



Your expert for
FCM compliance
in the EU

Food Contact Materials in the European Union

Securing your regulatory compliance and
market access

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WE CARE FOR YOUR SUCCESS

DEFINITION OF FOOD CONTACT MATERIALS

Food contact materials (FCM) are materials and articles coming into direct or indirect contact with food during its production, processing, storage, preparation and serving.

This includes, but not limited to:

- Packaging and food transport containers
- Tableware and kitchen equipment
- Cutlery and dishes
- Food processing machines.

THE EU REGULATORY FRAMEWORK

In the European Union, the [EU Framework Regulation \(EC\) No 1935/2004](#) sets out the general principles of safety and inertness for all food contact materials.

According to these requirements, FCM are not supposed to:

- Release their constituents into food at levels harmful to human health or,
- Change food composition, taste and odour in an unacceptable way.

*Active and intelligent materials are applied to extend the shelf-life by maintaining or improving the condition of packaged food, by releasing or absorbing substances to or from the food or its surrounding environment.

The regulation distinguishes 17 types of food contact materials:

Plastics, regenerated cellulose, elastomers and rubber, paper and cardboard, ceramics, glass, metals and alloys, wood, textiles, waxes, active materials and articles, adhesives, cork, ion exchange resins, printing inks, silicone, varnishes and coatings.

Alongside the general regulation, certain materials have individual European requirements.

This includes:

- Plastics ([Commission Regulation \(EU\) No 10/2011](#))
- Recycled plastics ([Commission Regulation \(EC\) No 282/2008](#))
- Ceramic materials ([Council Directive 84/500/EEC](#))
- Regenerated cellulose film ([Commission Directive 2007/42/EC](#))
- Active and intelligent materials* ([Commission Regulation \(EC\) No 450/2009](#))

Materials without European requirements, need to comply with national available requirements for the material.

All FCM should be manufactured in compliance with good manufacturing practice (GMP) as described in [Commission Regulation \(EC\) No 2023/2006](#).

Please visit our website for more information:

<https://www.scc-gmbh.de/food-contact-materials-compliance>

or contact one of our experts:

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COMPLIANCE PROCESS

Before placing a FCM on the EU market, all products should undergo a safety evaluation and compliance process.

This process starts with compliance checks of the products and their ingredients, followed by safety assessments of the chemicals and raw materials used to produce the FCM. Including the potential presence of any non-intentionally added substances (NIAS), i.e. side products, breakdown products and contaminants.

In addition, manufacturers of FCM containing plastics, recycled plastics, ceramics, regenerated cellulose film and active and intelligent materials need to provide a self-issued Declaration of Compliance (DoC). For other types of FCM such as paper, board, ink, DoC is currently not mandatory on a European level.

The DoC should be communicated along the manufacturing chain and upon request must be provided to the market surveillance authorities.

THE ROLE OF NATIONAL LEGISLATION

According to Regulation (EC) No 1935/2004, national FCM regulations may be applied by the EU Member States in case of absence of specific EU provisions.

Therefore, the majority of EU countries rely on their national legislations which may vary, sometimes significantly, from Member State to Member State. This includes the requirements to provide a DoC for materials not regulated on European level.

OUR SERVICE

Our experts help ensure the compliance of your food contact materials by providing support in:

- Compliance checks of products and ingredients
- Preparation of Document of Compliance (DoC) according to Regulation (EC) No. 1935/2004
- Development of registration strategy and test program to be performed (incl. coordination, management and supervision of testing)
- Assessment of the safety of chemicals used in the manufacture of FCM as well as of NIAS
- Migration calculations



Contact our
experts