

Assessing the Compliance of Food Contact Materials

All Food Contact Materials (FCM) need to comply with Regulation (EC) No. 1935/2004, also called the FCM Framework Regulation.

Each section of this diamond represents one of the main requirements included in the FCM Framework Regulation. Ensuring that a product complies with them is necessary to guarantee that the product is legally compliant and safe to be used as a FCM.

When assessing the compliance of an **FCM** remember these **four questions**:





Is it safe?

Article 3 of Regulation (EC) No 1935/2004 requires that food contact materials (FCMs) must be sufficiently inert so that substances do not migrate into food in quantities large enough to

- Endanger human health
- Bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties (taint)

Business operators using an FCM should be able to demonstrate its safety before placing it on the market. This can be done by means of risk assessment, migration testing, mathematical modelling, checking compliance with specific legislation, etc. Proof of the safety and compliance of the FCM with the applicable legislation should be made available to enforcement officers upon request



Is it properly labelled?

Article 15 of Regulation (EC) No 1935/2004 sets out the rules for the labelling of FCM. It states that all FCMs that are not yet in contact with foodstuffs must be accompanied by

- a) The words 'for food contact', b) a specification as to their use or c) the cup and the fork symbol. This is mandatory unless they are clearly intended to come into contact with food
- If necessary, special instructions to be observed for safe and appropriate use (such as the type of foods they can be in contact with, the temperature and time of storage, etc)
- The name or trade name and the address or registered office of the manufacturer, processor or seller responsible for placing the product on the EU market
- Adequate labelling or identification to ensure traceability of the material or article as described in Article 17

This information must be conspicuous, clearly legible and indelible. This information must be given in a language easily understood by purchasers.

Where can this information be displayed?

Retail stage	<ul style="list-style-type: none"> - On the materials and articles or their packaging - On labels affixed to them or their packaging - On a notice in their immediate vicinity provided that it is clearly visible to purchasers
All other marketing stages	<ul style="list-style-type: none"> - On the accompanying documents. - On the labels or packaging - On the materials or articles themselves

Exception: the name or trade name and address of the manufacturer, processor or seller should always be placed on the product or a label affixed to it unless this is impossible for technical reasons in previous stages of manufacture (e.g., product too small to bear the information in a legible way).



Is it traceable?

According to Article 17 of Regulation (EC) No 1935/2004 FCMs are subject to traceability requirements. These are similar to the requirements for traceability of food as laid down in Article 18 of Regulation (EC) No 178/2002. Traceability of FCMs should be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.

To comply with the requirements, business operators must have systems and procedures in place that allow correct identification of the businesses from which and to which FCMs are supplied.

Once the FCM has been used to package the food, the FCM and the food becomes one food product and the traceability requirements apply to it as a whole. Traceability of FCMs is required up to the retail stage but does not extend to the final consumer.



Is it covered by a specific measure?

According to Article 5 and Article 16 of Regulation (EC) No 1935/2004, additional legislation may be in place for some types of FCMs; these are referred to as specific measures.

These specific measures require FCMs to be accompanied by a written Declaration of Compliance (DoC) stating that they comply with the rules applicable to them. To date, the following types of FCMs have specific measures. Use the word **CAPER** to remember which types are subject to additional legislation.

C	Ceramics - Council Directive 84/500/EEC
A	Active and Intelligent FCMs - Regulation (EC) No 450/2009
P	Plastics - Regulation (EU) No 10/2011 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 Recycled plastics - Regulation (EC) No 282/2008
E	FCMs containing Epoxy substances - Regulation (EC) No 1895/2005 Teats and soothers made of rubber or elastomers - Commission Directive 93/11/EEC
R	Regenerated cellulose - Commission Directive 2007/42/EC