euro*
  - **and directly affecting food market**
  - **plastics and paper & board biggest markets**
  - **most materials except glass, inks and varnishes & coatings show significant presence of SMEs**
  - **in general – Germany, France, Italy, UK, Spain and Poland leading suppliers**
  - **source JRC baseline study on non-harmonised FCM in the EU**

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Overview of FCM legislation

All FCM

Framework Regulation

(EC) No 1935/2004

General requirements for all FCM + Mandate for specific measures

➔

GMP Regulation

(EC) No 2023/2006

requirements for Good Manufacturing Practices

Applicable to all FCM

SPECIFIC MEASURES

Specific FCM

- *Materials*
  - **ceramics**
  - **regenerated cellulose film**
  - **plastics (R 10/2011)**
  - **recycled plastics**
  - **active and intelligent materials**

Substances

- **vinyl chloride monomer**
- **nitrosamines**
- **BADGE, BFDGE & NOGE**
- **BPA**

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Discussion Topics

- *Legislation applicable to all FCM*
  - **Regulation (EC) No 1935/2004 – FCM Framework**
  - **Regulation (EC) No 2023/2006 – Good Manufacturing practices**
- *Selected legislation applicable to specific FCM*
  - **Regulation (EU) No 10/2011 – plastic FCMs**
  - **Regulation (EC) No 282/2008 – recycled plastics**
- *Other matters*
  - **Other harmonised specific legislation**
  - **National legislation**
  - **Impact Assessment Ceramics**
  - **Evaluation**

- *Regulation (EC) No 1935/2004*

Framework regulation

FCM Framework

- *Regulation (EC) No 1935/2004*
  - **Basic Act**
  - **covers all FCMs**
- *Three main functions*
  - **general principles for FCMs - Definition**
  - **provides a basis for the specific measures**
  - **defines procedure for authorisation of substances**
- *Next slides: discussion of main provisions*

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Framework: Article 1-2

- *Scope and definitions*
- *It applies to all materials that are*
  - **intended for food contact** (e.g. kitchen and tableware)
  - **already in contact with food** (packaging)
  - **can reasonably be expected to be brought into contact**
  - **can transfer their constituents to food under normal and foreseeable conditions of use**

  '*direct food contact materials*' do not exist under EU rules!
- *It does not apply to*
  - **antiques, edible coating materials, water supply equipment**
- *'Food' is defined under General Food Law*
  - **Excludes feed, vegetables prior to harvest, drinking water**
  - **i.e. materials in contact are not FCM**

Framework: Article 3

- *Central provision of FCM legislation!*

Article 3

General requirements

1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

(a) endanger human health;

or

(b) bring about an unacceptable change in the composition of the food;

or

(c) bring about a deterioration in the organoleptic characteristics thereof.

2. The labelling, advertising and presentation of a material or article shall not mislead the consumers.

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Framework: Article 5 + 6

- *Basis for specific Union legislation on materials*
  - **the Commission can set out specific legislation for the materials defined in Annex I**
  - **the Commission can modify Annex I**
- *However, Article 5 also defines the tools*
  - **main tool: <u>positive list</u>**
  - **restrictions and specifications**
  - **rules for compliance and enforcement**
  - **rules for processes**
- *Article 6: if no EU legislation, National legislation may be maintained and adopted*

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Positive lists (‘Union List’)

- *The FCM approach is centred around positive lists*
- *Positive lists set out which substances are authorised to manufacture a material*
  - **all other substances may not be used**
  - **specific to a material – does not apply to other materials**
- *Combined with restrictions and specifications*
- *Positive lists in FCM legislation*
  - **plastics Regulation** (the main list ~1000 substances)
  - **regenerated Cellulose** (a bit forgotten, material hardly used)
  - **active and intelligent materials** (under construction)

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Framework: Article 7-14

- *Defines role of EFSA*
  - **application procedure for substance authorisations**
- *Role of Member States:*
  - **business operators apply to Member States**
  - **Member State send application EFSA**
- *Other roles of Member States:*
  - **may ask EFSA whether authorisation is still OK**
  - **must notify the Commission of address for applications**

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Framework: Article 15-17

- *Article 15: Labelling provisions*
  - **however, explicit labelling only required to indicate that an Article is suitable for food contact in case of potential doubt**
- *Article 16: Requirement for Declaration of Compliance*
  - **directed at legislator, not at business operators**
  - **specific measures must require a DoC**
  - **DoC's are the starting point for enforcement**
  - **also requires supporting documentation**
  - **specific rules set out in specific measures, e.g. see Article 15, 16 and Annex IV to Regulation (EU) No 10/2011**
- *Article 17: Traceability*
  - **requires that materials on the market are identifiable and traceable**

Framework: Article 18 National Safeguard measures

- *Article 6: if no EU legislation, National legislation may be maintained and adopted*
- *However, Article 18 allows a Member State to take a safeguard measure in case it has evidence an authorised material is safe*
  - **only on its territory, only temporary**
  - **Commission shall take action**

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Framework: Other Articles

- *Article 19-21: access, confidentiality and sharing*
  - **(application dossiers)**
- *Article 22-23: Committee procedure*
  - **adoption of specific measures, mainly Article 5**
- *Article 24-25:*
  - **Member States shall carry out official controls**
  - **Member States shall lay down rules on sanctions, and,**
  - **Member States shall ensure they are implemented, and,**
  - **sanctions must be effective, proportionate and dissuasive**

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- *Regulation (EC) No 2023/2006*

Good manufacturing practices (GMP)

Good Manufacturing Practices (GMP)

- *Lightweight Regulation*
  - **important consequences**
- *All FCMs must be produced under GMP*
- *Operators shall implement*
  - **quality assurance system**
  - **quality control system**
  - **documentation system**
- *Annex with specific rules on:*
  - **printing inks** (mainly to prevent off-set transfer)
  - **recycling processes**

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- *Regulation (EU) No 10/2011*

Plastic materials

Plastic Regulation: approach

(Regulation (EU) No 10/2011; Specific measure under Article 5 of framework)

- *Applies to all plastics for FCM*
  - **plastic: 'Polymer to which additives may have been added'**
  - **rubbers** (vulcanised polymers) **and silicones excluded**
- *Positive list: Plastics may only be manufactured from authorised*
  - **starting substances** (monomers, …)
  - **additives**
  - **derogations** (Art 6)**; Art. 19 requires risk assessment**
- *Generic requirements*
  - **substances shall be suitable** (Art. 8)
  - **substances shall only be in nanoform, if specifically authorised**
  - **materials subject to migration limits** (Art. 10, 11, 12)
  - **rules for multi layer materials** (Art. 13, 14)
- *Verification of compliance (with migration limits)*
  - **Article 17, 18, Annex III, Annex V**
- *Documentation requirements*
  - **declaration of Compliance** (Art. 15, Annex IV)
  - **supporting documentation**

Plastics Regulation: Union List

- *Union list (positive list)*
  - **most visible part of the Regulation, <u>but not the only part</u>**
  - **it lists starting Substances and Additives**
  - **only listed substances allowed for manufacturing FCM plastics**
  - **total listing about 900**
  - **EFSA assessment before authorisation**
- *Assumption:*
  - **safety of the final material determined by the regulated substances**
  - **what happens with them during processing is responsibility business operators**
- *Not subject to authorisation*
  - **colorants, polymer production aids** (solvents)**, aids to polymerisation** (catalysts)
  - **'NIAS' not intentionally added substances**

- *A: monomers*
  - **authorises monomers, not polymers or plastics**
  - **'starting substances'**
  - **e.g. ethylene, not polyethylene**
- *B: additives*
  - **including some polymeric additives (low mol. weight)**
- *C: polymer production aids*

- *no other substances*
  - **no polymers**
  - **no colours, catalysts, …**

(4)	(5)	(6)
Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)
albumin	no	yes
albumin, coagulated by formal-dehyde	no	yes
alcohols, aliphatic, monohydric, saturated, linear, primary (C_4-C_{22})	no	yes
mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60 % w/w) 2,4,4-trimethyl-hexane-1,6-diisocyanate	no	yes
trialkyl(C_5-C_{15})acetic acid, 2,3-epoxypropyl ester	no	yes
trialkyl acetic acid (C_7-C_{17}), vinyl esters	no	yes

Plastic Regulation: NIAS

- *'Not Intentionally Added Substances'*
  - **presence permitted in accordance with Article 6(4)(a)**
- *Big group of:*
  - **impurities, reaction & decomposition products, oligomers**
  - **cannot have a technical function in final material**
- *Operators shall do risk assessment (Article 19)*
- *Significant discussion*
  - **EFSA: to what extent should they be taken into account?**
  - **Business Operators: how really to do the risk assessment?**
  - **Competent Authorities: how to enforce?**

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Plastic Regulation: Enforcement

- *Enforcement requires expertise, main steps:*
- *1: Is there a declaration of compliance?*
  and does it show compliance?
- *2: Is it supported by supporting documentation?*
  and does that demonstrate compliance?
  is it complete? NIAS? Calculations? Migration?
- *3: Was it produced in accordance with GMP?*
- *4: Are applicable limits actually met?*
  test in Official laboratory
  sometimes only!

- *Compliance and safety cannot be established only on the basis of migration testing!*
- *Enforcement of FCM is not about testing of limits!*
  (only 250 substances subject to a specific SML)

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Plastic Regulation: Guidance

- *General Guidance (2014)*
  - **Subject matter, scope, definitions, substances, derogations**
  - **Multi-layer materials and articles**
- *Information in the plastics supply chain (2013)*
  - **Information to be generated and exchanged in the supply chain**
  - **Aim and content of the DoC, roles and obligations**
  - **What constitutes 'adequate information'**
- *Technical guidelines for compliance testing*
  - **Future notes will be published by JRC**

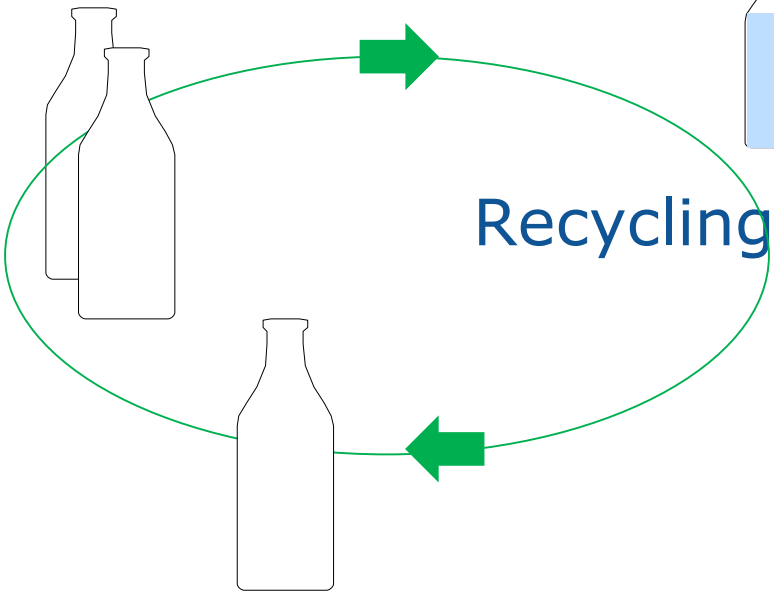
- *Regulation (EC) No 282/2008*

Recycling

Why Regulate recycled plastics?

"virgin" Plastic

Plastic compliant with Reg. 10/2011



⇨plastic packaging waste

residues/contaminants

- previous use (e.g. food, shampoo)
- "misuse" (e.g. paint, detergents)
- non-food use material (non-authorised substances)

Incidental Contamination

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‘Mechanical’ Recycling Process

- *Regulation on Recycled plastics for FCM*
  - **European Food Safety Authority (‘EFSA’) to evaluate the safety of the recycled plastic**
- *140 recycling processes have been evaluated*
  - **mostly PET recycling processes**
  - **Commission Authorising Decisions still required**

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Circular Economy and Plastic Strategy

- *Overlap with new key Commission environmental policy*
- *All plastic packaging must become 100% recyclable*
  - **this includes food packaging**
  - **25% obligatory recycled content by 2025 for PET beverage bottles**
- *'swiftly authorise recycling processes for food contact'*
- *Uptake of recycled materials must be increased*
  - **Trust + economics**
  - **But, not safe in contact with food? Not a FCM!**
- *Recycling important topic for next few years*

other Matters

Other FCM legislation

- *Ceramic Materials*
  - **Directive 84/500/EEC, sets out limits for lead and cadmium**
- *Active and Intelligent materials*
  - **Regulation (EC) No 450/2009**
  - **Need to establish a positive list**
  - **Applications on-going – implementation postponed**
- *Regenerated Cellulose Film*
  - **Directive 2007/42/EC**
  - **long positive list**
  - **material hardly used** (no activity)
- *Other measures:*
  - **Commission Regulation (EU) 2018/213 - on the use of bisphenol A in varnishes and coatings**
  - **Regulation 1895/2005/EC - restricting use of certain epoxy derivatives**
  - **Directive 93/11/EEC - release of N-nitrosamines and N-nitrosatable substances from rubber teats and soothers**
  - **Regulation EU No 284/2011 - kitchenware made of melamine or polyamide originating or consigned from China or Hong Kong**
    (obligatory import controls by competent authorities!)
- *See:*
  https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/legislation_en

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EURL - FCM

- *European Reference Laboratory for FCM*
  - **role defined in official feed and food control Regulation**
  - **Commission's Joint Research Centre**
  - **located in Geel (BE) and Ispra (IT)**

  https://ec.europa.eu/jrc/en/eurl/food-contact-materials
- *Tasks*
  - **ensure uniform application of control methods**
  - **assist national reference laboratories in their task**
  - **develop and maintain analytical methods**
  - **provide guidance, e.g. testing of kitchenware**
- *Yearly meeting of National Reference Laboratories*
- *Important Resource for Competent Authorities!*

BTSF courses on FCM

- *FCM is complex*
  - **this presentation covers only the surface**
- *'Better Training for Safer Food'*
- *e-learning*
  - **on-line course**
- *General course on FCM*
  - **presently taking place, still about 6 sessions**
- *Special course for recycling*
  - **being developed, late 2019, 2020**

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Non-Harmonised Materials

- *All materials not subject to EU legislation*
  - **e.g. paper and board, metals and alloys, adhesives, coatings, printing inks, rubber, glass, wood, cork, …**
  - **some aspects of plastics (colorants)**
  - **See Annex I to Regulation (EC) No 1935/2004 for 'complete' list**
- *National legislation applies, if it exists*
- *See our website*
  - **main explanation**

https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/non_harmonised_en

  - **JRC study**

https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/non-harmonised-food-contact-materials-eu-regulatory-and-market-situation-baseline-study

Ceramics: Impact Assessment

- *Ceramics Directive sets out limits lead + cadmium*
- *To protect health significant reductions may be required*
  - **Lead factor 1333 to 3 ppb** (or actually even lower)
  - **Cadmium factor 400 to 2 ppb**
  - **Other metals** (e.g. cobalt, chrome, nickel, aluminium)
  - **Also vitreous materials** (glass, and enamelled metals)
- *traditional and artisanal production particularly affected*
  - **traditional uses 'old' techniques**
  - **artisanal 'less' GMP**
  - (remaining) **European industry mostly traditional and artisanal**
- *Impact assessment before reduction of new limits*
  - **how to mitigate impact to traditional and artisanal produces**
  - **how to limit burden on other manufacturers**

FCM Evaluation: Background

- *FCM legislation is **40 years old** (Directive 76/893/EEC), and has **never been evaluated***
- *Old roadmap published in 2012 with options going forwards (withdrawn)*
- *Problems that are perceived today:*
  - *Materials other than plastic do not have specific rules at EU level*
  - *Artificial distinction of materials*
  - *Shifting priorities e.g. away from plastics to paper and board*
  - *Positive listing approach **slow and** does not focus on the safety of the final material*
  - *Risk assessment has become inefficient plus decreasing expertise*
  - *Information exchange in the supply chain is difficult*
  - *Demonstration of compliance and enforcement is lacking*
  - *Lack of coherence with other relevant legislation*

- ***Existing information sources***
  - *JRC Baseline report*
  - *DG SANTE work*
  - *Directorate F audits*
  - *European Parliament INI report*
  - *EFSA opinions*
  - *Other COM fitness checks, evaluations*
  - *Correspondence from stakeholders*
  - *Feedback on the evaluation roadmap*

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FCM Evaluation: Timeframe

- ***Roadmap*** *November 2017*
- ***First ISSG*** *February 2018*
- ***Publication of evaluation webpage*** *May 2018*
- ***Procuring contractor to undertake study*** *Current*
- ***Undertaking stakeholder consultation activities***
  September 2018 – June 2019
    1. **Targeted interviews**
    2. **Surveys** mainly targeting SMEs
    3. **Focus Group meetings** gathering specific expertise
    4. **Workshops** September 2018 and June 2019
    5. **Case studies**
    6. **12 – week public consultation** Beginning 2019
- ***Publication of final report and dissemination activities***
  September 2019 onwards
- ***Drafting and adoption of SWD*** *September 2019 – Jan 2020*

Provides a basis for the Commission "to consider what, if any, possible steps need to be taken in the future concerning the regulation of FCM in the EU"

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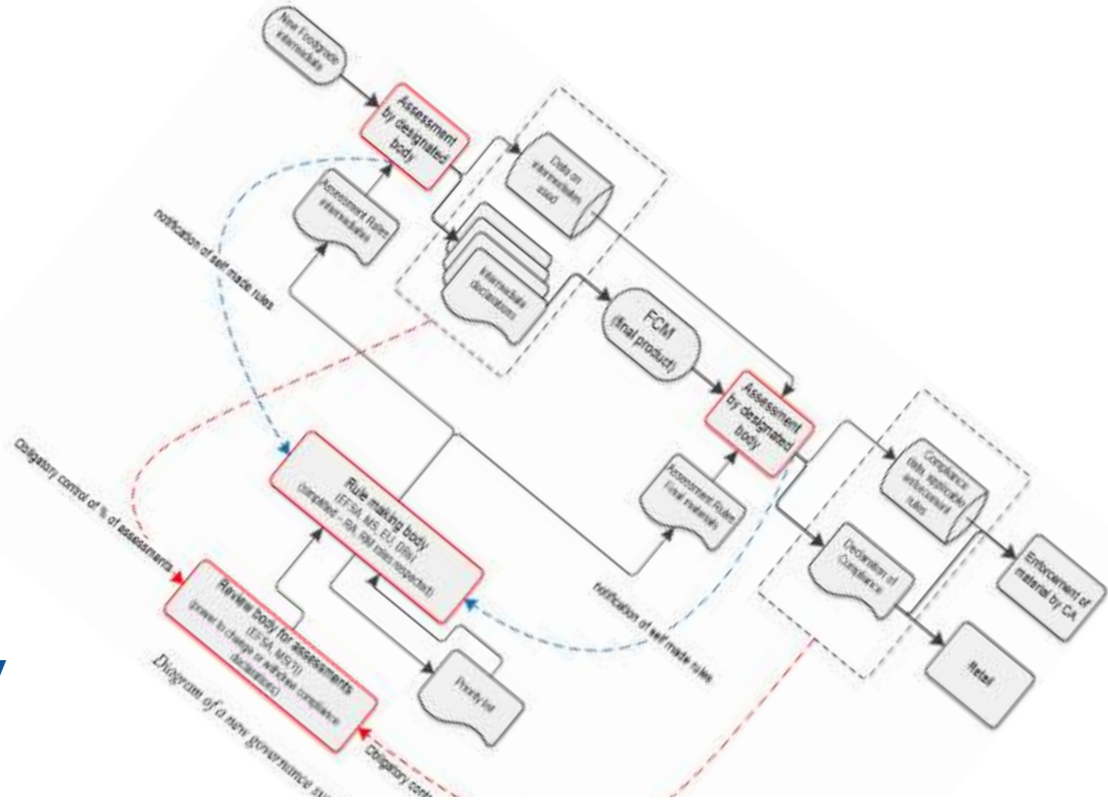
2020 onwards

- *Discussion on Future ways to Regulate FCMs*
  - **Maintain the present approach**
  - **Find another way**
- *Likely Topics*
  - **Harmonisation + Simplification**
  - **Risk Assessment responsibility of industry versus authorities**
  - **third party**
  - **Better use of REACH/ECHA**
  - **Transfer of information in the supply chain**
  - **Availability of data**
  - **Enforcement**

Based on outcome of evaluation



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