

Food Contact Materials

What is a Food Contact Material?

Any material intended to come into contact with food, that is already in contact with food, or that can reasonably be expected to come into contact with food, is considered to be a food contact material (FCM). This includes packaging materials, cutlery, dishes, containers, processing machinery, cutting boards, etc. Materials and articles which are in contact with water intended for human consumption from the point at which they enter a food business premises, are also considered to be food contact materials. All FCMs can potentially contaminate food by transferring substance into it so FCMs have to be made and used so that they don't cause unsafe levels of contamination (FCMs also have to be used hygienically – this is a requirement of food hygiene legislation).

Types of FCM

There is a wide range of FCM types. The following list illustrates examples of the most common types of FCMs:

1. **Active and intelligent materials (AIM) and articles:** These articles are either designed to improve shelf-life, maintain or improve the condition of packaged food or to monitor its condition
2. **Adhesives:** Adhesives have a wide range of uses in food contact materials, from sticking labels to food, to being used to hold together layers of plastic to create multilayer materials
3. **Ceramics**
4. **Cork**
5. **Glass**
6. **Ion-exchange resins**
7. **Metal and alloys**
8. **Paper and board:** Food businesses should ensure that in addition to packaging that is made of paper/ cardboard, all other paper products that may come into contact with food during food production, e.g. paper towels used to dry food or on which food is placed during production, also need to meet the requirements of food contact materials legislation, including the composition of any dyes etc. that may have been used in their manufacture
9. **Plastics**
10. **Printing inks and colours**
11. **Regenerated cellulose**
12. **Rubbers**
13. **Silicones**
14. **Textiles**
15. **Varnishes and coatings**
16. **Waxes**
17. **Wood**

Applicable Legislation

General measures

All food contact materials fall within the scope of two European pieces of legislation:

- Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food, also known as the Framework or FCM Regulation
- Regulation (EC) 2023/2006 on good manufacturing practices for materials and articles intended to come into contact with food, also known as the GMP Regulation

Therefore, any material considered to be a FCM will need to comply with this legislation.

Regulation (EC) No 1935/2004

The principle underlying this Regulation is that any material or article intended to come into contact with food should be sufficiently inert to preclude substances being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition or a deterioration in the organoleptic properties of the food, i.e. a taint in the food. Regulation 1935/2004 requires that FCMs are manufactured in compliance with good manufacturing practice. It also specifies labelling and traceability (one step forward and one step back) requirements for FCMs.

Regulation (EC) No 2023/2006

Regulation 2023/2006 lays down the rules on good manufacturing practice (GMP) that apply to all groups of materials and articles intended to come in contact with food. The list of FCMs covered by this Regulation includes the FCM listed in Annex I of Regulation (EC) No 1935/2004 and combinations of these FCMs, or recycled materials used in them.

This Regulation applies to all sectors and stages of manufacture, processing and distribution of materials and articles, but not the production of starting substances.

Specific measures

The Framework Regulation allows for specific measures to be adopted for the groups of FCMs mentioned above and so far, such specific measures have been put in place for four of the different material types, namely:

- Plastics and recycled plastics
- Active and intelligent food contact materials
- Regenerated cellulose
- Ceramics

Specific measures have also been put in place for FCM containing certain epoxy substances and for teats and soothers made of rubber or elastomers.

These FCMs need to comply not only with the Framework and the GMP Regulations but also with their specific measures, which can contain detailed restrictions on the manufacture and use of FCM.

Other Resources and Guidance

When a specific Regulation has not been adopted for a particular FCM, other documentation can be available to serve as guidance, such as:

- Guidance documentation or other specific legislation produced by food safety agencies from Member States or the EEA countries, the European Commission or by the European Food Safety Authority
- Policy statements by the Council of Europe
- Guidance documents produced by industry
- European and international standards (EN, ISO)

Guidance documents may also be available for FCM already covered by a specific Regulation in order to help better understand its implementation.

European legislation on FCM and other available resources are summarised in Table 1.

Who certifies compliance?

A company placing a product on the market is responsible for the safety and compliance of that product. Therefore, before placing it on the market, the company needs to gather enough information and documentation to be able to demonstrate that their product is safe and complies with all applicable legislation.

National bodies in Ireland such as the Food Safety Authority of Ireland do not certify compliance. Instead, they work to ensure that companies are placing safe products on the market by means of audits and inspections. When a non-compliant product is found, they may require it to be withdrawn from the market.

Food companies have a responsibility to ensure their FCMs, particularly food packaging, are:

- Clearly labelled and supplied as FCM
- Traceable back to their supplier
- Used in accordance with manufacturers' instructions
- Used in compliance with the legislation
- Used safely to ensure the food is not contaminated

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Table 1. European Legislation and Other Resources

TYPE OF PRODUCT/ CONTAINS	NEEDS TO COMPLY WITH			WHO CERTIFIES COMPLIANCE?		
	General Measures	Specific Measures and Guidances				
			Specific Regulations	Other Documents		
Active and Intelligent Materials and Articles	Regulation (EC) No 1935/2004	Regulation (EC) No 2023/2006	Regulation (EC) No 450/2009		Self-certification: A company placing a product on the market is responsible of the placing of that product. Therefore, before pacing it, the company needs to gather enough information and documentation to know and support without a trace of doubt that the product: <ul style="list-style-type: none"> • Is safe • Complies with all the regulations applicable to it 	
Adhesives	The principle underlying this Regulation is that any material or article intended to come into contact with food should be sufficiently inert to preclude substances to being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition or deterioration in its organoleptic properties. Regulation 1935/2004 is applicable to all FCM.	Regulation 2023/2006 lays down the rules on good manufacturing practice (GMP) that applies to all groups of material and articles intended to come in contact with food. The list of FCM covered by this Regulation includes the FCM listed in Annex I of Regulation (EC) No 1935/2004 and combinations of these FCMs or recycled materials used in them. This Regulation applies to all sectors and stages of: <ul style="list-style-type: none"> • Manufacture • Processing • Distribution Of materials and articles, but excludes the production of starting substances.				
Ceramics				Council Directive 84/500/EEC		
Cork						Council of Europe Policy Statement concerning cork stoppers and cork materials
Rubbers						Council of Europe Policy Statement concerning rubber products
Glass						Council of Europe Policy Statement concerning lead leaching from glass tableware into foodstuffs
Ion-exchange resins						Council of Europe Policy Statement concerning ion exchange and adsorbent resins in the processing of foodstuffs
Metals and alloys						Council of Europe Policy Statement concerning metal and alloys
Paper and board (including tissue paper and napkins)						None – but food businesses should ensure that in addition to packaging that is made of paper/cardboard, all other paper products that may come into contact with food during food production (such as paper towels used to dry food or on which food is placed during production) also needs to meet the requirements of food contact materials legislation, including the composition of any dyes etc that may have been used in its manufacture.

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TYPE OF PRODUCT/CONTAINS	NEEDS TO COMPLY WITH			WHO CERTIFIES COMPLIANCE?	
	General Measures		Specific Measures and Guidances		
			Specific Regulations	Other Documents	
Printing Inks	Regulation (EC) No 1935/2004	Regulation (EC) No 2023/2006	None – but see Annex I of Regulation (EC) No 2023/2006 for specific requirements for GMP for inks.	Council of Europe Policy Statement concerning packaging inks applied in the non-food contact surface area.	Self-certification: A company placing a product on the market is responsible for the placing of that product. Therefore, before placing it, the company needs to gather enough information and documentation to know and support without a trace of doubt that the product: <ul style="list-style-type: none"> • Is safe • Complies with all the regulations applicable to it
Plastics	The principle underlying this Regulation is that any material or article intended to come into contact with food should be sufficiently inert to preclude substances to being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition or deterioration in its organoleptic properties. Regulation 1935/2004 is applicable to all FCMs.	Regulation 2023/2006 lays down the rules on good manufacturing practice (GMP) that applies to all groups of material and articles intended to come in contact with food. The list of FCM covered by this Regulation includes the FCM listed in Annex I of Regulation (EC) No 1935/2004 and combinations of these FCM or recycled materials used in them. This Regulation applies to all sectors and stages of: <ul style="list-style-type: none"> • Manufacture • Processing • Distribution Of materials and articles, but excludes the production of starting substances.	Regulation (EC) No 10/2011	European Commission's Guidance on Regulation 10/2011 European Commission's Guidance on Information on the Supply Chain	
Recycled Plastics			Regulation (EC) No 10/2011		
Regenerated Cellulose			Regulation (EC) No 282/2008		
Silicones			Commission Directive 2007/42/EC	Council of Europe Policy Statement concerning silicone products	
Textiles					
Varnishes and coatings				Council of Europe Policy Statement concerning coatings	
Waxes					
Wood					
Products containing epoxy substances				Commission Regulation (EC) No 1895/2005	
Teats and soothers				Commission Directive 93/11/EEC	