State of play of Food contact materials

Advisory Group

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

OVERVIEW

The legislation

- **Framework, GMP, specific measures (focus on plastic)**

State of play

- **evaluation of FCM**
- **recycled plastics**

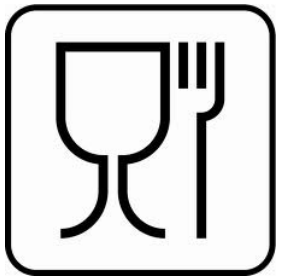
EU legislation – rationale

Food safety: Food contact materials 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**



What is a food contact material?

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**

Framework Regulation

(Regulation (EC) No 1935/2004)

Fully harmonises FCM

- **Article 3: Must not endanger human health!**
- **Commission can adopt specific measures on materials**
- **Member States can otherwise adopt national provisions**

Sets out general procedures and rules

- **requirements on specific measures, e.g. Declaration of Compliance**
- **definitions, traceability and labelling requirements**
- **requirements for active and intelligent materials**
- **procedures for authorising substances, role of EFSA**
- **obligations on Member States: safeguard measures, official controls, and sanctions**

Requires Good Manufacturing Practices for all FCM

legislative overview

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**
- **Recycled plastics**
- **Active and intelligent Materials**

Substances

- **Vinyl chloride monomer**
- **Nitrosamines**
- **BADGE, BFDGE & NOGE**

Framework Regulation (EC) No 1935/2004

SPECIFIC MEASURES

POSITIVE LISTS

called 'Union Lists' in legislation

Positive list of plastic monomers and additives

Positive list of substances in regenerated cellulose film (cellophane)

Authorization of plastic recycling processes

RESTRICTIONS OF USE

Migration limits in plastics

Leaching limits for cadmium and lead ceramics

Nitrosamines limits in rubber teats and soothers

BADGE limits in plastics, coatings and adhesives

Residual content of substances in plastics or cellophane

PROHIBITION OF USE

BFDGE and NOGE in plastics, coatings and adhesives

Bisphenol A in infant feeding bottles

Certain Phthalates in FCM intended for infants & young children

Substances which are not on a Positive lists that are not covered by a derogation

Regulation (EC) No 2023/2006 on Good Manufacturing Practice (GMP)

It requires the presence of

- **a quality assurance system**
- **a quality control system**
- **and a documentation system**

At all manufacturing stages, for all FCM

- **except for starting materials (chemicals)**

Specific GMP rules for printing inks and plastic recycling

STATE OF PLAY

Present Activities

Evaluation of the FCM legislation

- **ex-post evaluation**
- **concerns the functioning of the present legislation**

Recycling

- **140+ recycling Decisions to be taken in 2018**
- **other plastics**

Other activities

- **Authorisation of new substances under R 10/2011**
- **printed FCM**
- **ceramics**

EVALUATION

Why FCM Evaluation?

FCM legislation is 40 years old legislation (Directive 76/893/EEC), and has never been evaluated

*Recent work provides **preliminary evidence** on the functioning of the Regulation, particularly in relation with:*

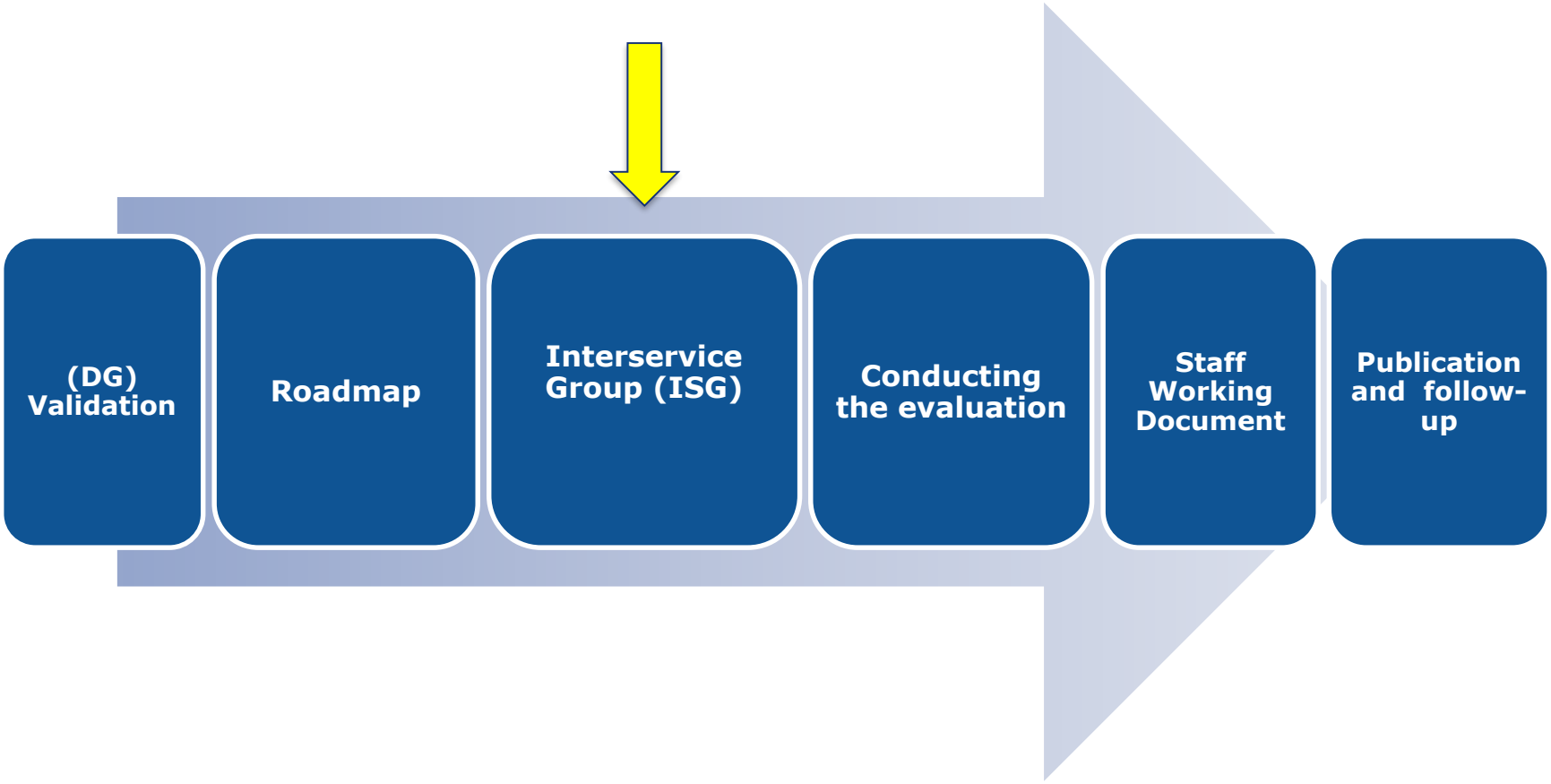
- *Non-harmonised (JRC study)*
- *Positive listing approach*
- *List of materials (Annex I Reg. (EC) 1935/2004)*
- *Risk Assessment*
- *Information exchange in supply chain*
- *Enforcement*
- *Coherence with other EU legislation (e.g. chemicals)*

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

***Retrospective FCM evaluation aimed at**:*

- *analysing provisional and actual effects of the Regulation and lessons learned.*
- *assessing whether the current EU legislative framework for FCM is fit for purpose and delivers as expected.*
- *providing 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.*

The Evaluation Process



Current and next steps

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*

Terms of Reference *for a study to support the evaluation – now being finalised. Discussed on 28 February 2018 in the first Interservice Group meeting.*

The **objective** of the study is to provide for **solid quantitative and qualitative data** and comprehensive **analysis** on the functioning of the FCM legal framework.

The study will feed into the ***SWD*** *containing the full evaluation work, including evidence based conclusions and possible recommendations.*

Conducting the Study

4 phases foreseen:

- ***Inception*** *- definition of research strategy and methodology*
- ***Data collection*** *- desk and field research (stakeholder consultation)*
- ***Analysis*** *of all information collected*
- ***Synthesis*** *- drawing conclusions*

Stakeholder Consultation

As a minimum, the Stakeholder Consultation will take the form of:

1. **Targeted interviews addressed to:**
    1. MSs' Authorities, including enforcement bodies and control laboratories;
    2. Businesses including specifically SMEs and microbusinesses
    3. Scientific experts in the field of FCM (e.g. EFSA, analytical laboratories, etc.)
    4. Consumer representatives
    5. NGOs
2. **Surveys** mainly targeting SMEs
3. **Focus Group meetings** gathering representatives from the Commission, the MSs and the Industry, as well as scientific experts in the field of FCM, NGOs and consumer groups;
4. **Workshops;**
5. **Case studies;**
6. **12 – week public consultation**

Staff Working Document

*The SWD will be delivered by the Commission at the end of the evaluation communicate the **results and conclusions** of the evaluation:*

- to policymakers, helping to inform their decision-making and
- to stakeholders, sharing the method, evidence base and analysis used for the evaluation.

It will provide:

- A description of the **intervention** (refined intervention logic) and the **current situation**
- A description of the adopted **methodology**, assumptions, limitations and robustness of findings;
- **Analysis** and answers to the evaluation questions addressing the **5 evaluation criteria** of effectiveness, efficiency, relevance, coherence and EU-added value.
- Main **conclusions** drawn from the evaluation identifying possible steps for the improvement of the current legal framework for FCM.

It will present stakeholder views and explain how these have been considered throughout the evaluation.

RECYCLING

Circular Economy and Plastic Strategy

Plastic packaging must become 100% recyclable

- **This includes food packaging**

Uptake of recycled materials must be increased

- **Trust**
- **Economics**

Safety very important for sensitive applications

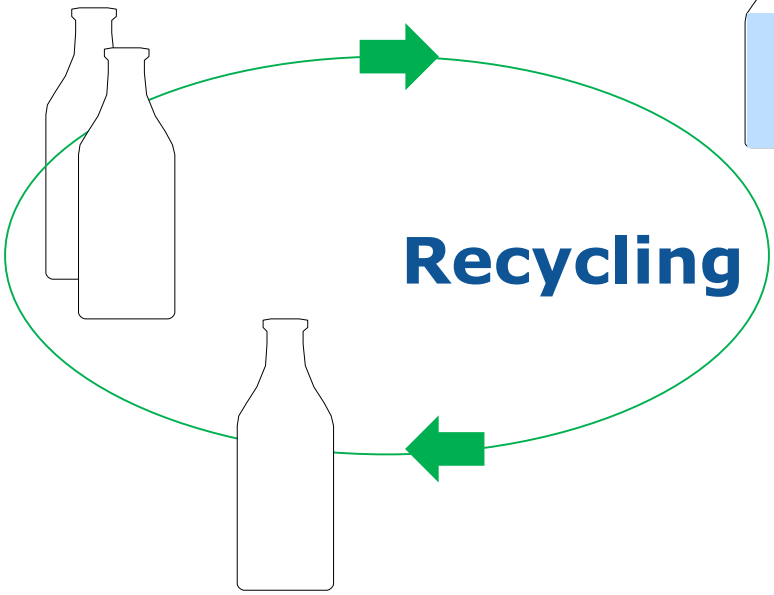
- **it is a constraint: Not safe? Not a FCM**

Incidental contamination

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

Recycling Process

Restrictions on Input, Process, output:

- **Input: source of the plastic, washing, shape (d)**
- **Process: unit operations, critical steps, parameters (e)**
- **Output: max percentage, conditions of use (f, g)**

In addition prescriptions on monitoring (h)

(letters refer to Article 6(3) of Regulation (EC) No 282/2008)

Potential Change:

Obligatory monitoring of incidental contamination

What?

- **to determine analytically the occurrence of contaminants in uncleaned and cleaned flakes**
- **central data collection**
- **only recurring contaminants to be identified**

Why?

- **to have a practical grasp of the contaminant level in view of a changing market**
- **to inform risk assessment**
- **to enforce**
- **to (eventually) improve and standardise waste collection**

What about the burden?

- **it is uptake that is important to us, and trust therefore**
- **less burden on collection systems and paper trails**

Implementation of the Recycling Regulation (R 282/2008)

Authorisation decisions on >140 recycling processes

- **EFSA opinions available**
- **by end of 2018**

Ensure high level of safety of recycled plastic FCM

- **safety should be achieved in practice**

The Decisions will be simple

- **rely on EFSA opinion, and dossier**
- **support self-assessment by operators**
- **compliance monitoring summary sheet**

Minimise restrictions on collection systems

- **only if really needed and enforceable**

Future

Focus towards Non-PET:

- **Work with EFSA and industry to increase recyclability**
- **Commission will be pro-active**
- **Focus on polyolefins**

Standardisation of waste streams

- **Achieve a standard for 'food grade waste'?**
- **Lower burden, higher safety**

Monitor shifts to other materials

- **Paper and board might not be safer, just not yet harmonised**

Bottom line: Safety first

OTHER ACTIVITIES

Other Activities

Ceramics:

- **Work in progress**

Printed FCM:

- **Work in progress**

Plastic materials:

- **Only authorisations on-going**

QUESTIONS?