

GUIDELINES FOR GOOD MANUFACTURING PRACTICE FOR CONTINUOUS FILAMENT GLASS FIBRE (CFGF) PRODUCTS INTENDED FOR FOOD CONTACT APPLICATIONS

These industry guidelines have been drafted to support individual companies in the supply chain to establish their company specific manufacturing processes and procedures according good manufacturing practice, but don't replace the respective requirements set by Commission Regulations.

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Summary

Compliance with Article 3 of Regulation (EC) No 1935/2004 - the Framework Regulation for food contact materials and articles - is the basis of the requirement for *Good Manufacturing Practice* in the production of materials and articles intended for contact with food. Commission Regulation (EC) No 2023/2006 sets more specific requirements on good manufacturing practice, applicable to all food contact materials.

The guidelines developed in this document are applicable to Continuous Filament Glass Fibre (CFGF) products subject to the specific Regulation (EU) No 10/2011 and its amendments. They have been established according to the position of the CFGF manufacturing operations within the supply chain of plastic materials and articles intended to be in contact with food.

These guidelines include specific requirements according to Regulation (EC) No 2023/2006. However each individual company should carefully review Regulation (EC) 2023/2006 to ensure all relevant requirements are properly addressed for its own manufacturing operation.

Three main concepts for *Good Manufacturing Practice* for the production of CFGF products for food contact are of primary importance:

- Communication: Creating and maintaining awareness within CFGF manufacturing operations.
- Contamination prevention: Maintaining compliance of the CFGF products through effective contamination prevention.
- Quality management system: Maintaining compliance of the CFGF products through effective management of change procedures preventing undesirable changes to the CFGF products.

1. Legal reference

Article 3 of Regulation (EC) No 1935/2004 (The Framework Regulation) clearly stipulates the requirements for materials and articles intended to come into contact with food:

"Materials and articles... shall be manufactured in compliance with good manufacturing practice so that, under normal or 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 the food or
- bring about a deterioration of the organoleptic characteristics thereof."

Regulation (EC) No 2023/2006 on good manufacturing practice defines more specifically the requirements with regards to good manufacturing practice, as required by Regulation (EC) No 1935/2004 (The Framework Regulation).

2. Field of application of Regulation (EC) No 2023/2006

The guidelines for *Good Manufacturing Practice* described in this document apply to CFGF products covered by Regulation (EU) No 10/2011.

CFGF products can be described as the combination of glass fibre and a glass fibre sizing and/or binder (for description of the CFGF manufacturing process, please refer to the chapter 6 of the *"Compliance Scheme regarding products of Continuous Filament Glass Fibre (CFGF) used in Glass*

Fibre Reinforced Plastic (GFRP) intended to come into contact with food” published by GlassFibresEurope in February 2016 <http://www.glassfibreeurope.eu/wp-content/uploads/20160216FCM-Guidance.pdf>)

The main starting substance of CFGF products is glass.

Glass can be defined as a highly viscous fluid behaving as a solid material at room temperature. It can be regarded as a new substance obtained after chemical reaction at high temperature between different mineral raw materials. None of the mineral raw material used to produce glass exist in their original form in the final CFGF product. Mineral Raw materials for glass fibre are not under the scope of the GMP, however it is good practice for the producers to include this part of the process in the quality control system. Glass, as a starting substance, is not in the scope of GMP.

The CFGF products (including the sizing and/or binder) are in the scope of GMP.

Good Manufacturing Practice for production of food contact CFGF products follows a chain beginning at approval and acceptance of the raw materials for sizing and binder production and ending when the CFGF products is delivered to the customer.

CFGF products are never directly in contact with food. Indeed the CFGF products are always embedded in a polymer matrix to form a Glass Fibre Reinforced Plastic (GFRP).

Note: Glass fibre as such is listed as an authorised additive to plastics in Annex I of Regulation (EU) No. 10/2011 under Ref. No. 55520 with no applicable restriction.

3. Definitions

Continuous Filament Glass Fibre (CFGF)

Continuous Filament Glass Fibre manufactured by continuous drawing of molten glass through a “bushing” (a device fitted with exactly defined holes) which forms continuous glass filaments with a defined and precisely controlled diameter. A surface treatment (sizing) is applied onto the glass filaments which are then gathered into strands.

CFGF products

CFGF products include: Single End or Direct Roving, Multi-end or Assembled Roving, Chopped Strands, Textile Yarns, Technical Fabrics and Milled Fibres. With the addition of a binder, other products like Chopped Strand Mats, Continuous Filament Mats and Veils can also be produced.

Raw Materials

Raw materials are any substances and mixtures that are used in the composition of glass fibre sizing and binder.

Sizing

An essentially organic surface treatment, applied to the glass filaments, composed of coupling agents, film formers and processing aids. The functions of the sizing are to allow processing of the glass fibres, to hold the individual filaments together and to promote the adhesion of the glass fibres to the polymer matrix.

Binder

An essentially organic secondary treatment applied to the glass fibre strands to bind them together (for instance: Chopped Strand Mats, Continuous Filament Mats and Veils).

Good manufacturing practice

According Regulation (EC) No 2023/2006 following definition for good manufacturing practice has been established for food contact materials and articles (article 3(a)):

“good manufacturing practice (GMP) means those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof”

Glass Fibre Reinforced Plastic (GFRP)

Compound or composite material made of plastics and CFGF products.

Food contact material

A material intended to come into contact with food or to come into contact with food after a suitable transformation or finishing process.

Food contact article

A finished article intended to come into contact with food.

4. Good Manufacturing Practice versus ISO 9001 certification requirements.

ISO 9001 quality system helps to ensure that products are produced according to documented procedures, specifications and customers expectations which do not necessarily ensure the respect of the general requirements as referred to in Article 3 of Regulation (EC) No 1935/2004 (the Framework Regulation).

Good Manufacturing Practice adds a framework of additional precautionary measures to facilitate meeting those regulatory requirements.

ISO 9001 can thus be an excellent system for implementing *Good Manufacturing Practice* requirements but should not be confused with *Good Manufacturing Practice* as such.

5. Requirements for CFGF products intended for food contact applications

The Framework Regulation clearly highlights that the safety, composition and organoleptic integrity of the packaged food is a regulatory requirement. This aspect is repeated in the definition of GMP in Regulation (EC) No 2023/2006.

The entire composition of a food contact CFGF product must be designed and consistently maintained up to the use of the CFGF product in the final article, so that meeting the regulatory requirements in terms of health, safety and organoleptic characteristics of the packaged food is consistently ensured.

Two stages can be considered:

First, the “design for compliance” stage in which sizing and binder raw materials are selected according to regulatory compliance with Regulation (EU) No 10/2011 as amended and the CFGF

manufacturing process is compliant with the requirements of Article 3 of Regulation (EC) No 1935/2004 (The Framework Regulation). During that stage, the effect of potential migrants is assessed.

Second, the stage of CFGF product manufacturing, where specific measures must be in place in order to effectively ensure:

- Communication: Creating internal awareness at all levels involved.
- Contamination prevention: Maintaining compliance with the CFGF composition as designed and preventing contamination of the CFGF product as supplied that would endanger the health, safety and organoleptic characteristics of the packaged food.
- Quality control system: Maintaining compliance of the CFGF composition including potential migrants through effective management of change procedures preventing undesirable changes in composition.

6. Scope of Good Manufacturing Practice

Good Manufacturing Practice for production of food contact CFGF product follows a chain beginning at approval and acceptance of the raw materials for sizing - and binder internal preparation and ending when the CFGF product is supplied to the customer.

Article 2 of Regulation (EC) No 2023/2006 defines the scope as follows:

“This Regulation shall apply to all sectors and all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances”

Building on the above the following scope can be summarized:

Good Manufacturing Practice for materials and articles for food contact is about:

1. Quality assurance system
2. Management leadership and awareness of the personnel
3. Documentation, labelling, document retention and traceability
4. Production
 - 4.1. Sizing and binder raw material specifications and acceptance
 - 4.2. Contamination prevention
 - 4.3. Management of change
 - 4.4. Storage packaging, warehousing and transportation
5. Quality control and specifications
6. Work contracted out
7. Complaint handling, product recall and incident management
8. Appropriate audits.

7. Guidelines for Good Manufacturing Practice

The guidelines clarify the requirements applicable to the manufacturing of the CFGF intended for food contact applications. In line with regulation (EC) No 2023/2006, they take into consideration the upstream position of the glass fibre sector in the overall plastic supply chain.

7.1 Quality assurance system

- There is an effective quality assurance system involving the active participation of management and personnel.

- Specific responsibility is assigned to designated individuals who have the authority to approve/reject all materials intended for food contact application.
- A risk analysis should be performed to identify relevant critical points of attention.

7.2 Management leadership and awareness of the personnel

- Management responsibilities for *Good Manufacturing Practice* implementation are assigned, defined and documented.
- The personnel supervising or performing the manufacture or control of food contact materials and articles must have the training, experience and skill to perform the assigned functions.
- Training of relevant personnel shall include awareness training on applicable Good Manufacturing Practice requirements.
- In a factory where food contact CFGF products are produced as well as non-food contact CFGF products, and when there is a risk that cross contamination may impact the conformity of the food contact CFGF products, production of food contact CFGF products shall be properly identified.

7.3 Documentation, labelling, document retention and traceability

- There is a system in which sizing/binder recipe, operating procedures, process specifications limits, product release specifications and other critical information shall be documented.
- There is a system to ensure traceability from raw material to outgoing food contact CFGF products, up and down the supply chain.
- Equipment, transfer lines, containers and tanks that are used for processing, filling or holding food contact CFGF products are identified either by labelling or by electronic control systems to indicate contents, batch designation, control status and other pertinent information consistently with the traceability system in place.
- Documents and data records relevant to the food contact compliance of CFGF products are retained according to the internal quality system requirements.

7.4 Production

7.4.1 Sizing and binder raw material specifications and acceptance

- The raw materials used in sizing and binder for CFGF product intended for food contact have a purchase acceptance specification covering technical quality and absence of contamination requirements.
- Specific requirements and information's related to the intended use of their product in food contact application are defined and communicated to the supplier.
- There is a procedure to approve raw materials. Only approved materials are used.
- Raw materials should be verified for acceptance based on pre-defined control plan before use.
- Raw materials not meeting the agreed acceptance criteria are properly identified and controlled to prevent misuse.
- Raw materials must be stored and handled in a manner which prevents their mix-up and/or contamination.
- Water that comes into contact with CFGF product during its manufacturing process should not impact the food contact compliance of the CFGF product.

7.4.2 Contamination prevention

- There is an adequate contamination prevention procedure based on risk assessment.
- The equipment and set up are adequate to preclude cross-contamination between materials for food contact and materials for non-food contact or their ingredients.
- There are effective transition procedures such as buffering or cleaning to avoid cross contamination when transitioning from non-food contact to food contact products (additive tanks, pipes, silo's,...).
- There should be a physical separation or a control system to segregate raw materials and product that has been released for use or distribution from material pending release, non conforming materials or product returns.
- Procedures are in place to ensure that transfer, packaging or loading operations are conducted in such a way as to avoid product contamination.

7.4.3 Management of change

- Operation procedures and process specifications limits have been established and documented. There is a management of change procedure in case operating procedures have to be changed. The management of change procedure is capable of detecting and indicating potential changes in the composition or increased risk of contamination.
- Changes in product formulations, raw materials or raw material suppliers are subject to a management of change.
- There are documented approval procedures to prevent negative impact of such changes on the final product quality, performance, composition and regulatory compliance status of the final CFGF product intended for food contact.

7.4.4 Storage, packaging, warehousing and transportation

- Sizing, binder and packaging raw material are stored according to the supplier recommendations.
- Silo's and bulk trucks can either be dedicated equipment receiving only food contact materials and/or alternatively there are effective measures or procedures (such as cleaning or transition procedures) to ensure that the containers do not contain any products or contaminants that are not compatible with the intended use of food contact.
- There are procedures in place to ensure correct labelling.
- Packaging materials that are directly in contact with CFGF products intended for food contact should not impact the food contact compliance of the CFGF product (for instance : plastic foil for individual bobbin protection).
- Packaging materials are designed to protect the CFGF products from contamination during storage and transport.
- Storage conditions are maintained in order to prevent contamination of the CFGF products intended to come into contact with food.

7.5 Quality control and specifications

- Documented specifications exist for raw materials and CFGF products.
- Raw materials and CFGF products are controlled to verify their conformance to specifications.

7.6 Work contracted out

- Any contracted out manufacturing operation or operation linked thereto (such as e.g. warehousing) is subject to a written contract and is performed according to *Good Manufacturing Practice*.

7.7 Complaint handling, product recall and incident management

- There is a system implemented for recording and investigating complaints including product recall if needed. The complaint investigation shall result in corrective actions if needed.
- There are measures in place to ensure that non-conforming or recalled products are not released for food contact use without extensive investigation and proper authorization.

7.8 Appropriate audits

- There is a procedure in place to ensure regular internal audits in order to monitor the implementation of *Good Manufacturing Practice* requirements as described here above.