Guidelines for the Application to the Glass Industries of Regulation (EC) 2023/2006 for the Production Chain of Materials and Articles Intended to Come into Contact with Food

EXECUTIVE SUMMARY

« Article 3 of Regulation (EC) No 1935/2004, the framework regulation for materials and articles intended to come into contact with food (FCM) requires the application of Regulation 2023/2006/EC which defines the elements of good manufacturing practice for these materials and requires at least the following to be implemented:

- Quality Assurance System
- Quality Control System
- Documentation.

Glass Alliance Europe advises manufacturers of food contact materials in glass to apply the following good manufacturing practices:

⇨ Maintain records of glass quality checks and data on process control (on the basis of a description)

⇨ Check on a regular basis the compliance with the limits set in existing regulations and standards (see annex 2)

CONTENTS

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FOREWORD

The guidelines presented in this document are applicable to the glass industry supply chain where the end use involves food contact, and include the specific requirements as set by 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.

GENERAL INTRODUCTION

Glass Alliance Europe is the European Alliance of Glass Industries. It has the unique feature of regrouping all the glass industries to work on common topics of interest. It is composed of 14 national glass associations and of the 5 main sectors of the glass industries: container glass, flat glass, special glass, domestic glass and continuous filament glass fibres.. These sectors are quite diverse in nature, be it in terms of manufacturing process, products, markets, economics of the sectors and manufacturers.

The use of glass products for food contact is a major part of the market for container, hollow ware and domestic glass (tableware) production. Flat glass has a very limited application (less than 0.5% of output), and fibres are essentially out of scope of these guidelines as a food contact material.

Glass products currently fall under the Framework Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food. They are not covered by specific measures like those established for ceramic articles under the Directive 84/500/EEC.

With all food contact materials, glass products are covered by the Regulation (EC) 2023/2006 on GMP (Good Manufacturing Practice) [published in Official Journal of the European Union L384/75-78, December 29, 2006]. The purpose of this Guideline is to help glass manufacturers, especially SME (Small and Medium Enterprises), in the implementation of Regulation (EC) 2023/2006. It is primarily based on the Italian guideline issued by the Istituto Superiore di Sanità (ISS, the National Institute of Health in Italy), and the outcome from the CAST (Contatto Alimentare Sicurezza e Tecnologia: Food Contact Safety and Technology) project.

Glass Alliance Europe has also coordinated a European wide consultation with experts from glass manufacturers and national associations.

All stakeholders can send comments for the subsequent revision of the guidelines to: info@glassallianceeurope.eu

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1. Legal reference

Article 3 of Regulation (EC) No 1935/2004 (The Framework Regulation)[1] stipulates the objective for materials and articles intended to come into contact with food as follows: *"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."

The good manufacturing practices, as required by Article 3 of Regulation (EC) No 1935/2004, are defined more specifically in Regulation (EC) No 2023/2006, which provides guidance and fundamental principles. When looking to apply these guidelines it should be remembered that the regulation states *"the rules on GMP should be applied proportionately to avoid undue burdens for small businesses"* (point 6).

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

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****".*
In the case of glassware manufacture, **the starting material is glass:** it can be regarded as a new substance obtained after chemical reactions at high temperature between different raw materials, and cullet (recycled glass). None of the raw materials used to produce glass exist in their original form in the final glass product. Glass can better be identified by its chemical formula:

$$\mathbf{Na_nCa_oMg_pAl_q\ldots\ldots Si_mO_s\ [glass]}$$

Where: $s = n/2 + o + p + 3q/2 + \ldots + 2m$

Containers and articles for food contact are mainly made of soda-lime-silicate glass, although other glass types such as opal, borosilicate and crystal glass are used.
Raw materials and cullet are not explicitly included in the scope of the GMP; however it is good practice for producers to include this part of the process in the quality control system.

Good manufacturing practice for food contact materials and articles follows a process flow beginning with the approval and acceptance of the starting materials (glass) and progressing through production, packaging, warehousing and shipment to the point in the supply chain where the article is brought into contact with food.

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3. Scope of this guideline

This guideline is applicable to glass manufacturers that produce glass products that will be used as food contact materials. Special conditions apply to the flat glass sector.
The main categories are hollow glass **articles: containers and tableware**. Containers primarily consist of bottles (for instance for wine, oil, etc.), and jars (for instance for yoghurt, baby food, etc.). In most cases, the bottles and jars are not directly brought into food contact by the glass manufacturers; They are normally shipped to food packagers to be filled with the food product. Tableware primarily consists of items used for consumption of food (plates, tumblers, stemware glasses, etc.). Most glass containers and tableware articles are produced in a similar two-stage process by pressing and blowing the molten glass in moulds.

Articles made of **fibre glass** are out of the scope of this guideline, as this case is covered by specific regulations.

Flat glass is a specific case, as use of flat glass for food applications is very limited. More than 99% of flat glass production (over 8 million tons in the EU) is used in glazing, facades, automotive, solar energy modules and other appliances. Only a very small proportion of flat glass production, lower than 0.5%, is used in products intended for food contact materials with no information for the manufacturers at time of production on the final destination of the product. This limited number of articles includes cutting boards, decorative serving plates, tables and counter tops and fridge shelves. Given the shape of the articles (flat articles), only solid food are concerned and no liquids. Some of following requirements might then not to be applied to flat glass where the flat glass manufacturers have no influence over the final use of the product and whether it is used to make a food contact material.

4. General requirements

The application of Regulation 2023/2006/EC to all manufacturers producing materials and articles used in contact with food (FCM) requires at least the following to be implemented:

- Quality Assurance System;
- Quality Control System;
- Documentation in paper or electronic format; and,
- Storage of the operative and recorded documentation.

The following are strongly recommended but the degree of application can vary with size of the organisation and its position in the supply chain.

4.1. Quality assurance and quality control systems:

- ⇨ There is a quality system which is adequate to consistently produce articles for food contact in compliance with the applicable European and National FCM Regulations.
- ⇨ There is an effective quality assurance system involving the active participation of management and personnel.

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- ⇨ A quality control department must exist with responsibility and authority to independently approve/reject all products in the process.
- ⇨ ISO 9000 certification can reinforce the GMP as the ISO quality systems can support GMP with the requirement to have controlled documented procedures and specifications. But ISO 9000 certification is not essential and may not cover all of the required aspects of GMP.

4.2. Quality control and specifications

- ⇨ Documented specifications exist for starting materials (glass) and finished products (glass articles)
- ⇨ The quality of the starting material, glass, is suitably controlled to a level appropriate for the intended and foreseeable use of the articles as food contact materials.
- ⇨ Finished products (articles) are monitored to verify their compliance and conformity with applicable regulations related to contact with food. Glass Alliance Europe recommends referring to the regulations, standards and others reference documents listed in annex 2.
- ⇨ Sensory evaluation of glass articles by method DIN 10955 or equivalent should not be required.
    - Glass is odourless, undergoes minimal physical or chemical reactions with the air sample and has low permeability in order to minimize sample losses through diffusion and/or adsorption. this is acknowledged by standard EN3725 ("considered appropriate materials for odour sampling")

- ⇨ Although not a legal obligation, it is good practice for producers to include in the quality control system, the regular verification of the compliance of the glass products with the methodology and the permissible limits set by the standards ISO 6486 or ISO 7086 according to the type of articles produced.
    - This does not apply to flat glass where the flat glass manufacturers have no influence over the final use of the product and whether it is used to make a food contact material.

4.3. Documentation, document record retention, and traceability

- ⇨ There is a system in which operating procedures and operating conditions and other critical information related to the production of the starting material, glass as a food contact material, to the production of the finished product is documented.
- ⇨ There are procedures to permit traceability from the production of the starting material, glass, to the delivery of the outgoing food contact material or article.
    - These do not apply to flat glass where the flat glass manufacturers have no influence over the final use of the product and whether it is used to make a food contact material.

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ANNEX 1 - PROCESS DESCRIPTION: flowchart and description

Before describing the production cycles and their differences for each manufacturing process (jars, bottles, tableware, flat glass), it is essential to point out characteristics specifically concerning glass and glass function related to food contact suitability.

Containers and articles for food contact are mainly made of soda-lime-silicate glass, although other glass types such as opal, borosilicate and crystal glass are used.

Glass is an inorganic amorphous solid. At a temperature between 1450°C and 1550°C chemical reactions between the raw materials will result in a liquid with the viscosity similar to that of treacle. As the glass is cooled down between 1000°C and 1300°C the viscosity increases to a point where it can be formed into the finished shape. As it cools further the viscosity continues to increase until it reaches a point known as the glass transition temperature typically around 550°C ; after this point the glass has the properties of a solid and will not flow under its own weight.

The glass composition defines the melting and forming temperature, machine speed, annealing temperature, and the chemical resistance of the glass for contact with food. During the glass manufacturing process, each step from the raw materials to the finished product undergoes rigorous quality control checks to assure the consistency and efficiency of the whole production process. Therefore, process controls assure continuity with Regulation (EC) 2023/2006.

Brief description of the general glass-making process

The process can be split into three main areas:

– *Hot-End,* made up of the sub processes: batch composition, melting, forming and annealing.

– *Cold-End,* made up of sub processes: finished product control, packaging / palletisation.

– *Warehouse,* made up of storage and shipping areas.

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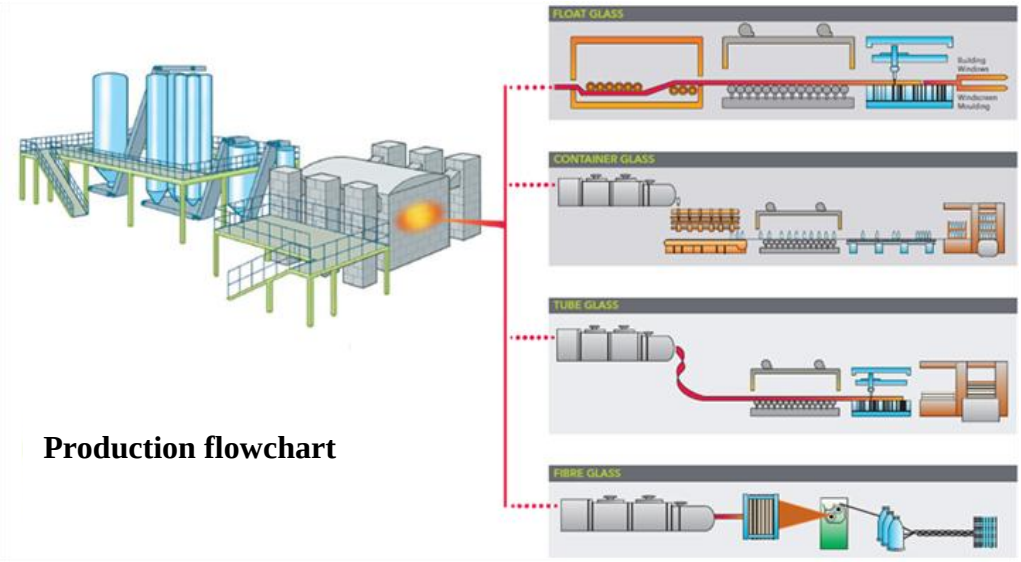

Production flowchart

Hot-End

Composition

The composition of the mixed raw materials known as batch is the first hot-end stage. Raw materials such as silica sand, soda, lime, dolomite etc. (mainly stored in silos) are weighed and mixed in order to obtain a mixed batch which can be melted to form a glass of the desired composition. The mixed batch is normally sent to the furnace via belts, hoppers, bins or pneumatic systems into the furnace chargers. Another important component of the mixture delivered to the furnace is glass cullet (recycled glass) from the internal manufacturing process and/or from end of consumer use from the regional glass recycling schemes, which, after being sorted and quality assessed, is added to the mixed batch.

Melting

The melting and refining process is composed of a complex sequence of chemical reactions. The initial stage is the dissolution of all raw materials to generate a homogenous glass melt. A subsequent refining phase is then necessary to promote the removal of gas trapped in the molten glass in order to comply with the agreed specifications. The melting and refining process takes place in the furnace, which is built with refractory material and is able to resist the high temperature conditions for many years, typically in excess of 10 years. The glass manufacturing plant usually operates continuously (24/7), and computer based process control allows the operational parameters to be constantly maintained.
In the glass melting process, any recycled glass content is completely and evenly dispersed throughout the finished glass containers. Glass produced with recycled glass is chemically and physically indistinguishable form glass made from virgin raw materials.

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At the end of the melting stage, comes the conditioning stage which consists of a controlled cooling of the glass to the forming temperature, between 1000 and 1350°C. At these temperatures, microbiological contaminants and allergens can be considered to have been eliminated.

Container forming process

Glass containers for foods are manufactured by automatic machines, which are able to produce a high number of pieces per minute. It is appropriate to distinguish between the manufacturing process of normal containers (bottles and jars), tableware (wine glasses, glasses and dishes), and the process used in the production of flat glass.
The container manufacturing process consists of the following steps:

- Cutting of the glass stream exiting from an opening in the bottom of the furnace channel into pieces of suitable weight, shape and temperature pieces of glass known as Gobs;
- Gob delivery to a machine blank mould, by gravity (but sometimes with air assist);
- Parison pre-forming in a blank mould;
- Parison transfer from the blank mould to the blow mould;
- Application of compressed air to the parison in the blow mould to achieve the final container shape;
- Container removal from the blow mould and its transfer to the annealing lehr by conveyor belts.

The first shaping of the parison in the blank mould may be obtained by a pressing process with a metal plunger or by a blowing process with compressed air. The final shape in the blow mould (finishing mould) is always obtained by a glass blowing process. Subsequently, the two processes are named, respectively “press and blow” and “blow and blow”. The first one is primarily used for wide mouth containers (jars) and light weight bottles. The second one is preferred for traditional manufacturing requirements.
The glass containers are subject to external surface treatments in order to improve their performance in both the handling phase in the glass plant and at the customer filling lines, and subsequent handling along the supply chain. The surface treatment is applied in two stages; at the exit of the forming machine, when the ware is still at temperature of about 500°C (hot-end coating) and, afterwards, at the exit of the annealing lehr (cold-end coating). The hot-end treatment is a coating that conditions the glass surface to enable the subsequent cold-end treatment to bond to the glass. The cold end coating is a low friction coating that reduces the risk of surface damage caused by container to container contact along the supply chain that in turn maintains the strength of the container. It is generally accepted that glass is an effective barrier that prevents the transfer of any coating materials applied to the outer surface through the glass into a product on the inside of a container.

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Tableware manufacturing

The following are the main forming techniques used in manufacturing tableware:

- press-blow,
- blow-blow,
- press,
- spinning or centrifuge.

The first two are similar to the container manufacturing techniques. The press process is relatively simple and can be applied in the case of ware having a mouth at least as large as its base. It consists of pressing glass gobs between a metallic plunger and a mould. The centrifuge spinning is used to produce circular goods such as plates or bowls, by applying molten glass into a spinning mould. In most cases, the manufacturing of stemware requires the joining of two parts by thermal fusion. The two components are separately obtained by one of the other forming techniques. Drinking vessels are manufactured with the press and blow process that then requires the removal of surplus glass in the upper part which is used for handling the article during forming. This can either be undertaken at high temperature immediately after forming or at low temperature after annealing. In the latter case, the rim must be finished by grinding and polishing and this tends to be used on higher value products.

Note that for crystal manufacturing, specific manual techniques such as gathering and mouth blowing are used.

Flat glass manufacturing

In the float process a continuous ribbon of molten glass from the furnace at around 1100°C is fed onto an enclosed bath of molten tin in order to achieve a flat smooth surface. The molten glass floats on top of the molten tin and as it flows along the surface of the tin it is pulled and stretched by rollers along the top edge to achieve the desired glass thickness. Then the glass continues on underside rollers into the annealing lehr for controlled cooling down to room temperature. The glass is then cut into the desired size, before being stacked for transportation. The float process produces glass sheets with a uniform thickness with an exceptionally flat surface that needs no further process such as grinding or polishing. The glass is then sold to customers with or without any further treatment. At the flat glass plant, no treatment is performed for glass sold to customers who will manufacture food contact materials (less than 0.5% of the output).

Annealing

If the glass is allowed to cool rapidly after forming this induces excessive uneven stress within the material in most glass container articles these stresses are undesirable when they reach excessive levels. In order to reduce the stress the ware is passed through an annealing lehr.

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The purpose of annealing glass is the reduction of residual stresses. The first part of the process involves the raising of the temperature of the glass articles to a temperature called the annealing point and maintaining this temperature for a sufficient time to relieve the existing strains and to stabilise the glass. The containers must then be cooled at a rate sufficiently slowly so that the residual stresses will not reappear when the container is at room temperature. If the requirements above are not achieved then excessive residual stresses will be present in the glass articles at the cold end.
In the case of certain glass articles, principally for flat glass or where the article comprises what is described as "toughened glass", a thermal treatment is used to induce compressive stress in the glass surface, known as "tempering" or "toughening". This process improves the mechanical performance of the glass product.

Cold-End

Quality control

After annealing qualitative checks are carried out either manually and/or automatically to verify the glass products conformity to agreed physical, mechanical and visual specifications. Unsuitable products are rejected from the process line and immediately recycled and returned to the furnace as cullet. The physical and mechanical checks are performed by the means of specialist equipment, in order to ensure that only high quality product are released from the glass manufacturing facility in accordance with consumer expectations and requirements.

Packaging/palletizing of containers or tableware

The packaging unit is usually the "pallet" and is commonly composed of a wooden pallet with a base protective layer on top. The containers are stacked in layers on the pallet which are separated by dividers made from either corrugated or cardboard or plastic. The top layer has a capping tray or top frame with plastic pad attached. The pallet is usually wrapped with a polyethylene shroud (film stretch wrapping and compression strapping provide two alternative methods for securing the glass) which represents the factory's sale unit after labelling and marketing. This packaging is able to protect the ware in the warehouse and during transport to the packer/filler. Tableware goods and occasionally glass containers are packed in a primary packaging (box of multiple items) which is placed in a secondary packaging consisting of an American box or master. The pallet is wrapped with polyethylene elastic tubular material or covered with a polyethylene hood which is shrunk wrapped over the entire pallet. Glass manufacturers have adopted the standard procedure to label and so clearly to identify the single sale unit to the client, in order to fulfil the requirement of traceability.

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Storage and transportation

Once packed and labelled, the product is generally stored in warehouses with a stock management system in order to locate pallets and allow traceability of the product through to delivery to the customer. In general glass packaging requires no particular storage controls such as temperature and humidity as might be encountered by other packaging materials.

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ANNEX 2: DOCUMENTS LIST : Applicable legislation, standards and reference documents

European legislation:

- Regulation (EC) 1935/2004 of the European Parliament and of the European Council of 27th October 2004 on materials and articles intended to come into contact with food and repeal Directives 80/590/EEC and 89/109/EEC.
- Regulation (EC) 2023/2006 of the European Commission of 22nd December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

National legislation or reference document:

- Italy: Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, intended to come into contact with food or substances for personal use and subsequent updates.
- Netherlands : Commodities Act Regulation on packaging and consumer articles coming into contact with foodstuffs (Commodities Act (Packaging and Consumer Articles) Regulation [Warenwetregeling verpakkingen en gebruiksartikelenStaatcourant Nr. 8531, 27 Maart 2014])
- France : Reference Document " Glass – Crystal – Ceramics – Glass ceramics – Enamelled ware" - updated 23 February 2015 by the General Directorate for Competition Policy, Consumer Affairs and Fraud Control (French Ministry for the Economy and Finance)

Other reference documents:

- Policy statement concerning Lead leaching from glass tableware into foodstuffs – Committee of Experts on materials coming into contact with food (Council of Europe) – 22.09.2004

International standards:

- ISO 6486-1:1999 , Ceramic ware, glass-ceramic ware and glass dinnerware in contact with food -- Release of lead and cadmium -- Part 1: Test method
- ISO 6486-2:1999 Ceramic ware, glass-ceramic ware and glass dinnerware in contact with food -- Release of lead and cadmium -- Part 2: Permissible limits
- ISO 7086-1:2000 Glass hollowware in contact with food -- Release of lead and cadmium -- Part 1: Test method
- ISO 7086-2:2000 Glass hollowware in contact with food -- Release of lead and cadmium -- Part 2: Permissible limits European standards

European standards

- EN 1388-1:1996 Materials and articles in contact with foodstuffs. Silicate surfaces. Determination of the release of lead and cadmium from ceramic ware
- EN 1388-2:1996 Materials and articles in contact with foodstuffs, silicate surfaces - Part 2: Determination of the release of lead and cadmium silicate surface other than ceramic ware

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