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Legislation – Food Packaging – EU - Framework Regulation

The Food Contact Materials Framework Regulation (EC) No 1935/2004 provides a harmonised legal EU framework, has legal status in all Member States and covers all materials in contact with food, including packaging. It sets out the general principles of safety and inertness for all FCMs in relation to human health, providing further powers to enact specific EU measures for specified materials and articles. It lays down the procedure to perform safety assessments of substances used to manufacture FCMs as well as rules on labelling, compliance documentation and on traceability. In general terms food packaging legislation covers the guiding principle that food packaging should not transfer materials to the packaged food in quantities that could bring about a change in the nature, substance or quality of the food and must not be injurious to health.

The principles set out in Regulation (EC) No 1935/2004 require that materials do not:

- Release their constituents into food at levels harmful to human health
- Change food composition, taste and odour in an unacceptable way

Moreover, the framework provides:

- for special rules on active and intelligent materials (they are by their design not inert)
- powers to enact additional EU measures for specific materials (e.g. for plastics)
- the procedure to perform safety assessments of substances used to manufacture FCMs involving the European Food Safety Authority (EFSA)
-  rules on labelling including an indication for use (e.g. as a coffee machine, a wine bottle, or a soup spoon) or by reproducing the appropriate symbol
- for compliance documentation and traceability

Inertness

Article 3 of the Framework Regulation requires that food contact materials must not transfer their constituents to food in quantities which could endanger human health. Further details are not specified in the Regulation, although this is taken into account during EFSA's safety assessment of substances. In addition, the specific measures envisaged for individual groups of materials (see below), may include limits on migration, special conditions of use and purity requirements.

Article 3 also requires that packaging must not change the organoleptic properties in an unacceptable way. Measurements can be made in accordance with European Standards EN 1230-1 and EN 1230-2. A European Standards Agency (CEN) technical report (TR 15645) provides additional information regarding calibration of these sensory tests.

Traceability

Regulation (EC) No 1935/2004 requires traceability of food contact materials at all stages. The requirements can be summarised as follows:

- The traceability of materials and articles shall be ensured at all stages to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.
- With due regard to technological feasibility, business operators shall have in place systems and procedures to allow identification of the businesses from which and to which food contact materials and articles and, where appropriate, substances or products used in their manufacture, are supplied. That information shall be made available to the competent authorities on demand.
- The materials and articles which are placed on the market in the European Union shall be identifiable by an appropriate system which allows their traceability by means of labelling or relevant documentation or information.

Specific measures

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

These specific measures for groups of FCMs may include:

- A list of authorised substances
- Purity standards
- Special conditions of use
- Specific limits on migration of certain substances
- An overall migration limit
- Other rules to ensure compliance

<u>List of groups of materials and articles which may be covered by specific measures</u>

1.	Active and intelligent materials and articles
2.	Adhesives
3.	Ceramics
4.	Cork
5.	Rubbers
6.	Glass
7.	Ion-exchange resins
8.	Metals and alloys
9.	Paper and board
10.	Plastics

11.	Printing inks
12.	Regenerated cellulose
13.	Silicones
14.	Textiles
15.	Varnishes and coatings
16.	Waxes
17.	Wood

Declaration of compliance

The specific measures require that FCMs be accompanied by a written declaration stating that they comply with the rules applicable to them. Appropriate documentation to demonstrate such compliance shall be made available to the competent authorities on demand.

Enforcement

Enforcement of compliance with FCM legislation is the responsibility of the Member States. Their competent authorities check the documentation held by FCM producers, visit their premises and collect samples there or on the market to perform laboratory tests. At Member State level, the National Reference Laboratories (NRLs) assist in this task while the European Union Reference Laboratory for Food Contact Materials provides scientific and technical assistance to the NRLs.

Transparency

The Framework Regulation was amended by Regulation (EU) No 2019/1381 on the **transparency** and sustainability of the EU risk assessment in the food chain with effect from 27 March 2021. The new rules will improve the transparency of the EU risk assessment regarding food and cover a wide range of products of great concern for citizens. The Regulation will strengthen the reliability, objectivity and independence of studies submitted to EFSA and give a greater role to Member States in EFSA's governance. Early on in the EU risk assessment process all submitted scientific studies and data will proactively be disclosed to the public. In addition, and to identify whether other relevant scientific data or studies are available, EFSA will consult the public and all other partners involved before preparing its scientific output. When studies have been commissioned to support a future EU-wide authorisation application or notification, the concerned business operators and laboratories must notify these studies to EFSA at pre-submission phase. This measure is to guarantee that companies applying for authorisations submit all relevant information and do not hold back unfavourable studies.

More information on FCMs can be found on the European Commission's website at: http://ec.europa.eu/food/food/chemical safety/foodcontact/index_en.htm
including links to all the relevant legislation, and on the European Food Safety Authority's website at: https://www.efsa.europa.eu/en/topics/topic/food-contact-materials.
Further information on the general and specific EU FCM legislation can be found on the FCM legislation page:
https://ec.europa.eu/food/food/chemical-safety/food-contact-materials/legislation_en

Evaluation and review of current legislation

The first Directive 76/893/EEC on food contact materials (FCMs) applicable in the EU was introduced in 1976 and rules on FCMs have been in place ever since. Since the inception of its basic provisions set out over 40 years ago, the EU legislation on FCMs has never been evaluated. Several concerns have been expressed regarding the existing approach to regulating FCMs at EU level, including the listing of authorised substances, approaches to risk assessment and risk management, information flow and compliance in the supply chain, enforcement, and coherence with other EU legislation. Furthermore, the lack of EU specific rules beyond plastic FCMs is considered by many stakeholders to negatively impact the correct functioning of the internal market and moreover the possible safety of FCMs. Consequently, the European Commission **announced an evaluation** of the current EU legislative framework for FCMs.

The final report on **the evaluation of the EU food contact materials legislation** was published on July 1st 2020. The evaluation by the consultancy *Ecorys* focused on five criteria, namely effectiveness, efficiency, relevance, coherence, and EU added value provided by the current legislation, and will serve as input in the development of a Commission Staff Working Document. The overall evaluation is expected to be completed in early 2022, including dissemination activities and preparation of the Staff Working Document. Work on the postponed printed food contact materials measure is not expected to commence until after this study is finished. The report makes several important conclusions:

1. The persistence of national requirements for non-harmonised substances creates a burden for companies, especially SMEs.
2. Resources allocated to risk assessment, risk management and enforcement are insufficient.
3. There are particular concerns regarding the feasibility of establishing positive lists for all material groups. Resources are lacking and the costs could be prohibitively high.
4. It is estimated that between 7,000 and 9,000 substances would need to be assessed, representing total costs above EUR 256 million for the public sector and up to EUR 5 billion for industry.
5. With the current resources available at the European Food Safety Authority (EFSA), it would take between 140 and 360 years to perform all the necessary risk assessments.
6. It is very unlikely that it will be possible to establish positive lists of authorised substances for all food contact materials (FCM).
7. There is a need for a legislative framework that stimulates innovation along the entire food supply chain.

The Commission also asked Member State Competent Authorities to conduct new sample tests on certain substances migrating from food contact materials and articles, and to report any data generated within the past five years. This **request** is to assist the Commission in determining the prevalence of substances migrating into food from food packaging and whether further regulatory action may be needed, for example, additional control measures for substances leaching from plastic FCMs. The information may also contribute to setting priorities for other materials, which currently lack specific EU measures.

Following publication of the evaluation report as part of the ongoing review and revision of European Union (EU) food contact material (FCM) legislation, the European Commission has published an **Inception Impact Assessment** (IIA) road map. Two options are to be evaluated – either revise the current regulatory framework (with Regulation (EC) 1935/2004 as the cornerstone) or create a new regulatory framework to replace the current Regulation. The Commission proposes that the regulation should:

- shift the focus onto final food contact article rather than the starting substances
- include a three-tier system to prioritise the most hazardous chemicals used in FCMs
- use a generic assessment for tier one substances
- incorporate 'essential use' criteria into the assessment
- develop an approach to support and guide business operators in their assessment of more benign (tier three) substances
- streamline and consolidate enforcement with clear and consistent rules on data requirements and information transfer throughout the supply chain

The European Printing Ink Manufacturers' trade association (EuPIA) and the Packaging Ink Joint Industry Task Force (PIJITF), amongst 300 others, provided **feedback** to the public consultation, in particular, emphasising that the priority should be on the timely development of further specific measures for non-harmonised materials, especially printed FCMs, and such specific measures should incorporate industry risk assessment for non-listed substances.

A further consultation on the Commission's proposals is expected, with adoption of the new legislation currently planned for the end of 2022. The European Printing Ink Association, EuPIA, and the Printing Ink Joint Industry Task Force (PIJITF) will continue to work with the European Commission to ensure that **new legislation** addresses these issues, whilst being workable and protecting consumer safety.

The information contained herein is based on data believed to be up-to-date and correct at the time writing. It is provided to our customers in order that they are able to comply with all applicable health and safety laws, regulations, and orders. In particular, customers are under an obligation to carry out a risk assessment under relevant Good Manufacturing Practices (GMP) in line with legislation and as a result take adequate measures to protect consumers.