

The Principal Legislation on Food Contact Materials

Regulation 1935/2004

The EU measure controlling all materials and articles intended to come into contact with food is European Parliament and Council Regulation (EC) No. 1935/2004, commonly referred to as 'The Framework Regulation'.¹ This Regulation is directly applicable to these materials in the UK.

This Regulation applies to materials and articles that:

- are intended to be brought into contact with food
- are already in contact with food
- can reasonably be expected to be brought into contact with food

Article 3 of this Regulation sets out the general requirement that all materials and articles shall be manufactured in compliance with 'good manufacturing practice' (GMP - as defined in Commission Regulation (EC) No. 2023/2006), so that under normal and foreseeable conditions of use they do not transfer their constituents to food in quantities which could:

- endanger human health; or
- bring about an unacceptable change in the composition of food; or
- bring about deterioration in the organoleptic characteristics (i.e. texture, taste, aroma)

Regulation 1935/2004 provides for specific measures to be adopted for particular groups of materials and substances. Specific measures currently exist for ceramics, plastics, plastic recycling processes for food contact use, regenerated cellulose film and epoxy resins. There are also provisions for the testing of vinyl chloride monomer.

Regulation 1935/2004 is directly applicable in the United Kingdom. However, national regulations² were made in each country of the UK to ensure the proper enforcement of the EU Regulation, to put in place offences and penalties for breaching it, and define what constitutes a competent authority, for the following European legislation:

- Regulation 1935/2004 – The Framework Regulation
- Regulation 2023/2006 – The 'Good Manufacturing Practice' Regulation
- Regulation 450/2009 – Concerning 'Active & Intelligent Materials'

¹ EU legislation on food contact materials including Regulation (EC) No. 1935/2004 can be found at the following website:

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm

² UK legislation can be found at the following website: <http://www.legislation.gov.uk>

- Regulation 10/2011 – Concerning food contact plastics

Regulation 1935/2004 is only applicable to expected or likely contact of recognised foods with the material or article in question. It is for enforcement authorities at the time of an inspection to determine whether any particular instance falls under the legislation.

The European Union's 'wine glass and fork' symbol can be used to indicate an item is suitable for food contact where it is not obvious. This is in Article 15 of Regulation 1935/2004. If there is the potential for doubt it is appropriate to have the wine glass and fork symbol.



Good Manufacturing Practice

Regulation 1935/2004 is reinforced by Commission Regulation (EC) No. 2023/2006, which requires businesses to establish and document good practices and procedures.

'Good Manufacturing Practice' (GMP) is the control and management systems that oblige manufacturers to take proactive steps to ensure that, during production, errors and problems in processes are minimised or eliminated. GMP for food contact materials expects companies to have in place a:

- 'quality assurance system' (a company needs pre-established instructions and procedures to maintain compliance during production);
- a 'quality control system' (which monitors that systems effectiveness);
- the proper documenting of production records. The whole production process should be carefully planned and controlled in order to secure compliance.

Good Manufacturing Practice will, for example, cover:

- Design stage considerations, so that problems are designed out at the onset, not only for the finished article but for the design of its manufacture.
- Contractual obligations to source appropriate materials
- Equipment and facilities
- The training and management of staff
- The production processes themselves
- Prevention measures to counter contamination
- Identifying and managing changes in pertinent legislation
- Segregation and disposal of non-conforming products
- Labelling and traceability, Record keeping and documentation
- Management of complaints – procedures for 'worst-case scenarios' such as product recall.

Packaging Hygiene

The hygiene provisions applicable to the wrapping and packaging of foodstuffs are laid down in Chapter X of Annex II of Regulation (EC) No 853/2004 of the European Parliament and the Council on the hygiene of foodstuffs. There are four requirements specific to packaging:

1. Material used for wrapping and packaging are not to be a source of contamination.
2. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.
3. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products. Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness is to be assured.
4. Wrapping and packaging material re-used for foodstuffs is to be easy to clean and, where necessary, to disinfect.

Packaging must also prevent foods from becoming contaminated or from deterioration (Chapter IX, point 1).