



# **40 years of Food Contact Materials legislation: The current intervention and evaluation process**

**Stakeholder Workshop on the  
Evaluation of Food Contact Materials Legislation  
24 September 2018**

**European Commission  
DG SANTE**

**This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion and understanding of existing legislation and the evaluation process, but should not in anyway be seen as giving a final interpretation of existing legislation or a proposal of new legislation.**

# 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**



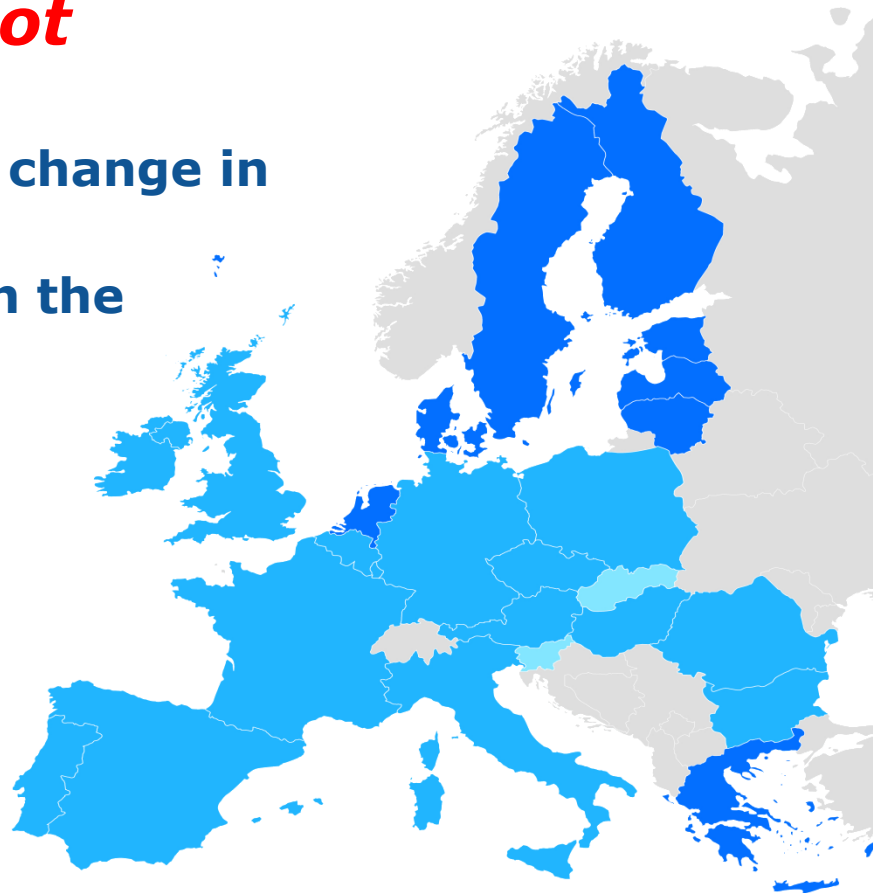
# EU FCM legislation – purpose

*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**



# EU FCM legislation – milestones



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# Legislation applicable to all FCMs

## ***'Framework' Regulation (EC) No 1935/2004 sets out general rules and procedures***

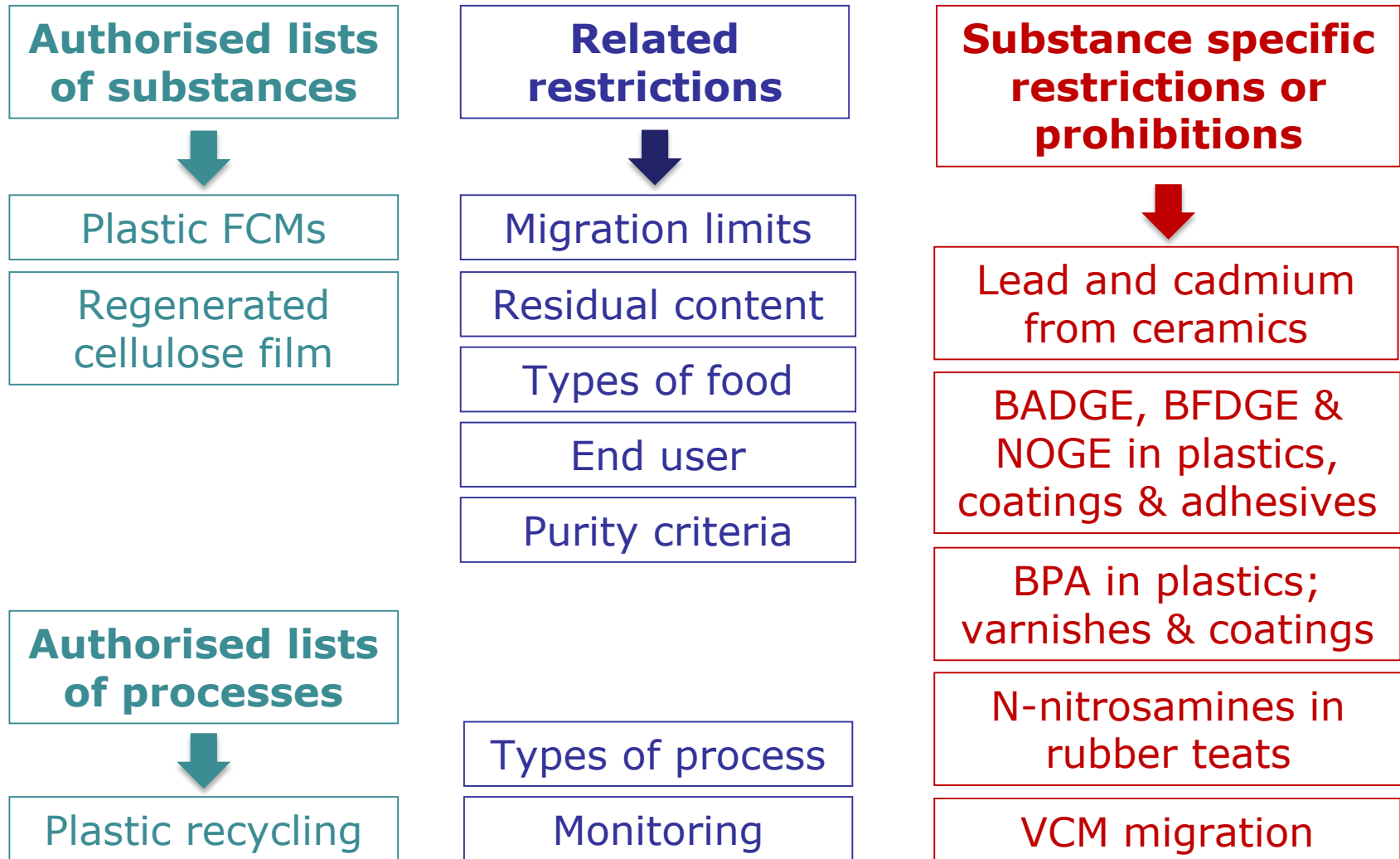
- Allows for specific EU measures or national provisions
- Procedures for authorising substances inc. role of EFSA
- Requirements on specific measures, e.g. Declaration of Compliance
- Special requirements for active and intelligent materials
- Definitions, traceability and labelling requirements
- Obligations on Member States



## ***Commission Regulation (EC) No 2023/2006 requires Good Manufacturing Practices for all FCMs***

- ✓ Quality assurance system
- ✓ Quality control system
- ✓ Documentation

# Specific measures applicable in EU



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# Risk management of substances

**Starting substances and additives risk assessed by EFSA**

**Only those listed can be used to manufacture a [plastic] FCM**

**Typical restrictions include**

- Limitation to a certain kind of plastic or food
- Specific Migration Limit (SML)
- Overall Migration Limit for all plastic FCMs

**Derogations in Article 6 and 14**

- Polymer production aids, solvents, salts, some polymeric additives, aids to polymerisation
- Not intentionally added substances - Impurities, reaction + decomposition products, includes oligomers must be risk assessed in accordance with internationally recognised principles
- Functional barrier concept

**Declaration of compliance and supporting documentation**

**Subject to rules on verification of compliance**

# Materials not subject to specific EU measures

**13/17: Paper and board, adhesives, rubbers, printing inks, glass, metals, wood, cork, varnishes and coatings, ion-exchange resins, silicones, textiles, waxes**

## *Article 6*

### **National specific measures**

In the absence of specific measures referred to in Article 5, this Regulation shall not prevent Member States from maintaining or adopting national provisions provided they comply with the rules of the Treaty.



# Evaluation of FCM legislation: Why?

- **FCM legislation is over 40 years old and has not been evaluated**
- **Some issues that are perceived today:**
  - Questions over materials other than plastic that do not have specific rules at EU level
  - Questions regarding the current approach for plastic FCMs
    - Positive authorised lists
    - Risk assessment approach
    - Information exchange in the supply chain
    - Verification of compliance
    - Enforcement
  - Coherence with other relevant legislation

***Need to substantiate perceived problems and how legislation is functioning with concrete documented evidence, transparency and accountability***

# The EU Policy Cycle



**Strengthened evaluation process –  
evaluate first before revising legislation**

# Evaluation types

## PROSPECTIVE

### *Ex-ante & Impact Assessment*

Before the intervention

Identify problems

Define objectives

Analyse expected effects of different options

Outline monitoring and (retrospective) evaluation arrangements



**Forward-looking**

## RETROSPECTIVE

### *Evaluations and Fitness Checks*

During or after implementation

Analyse provisional and actual effects and lessons learnt

Assess what works, what does not and why

*"Evaluate first"*



**Backward-looking**

# Definition

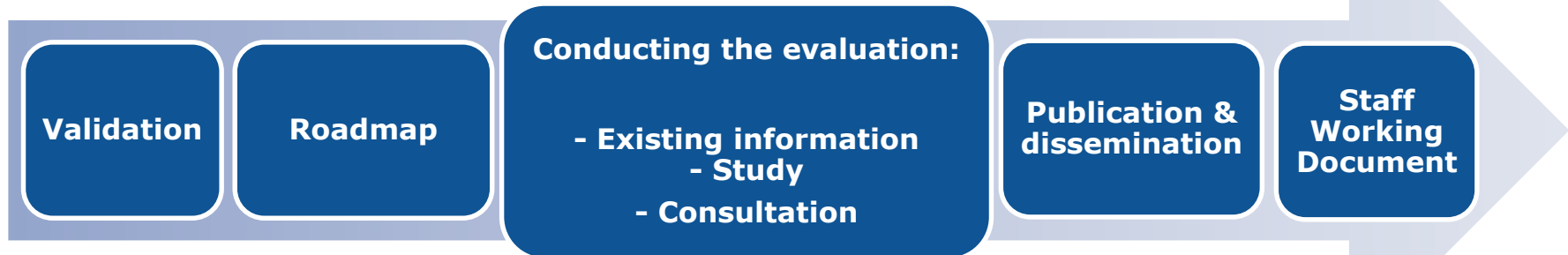
## What is evaluation?

It is an **evidence-based judgement** of the extent to which an intervention has been effective and efficient, relevant given the needs and its objectives, coherent both internally and with other EU policy interventions, and achieved EU value added

## Key elements

- ↘ Takes a critical look
- ↘ *Independent* and objective judgement based on evidence
- ↘ Also looks at unintended or unexpected changes
- ↘ Not what has happened but why and *how much* has changed
- ↘ Looks for evidence of causality

# Evaluation of FCM legislation: Timeframe



- ✓ **Validation**
- ✓ **Roadmap** open for comments from 28 November to 26 December 2017. 30 feedbacks received, reaffirming the existence of a number of perceived issues in relation to the functioning of the Regulation. All comments are available at [https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429\\_en](https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429_en)
- ✓ **Publication of evaluation website** May 2018  
[https://ec.europa.eu/food/safety/chemical\\_safety/food\\_contact\\_materials/evaluation\\_en](https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/evaluation_en)
- **Study** to support evaluation July 2018 → September 2019
- **Consultation** main part: September 2018 → September 2019
- **Publication and dissemination activities** October 2019 →
- **Staff Working Document** early 2020



# Available information: Feedback on the Roadmap

- Need for harmonisation of national measures
- Information flow along the FCM supply chain are not effective
- Technological and scientific developments in the area of FCM should be taken into account
- Transparency and traceability should be better ensured;
- More attention should be placed on the final article not starting substances
- Alternative approaches to risk assessment and management of substances may be considered
- EFSA capacity to cope with substance authorisation is limited;
- Better coordination with other chemical legislations (REACH) and EU policies (circular economy); address specific substances e.g. EDC
- Participation of stakeholders, including civil society must be ensured throughout the evaluation process.



# Available information: Other Commission initiatives

- DG SANCO [SANTE] surveys of Member States and European Professional Organisations carried out 2012 – 2013
- DG SANTE Fact-finding and audits to Member States 2017-2018
- Fitness Check on General Food Law
- Fitness Check on the most relevant chemicals legislation
- The second REACH Review (REACH REFIT Evaluation)
- Single Market Strategy: Improving the principle of mutual recognition
- Strategy for plastics in the circular economy including the interface between chemical, product and waste legislation
- Refit of the Drinking Water Directive 98/83/EC
- Evaluation of the Toy Safety Directive 2009/48/EC

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# Available information: Other EU initiatives

- European Implementation Assessment report on Regulation (EC) No 1935/2004, European Parliament
- Position papers and correspondence provided by Professional European Associations, individual businesses, Member States Competent Authorities and other stakeholders including NGOs.
- EFSA CEF Panel Scientific opinion on recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials
- Report of EFSA ESCO WG on non-plastic FCM

# Further information

## *DG SANTE, Unit E2*

FCM Evaluation web-page:

[https://ec.europa.eu/food/safety/chemical\\_safety/food\\_contact\\_materials/evaluation\\_en](https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/evaluation_en)

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