

Food contact regulations in the EU and their implications

While some progress has been made towards achieving harmonised EU food safety legislation, an examination of Regulation (EC) 1935/2004 is useful for understanding implications for gasket materials.

*By Francesca Torriani,
Chairwoman of ESA Flange
Gaskets Division*



Food safety is a central concern for both regulatory authorities and consumers across the European Union (EU). For this reason, with the publication of Regulation (EC) No. 1935/2004, the EU sought to establish a common Framework Regulation for materials and articles intended to come into contact with food, overcoming the differences that at the time existed between the national legislations of the various Member States. Despite the progress made and the introduction of several specific regulations linked to this Framework Regulation, a harmonised EU legislative framework covering all materials on the market has yet to be achieved. It is therefore useful to examine Regulation (EC) 1935/2004 and its related measures, in order to understand their implications for gasket materials.

Regulation 1935/2004

The principle underlying Regulation (EC) No. 1935/2004 is that any material or article intended to come into contact, directly or indirectly, with food must be sufficiently inert to prevent substances from being transferred to food in quantities large enough to endanger human health, or to cause an unacceptable change in the composition of the food, or a deterioration in its organoleptic properties. This principle is set out in Article 3, which also introduces the concept of good manufacturing practice (GMP). Further provisions are included

in Articles 15, 16 and 17, addressing labelling, declarations of compliance and traceability requirements.

Products that are not yet in contact with food when placed on the market must have labelling that includes: the words “for food contact”, the name or trade name and the address or registered office of the manufacturer, processor or seller responsible for placing the product on the market, an identification number to ensure traceability and, if necessary, special instructions to be observed for safe and appropriate use.

The traceability of materials and articles, by means of labelling or relevant documentation, must be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility. Such information must be made available to the competent authorities on demand.

Written declaration

It is also required that materials be accompanied by a written declaration stating that they comply with applicable rules relating to food contact materials. Appropriate documentation must be available to demonstrate such compliance and made available to the competent authorities on request. The declaration of compliance typically contains information on the identity of the producer or importer and of the recipient company, a description of the product and its composition (with particular attention to substances subject to

About the author

Francesca Torriani is the Head of the Technical Department at General Packing Italy SpA and Chairwoman of the ESA Flange Gaskets Division. She holds a degree in Energy Engineering from the Polytechnic University of Turin.



restrictions or dual-use additives), as well as the identification number that links the declaration to specific batches. The document also refers to the relevant legislation, indicates the intended conditions of use (for example, the type of food, contact times and temperatures), and bears the date, name and signature of the person responsible.

GMP for materials

In 2006, alongside the framework Regulation (EC) No. 1935/2004, Regulation (EC) No. 2023/2006 was introduced. This regulation lays down the rules on good manufacturing practice (GMP) for materials and articles intended to come into contact with food, as required by Article 3. GMP refers to those aspects of quality assurance which guarantee that materials and articles are consistently produced and controlled so as to comply with the applicable rules and meet the quality standards appropriate to their intended use, without endangering human health or causing unacceptable changes in the composition or sensory characteristics of food.

While the framework regulation envisages the adoption of specific safety rules for each material class (as implied in Article 3), to date, only some categories benefit from harmonised EU measures. For others, national legislation or industry standards continue to fill the gap, often resulting in a fragmented and non-uniform regulatory environment across Member States.



Regulation (EC) No. 2023/2006 lays down the rules on good manufacturing practice for materials and articles intended to come into contact with food.

For example, plastic materials are regulated by Regulation (EU) No. 10/2011, which sets specific requirements for the manufacture and marketing of plastic materials and articles intended to come into contact with food or which can reasonably be expected to do so. This regulation outlines the requirements on the composition of plastic materials and articles and establishes the contents of the Union list of authorised substances. It also details the procedures for migration testing and defines the limits within which compliance must be assessed, thereby ensuring the suitability of the material for food contact.

Rubber materials

The case of rubber materials is considerably more complex, since no EU regulation currently exists and national regulations remain the main reference. Each country applies its own approval schemes, safety requirements and testing protocols, often leading to significant differences, with notable examples including:

- BfR Recommendation XXI “Commodities based on natural and synthetic rubber”, BfR Recommendation XXI/1 “Commodities based on natural and synthetic rubber in contact with food” and BfR Recommendation XXI/2 “Special consumer goods made of natural and synthetic rubber and of lattices made of natural and synthetic rubber (formerly special category)” for Germany.
- Arrêté of August 5th, 2020 for France.
- D.M. 21/03/1973 for Italy.
- Royal Decree 847/2011 for Spain.

Advancing food safety

Although the points discussed here represent only a fraction of the complex regulatory

framework governing food contact materials, it is clear that EU legislation has undoubtedly advanced food safety by establishing clear principles and introducing specific rules for certain material classes. Regulation (EC) No. 1935/2004, together with its related measures, has provided a solid foundation for ensuring consumer protection, while instruments such as Regulation (EU) No. 10/2011 for plastics demonstrate how harmonised legislation can foster both safety and market consistency. However, the lack of a fully harmonised approach for all material categories, particularly for elastomers, creates significant challenges for manufacturers and end users. The coexistence of national legislations, often divergent in scope and testing requirements, increases complexity, raises compliance costs, and sometimes generates uncertainty in cross-border trade.

A common European framework covering all materials would not only enhance consumer safety but also streamline regulatory compliance for industry operators, promoting innovation and ensuring fair competition. Until such harmonisation is achieved, companies must continue to navigate a fragmented landscape, relying on a combination of EU regulations, national provisions and recognised industry standards.

References

- EC 1935/2004
- EC 2023/2006
- EU 10/2011
- Explanatory views on Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food – Plastic Europe
- Position paper Rubber materials in contact with food and drinking water – ETRma ■

