

EC1935/2004 Food Contact Materials



What is the EC 1935/2004 Regulation?

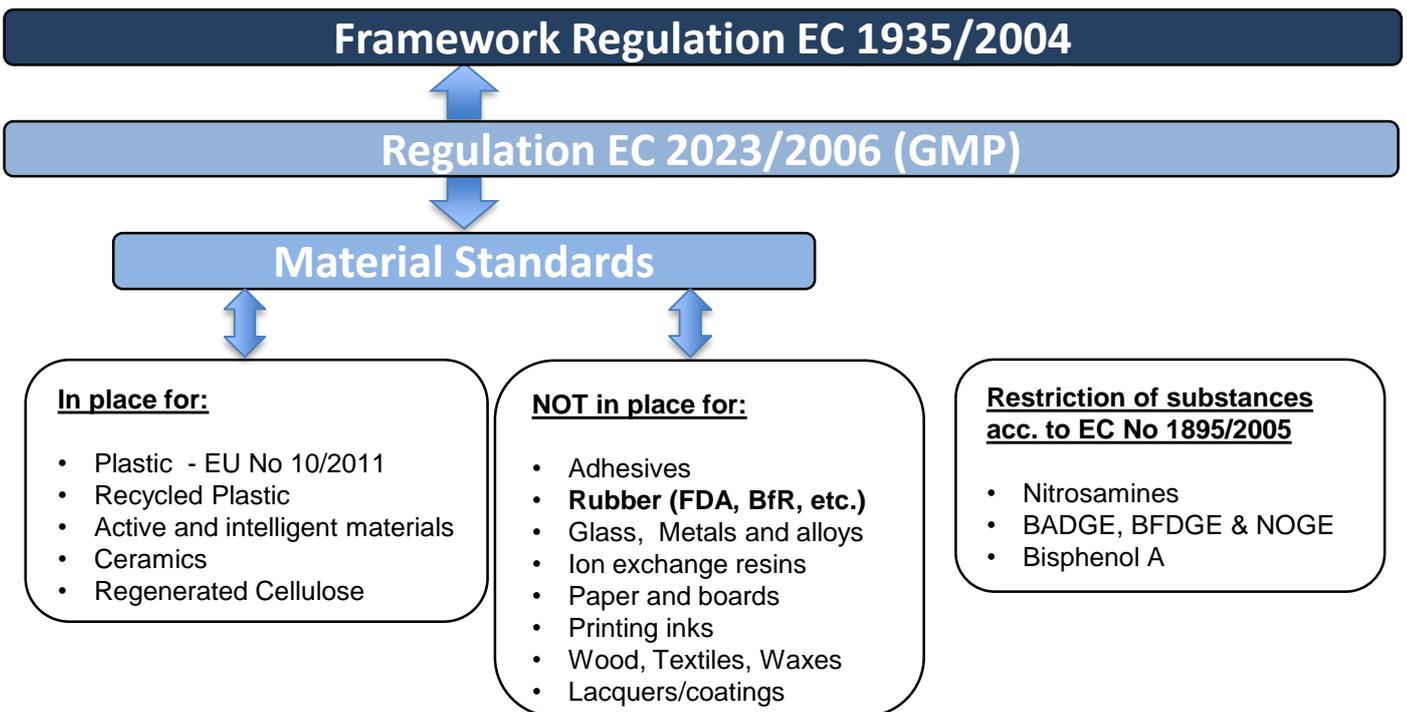
In the E.U. the general requirements for all Food Contact Materials are contained in Regulation EC 1935/2004, which is sometimes referred to as “**The framework Regulation**”. Conformity with the EC1935/2004 framework is a common requirement primarily in the Food industry. Beyond that, Rubber Fab recognizes an increasing demand for EC1935/2004 compliant product in the Pharmaceutical industry.

The Commission Regulation EC 1935/2004 provides a harmonized legal EU framework. It sets out the general principles of safety and inertness for all Food Contact Materials (FCMs).

The principles set out in Regulation EC 1935/2004 Article 3 require that materials do not:

- Endanger human health
- Change food composition, taste and odour in an unacceptable way
- Bring about a deterioration in the organoleptic characteristics thereof.

Structure of the Framework Regulation



Moreover, the framework provides:

- The scope of materials covered by the EC 1935/2004 can be found in Annex I of the regulation.
- Refers to Specific Measure EU 10/2011: It sets out rules on the composition of plastic FCMs (e.g. PTFE), and establishes a Union List of substances that are permitted for use in the manufacture of plastic FCMs. The Regulation also specifies restrictions on the use of these substances and sets out rules to determine the compliance of plastic materials and articles.
- Currently there is no specific measure for rubber materials on EU level, alternatively other measures (e.g. FDA, BfR) can be used to proof compliance with Article 3 of the framework regulation.
- Refers to Good Manufacturing Practices EC 2023/2006: Materials and articles shall be manufactured in compliance with good manufacturing practice. Article 17 is of practical relevance for compliance documentation and traceability of a material or article through all stages of manufacturing, processing and distribution.
- Refers to EC 1895/2005: Covers restriction of certain epoxy derivatives (e.g. Nitrosamines, Bisphenol A, BADGE, etc.) in materials and articles intended to come into contact with food.

Rubber Fab Products that comply with the EC 1935/2004 framework regulation

Rubber Fab offers a wide range of products and materials, that are in full compliance with the EC1935/2004 framework regulation, including EC2023/2006 (GMP) and EU10/2011. All products shown below are in full compliance with the applicable EU regulatory requirements and suitable for use in direct food contact applications:

Rubber Fab Tri-Clamp Gaskets:



Tuf-Flex®



Tuf-Steel®



GYLON® BIO-PRO PLUS™



GYLON BIO-PRO®

Rubber Fab **PTFE gaskets**, that are in full compliance with the applicable European Food Contact regulations include: Tuf-Flex®, Tuf-Steel®, GYLON BIO-PRO® PLUS and GYLON BIO-PRO®. All PTFE gaskets from Rubber Fab can be laser marked on demand. The marking may include the lot number for full and easy traceability.



Silicone - Platinum cured



FKM - Peroxide cured



EPDM - Peroxide cured

Rubber Fab **Elastomeric gaskets**, that are in full compliance with the applicable European Food Contact regulations include: Next Generation Silicone, Next Generation FKM and Next Generation EPDM. All Next Generation gaskets from Rubber Fab are laser marked by default. The marking includes the lot number and the material name for full and easy traceability.

Rubber Fab Hose Range



Rubber Fabs EU-Range of hoses is classified into two divisions, the Food & Beverage hoses and the Pharma hoses. All hoses from these product groups have EC 1935/2004 compliance and are therefore suitable for use in many applications. The EU range includes various materials such as Peroxide Cured EPDM, Platinum Cured Silicone, FEP, PFA, BIIR, NBR and Technopolymer. The hoses can also be easily traced, as the fittings can be engraved as well. Rubber Fab offers a pressure test of the hoses and a 3.1 certificate for Fittings. In addition, all tubes can be sterilized with the appropriate parameters for the material and are thus suitable for several production cycles without disassembly.