



Regulating FCM

EUPC Food Contact Plastic Seminar

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OVERVIEW

The legislation

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

Current initiatives

- **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

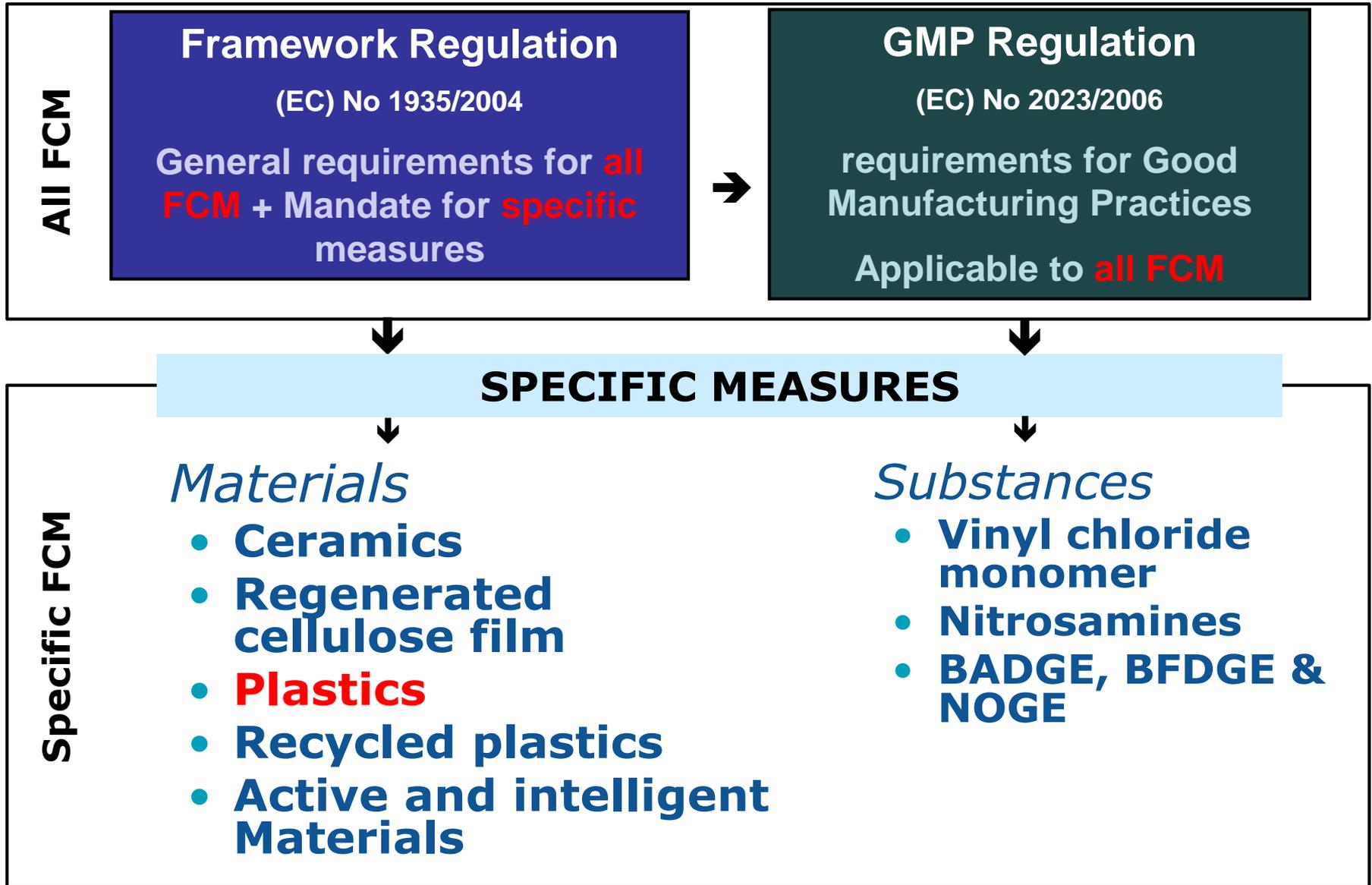
- **Article 3: Must not endanger human health!**
- **Commission can adopt specific measures on materials**
- **Member States can otherwise adopt national provisions**

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



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

Plastics Regulation (Regulation (EU) No 10/2011)

Important provisions:

- **scope**
- **suitability**
- **authorisations for individual substances → Union List**
- **compositional requirements (including migration limits)**
- **derogations**
- **testing procedures**
- **declaration of compliance + supporting documentation**
- **risk assessment**

Substances

Regulation (EU) No 10/2011 requires authorisation

- **Starting Substances and Additives**
- **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**
- **Oligomers**

Documentation

DoC

- to declare compliance with rules set out in Regulation
- must include adequate information needed for downstream business operators to determine compliance

SD

- documents why compliance could be declared

Applicable to the whole FCM production chain

- From, but excluding, starting substances
- To, but excluding, retail

See

- Article 15, 16 and Annex IV to the Regulation
- Guideline on information in the supply chain

EU Guidance on plastic FCMs

EU Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

- **Published February 2014**

Subject matter, scope, definitions, substances, derogations
Multi-layer materials and articles
Compliance, supporting documents and migration testing
Repeals and transitional periods

EU Guidance on information in the plastics supply chain

- **Published November 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

- **Publication expected soon**

Do not forget our website:

- https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials_en

PRESENT ACTIVITIES

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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**

Ceramics

Other activities

- **Authorisation of new substances under R 10/2011**
- **Regulation 284/2011 (imports from China and HK)**
- **Biocides**
- **printed FCM**

EVALUATION

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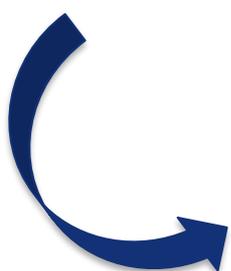
Why FCM Evaluation?

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)*

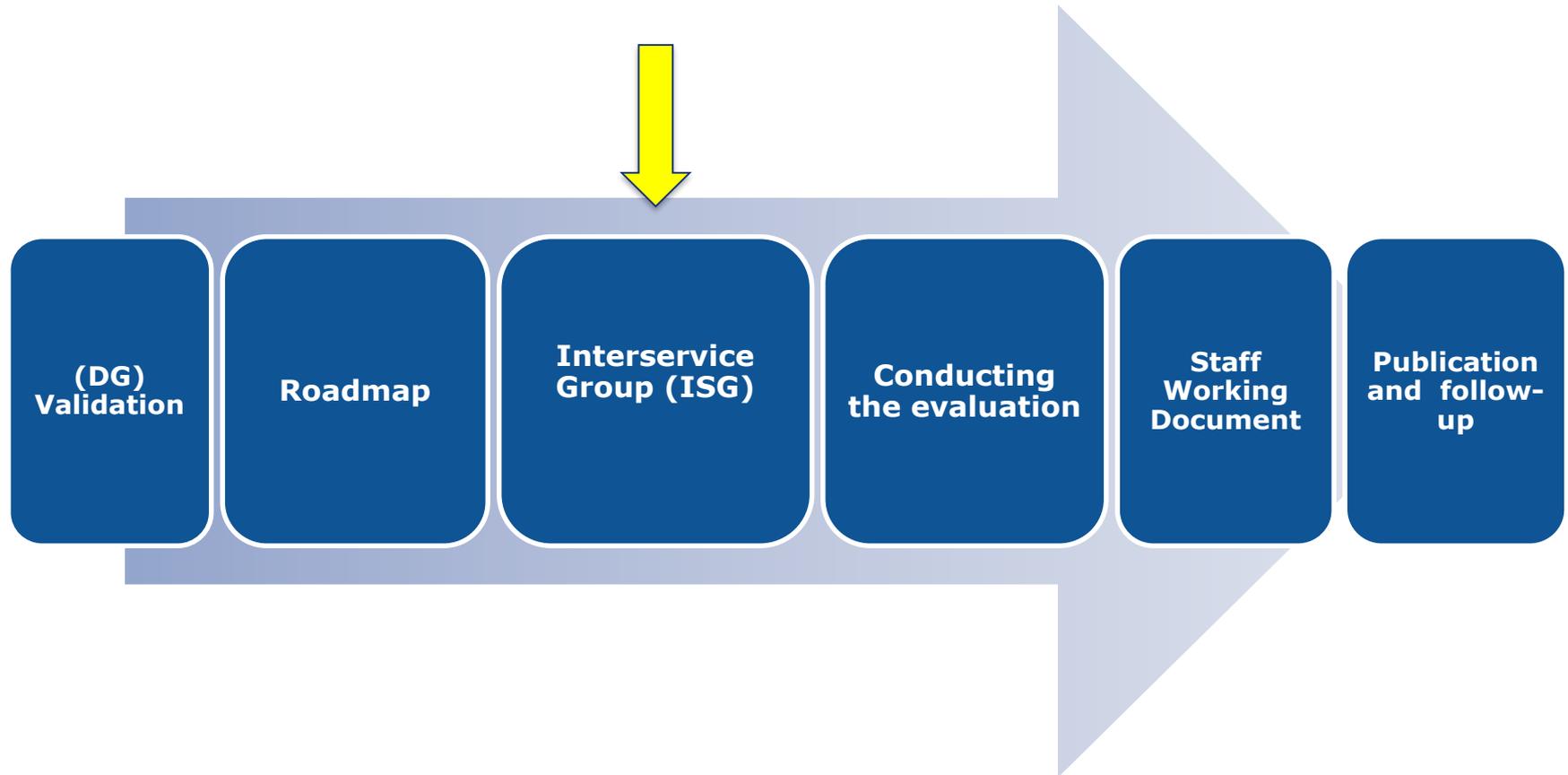
Need to substantiate perceived problems and how legislation is functioning with concrete documented evidence, transparency and accountability.



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

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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

Incidental Contamination

Unpredictable presence of potentially toxic and unidentified substances originating from

- **production of plastics (e.g. decomposition products)**
- **the use phase (e.g. a pesticide)**
- **misuse (e.g. paint thinner stored in a PET bottle)**
- **cross-contamination during collection (e.g. leaking fluid)**
- **used non-FCM plastics (e.g. non-FCM additives)**

Limited knowledge

- **risk assessment therefore very conservative**
- **leads to burdensome restrictions**

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**

Obligatory monitoring of incidental contamination

Obligatory monitoring is presently being considered to be potentially required for all authorised recyclers

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**

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**

OTHER MATTERS

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Please read our legislation

It is directed at you!

- We do an effort to keep it readable
- In all languages

Interpretation is not difficult

- interpret as is written
- do not read what you think it should say
- use the definitions provided

recitals may help you

- Only Articles are legally binding
- recitals help you to understand the rationale and interpretation by the legislator

Use a consolidated version with caution

- Once amendments enter into force the Commission will update the overall text and provide it as a consolidated version
- No recitals, not necessarily fully correct, just a tool
- No transitional provisions

Do not use our substance database, it is outdated!

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- (7) The Authority adopted a favourable scientific opinion (7) on the use of the mixture of methyl-2-branched and linear C₁₆-C₁₈ alkanamides, derived from fatty acids (FCM substance No 1065 and CAS No 83711-28-0). The Authority concluded that the substance is not of a safety concern for the consumer if used in the manufacture of polyolefin articles intended for contact with all foodstuffs other than fatty foods (as defined by simulant D2) and when its migration does not exceed 5 mg/kg food. That mixture should therefore be included in the Union list of authorised substances with the restriction that these applications should be met.
- (8) Annex I to Regulation (EU) No 10/2011 should be amended accordingly.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed.

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 10/2011 is amended in accordance with the Annex to this Regulation.

Article 2

Plastic materials and articles complying with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation, may be placed on the market on 19 February 2019 and may remain on the market until exhaustion of stocks.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This text is meant purely as a documentation tool and has no legal effect. The Union's institutions do not assume any liability for its contents. The authentic versions of the relevant acts, including their preambles, are those published in the Official Journal of the European Union and available in EUR-Lex. Those official texts are directly accessible through the links embedded in this document.

► **B** COMMISSION REGULATION (EU) No 10/2011
of 14 January 2011
on plastic materials and articles intended to come into contact with food
(Text with EEA relevance)
(OJ L 12, 15.1.2011, p. 1)

Amended by:

		No	page	date
► M1	Commission Implementing Regulation (EU) No 10/2011 of 14 January 2011			2.4.2011
► M2	Commission Regulation (EU) No 1282/2012 of 20 November 2012	L 338	11	10.12.2012
► M3	Commission Regulation (EU) No 1183/2012 of 30 November 2012	L 338	11	12.12.2012
► M4	Commission Regulation (EU) No 202/2014 of 3 March 2014	L 62	13	4.3.2014
► M5	Commission Regulation (EU) No 865/2014 of 8 August 2014	L 238	1	9.8.2014

Consolidated Version

The screenshot shows the homepage of the Food Contact Materials database. The page includes a navigation menu with links for Welcome, Homepage, Substances, Categories, Group Restrictions, Legislation, Documents, Notes, and Reports. The main content area features an introduction, a 'Getting started' section with links to various guides, and a disclaimer. A large red 'X' is superimposed over the entire screenshot, indicating that the database is outdated and should not be used.

Our website: your first source of information

https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials_en

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European Commission

FOOD

European Commission > Food Safety > Food > Chemical safety > Food Contact Materials

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CHEMICAL SAFETY

- Contaminants
- Residues of Veterinary Medicines
- Hormones in Meat
- Pesticide Residues
- Food Contact Materials**
 - Legislation
 - Authorisations
 - Non-harmonised
 - Consultation
- FCM Document Library

[Expand All]

Food Contact Materials

Brexit

Notice to stakeholders withdrawal of the United Kingdom and EU Food Law

Food comes into contact with many materials and articles during its production, processing, storage, preparation and serving, before its eventual consumption. Such materials and articles are called **Food Contact Materials (FCMs)**. Food contact

Amendments to Regulation (EU) No 10/2011

Regulation (EU) 2017/752 - amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

Regulation (EU) 2016/1416 - amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

The amendments below only amend Annex I of **Regulation (EU) No 10/2011**, thus changing the Union list of authorised substances.

- Commission Regulation (EU) 2018/213 - on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials
- Regulation (EU) 2018/79 - plastic materials and articles intended for contact with food amending Regulation (EU) No 10/2011
- Regulation EU 2015/174 - plastic materials and articles intended for contact with food amending Regulation (EU) No 10/2011
- Regulation EU 202/2014 - plastic materials and articles intended for contact with food amending Regulation (EU) No 10/2011
- Regulation EU 1183/2012 - plastic materials and articles intended for contact with food amending Regulation (EU) No 10/2011
- Corrigendum to Regulation EU 1183/2012 - plastic materials and articles intended for contact with food amending Regulation (EU) No 10/2011.
- Regulation EU 1282/2011 - plastic materials and articles intended for contact with food amending Regulation (EU) No 10/2011
- Regulation EU 321/2011 - restricting Bisphenol A use in plastic infant feeding bottles

Share

RELATED LINKS

- Multi-language versions of brochures and guidance

RELATED DOCUMENTS

- 28 February 2018: Technical expert seminar on the preparation of the UK withdrawal in the SPS area - food and Water
- Questions & Answers on IPA
- EU guidelines on conditions and procedures for the import of polyamide and melamine kitchenware originating in or consigned

II. EU legislation on specific materials

In addition to the general legislation, certain FCMs — ceramic cellulose film, plastics (including recycled plastic), as well as materials — are covered by specific EU measures. There are some starting substances used to produce FCMs.

- Plastic Materials**
- Active and Intelligent Materials
- Recycled Plastic Materials
- Ceramics
- Regenerated Cellulose Film



Organisation

Head of Unit

- **Mr Bruno Gautrais**
- **(note, our unit covers also food additives, novel foods and contaminants)**

Our present team:

- **Jonathan Briggs (Evaluation, Biocides, general matters)**
- **Takis Daskaleros (Plastics, 50% on novel foods)**
- **Marianna Paolino (China measure, Biocides, other projects)**
- **Bastiaan Schupp (Recycling, Ceramics, general matters)**

Support:

- **Agnieszka Turek (legal matters, confidentiality)**
- **Angele Aquilina (administrative matters, secretary)**

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QUESTIONS?

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