RAPPORTI ISTISAN 26|1

ISSN: 1123-3117 (cartaceo) • 2384-8936 (online)

CAST Project
(Contatto Alimentare, Sicurezza e Tecnologia)

Guideline for documental verification on the application of Regulation (EC) 2023/2006

English version of Rapporto ISTISAN 24/36

Edited by C. Gesumundo, M.R. Milana, F. Vanni, G. Padula, S. Giamberardini, M. Denaro, M. Massara, M. De Felice, R. Feliciani, V. Mannoni

AMBIENTE E SALUTE

ISTITUTO SUPERIORE DI SANITÀ

CAST Project
(Contatto Alimentare Sicurezza e Tecnologia)

Guideline for documental verification on the application of Regulation (EC) 2023/2006

English version of *Rapporto ISTISAN* 24/36

Edited by
Cinzia Gesumundo (a), Maria Rosaria Milana (a)*,
Fabiana Vanni (a), Giorgio Padula (a), Silvia Giamberardini (a),
Massimo Denaro (b), Michele Massara (b), Marco De Felice (a),
Roberta Feliciani (b), Veruscka Mannoni (a)

(a) Dipartimento Ambiente e Salute
(b) Organismo Notificato

**retired since July 1, 2022*

ISSN: 1123-3117 (cartaceo) • 2384-8936 (online)

Rapporti ISTISAN
26/1

Istituto Superiore di Sanità
CAST Project (Contatto Alimentare Sicurezza e Tecnologia). Guidelines for documental verification of the application of the Regulation (EC) 2023/2006. English version of *Rapporto ISTISAN* 24/36.
Edited by Cinzia Gesumundo, Maria Rosaria Milana, Fabiana Vanni, Giorgio Padula, Silvia Giamberardini, Massimo Denaro, Michele Massara, Marco De Felice, Roberta Feliciani, Veruscka Mannoni
2026, xii, 194 p. Rapporti ISTISAN 26/1

In the frame of the CAST Project (*Contatto Alimentare Sicurezza e Tecnologia*: Food Contact Safety and Technology) commented working sheets have been developed for the documental verification of the application of the Regulation (EC) 2023/2006 on good manufacturing practice. The guidelines are structured in a part of general application and in a part of specific applications, distinct for the supply chains of materials and articles in aluminium, paper and cardboard, flexible packaging, wood, plastics, metals and coated metal alloys, cork, glass, coated products, sealing adhesives, printing inks. In addition, four new supply chains have been included in this edition: coated metal articles for cooking, rubber, food packaging machines, gas distribution systems food additives.
Key words: Good manufacturing practice; Materials; Contact; Food

Istituto Superiore di Sanità
Progetto CAST (Contatto Alimentare Sicurezza e Tecnologia). Linea guida per il riscontro documentale sull'applicazione del Regolamento (CE) 2023/2006. Versione inglese del *Rapporto ISTISAN* 24/39.
A cura di Cinzia Gesumundo, Maria Rosaria Milana, Fabiana Vanni, Giorgio Padula, Silvia Giamberardini, Massimo Denaro, Michele Massara, Marco De Felice, Roberta Feliciani, Veruscka Mannoni
2026, xii, 194 p. Rapporti ISTISAN 26/1 (in inglese)

Nell'ambito del Progetto CAST (Contatto Alimentare Sicurezza e Tecnologia) sono state sviluppate schede pratiche commentate per il riscontro documentale sull'applicazione del Regolamento (CE) 2023/2006 e s.m.i. sulle buone pratiche di fabbricazione. Le linee guida sono strutturate in una parte di applicazione generale e in una parte di applicazione specifica, distinta per le filiere dei materiali e oggetti in alluminio, carta e cartone, imballaggi flessibili, legno, materie plastiche, metalli e leghe metalliche rivestiti e non rivestiti, sughero, vetro, prodotti verniciati su metalli (*coating*), adesivi sigillanti, inchiostri da stampa. Inoltre, in questa edizione sono state inserite quattro nuove filiere: articoli in metallo rivestito destinati alla cottura, gomma, macchine per il confezionamento degli alimenti, impianti di distribuzione di gas additivi alimentari.
Parole chiave: Buone pratiche di fabbricazione, Materiali, Contatto, Alimenti

Si ringrazia Sandra Salinetti (Servizio Comunicazione Scientifica) per il prezioso contributo nella organizzazione funzionale dei contenuti delle presenti linee guida migliorandone chiarezza e leggibilità.

Per informazioni su questo documento scrivere a: cast2021@iss.it

Il rapporto è accessibile online dal sito di questo Istituto: www.iss.it

Citare questo documento come segue:
Gesumundo C, Milana MR, Vanni F, Padula G, Giamberardini S, Denaro M, Massara M, De Felice M, Feliciani R, Mannoni V (Ed.). *CAST Project (Contatto Alimentare Sicurezza e Tecnologia). Guidelines for documental verification of the application of the Regulation (EC) 2023/2006. English version of Rapporto ISTISAN 24/36.* Roma: Istituto Superiore di Sanità; 2026. (Rapporti ISTISAN 26/1).

Legale rappresentante dell'Istituto Superiore di Sanità: *Rocco Bellantone*
Registro della Stampa - Tribunale di Roma n. 114 (cartaceo) e n. 115 (online) del 16 maggio 2014

Direttore responsabile della serie: *Antonio Mistretta*
Redazione*: Sandra Salinetti*

viale Regina Elena, 299 – 00161 Roma

The following associations took part in the present guideline:

ANFIMA
Italian National Association of Metal Packaging Manufacturers (Milan)

Assocarta
Italian Association of Pulp, Paper and Board Industry (Milan)

Assogastecnici - Federchimica
Italian Association of Technical, Special and Medical Gases Industry (Milan)

Assogomma - Federazione Gomma Plastica
National Association of Rubber, Electrical Cables, and Related Industries (Milan)

Assografici
Italian Association of Printing and Paper Converting Industries (Milan)

Assoimballaggi - FederlegnoArredo
National Association of Wood, Pallet, Cork Packaging Industries, and Logistics Services (Milan)

ASSOMET/CIAL
Associazione Italiana Industrie Metalli non Ferrosi. / Consorzio Nazionale Imballaggi Alluminio
Aluminium Packaging Consortium (Milan)

Assovetro
National Association of Glass Manufacturers (Rome)

AVISA - Federchimica
Associazione nazionale Vernici, Inchiostri, Sigillanti e Adesivi
National association of producers of lacquers, inks, sealers and adhesives (Milan)

Federchimica
National Federation of the Chemical Industry (Milan)

FIAC (ANIMA)
Associazione Fabbricanti Italiani Articoli per la Casa, la tavola e affini
Italian association of manufacturers of household and table articles, and related items

III (contracting partner)
Istituto Italiano Imballaggio, the Italian Institute of Packaging (Milan)

ISS (scientific coordinator)
Istituto Superiore di Sanità, the National Institute of Health in Italy (Rome)

PlasticsEurope Italia - Federchimica
Italian Association of Plastics Producers (Milan)

UCIMA
Unione Costruttori Italiani Macchine Automatiche per il confezionamento e l'imballaggio
Italian Association of Manufacturers of Automatic Packaging Machines

Unionplast (Federazione Gomma Plastica)
Italian Association of Plastics Converters (Milan)

The following associations collaborated in the drafting of the guidelines published in the previous volume (*Rapporto ISTISAN* 13/14 and *Rapporto ISTISAN* 16/43):

AIDEPI
Associazione delle Industrie del Dolce e della Pasta Italiane
Association of Italian Dessert and Pasta Industries (Rome)

AIIPA
Associazione Italiana Industrie Produttori Alimentari
Italian Association of Food Producer Industries (Milan)

AIPE
Associazione Italiana Polistirolo Espanso
Italian Expanded Polystyrene Association (Milan)

ANFIMA
Italian National Association of Metal Packaging Manufacturers (Milan)

Assocarta
Italian Association of Pulp, Paper and Board Industry (Milan)

Assocomaplast
National Italian Association of machine and mould builders for plastics and rubber materials (Milan)

Assografici
Italian Association of Printing and Paper Converting Industries (Milan)

Assoimballaggi – FederlegnoArredo
National Italian Association of wood packing, pallet, cork and logistics services (Milan)

ASSOMET/CIAL
Associazione Italiana Industrie Metalli non Ferrosi. / Consorzio Nazionale Imballaggi Alluminio
Italian Association of non-ferrous metal industries /Aluminium Packaging Consortium (Milan)

Assorimap
National Association of plastics recyclers and regenerators (Milan)

Assovetro
National Association of Glass Manufacturers (Rome

AVISA – Federchimica
Associazione nazionale vernici, inchiostri, sigillanti e adesivi
National Association, Paints, Inks, Sealants and Adhesives (Milan)

CENTROAL
Centro Italiano Alluminio
Italian Aluminium Center (Milan)

Centro di Informazione sul PVC
PVC Information Center (Milan)

ConLegno
Wood-Cork Service Consortium (Milan)

Federalimentare
Italian Food Industry Federation (Rome)

GIFLEX – Assografici
Gruppo Imballaggio Flessibile
Flexible Packaging Group (Milan)

GIFCO – Assografici
Gruppo Italiano Fabbricanti Cartone Ondulato
Italian Group of Corrugated Cardboard Manufacturers (Milan)

III (*contracting partner)*
Istituto Italiano Imballaggio, the Italian Institute of Packaging (Milan)

ISS (*scientific coordinator*)
Istituto Superiore di Sanità, the National Institute of Health (Rome)

PlasticsEurope Italia - Federchimica
Italian Association of Plastics Producers (Milan)

Unionplast – Federazione Gomma Plastica
Italian Association of Plastics Converters (Milan)

TABLE OF CONTENTS

B5. Wood or wood fibre

B6a. Plastics. Polymer production and masterbatches

B6b. Plastics. Processing: production of semi-finished products and packaging

B7. Metals and metal alloys, coated and not-coated

B8. Cork: cork stoppers

B9. Glass

B10. Coating

B11. Adhesives and sealants

B12. Printing inks

B13. Coated metal articles intended for cooking

B14.a. Rubber. Production of elastomers, compounds and masterbatches

B14.b. Rubber. Processing: production of finished articles

B15. Food packaging machines

B16. Food gases distribution equipment

PREFACE TO THE ENGLISH VERSION

This document is the English version of "Progetto CAST (Contatto Alimentare Sicurezza e Tecnologia). Guidelines for documental verification on the application of Regulation (EC) 2023/2006", published in 2024 in the series *Rapporti ISTISAN* (*Rapporto ISTISAN* 24/36) (1).

This translation is published after strong request from European both Public and Private Bodies, which recognized in the CAST guidelines a valid tool to help the preparation of Supporting Documentation (SD) for Declarations of Compliance (DoC) for materials and articles in contact with foodstuffs (Food Contact Materials, FCMs).

The CAST guidelines are a unique example of integrated knowledge and expertise between Public and Private stakeholders in the European Union (EU), presenting a document that is easy to use especially for Small and Medium Enterprises (SMEs), but in the meantime offering a valid tool to the Public Inspectors too for enforcement activities, too.

The English version is faithful to the original Italian document, to save as much as possible the ideas behind the CAST guidelines. For this reason, also the alphabetic order of the supply chains reflects the Italian version.

Only minor modifications were done, for the convenience of the non-Italian users of this document, such as the splitting between EU and Italian Regulation, some notes addressing new EU legislation on food contact materials (Regulation (EC) 10/2011 as amended), and some adaptations of the technical parts.

PRESENTATION

The CAST (*Contatto Alimentare Sicurezza e Tecnologia*: Food Contact Safety and Technology) Project was started up in 2007 with the objective of testing a new integrated strategic approach to ensuring food safety for materials and articles in contact with foodstuffs (Food Contact Materials, FCMs).

From the beginning, the name of the Project has described its configuration: CAST means "fusion" in English. The innovative tool of the Project was precisely the fusion of knowledge between public and private stakeholders in order to:

- improve the technical application of the rules;
- to make the interpretation of the dictate of the legislation homogeneous;
- identify methodologies in approaching food safety using technical solutions from a common knowledge base between the Industrial Associations and Public Bodies operating in the sector;
- make the transmission of information in the supply chain more efficient.

The CAST Project is aimed at studying issues concerning compliance with FCMs regulations, through the joint activity of the various stakeholders related to the food supply chain, under the scientific responsibility of the Istituto Superiore di Sanità (ISS, the National Institute of Health in Italy), with the organizational support of the Istituto Italiano Imballaggio (III, Italian Packaging Institute).

The guidelines, drawn up by the CAST Project team, are the result of the joint activity of the trade associations of the individual supply chains up to the producers of materials and objects and food companies.

This guideline has been developed as per the CAST Project, divided into the Working Groups divided into different sectors:

- aluminium;
- paper and board (in separate groups to cover production and converting);
- flexible packaging;
- wood or wood fibre;
- plastics (in separate supply chain to polymer production, masterbatch and processing)
- metals and metal alloys both coated and not-coated;
- cork;
- glass;
- coating;
- adhesives and sealants;
- printing inks;
- coated metal articles intended for cooking;
- rubber (in separate supply chain to production of elastomers, compounds and masterbatch and processing: production of finished articles);
- food packaging machines;
- food gases distribution equipment.

In the CAST Project, within each Working Group, a document was developed on the application of Regulation (EC) 2023/2006 as amended on Good Manufacturing Practice (GMP) in the FCMs sector. The different materials and objects covered by the scope of the guideline have been identified, as well as the different stages of the supply chain considered so that operators in the sector can easily recognize themselves.

This volume was published in September 2009 first in Italian "Linee guida per l'applicazione del Regolamento 2023/2006/CE alla filiera di produzione dei materiali e oggetti destinati a venire in contatto con gli alimenti" (*Rapporto ISTISAN* 09/33) (2) and subsequently, at the request of the European Commission Services DG Sanco (now DG Santé), and requested by representatives of numerous Member States of the European Union, the document was also translated into English (*Rapporto ISTISAN* 11/37) (3).

In addition to the previous guidelines, the Project has drawn up documental verification sheets on the implementation of Regulation (EC) 2023/2006 as amended for FCMs in the various supply chains (*Rapporto ISTISAN* 13/14) (4).

Subsequently, the supply chains of paints, adhesives and sealants, and printing inks were added to the CAST Project Working Group. Additional guidelines on the application of Regulation (EC) 2023/2006 have therefore been published (*Rapporto ISTISAN* 16/42) (5) and on the document confirmation sheets on implementation in the aforementioned supply chains (*Rapporto ISTISAN* 16/43) (6).

The CAST Project, in 2018, also addressed one of the fundamental aspects for FCMs, namely the documentation supporting the Declarations of Compliance (DoC). The guideline was developed by the 12 participating supply chains at the time and was issued as *Rapporto ISTISAN* 18/24 (7) updated in 2024 (*Rapporto ISTISAN* 24/29) (8).

In the following years, the CAST Project was further enriched with the participation of four supply chains: coated metal items for cooking, rubbers, food packaging machines and food additive gas distribution systems.

In view of the new supply chains and the issuance and update of other regulations, an update of the documents *Rapporto ISTISAN* 09/33 (2) and *Rapporto ISTISAN* 16/42 (5) with the *Rapporto ISTISAN* 23/4 Rev. (9). Therefore, even the *Rapporto ISTISAN* 11/37 (3) in English has been updated and is therefore currently replaced by the *Rapporto ISTISAN* 24/8 (10).

This document represents a further advancement of the CAST guidelines on documental verification on the application of Regulation (EC) 2023/2006 (*Rapporto ISTISAN* 13/14) (4) and (*Rapporto ISTISAN* 16/43) (6). Therefore, the Guidelines for documental verification on the application of Regulation (EC) 2023/2006 have been updated, in the legislative references, brought together and integrated with the new supply chains and are now presented in a single document, the result of a revision within the Working Groups of the CAST Project.

The basic idea in the development of the CAST Project guidelines is the enhancement of what already exists at the company and sector level by indicating and finalizing the most widespread management systems, always in compliance with Regulation (EC) 2023/2006 as amended.

Particular attention is paid to the reality of small and medium-sized enterprises, with the aim of providing guidance tools to make the most appropriate operational choices.

INTRODUCTION

This document constitutes a further contribution to the implementation of Regulation (EC) 2023/2006 as amended. In fact, sheets are presented that can be used to verify the documentation relating to the implementation of the system of Good Manufacturing Practice (GMP) as defined by Regulation (EC) 2023/2006 as amended.

During the development of the guidelines, since the beginning of the Project, it has become increasingly evident that, regardless of the achievements and operational choices, the correct implementation of GMP standards cannot be separated from a constructive dialogue between all the players in the food packaging supply chain and more generally in the supply chain of materials intended to come into contact with food, communicating effectively with the food industry itself.

This presupposes both the correct selection of the starting materials and the transfer of the specific information relating to each phase (e.g. Declarations of Compliance, Declarations of Composition, indications on use, etc.) that really allow, throughout the supply chain, the flow and maintenance of the information necessary to ensure the Compliance of the materials and objects intended for contact with food and the safety (from this point of view) of the food product.

This guideline is therefore intended to be used by all operators in the sector and is closely linked to the guideline for the application of Regulation (EC) 2023/2006 as amended to the supply chain of materials and articles in contact with foodstuffs (Food Contact Materials, FCMs).

The contributors to this edition of the guideline include:

- ANFIMA (Italian National Association of Metal Packaging Manufacturers);
- Assocarta (Italian Association of Pulp, Paper and Board Industry);
- Assogastecnici – Federchimica (Italian Association of Technical, Special and Medical Gases Industry);
- Assogomma – Federazione Gomma Plastica (National Association of Rubber, Electrical Cables, and Related Industries);
- Assografici (Italian Association of Printing and Paper Converting Industries);
- Assoimballaggi – FederlegnoArredo (National Association of Wood, Pallet, Cork Packaging Industries, and Logistics Services);
- ASSOMET/CIAL (*Associazione Italiana Industrie Metalli non Ferrosi/Consorzio Nazionale Imballaggi Alluminio*, Italian Association of non-ferrous metal industries/Aluminium Packaging Consortium);
- Assovetro (National Association of Glass Manufacturers);
- AVISA – Federchimica (*Associazione nazionale Vernici, Inchiostri, Sigillanti e Adesivi*, National Association, Paints, Inks, Sealants and Adhesives);
- Federchimica (Italian food industry federation);
- FIAC (ANIMA) (*Associazione Fabbricanti Italiani Articoli per la Casa, la tavola e affini,* Italian association of manufacturers of household and table articles, and related items);
- III (contracting partner) (*Istituto Italiano Imballaggio*, the Italian Institute of Packaging);
- ISS (scientific supervisor) (*Istituto Superiore di Sanità*, the National Institute of Health in Italy);
- PlasticsEurope Italia – Federchimica (Italian Association of Plastics Producers);
- UCIMA (*Unione Costruttori Italiani Macchine Automatiche per il confezionamento e l'imballaggio,* Italian Association of Manufacturers of Automatic Packaging Machines);
- Unionplast – Federazione Gomma Plastica (Italian Association of Plastics Converters).

The present document is divided into two parts:

- *Part A. General guidelines*
  Section on operational indications on documental verification valid for all supply chains (legislative references and applications from a general point of view).
- *Part B. Specific guidelines*
  Section on the description of the type of document for each supply chain (implementations that the supply chains carry out to ensure compliance with legislative requirements).

All stakeholders, if they wish, can send comments and observations for the subsequent revision of the guidelines to the address: cast2021@iss.it.

PART A
General guideline

A1. GENERAL ASPECTS

A1.1. Purpose of the guideline

This guideline provides operational guidance on the documental evidence relating to the application of Commission Regulation (EC) 2023/2006 as amended on good manufacturing practices for materials and articles intended to come into contact with foodstuffs.[1] The regulation, in full application since August 2008, concerns all materials, all phases and all sectors of the production chain of Food Contact Materials (FCMs).

This document, like the *Rapporto ISTISAN* 23/4 Rev. (9) (hereinafter referred to as the "CAST GMP guideline"), from which it derives is not binding but can constitute a useful reference for the various players in the supply chain who, depending on their respective position in the same, may find technical and application guidance for documental verification of the activities of implementation, maintenance or finalization of management systems that meet the requirements of Regulation (EC) 2023/2006 as amended.

A1.2. Feld of application of the guideline

The present guideline applies to FCMs produced in the manufacturing supply chains listed below. The types of application are reported in the specific chapters for each supply chain.

The guidelines relating to the supply chains considered are:

- B1. Aluminium;
- B2. Paper and cardboard: production;
- B3. Paper and cardboard: converting;
- B4. Flexible packaging;
- B5. Wood or wood fibre;
- B6. Plastics:
  B6a. Polymer and masterbatch production,
  B6b. Processing: production of semi-finished products and packaging;
- B7. Metal and metals alloys, coated and not-coated;
- B8. Cork: cork stoppers;
- B9. Glass;
- B10. Coating;
- B11. Adhesives and sealants;
- B12. Printing inks;
- B13. Coated metal articles intended for cooking;
- B14. Rubber:
  B14a. Production of elastomers, compounds and masterbatch,
  B14b. Processing: production of finished articles;
- B15. Food packaging machines;
- B16. Food gases distribution equipment.

[1] Regulation published in the *Official Journal of the European Union* L384/75-78 of 29/12/2006.

A1.3. General legislation on FCMs

All FCMs are subject to general regulations which are harmonized at a community level and are applicable to all sectors and to all the phases of production, processing and distribution. Some regulations issued at Italian level are still valid as they have not been superseded by harmonized regulations. The list of the Regulations is as follows:

European legislation

- Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/CEE and 89/109/CEE as amended.
- Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as amended.
- Regulation (UE) 2017/625 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Italian legislation

– DPR 777/1982 - Decree of the President of the Republic No. 777/1982 on implementation of the Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs as amended.

– DL.vo 108/1992 - Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.

– DL.vo 29/2017 - Legislative Decree No. 29 /2017 on sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food.

A2. DEFINITIONS

The following definitions, most of which have already been given in CAST GMP guideline, illustrate the most important terms used in this text. When they exist, these definitions are taken verbatim from the relevant legislation, i.e. from Regulation (EC) 1935/2004 as amended, from Regulation (EC) 2023/2006 as amended and from Regulation (EU) 10/2011 as amended.

- *Good Manufacturing Practice* (GMP)
  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 (Regulation (EC) 2023/2006 as amended, art. 3).

- *Formulations*
  By formulations is meant the composition of the constituents of the semifinished or finished products. The constituents are used in the phases of the manufacturing process. In the formulation, as well as the constituents, technological coadjuvants can also be contemplated, should these be considered within the system and objectives of the GMP.

- *Business*
  Any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of manufacture, processing and distribution of materials and articles for food contact (Regulation (EC) 1935/2004 as amended, art. 2).

- *Food Contact Materials (FCMs)*
  Materials and articles, in the state of finished products that are for contact with food products; or that are already in contact with food products and are for that purpose; or that it be reasonably presumed they may be placed in contact with food products or that transfer their own components to food products in normal or foreseeable conditions of use (Regulation (EC) 1935/2004 as amended, art. 2.

- *Industry Operator*
  Expression equivalent to Business Operator (Regulation (EC) 2023/2006 as amended, art. 3). [2]

[2] In this case, reference must be made to the English text. In fact, in the English texts of Regulation (EC) 1935/2004 as amended and Regulation (EC) 2023/2006 as amended, the same term “business operator” is used, translated in Regulation (EC) 1935/2004 as amended as “economic operator” and in Regulation (EC) 2023/2004 as amended as “operator in the sector”. Moreover, it should be noted that in Regulation (EC) 2023/2006 as amended, there is no definition of “business operator”, thus considering applicable what has already been defined in Regulation (EC) 1935/2004 as amended.

- *Business operator*
  The natural or legal person responsible for ensuring that the requirements of this Regulation (EC) 1935/2004 as amended are met with in the business under his/her control (Regulation (EC) 1935/2004 as amended, art. 2).[3]

- *Manufacturing or production processes*
  All the phases of converting of raw materials, starting substances and semifinished articles for obtaining semifinished articles and finished products. In the manufacturing process, within the context of the Regulation (EC) 2023/2006 as amended, the phases of storage and handling of the raw materials, starting substance and semifinished articles are considered along with the final phases of packaging and palletisation of the semifinished article and finished product, as well as the storage and transport phases.

- *Quality Assurance System* (QAS)
  The total sum of the organised and documented arrangements made with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use (Regulation (EC) 2023/2006 as amended, art. 3).

- *Quality Control System* (QCS)
  The systematic application of measures established within the quality assurance system that ensure compliance of starting materials and intermediate and finished materials and articles with the specification determined in the Quality Assurance System (Regulation (EC) 2023/2006 as amended, art. 3).

- *Specifications*
  As understood under Regulation (EC) 2023/2006 as amended, art. 3, the same are specifications concerning the "requisites" defined for the raw materials and semifinished articles. The specifications for the requisites for the raw materials and semifinished articles fall under the conformity with the legislation on materials and articles for food contact.

[3] The Regulation (EC) 2023/2006 as amended does not contain a definition of business operator, hence considering what has already been defined in Regulation (EC) 1935/2004 as amended as applicable.

PART B
Specific guidelines

INTRODUCTION

In this Part B, the specific chapters describe the type of documentation that the packaging supply chains, considered in this guideline, prepare and use to demonstrate the compliance of their implementations with the requirements of Regulation (EC) 2023/2006 as amended.

The description is divided into separate and independent chapters for each supply chain, reflecting and respecting the peculiarities of the supply chains themselves.

However, for the sake of clarity of reading and interpretation, an attempt has been made to maintain homogeneity in the structure and terminology of the text wherever possible.

The specific guidelines are set out as follows:

- B1. Aluminium;
- B2. Paper and board production;
- B3. Paper and board: converting;
- B4. Flexible packaging;
- B5. Wood or wood-based;
- B6. Plastic:
  - B6a. Polymer production and masterbatch,
  - B6b. Processing: production of semi-finished products and packaging;
- B7. Metals and metal alloys both coated and not-coated;
- B8. Cork;
- B9. Glass;
- B10. Coating;
- B11. Adhesives and sealants;
- B12. Printing inks;
- B13. Non-stick coated metal articles intended for cooking;
- B14. Rubber:
  - B14a. Production of elastomers, compounds and masterbatch,
  - B14b. Processing: production of finished articles;
- B15. Food packaging machines;
- B16. Food gases distribution equipment.

It should be noted that in order to immediately integrate what has already been indicated in the *Rapporto ISTISAN* 23/4 Rev. Edition 2023 (9), this document maintains the same numbering, and refers to the aforementioned guideline, of which it therefore becomes a part of the accompaniment.

Within each specific guideline, the following is described:

- the field of application;
- the sheets relating to the documentation corresponding to the obligations deriving from the application of Regulation (EC) 2023/2006 as amended;
- the production process in graphic scheme.

The sheets show the correspondence with the parts of the CAST GMP guideline followed by the relative section, e.g. CAST GMP → guideline B1.2.1.

The flow diagrams are those already published in the CAST GMP guidelines and are reported at the end of each chapter for quick reference.

GUIDE TO THE SHEETS FOR DOCUMENTAL VERIFICATION

An important premise for introducing this document is the reference to what is written in the document *Rapporto ISTISAN* 23/4 Rev. (9) and in its translation *Rapporto ISTISAN* 24/8 (10):

> "Regulation (EC) 2023/2006 as amended constituted a novelty as far as the rules on FCMs are concerned, because for the first time it lays down the implementation of the quality system at legislative level.
> In fact, the Framework Regulation (EC) 1935/2004 as amended, at art. 3 only demands in general terms that "Materials and articles, […] should be manufactured in compliance with good manufacturing practice so that […]". Therefore, no way to ensure compliance with GMP is made explicit, while Regulation (EC) 2023/2006 as amended, give the basic indications and essential tools to respond to the above. The main concept is precisely the implementation (or extension) of quality systems, with the requirements described in the articles and annexes.
> Practically speaking, while the Framework Regulation deals with the aspects of system management in relations outside the business (documented traceability, declaration of compliance), the GMP Regulation concerns the internal management of the company, for the aspects finalised for the production of materials and articles conforming to art. 3 of the Framework Regulation (EC) 1935/2004 as amended and it is established that the management of the system is through the implementation or the extension of the quality system.
> When we speak of quality systems, ISO standards constitute a sound technical benchmark, as the spread of their use in the most different industrial fields shows, but Regulation (EC) 2023/2006 as amended does not implicate the obligatory adoption of ISO standards, nor the certification of the system.
> It should also be reiterated that, in the field of regulated obligations for FCM, the implementation of a quality system, even if certified, does not automatically entail the fulfilment of the requisites of the Regulation (EC) 2023/2006 as amended.
> This document is above all intended as a guidance, in order to give all [businesses] a useful tool for a better understanding and an easier application of the Regulation, regardless of the size of the company and their staff, independently of their organization.
> In the wording of the Regulation (EC) 2023/2006 as amended terms like Quality Assurance System, GMP, etc. are used; these terms already have fairly consolidated meanings among those that deal with the management of company quality, especially under ISO 9000, this following many years of use. Their interpretation could thus not be perfectly in line with what is laid down by the Regulation, that is the benchmark to be referred to.
> For greater clarity, chapter A2 contains the most important terms used in the present text, accompanied by the respective definitions that, when present, are textually covered by Regulation (EC) 1935/2004 as amended and Regulation (EC) 2023/2006 as amended."

In addition, this document is part of an even more applicative plan, in support of the aforementioned guideline.

In fact, some practical sheets are proposed that link Regulation (EC) 2023/2006 as amended with the specific chapters of the CAST GMP guideline and illustrate the type of documentation that can be prepared to comply with the legal obligation. Where necessary, the rationale behind the operational choice is also commented on, in the parts relating to each supply chain, which remains the responsibility of the company.

The format of the sheets, considered useful and uniform for practical purposes, is in any case secondary to their content, which instead constitutes from an operational point of view a set of commented suggestions for the documental verification of the management system implemented.

The sheets reported in the chapters for the specific supply chains should therefore not be considered as classic pre-filled checklists, used by the inspector (public inspector or company personnel, or third party) to verify the presence of documentation, but an operational guide to support the correct implementation of Regulation (EC) 2023/2006 as amended, according to the approach of the CAST GMP guideline, which must always accompany the use of these cards.

The following fields are distinguished in the tabs:

- *Title*
  where the topic of the sheet and the correspondence with the chapter(s) of the CAST GMP guideline are indicated;
- *Legislative reference*
  where the article of Regulation (EC) 2023/2006 as amended or additions or its part considered is reported;
- *Fulfilment*
  where the type of compliance required by the relevant article of Regulation (EC) 2023/2006 as amended is summarized;
- *Document type and description*
  where the type of documentation, corresponding to the chapter of the CAST GMP guideline, that supports compliance with the requirement of the legislative reference (e.g. manuals, procedures, instructions, records, etc.) is described;
- *Notes*
  where clarifications, explanatory comments, etc. are reported.

A facsimile of the form used is shown in Annex B0 to this chapter.

It should be noted that in the sheets filled in in the specific part, the technical content of the document is not described, except briefly, but attention is paid to its type (e.g. procedure, registration form, etc.) which will then correspond to a more extensive documentation in the Company's management system. The peculiarity of each supply chain, but even more so the size and organization of the company, will also involve operational choices that are often different, but which can be equally valid and meet the requirements of the law.

ANNEX. Facsimile sheet for documental verification

Sheet BX

INDICATION	DESCRIPTION
Legislative reference	
Fulfilment	
Document type and description	
Notes	

B1. ALUMINIUM

B1.1. Characterization of the sector

B1.1.1. Field of application of the guideline

This guideline applies to companies producing thin aluminium foil and rolled products intended for the manufacture of uncoated aluminium trays.

B1.1.2. Phases of the production process: flowchart and description

The production flow diagram is given in Annex B1.1 at the end of this chapter. The summary description of the process steps is given in chapter B1.1.3.2 of the CAST GMP guideline.

B1.2. Sheets for documental verification of the application of Regulation (EC) 2023/2006

This guideline defines the activities and documentation required to implement the requirement of Regulation (EC) 2023/2006 as amended concerning the GMP standards for the supply chain of rolled products, thin sheets and finished products of aluminium as it is or transformed.

Any other documents related to the legal provisions on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs) are included in separate documentation systems, such as the Supporting Documentation (SD).

Below are reported sheet (B1.2.a.-B1.2.h) for documents review of activities and/or implementations that may be put in place by the Company to be in compliance with the provisions of Articles 5, 6 and 7 of Regulation (EC) 2023/2006 as amended.

The form presented are not binding for the supply chain discussed here, but their content must be considered a set of operational suggestions. The cards should always be used in conjunction with the CAST GMP guideline.

Sheet B1.2.a. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Quality Assurance Systems* (guideline CAST GMP → B1.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective; – documented; – appropriate to the size of the Company.
Document type and description	The documentation relating to the QAS may consist of the Quality Manual, if available, or other similar document demonstrating that the system is applied and implemented. Specific procedures must be available to define how the system is implemented and enforced and the methods for consulting company documentation with respect to Regulation (EC) 2023/2006 as amended. The documentation should contain references to roles and responsibilities within the Company itself (e.g. nominative organization chart). The Company should identify within its organization the Function responsible for the application of Regulation (EC) 2023/2006 as amended.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended. Any certification by third parties could guarantee the adequacy of the QAS with respect to the size of the company. ISO 9001 quality management systems include several requirements also provided by the Regulation (EC) 2023/2006 as amended.

Sheet B1.2.b. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Human resources and training* (guideline CAST GMP→ B1.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Adequacy of staff. Staff knowledge and skills.
Document type and description	Training is planned and documented, for example, by: – procedures and/or Instructions for the training and refresher training of personnel containing indications for verifying effectiveness; – specific training activity on the GMP system and FCMs.
Notes	Company can define roles and responsibilities to explain the internal organization (job description) and report them in documents such as the Quality Manual or other suitable document.

Sheet B1.2.c. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Production* (guideline CAST GMP→ B1.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Production system compliance.
Document type and description	For each phase of the production process (order of raw materials, eventual product design, production planning, production according to defined recipe, production controls) the specific operating methods for that operation and the necessary related recordings can be defined through appropriate documentation: – procedure; – guidelines; – records of the relevant activities carried out.
Notes	-

Sheet B1.2.d. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Selection of raw materials and suppliers* (guideline CAST GMP→ B1.2.1.2)**
QUALITY CONTROL SYSTEMS
***Management of raw materials warehouses* (guideline) CAST GMP→ B1.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Selection of raw materials and suppliers.
Document type and description	Company should prepare documents relating to: – technical specifications, safety data sheets, any documentation of legislative compliance of raw materials with reference to FCMs; – procedures for the selection and qualification of suppliers of external goods, materials and services; – procedures and records relating to the evaluation of suppliers; – operating procedures/instructions for any acceptance checks in order to verify the compliance of raw materials with specifications; – records of control results.
Notes	Controls of storage arrangements should be defined on the basis of an assessment of the risks of contamination and/or deterioration of raw materials. As far as the risk of contamination during warehouse storage is concerned, in the case of slabs and semi-finished coil, it can be considered irrelevant. raw materials controls and suppliers qualification must be applied Only in case of relevance for compliance to Ministerial Degcree 76/2007. Acceptance controls are not mandatory for all raw materials, unless they are mandatory to ensure legislative compliance (e.g. radioactivity assessment for plates, semi-finished rolls and evaluation of the chemical composition of aluminium). In particular, for approved materials/suppliers, the Company may decide to release the goods into production without preventive checks.

Sheet B1.2.e. QUALITY CONTROL SYSTEMS
***Production controls* (guideline CAST GMP→ B1.2.2.2)**
***Quality Control of finished product* (guideline CAST GMP→ B1.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Production controls and quality control of finished products.
Document type and description	The following should be defined: – procedures/work instructions for process control to define: – the critical points of the process; – the checks to be carried out (measurements, tolerances, frequencies); – levels of responsibility; – product control procedures to define: – the critical parameters and reference values in relation to the specification of each product; – the control methods (tolerances/frequency); – the levels of responsibility for controls; – procedures/instructions describing the methods for ensuring the controls and traceability of the product starting from the raw materials used through the various work steps of production up to the finished goods warehouse; – procedures/instructions for delivery to the warehouse storage; – recording of process and product controls.
Notes	-

Sheet B1.2.f. QUALITY CONTROL SYSTEMS
***Management of finished products warehouses* (guideline CAST GMP→ B1.2.2.4)**
***Distribution, shipment and delivery* (guideline CAST GMP→ B1.2.2.5)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2060 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the management of the finished products warehouse, for transport and delivery.
Document type and description	The following should be defined: – procedures/instructions for the storage of finished products (with identification of the condition: material meeting the established specification, under test, contested, etc.) and related records; – procedures/instructions for the identification and traceability of stored products. – procedures/instructions for the traceability of picking operations and authorization for shipment to customers (finished products) and related records; – procedures/instructions for the definition of the criteria for the selection of transporters and the checks to be carried out on the means of transport (any supply/service specifications) and related records; – operating instructions for issuing a transport document.
Notes	-

Sheet B1.2.g. QUALITY CONTROL SYSTEM
***Conformity of the application of the GMP and claims management, corrective and preventive actions* (guideline CAST GMP→ B1.2.2.6)**

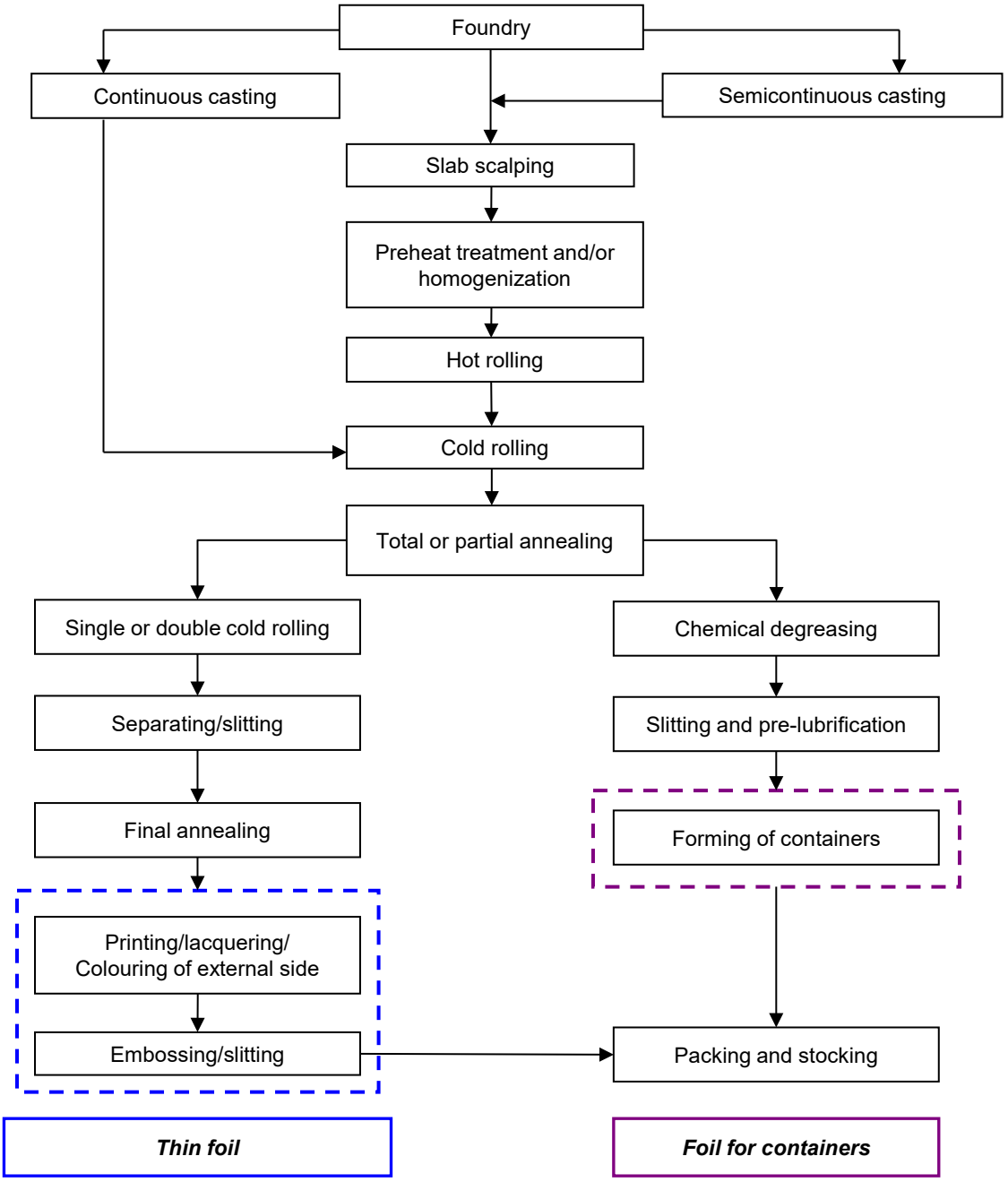
INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.*
Fulfilment	Instructions and procedures for monitoring the implementation of Regulation (EC) 2023/2006 as amended
Document type and description	The following should be defined: – procedures/operating instructions for performing internal audits. Internal audits shall be planned, carried out and appropriately recorded for all business areas involved in the implementation of Regulation (EC) 2023/2006 as amended and supplemented in order to verify its correct implementation; – procedures for the management of claims and management of any non-conformities; – procedures for the implementation of corrective and preventive actions for the resolution of non-conformities (verification of the effectiveness of the corrective/preventive actions implemented).
Notes	-

Sheet B1.2.h. DOCUMENTATION
***Documentation* (guideline CAST GMP→ 1.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 2: *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant for the conformity and safety of finished materials and articles, and relating to the results of the quality control system.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by operators in the sector.*
Fulfilment	Preservation of QAS and Quality Control System (QCS) documentation. Continuous updating and transposition of legislation developments.
Document type and description	The following should be defined: – procedures, operating instructions for the archiving and storage of documents relating to the QAS (procedures, specifications, formulations, etc.); – procedures, operating instructions for the archiving and storage of documents relating to the QCS (instructions, records of process and control data); The Quality Manual or other company document defines an adequate time for the storage of all documents concerned with to the implementation of the GMP system; Procedures/instructions must be defined to ensure continuous compliance with the regulatory requirements of current legislation.
Notes	Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/2004 as amended). Copies of the declarations of conformity issued are an integral part of the archive (art. 16 of Regulation (EC) 1935/2004 as amended).

Annex B1.1.

Production flowchart of thin foil and foil for containers



B2. PAPER AND CARDBOARD: PRODUCTION

B2.1. Characterization of the sector

B2.1.1. Field of application of the guideline

This guideline applies to all companies that produce paper and cardboard from virgin or waste fibre up to the formation of the sheet and preparation in reels or sheets.

B2.1.2. Phases of the production process: flowchart and description

The production flowchart is given in Annex B2.1 at the end of this chapter.

A brief description of the process steps is provided in chapter B2.1.3.2 of the guideline CAST GMP.

B2.2. Sheets for documental verification of the application of Regulation (EC) 2023/2006

This guideline defines the activities and documentation required to implement the provisions of Regulation (EC) 2023/2006 as amended relating to GMP standards for the paper and cardboard production chain.

Any other documents related to the legal provisions on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs) are included in separate documentation systems, such as the Supporting Documentation (SD).

Below are the sheets (B2.2.a.-B2.2.m.) for documental verification that describe the activities and/or implementations that can be implemented by the Company to implement the provisions of Articles 5, 6 and 7 of Regulation (EC) 2023/2006 as amended.

The form presented are not binding for the supply chain discussed here, but their content must be considered a set of operational suggestions. The cards should always be used in conjunction with the CAST GMP guideline.

Sheet B2.2.a. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Quality Assurance Systems* (guideline CAST GMP→ B2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective. – documented. – appropriate to the size of the company.
Document type and description	The documentation relating to the QAS may consist of the Quality Manual, if available, or other similar document demonstrating that the System is applied and implemented. The system must contain: – Regulation (EC) 2023/2006 as amended; – procedures, instructions and documents that define how the system is implemented and enforced; – roles and responsibilities within the Company itself. The Company should identify within its organization the Function responsible for the application of Regulation (EC) 2023/2006 as amended.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended. Any certification by third parties (e.g. according to ISO 9001) could guarantee the adequacy of the QAS with respect to the size of the company. ISO 9001 quality management systems include multiple requirements also for GMP standards. Where appropriate, adequate and controlled signage and signage can be a valid alternative to written procedures and instructions.

Sheet B2.2.b. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Size of the business* (guideline CAST GMP→ B2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Organization of the necessary locations and equipment
Document type and description	The organization of the offices and their structure should be reported in the Quality Manual or in other specific company documentation. Documents relating to the adequacy of production equipment, where relevant for the production of FCMs, and control of finished materials and articles; Manuals/production procedures/technical documentation of the machinery and its calibration status, where relevant for the production of FCMs. Manuals and technical documentation of machinery and equipment can be recalled/inserted/attached in the documentation of the Quality System.
Notes	-

Sheet B2.2.c. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Human resources and training* (guideline CAST GMP→ B2.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Adequacy of staff. Staff knowledge and skills.
Document type and description	Training is recorded and documented for example by: – procedures and/or instructions for the training and updating of personnel containing indications for verifying effectiveness; – specific training activities on the GMP system and FCMs; – specific training and refresher courses in relation to the assigned task.
Notes	Company can define roles and responsibilities to explain the internal organization (job description) and report them in documents such as the Quality Manual or other suitable document.

Sheet B2.2.d. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Raw materials and suppliers' SELECTION* (guideline CAST GMP → B2.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Selection of raw materials and suppliers.
Document type and description	The Company should prepare documents relating to: – specifications of the raw materials (wood, paper pulp, waste paper, auxiliaries, fillers and adjuvants) which contain indications of the physical and/or chemical parameters that identify the raw materials; – procedures for the selection and qualification of suppliers of external goods, materials and services, which are relevant for the production of FCMs, which define: – the evaluation criteria and inclusion in the list of approved suppliers; – the operating methods to assess over time the ability of suppliers to maintain the required quality level. The selection, qualification and listing of qualified suppliers and the monitoring of qualified suppliers must be properly recorded.
Notes	-

Sheet B2.2.e. QUALITY CONTROL SYSTEMS
***Management of raw materials warehouses* (guideline CAST GMP→ B2.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Compliance of raw materials with defined specifications.
Document type and description	Procedures/operating instructions for acceptance checks, according to any sampling plans, should be defined in order to verify the compliance of raw materials with the specifications. Records of the results of both documental and analytical checks.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, internal methods, standards) by means of suitable, adequately calibrated instrumentation. Visual inspections must be carried out after training of the personnel in charge. The data resulting from quality control operations should be appropriately recorded in computerized tables, databases, etc.

Sheet B2.2.f. QUALITY CONTROL SYSTEMS
***Management of raw materials warehouses* (guideline CAST GMP→ B2.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures*
Fulfilment	Instructions and procedures for the production process.
Document type and description	Documents describing the management operating modes and relevant process parameters should be defined for each step of the process, for example: – manuals, procedures, instructions, recipes, technical standards; – records of relevant activities carried out and controls; – adequate records of the trend of the parameters significant for the production of FCMs, including any deviations.
Notes	A process flow chart can help identify critical points in the process that need operating instructions and or other documents necessary to maintain and demonstrate control of activities for the purposes of FCMs and GMP standards.

Sheet B2.2.g. QUALITY CONTROL SYSTEMS
***Quality Control of finished products* (guideline CAST GMP→ B2.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the production process.
Document type and description	The following should be defined: – operating instructions or procedures aimed at verifying the conformity of the quality of the finished product with the expected requirements and codified in the respective product specifications for the purpose of contact with food.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, internal methods, standards) by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be appropriately recorded in computerized tables, databases, etc.

Sheet B2.2.h. QUALITY CONTROL SYSTEMS
***Management of finished product warehouses* (guideline CAST GMP → B2.2.2.4)**
***Distribution, shipment and delivery* (guideline CAST GMP → B2.2.2.5)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the management of the finished products warehouse, for transport and delivery.
Document type and description	The following should be defined: – procedures/instructions for the storage of finished products (with identification of the condition: material meeting the established specification, under test, contested, etc.) and related records; – procedures/instructions for the identification and traceability of stored products and related records; – procedures/instructions for the traceability of picking operations and authorization for shipment to customers (finished products) and related records; – procedures/instructions for the definition of the criteria for the selection of transporters and the checks to be carried out on the means of transport (supply / service specifications) and related records; – operational instruction for issuing a transport document.
Notes	-

Sheet B2.2.i. QUALITY CONTROL SYSTEMS
***Quality Control System* (guideline CAST GMP → B2.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art.6, paragraph 1: *Operators in the sector must establish and maintain an effective quality control system.*
Fulfilment	Development of a Quality Control System suitable for its activity, structure, product.
Document type and description	The reference documents are, for example: – Quality Manual; – procedures and operating instructions that establish control methods (references to laws, standards, specifications, internal methods, etc.); – records of the activities of verification of conformity of products with their respective specifications, e.g. control sheets, computerized tables.
Notes	The Quality Manual is not a requirement expressly required by Reg. 2023/2006.

Sheet B2.2.l. QUALITY CONTROL SYSTEMS
Conformity of the application of the GMP and claims management, corrective and preventive actions (guideline CAST GMP → B2.2.2.6)

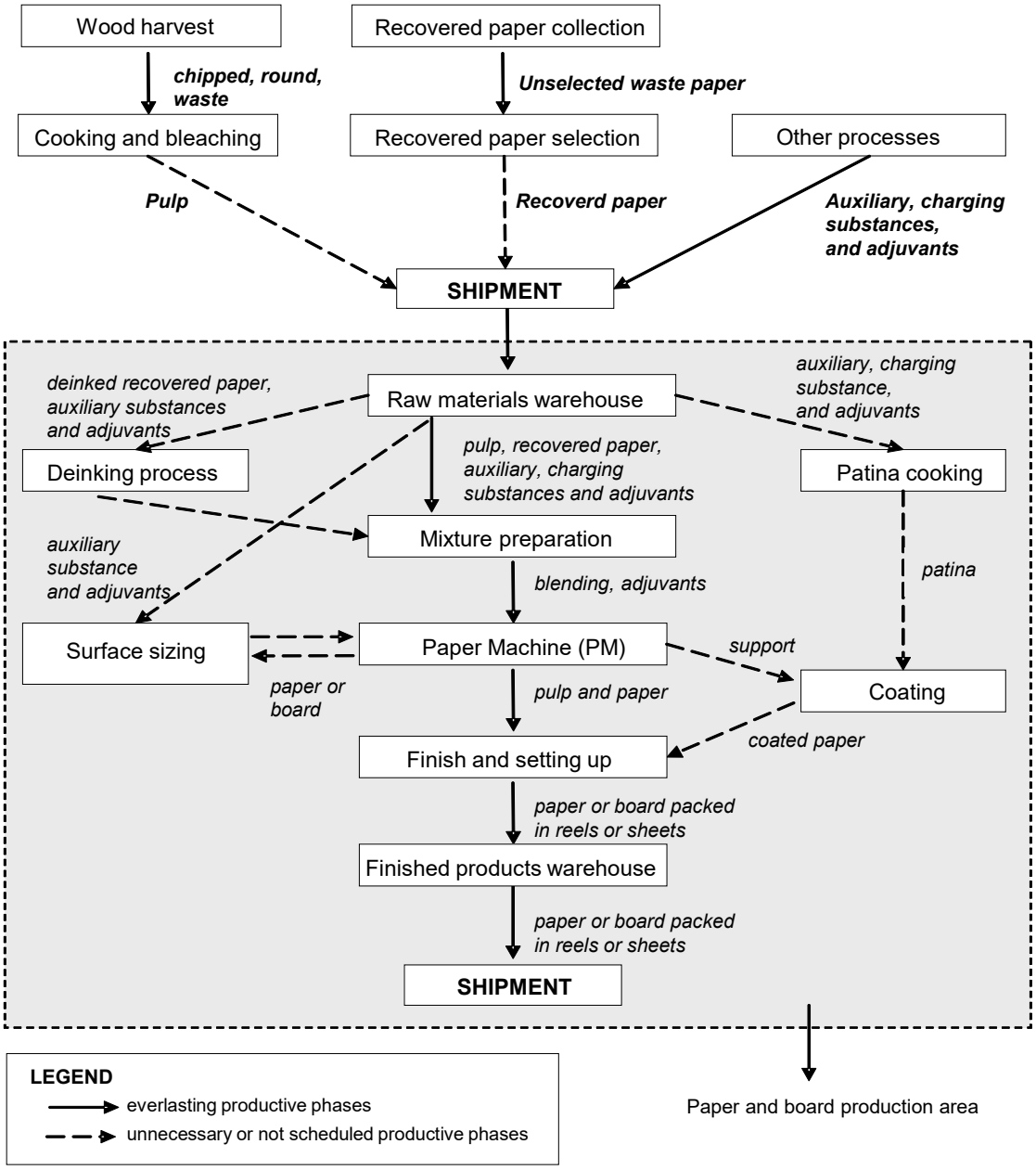
INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.*
Fulfilment	Instructions and procedures for monitoring the implementation of GMP standards.
Document type and description	The following should be defined: – procedures/operating instructions for performing internal audits. Internal audits are planned, carried out and appropriately recorded for all business areas involved in the implementation of the GMP regulations, in order to verify their correct implementation; – procedures for the management of complaints and management of any non-conformities; – procedures for the implementation of corrective and preventive actions for the resolution of non-conformities. The latter procedure must include the verification of the effectiveness of the corrective/preventive actions implemented.
Notes	-

Sheet B2.2.m. DOCUMENTATION
***Documentation* (guideline CAST GMP→ B2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* art. 7, paragraph 2: *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant for the conformity and safety of finished materials and articles, and relating to the results of the quality control system.* art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by operators in the sector.*
Fulfilment	Preservation of QAS and Quality Control System (QCS) documentation. Continuous adaptation and transposition of legislation.
Document type and description	They should be defined as: – procedures, operating instructions for the archiving and storage of documents relating to the QAS (procedures, specifications, formulations, etc.); – procedures, operating instructions for the archiving and storage of documents relating to the SCQ (instructions, records of process and control data). The Quality Manual or other company document defines an adequate time for the storage of all documents pertinent to the implementation of GMP standards. Procedures/instructions should be defined to ensure continuous adaptation to the regulatory requirements of existing legislation.
Notes	Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/2004 asamended). Copies of the declarations of Compliance issued are an integral part of the archive (art. 16 of Regulation (EC) 1935/2004 as amended).

Annex B2.1.

Flowchart of the production of paper and in reels or sheets



B3. PAPER AND CARDBOARD: CONVERTING

B3.1. Characterization of the sector

B3.1.1. Field of application of the guideline

This guideline applies to all companies that produce paper and cardboard packaging regardless of the materials that compose it. The paper and board packaging cycle includes the processing of used paper and board alone or in combination for primary and/or secondary packaging intended to contain foodstuffs. For the starting raw materials, reference must be made, where existing, to the guidelines of the specific material (plastic films, paper, aluminium, etc.).

B3.1.2. Phases of the production process: flowcharts and descriptions

The production flow diagrams, taken from the CAST GMP guideline, are given in Annexes B3.1-B3.3 at the end of this chapter.

The summary description of the process steps is given in chapters B3.1.3.2, B3.1.3.4 and B3.1.3.6 of the CAST GMP guideline.

B3.2. Sheets for documental verification of the application of Regulation (EC) 2023/2006

This guide defines the activities and documentation required to implement the provisions of Regulation (EC) 2023/2006 as amended relating to GMP standards for the converting chain of paper and cardboard for the production of packaging.

Any other documents related to the legal provisions on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs) are included in separate documentation systems, such as the Supporting Documentation (SD).

Below are the sheets (B3.2.a-B3.2.o) for documental verification that describe the activities and/or implementations that can be implemented by the Company to implement the provisions of Articles 5, 6 and 7 of Regulation (EC) 2023/2006 as amended.

The form presented are not binding for the supply chain discussed here, but their content must be considered a set of operational suggestions. The cards should always be used in conjunction with the CAST GMP guideline.

Sheet B3.2.a. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Quality Assurance Systems* (guideline CAST GMP → B3.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective. – documented. – appropriate to the size of the company.
Document type and description	The documentation relating to the QAS may consist of the Quality Manual, if available, or other similar document demonstrating that the System is applied and implemented. The system must contain: – references to Regulation (EC) 2023/2006 as amended; – procedures, instructions and organization chart with definition of roles and responsibilities within the Company. The Company should identify within its organization the Function responsible for the application of Regulation (EC) 2023/2006 as amended.
Notes	The Quality Manual is not a mandatory requirement of Regulation (EC) 2023/2006 as amended. The QAS is here intended only as compliance with Regulation (EC) 2023/2006 as amended, and should not be confused with the ISO 9000 system.

Sheet B3.2.b. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Size of the business* (guideline CAST GMP→ B3.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them*. Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter b): *Be applied taking into account the size of the company, so as not to constitute an excessive burden for the company.*
Fulfilment	Production sites. Production equipment.
Document type and description	Company organization chart. The QAS must include: – organization of the production site and production processes; – documents relating to the adequacy of production equipment, control processes and calibration of production tools (e.g. list of equipment and machines used to produce FCMs). The documents will contain: – the list of actors involved reported by company function; – the list of machines and their location.
Notes	-

Sheet B3.2.c. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Human resources and training* (guideline CAST GMP→ B3.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *This system must take into account the adequacy of the staff, their knowledge and skills.*
Fulfilment	Adequacy of staff. Staff knowledge and skills.
Document type and description	The QAS must include: – procedures to identify staff skills; – company training plan; – procedures for verifying the effectiveness of training regarding the application of Regulation (EC) 2023/2006 as amended (e.g. tests and evaluation sheets, tests relating to knowledge of FCMs manufacturing practices); – recording of the training, dates and topics covered.
Notes	It is advisable to define company roles and skills through a job description (organization chart and job description).

Sheet B 3.2.d. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Selection of the starting materials and the suppliers of goods and/or services and/or third parties* (guideline CAST GMP → B3.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Qualification of raw materials. Qualification of suppliers of goods and/or services.
Document type and description	The QAS must include: – procedures for the selection and qualification of starting materials; – procedures for the qualification and approval of suppliers of starting materials; – procedures for the qualification and approval of suppliers of goods and/or services; – list of qualified and approved suppliers; – audit procedures of approved suppliers. A record of selections, supplier qualification and monitoring of suppliers must be available.
Notes	The declarations should be updated with each change of starting materials. For the selection and qualification of starting materials, *"technical specifications"* can be used, which specify the necessary requirements that may affect compliance with contact with food products.

Sheet B3.2.e. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Production* (guideline CAST GMP → B3.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures*.
Fulfilment	Instructions and procedures for the production process.
Document type and description	For each phase of the production process, there must be specific documents describing the management operating methods and the process parameters to be kept under control. Useful documents include, for example: – production operating instructions; – recording of process operations; – recording of the values of the controlled parameters and their deviations from the pre-established tolerances.
Notes	A brief description of the raw materials used and the production and storage process may be useful. The process flowchartcan help identify critical points in the process that need specific instructions and controls to demonstrate compliance with GMP standards and FCMs legislation.

Sheet B3.2.f. QUALITY CONTROL SYSTEMS
***Quality Control Systems* (guideline CAST GMP→ B3.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art.6, paragraph 1: *Operators in the sector must establish and maintain an effective quality control system.*
Fulfilment	Define an effective and organized quality control system.
Document type and description	The system must include: – responsibilities within the Company for all decisions in terms of quality control; – the procedures and operating instructions that supervise all product control actions (e.g. list of checks to be carried out and implementation methods); – the recording systems of all the checks carried out. (e.g. sheets/reports).
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended but if present it can be a useful tool to certify compliance with GMP standards. The controls referred to are those on products/materials to certify the conformity of FCMs.

Sheet B3.2.g. QUALITY CONTROL SYSTEMS
***Management of raw materials warehouses* (guideline CAST GMP → B3.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.* Regulation (EC) 2023/2006 as amended, art. 6, paragraph 1: *Operators in the sector must establish and maintain an effective quality control system.*
Fulfilment	Raw material warehouse management. Verification of incoming materials. Raw material storage.
Document type and description	The following must be provided: – procedures to define any incoming controls to be carried out on raw materials/semi-finished products to identify any anomalies with respect to what is required for FCMs; – procedures with storage rules (approved, tested, contested material, etc.). Important are the rules for the separation and segregation of non-compliant materials; – records of any differences/anomalies found; – procedures for sending it to production.
Notes	A control document or check-list may be useful for the compliance of raw materials with purchasing specifications/regulations on FCMs.

Sheet B3.2.h. QUALITY CONTROL SYSTEMS
***Production controls* (guideline CAST GMP → B3.2.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.* Regulation (EC) 2023/2006 as amended, art. 6: *Quality control systems.*
Fulfilment	Identification of critical issues in controls and corrective actions. Evaluation of tolerances. Assignment of responsibilities.
Document type and description	The following must be provided: – procedures and instructions that specify the controls to be carried out on the production process to ensure compliance and traceability in accordance with the legislative requirements on FCMs; – for each measured quantity, the nominal value, the accepted tolerance, and the frequency of checks must be fixed and indicated. The measurement methods shall also be specified and a description of the methods shall be available.
Notes	Examples of parameters that can be checked on the product are: – dimensional quantities (print pitch, etc.); – colour measurements (density, etc.); – printing press conditions; – set off (counterprint).

Sheet B3.2.i. QUALITY CONTROL SYSTEMS
***Quality Control of finished products* (guideline CAST GMP→ B3.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.* Regulation (EC) 2023/2006 as amended, art. 6: *Quality control systems.*
Fulfilment	Define non-compliance policies. Define which checks to carry out and their frequency. Allocation of responsibilities.
Document type and description	The following must be provided: – procedures to identify responsibilities; – procedures and/or instructions that make it possible to verify the conformity of the finished product with the requirements of the reference legislation; – instructions establishing the quantities to be checked, the validated test methods to be used, the reference values and tolerances allowed; – The records of the measurements carried out must be kept in special paper documents or on computer supports. A list of suitable instrumentation for measuring and recording calibrations shall be available.
Notes	It is useful to define a product sheet.

Sheet B3.2.l. QUALITY CONTROL SYSTEMS
***Management of finished product warehouses* (guideline CAST GMP→ B3.2.2.4)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.* Regulation (EC) 2023/2006 as amended, *art. 6:* *Quality control systems.*
Fulfilment	Control of the storage area of finished products. Storage conditions.
Document type and description	The following must be provided: – procedures for the storage of finished products; – procedures for the identification and traceability of finished products; – procedures for authorization of shipment; – procedures for the identification, segregation of non-compliant products and/or products in *a standby* state pending other controls.
Notes	The documentation could also define how to check the status of the pallets.

Sheet B3.2.m. QUALITY CONTROL SYSTEMS
***Distribution, shipment and delivery* (guideline CAST GMP → B3.2.2.5)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.* Regulation (EC) 2023/2006 as amended, art. 6: *Quality control systems.*
Fulfilment	Define any agreements with hauliers. Verification of the adequacy conditions of own vehicles.
Document type and description	If the packaging manufacturer is responsible for the transport and delivery of the finished product to its destination, the following must be provided: – procedures that guarantee, during transport, the quality of the material by preserving it from any damage and risks of contamination that may compromise its conformity; – procedure for defining the qualification and selection criteria for external transporters and the checks to be carried out on means of transport.
Notes	The documentation should also clarify the possible presence of a contractors

Sheet B3.2.n. QUALITY CONTROL SYSTEMS
***Conformity of the application of the GMP and claims management, corrective and preventive actions* (guideline CAST GMP → B3.2.2.6)**

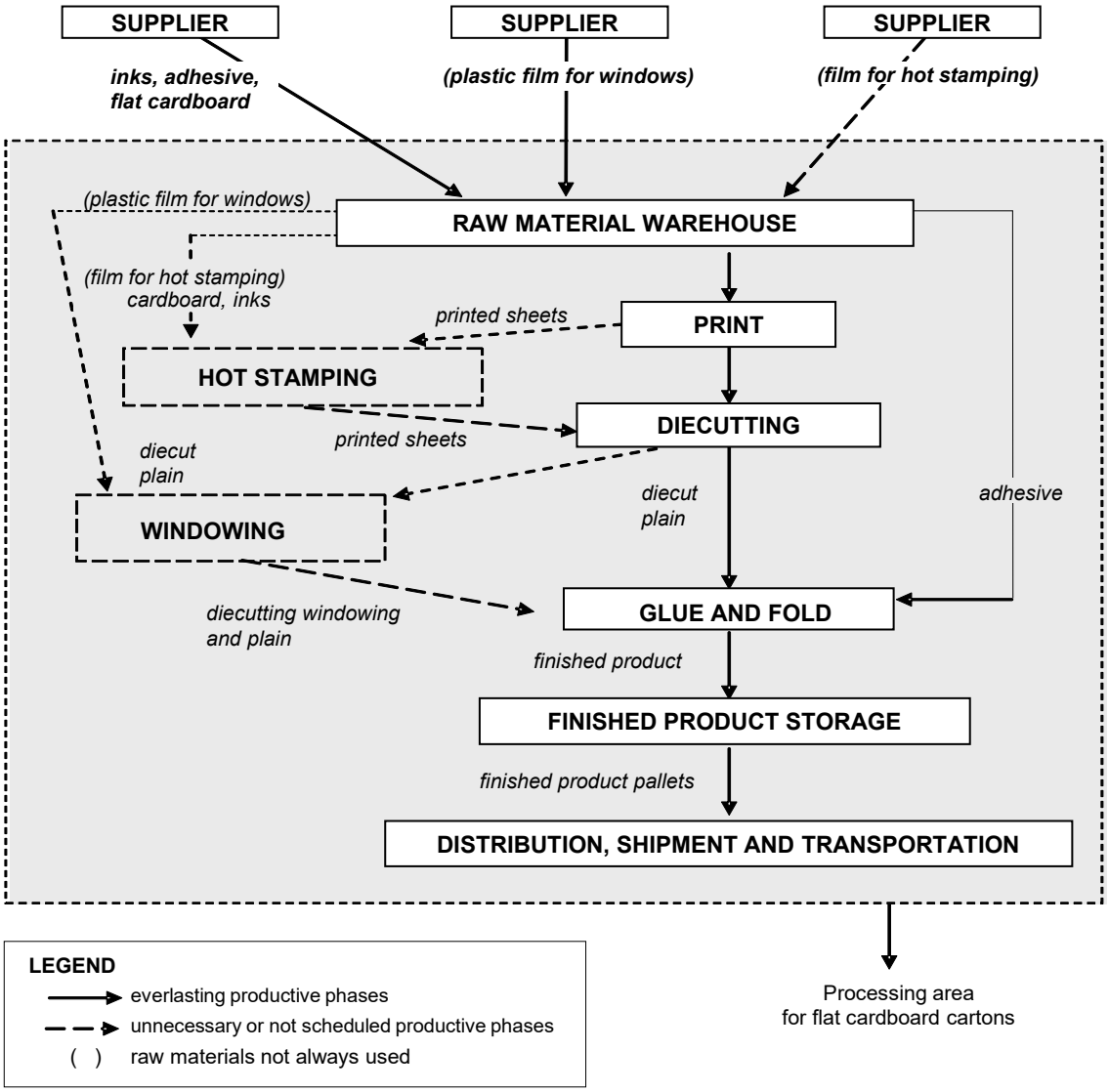
INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP.*
Fulfilment	Instructions and procedures for monitoring the implementation of GMP regulations, handling complaints, corrective and preventive actions.
Document type and description	The system must include: – procedures for carrying out internal audits to monitor the implementation and compliance with GMP standards; – procedures for the management of non-compliance with GMP standards; – procedures for handling complaints; – procedures for implementing corrective and preventive actions.
Notes	-

Sheet B3.2.o. DOCUMENTATION
***Documentation* (guideline CAST GMP→ B3.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 2: *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant to the conformity and safety of materials and finished articles, and relating to the results of the Quality Control System.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by operators in the sector.*
Fulfilment	Preservation of QAS documentation and Quality Control System (QCS). Constant adaptation and transposition of new legislation.
Document type and description	The system must include: – rules for establishing the criteria for archiving all documentation relating to GMP regulations; – list of reference documents to certify compliance with GMP standards; – rules to ensure constant adaptation to the relevant legislative changes.
Notes	Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/2004 as amended). Copies of the declarations of conformity issued (art. 16 of Regulation (EC) 1935/2004 as amended and additions are an integral part of the archive.).

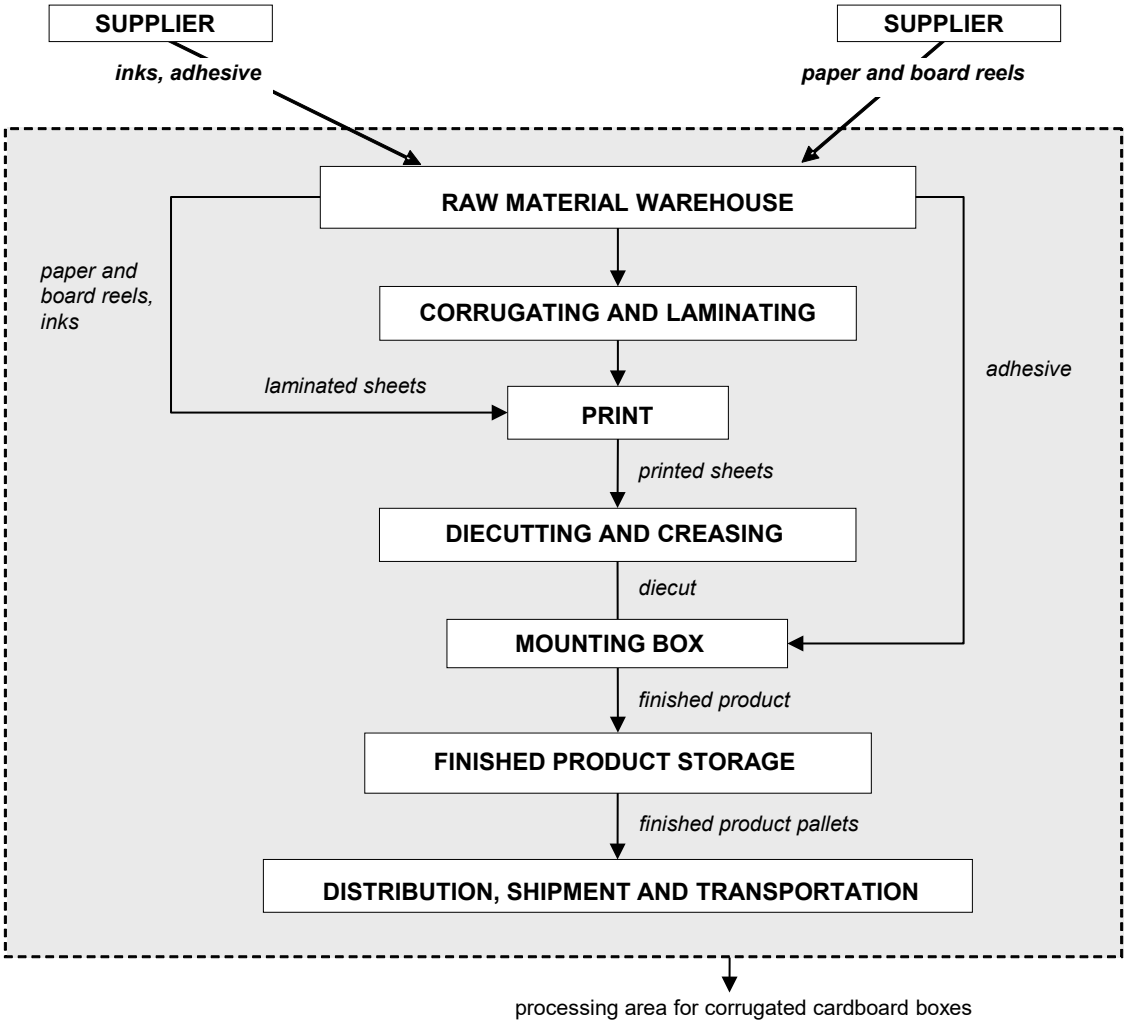
Annex B3.1.

Production flowchart for the production of cardboard boxes



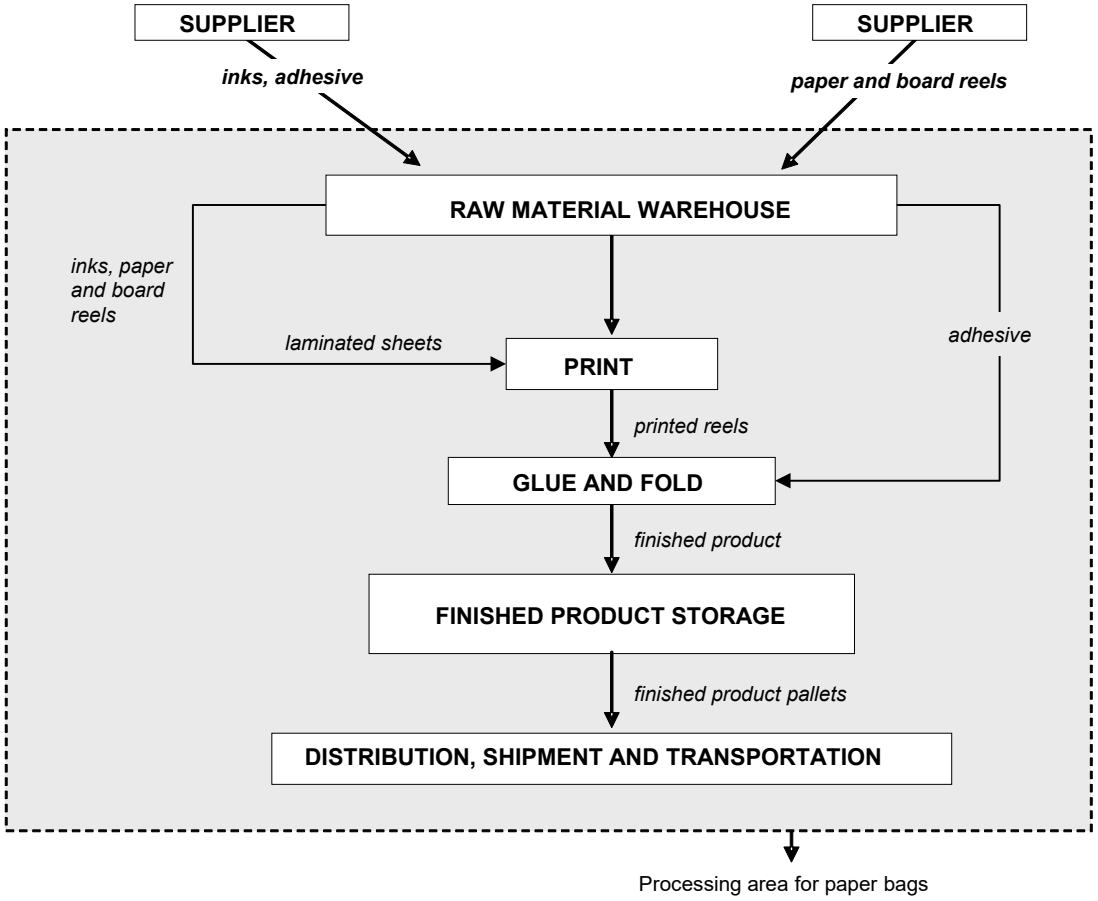
Annex B3.2.

Production flowchart for the production of corrugated cardboard boxes



Annex B3.3.

Flowchart for the production of paper bags



B4. FLEXIBLE PACKAGING

B4.1. Characterisation of the sector

B4.1.1. Field of application for the guideline

This guideline applies to all companies that produce flexible packaging regardless of the materials it is made of. For the starting raw materials, reference must be made, where existing, to the guidelines of the specific material (plastic films, paper, aluminium, etc.). The flexible packaging cycle includes the transformation of paper, plastic films, regenerated cellulose, aluminium foil that are used alone or in combination for primary and/or secondary packaging intended to contain food products. This definition specifically excludes stretch and shrink films used for secondary packaging of products on pallets, take-away bags (shopping bags), supermarket self-service bags, sealable neutral bags and bags with large contents for the transport of products in bulk. Polyvinyl chloride (PVC) or other polymer films sold for domestic use are also excluded, as well as aluminium foil sold directly to consumers. The definition of flexible packaging does not include paper or cardboard-based polylaminates used for the packaging of liquid products.

B4.1.2. Phases of the production process: flowchart and description

The production flow diagram, taken from the CAST GMP guideline, is given in Annex B4.1 at the end of this chapter.

A summary description of the process steps is given in chapter B4.1.3.1 of the guideline CAST GMP.

B4.2. Sheets for documental verification of the application of Regulation (EC) 2023/2006

This guideline defines the activities and documentation required to implement the provisions of Regulation (EC) 2023/2006 as amended concerning GMP standards for the flexible packaging production chain.

Any other documents related to the legal provisions materials and articles in contact with foodstuffs (Food Contact Materials, FCMs) are included in separate documentation systems, such as the Supporting Documentation (SD).

Below are the sheets (B4.2.a.-B4.2.o.) for documental verification that describe the activities and/or implementations that can be implemented by the Company to implement the provisions of Articles 5, 6 and 7 of Regulation (EC) 2023/2006 as amended.

The form presented are not binding for the supply chain discussed here, but their content must be considered a set of operational suggestions. The cards should always be used in conjunction with the CAST GMP guideline.

Sheet B4.2.a. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
Quality Assurance Systems (guideline CAST GMP → B4.2.1)

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective. – documented. – appropriate to the size of the company.
Document type and description	The documentation relating to the QAS may consist of the Quality Manual, if available, or other similar document demonstrating that the System is applied and implemented. The system must contain: – references to Regulation (EC) 2023/2006 as amended; – procedures, instructions and organization chart with definition of roles and responsibilities within the Company. The Company should identify within its organization the Function responsible for the application of Regulation (EC) 2023/2006 as amended.
Notes	The Quality Manual is not a mandatory requirement of Regulation (EC) 2023/2006 as amended. QAS is intended here only as compliance with Regulation (EC) 2023/2006 as amended, and should not be confused with the ISO 9000 system.

Sheet B4.2.b. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Size of the business* (guideline CAST GMP → B4.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.* Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter b): *Be applied taking into account the size of the company, so as not to constitute an excessive burden on the company.*
Fulfilment	Production sites. Production equipment.
Document type and description	The QAS must include: – organization of the production site and production processes; – documents relating to the adequacy of production equipment, control processes and calibration of production tools.
Notes	The technical manuals and the description of the equipment do not necessarily have to be included in the QAS but must always be available in the Company for the operating staff.

Sheet B4.2.c. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Human resources and training* (guideline CAST GMP→ B4.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Adequacy of staff. Staff knowledge and skills.
Document type and description	The QAS must include: – procedures to identify staff skills; – company training plan; – procedures for verifying the effectiveness of training with regard to the application of Regulation (EC) 2023/2006 as amended; – registration of training.
Notes	It is advisable to define company roles and skills through a job description (organization chart and job description).

Sheet B4.2.d. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Selection of raw materials and suppliers* (guideline CAST GMP → B4.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Qualification of raw materials. Qualification of suppliers of goods and/or services.
Document type and description	The QAS must include: – procedures for the selection and qualification of starting materials; – procedures for the qualification and approval of suppliers of starting materials; – procedures for the qualification and approval of suppliers of goods and/or services; – list of qualified and approved suppliers; – audit procedures of approved suppliers. A record of selections, supplier qualification and monitoring of suppliers must be available.
Notes	For the selection and qualification of starting materials, “technical specifications” can be used, which specify the necessary requirements that may affect compliance with contact with food products.

Sheet B4.2.e. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Production* (guideline CAST GMP→ B4.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures*.
Fulfilment	Instructions and procedures for the production process.
Document type and description	For each phase of the production process, there must be specific documents describing the management operating methods and the process parameters to be kept under control. Useful documents include, for example: – production operating instructions; recording of process operations; recording of the values of the controlled parameters and their deviations from the pre-established tolerances.
Notes	The process flowchart can help identify critical points in the process that need specific instructions and controls to demonstrate compliance with GMP standards and FCMs legislation.

Sheet B4.2.f. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Production* (guideline CAST GMP→ B4.2.1.2)**
SISTEMA DI CONTROLLO DELLA QUALITÀ
***Management of raw materials warehouses* (guideline CAST GMP → B4.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.* Regulation (EC) 2023/2006 as amended, art. 6 paragraph 1: *Operators in the sector must establish and maintain an effective quality control system.*
Fulfilment	Raw material warehouse management. Verification of incoming materials. Storage of raw materials. Sending to production.
Document type and description	The following must be provided: – procedures to define any incoming controls to be carried out on raw materials; – procedure with storage rules (approved, tested, contested material, etc.). Important are the rules for the separation and segregation of non-compliant materials; – procedure for sending to production.
Notes	The documents must give the rules for warehouse management (e.g. *first in first out*) for controls and to control the risks of contamination and/or deterioration of raw materials. Entrance checks are not always mandatory but can also be done on a statistical basis.

Sheet B4.2.g. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Production* (guideline CAST GMP → B4.2.1.2)**
QUALITY CONTROL SYSTEM
***Production controls* (guideline CAST GMP → B4.2.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.* Regulation (EC) 2023/2006 as amended, art. 6: *Quality control systems.*
Fulfilment	Fix the critical points. Establish the checks to be carried out (measurements, tolerances and frequencies). Levels of responsibility.
Document type and description	They must be: – procedures and instructions are provided that specify the controls to be carried out on products (including intermediates and semi-finished products) to ensure compliance and traceability in accordance with the legislative requirements on FCMs; – set and indicated for each measured quantity the nominal value, the accepted tolerance, and the frequency of checks; – the measurement methods shall also be specified and a description of the methods shall be available.
Notes	Examples of some characteristic parameters that can be checked on the product are: – dimensional quantities (thickness, band, etc.); – chemical and physical properties (adhesion of the layers, weldability, etc.); – solvent residue (when necessary).

Sheet B4.2.h. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Production* (guideline CAST GMP → B4.2.1.2)**
SISTEMA DI CONTROLLO DELLA QUALITÀ
***Quality control of finished product* (guideline CAST GMP → B4.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.* Regulation (EC) 2023/2006 as amended, art. 6: *Quality control systems.*
Fulfilment	Establish critical issues. Define control methods and measures. Levels of responsibility.
Document type and description	The following must be provided: – procedures and/or instructions that make it possible to verify the conformity of the finished product with the requirements of the reference legislation; – instructions establishing the quantities to be checked, the validated test methods to be used, the reference values and tolerances allowed; Records of the measurements taken must be kept in special paper documents or on computer supports. A list of suitable instrumentation for measuring and recording calibrations shall be available.
Notes	-

Sheet B4.2.i. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Production* (guideline CAST GMP → B4.2.1.2)**
QUALITY CONTROL SYSTEM
***Management of finished products warehouses* (guideline CAST GMP→ B4.2.2.4)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.* Regulation (EC) 2023/2006 as amended, art. 6: *Quality control systems.*
Fulfilment	Product acceptance. Storage. Packaging conditions.
Document type and description	The following must be provided: – procedures for the storage of finished products; – procedures for the identification and traceability of finished products; – procedures for authorization to ship; – procedures for the identification, segregation of non-compliant products and/or products in *a standby* state pending other controls.
Notes	The documents must give the rules for warehouse management and to control the risks of contamination and/or deterioration of the finished product. Any returns for non-compliance by customers must be properly stored in separate areas to avoid the risk of mixing up.

Sheet B4.2.l. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Production* (guideline CAST GMP → B4.2.1.2)**
QUALITY CONTROL SYSTEM
***Distribution, shipment and delivery* (guideline CAST GMP → B4.2.2.5)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.* Regulation (EC) 2023/2006 as amended, art. 6: *Quality control systems.*
Fulfilment	Qualification of transporters (if applicable). Packaging & Shipping.
Document type and description	If the *converter* is responsible for the transport and delivery of the finished product to its destination, the following must be provided: – procedures that guarantee, during transport, the quality of the material by preserving it from any damage and risks of contamination that may compromise its conformity; – procedure for defining the qualification and selection criteria for external transporters and the checks to be carried out on means of transport.
Notes	It is advisable to have a list of qualified carriers and a record of the checks carried out at the carriers.

Sheet B4.2.m. QUALITY ASSURANCE SYSTEMS
***Quality Control Systems* (guideline CAST GMP→ B4.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 1: *Operators must establish and maintain an effective Quality Control System.*
Fulfilment	Define an effective and organized quality control system.
Document type and description	The system must include: – the responsibilities within the Company on all decisions in terms of quality control; – the procedures and operating instructions that supervise all product control actions (including semi-finished and intermediate products); – the recording systems of all the checks carried out.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended but if present it can be a useful tool to certify compliance with GMP standards. The controls referred to are those on products/materials to certify the conformity of FCMs.

Sheet B4.2.n. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Conformity of the application of the GMP and claims management, corrective and preventive actions* (guideline CAST GMP→ B4.2.2.6)**

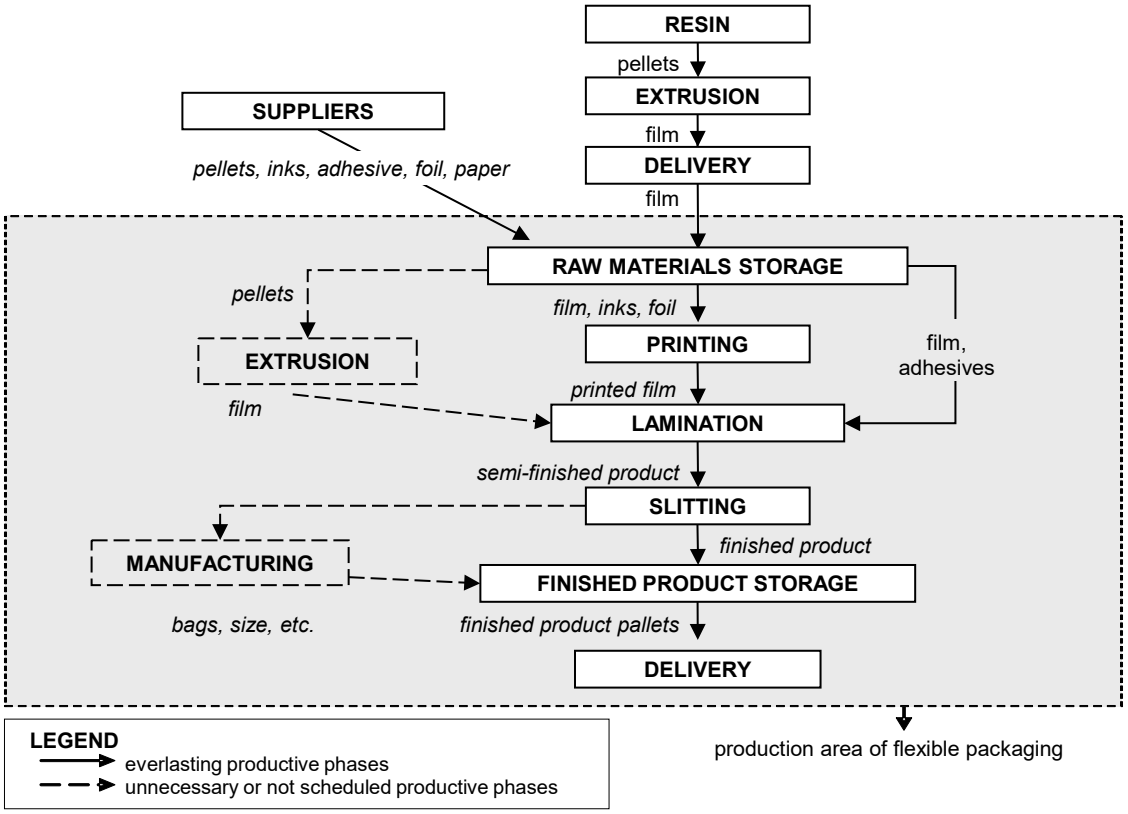
INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6: *Quality control systems*. Regulation (EC) 2023/2006 as amended, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP*.
Fulfilment	Instructions and procedures for monitoring the implementation of GMP standards, handling complaints, corrective and preventive actions.
Document type and description	The system must include: – procedures for carrying out internal audits to monitor the implementation and compliance with GMP standards; – procedures for the management of non-compliance with GMP standards; – procedures for implementing corrective and preventive actions.
Notes	It is advisable that internal audits are scheduled and the results are recorded. It is important to define the timing of intervention and to verify the effectiveness of corrective actions.

Sheet B4.2.o. DOCUMENTATION
***Documentation* (guideline CAST GMP→ B4.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 2: *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant to the conformity and safety of materials and finished articles, and relating to the results of the Quality Control System.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by operators in the sector.*
Fulfilment	Preservation of QAS documentation and Quality Control System (SCQ) Constant adaptation and transposition of new legislation
Document type and description	The system must include: – rules to establish the criteria for archiving all documentation relating to GMP standards; – list of reference documents to certify compliance with GMP standards; – rules to ensure constant adaptation to the relevant legislative changes.
Notes	Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/2004 as amended). Copies of the declarations of conformity issued are an integral part of the archive (art. 16 of Regulation (EC) 1935/2004 as amended).

Annex B4.1.

Production flowchart for production of flexible packaging



B5. WOOD OR WOOD FIBRE

B5.1. Characterisation of the sector

B5.1.1. Field of application of the guideline

This guideline is applicable to companies of wood producing and/or wood fibre intended to come into contact with food. For wood that is intended for the production of articles coming into contact with food, the starting material, pursuant to the Regulation (EC) 2023/2006 as amended is round timber, sawn timber and semi-processed articles that have undergone a reduction in volume but that have not been chemically treated (e.g. with glue).

The starting substances for glue production fall outside the scope of the GMP Regulation and therefore of these guidelines.

B5.1.2. Phases of the production process: flowcharts and description

The production flow diagrams are given in Annexes B5.1-B5.6 at the end of this chapter. The summary description of the process steps is given in chapters B5.1.3.1.3, B5.1.3.1.4, B5.1.3.1.4.1a, B5.1.3.1.4.1b, B5.1.3.1.4.2 and B5.1.3.2.1 of the CAST GMP guideline.

B5.2. Sheets for documental verification of the application of Regulation (EC) 2023/2006

This guideline defines the activities and documentation required to implement the provisions of Regulation (EC) 2023/2006 as amended relating to GMP standards for the production chain of wooden packaging.

Any other documents related to the legal provisions on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs) are included in separate documentation systems, such as the Supporting Documentation (SD).

Below are the sheets (B5.2.a.-B5.2.n.) for documental verification that describe the activities and/or implementations that can be implemented by the Company to implement the provisions of Articles 5, 6 and 7 of Regulation (EC) 2023/2006 as amended.

The form presented are not binding for the supply chain discussed here, but their content must be considered a set of operational suggestions. The cards should always be used in conjunction with the CAST GMP guideline.

Sheet B5.2.a. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Quality Assurance Systems* (guideline CAST GMP → B5.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective. – documented. – appropriate to the size of the company.
Document type and description	The documentation relating to the QAS may consist of the Quality Manual, if available, or other similar document demonstrating that the System is applied and implemented. The system must contain: – Regulation (EC) 2023/2006 as amended; – procedures, instructions and documents that define how the system is implemented and enforced; – roles and responsibilities within the Company itself. The Company should identify within its organization the Function responsible for the application of Regulation (EC) 2023/2006 as amended.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended. Any certification by third parties (e.g. according to ISO 9001) could guarantee the adequacy of the QAS with respect to the size of the company. ISO 9001 quality management systems include multiple requirements also for GMP standards.

Sheet B5.2.b. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Size of the business* (guideline CAST GMP → B5.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.* Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter b): *Be applied taking into account the size of the company, so as not to constitute an excessive burden on the company.*
Fulfilment	Organization of the necessary locations and equipment
Document type and description	The organization of the offices, their structure, should be reported in the Quality Manual or in other specific company documentation. Documents relating to the adequacy of production equipment and control of finished materials and objects; manuals/production procedures/technical documentation of machinery and its calibration status, etc. Manuals and technical documentation of machinery and equipment may be recalled/inserted/attached in the relevant Quality System documentation.
Notes	-

Sheet B5.2.c. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Human resources and training* (guideline CAST GMP→ B5.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Adequacy of staff. Staff knowledge and skills.
Document type and description	For example, training is recorded and documented by: – procedures and/or instructions containing indications for verifying effectiveness (staff training and refresher courses); – specific activity for the GMP system and on FCMs; – specific refresher courses in relation to the assigned task.
Notes	The Company can define roles and responsibilities to explain the internal organization (job description) and report them in documents such as the Quality Manual or other suitable document.

Sheet B5.2.d. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Selection of starting materials and suppliers of goods and/or services and or subcontractors* (guideline CAST GMP→ B5.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Selection of starting materials and substances, suppliers of goods and/or services and/or subcontractors.
Document type and description	The Company should prepare documents relating to: – specifications of the raw materials, established in “specifications” that report the indications of the physical and chemical parameters that identify the raw material. – procedures for the selection and qualification of suppliers of external goods, materials and services that define: - the criteria for evaluation and inclusion in the list of approved suppliers, - the operating methods to assess over time the ability of suppliers to maintain the required quality level. The selection, qualification, listing and monitoring of qualified suppliers must be properly recorded.
Notes	-

Sheet B5.2.e. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Production* (guideline CAST GMP→ B5.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the production process
Document type and description	Specific documents describing the management operating modes and relevant process parameters should be defined for each stage of the production process, for example: – manuals, procedures, instructions, technical standards; – records of relevant activities carried out; – adequate records of the trend of significant parameters, including any deviations.
Notes	A process flow chart can help identify critical points in the process that need operating instructions and or other documents necessary to maintain and demonstrate control of activities for the purposes of FCMs and GMP standards.

Sheet B5.2.f. QUALITY CONTROL SYSTEMS
***Quality Control Systems* (guideline CAST GMP→ B5.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art.6, paragraph 1: *Operators in the sector must establish and maintain an effective quality control system.*
Fulfilment	Development of a Quality Control System suitable for its activity, structure, product
Document type and description	The reference documents are, for example: – Quality Manual; – procedures and operating instructions that establish control methods (references to laws, standards, specifications, internal methods, etc.); – records of the activities of verification of conformity of products with their respective specifications, e.g. control sheets, computerized tables.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended.

Sheet B5.2.g. QUALITY CONTROL SYSTEMS
***Management of raw materials warehouses* (guideline CAST GMP→ B5.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Raw material warehouse management.
Document type and description	Procedures/operating instructions for acceptance checks, according to any sampling plans, should be defined in order to verify the compliance of raw materials with the specifications. Records of the results of both documental and analytical checks.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, standards) by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be recorded in computerized tables, databases, etc.

Sheet B5.2.h. QUALITY CONTROL SYSTEMS
***Production controls* (guideline CAST GMP→ B5.2.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the production process
Document type and description	The following should be defined: – operating procedures/instructions that describe the methods to ensure the controls and traceability of the product starting from the raw materials used through the various stages of production up to the delivery to the warehouse; – procedures/instructions for delivery to the warehouse.
Notes	The product can be stored and identified in various ways as “not shippable” until its quality level and/or compliance with all the requirements of the production phase is ascertained.

Sheet B5.2.i. QUALITY CONTROL SYSTEMS
***Quality Control of finished product* (guideline CAST GMP→ B5.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the production process
Document type and description	Operating instructions or procedures for verifying the conformity of the quality of the finished product with the expected requirements should be defined and codified in the respective product specifications.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, standards) by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be recorded in computerized tables, databases, etc.

Sheet B5.2.l. QUALITY CONTROL SYSTEMS
***Management of finished products warehouses* (guideline CAST GMP→ B5.2.2.4)**
***Distribution, shipment and delivery* (guideline CAST GMP → B5.2.2.5)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures*.
Fulfilment	Instructions and procedures for the management of the finished products warehouse, for transport and delivery.
Document type and description	The following should be defined: – procedures/instructions for the storage of finished products (with identification of the condition: material meeting the established specification, under test, contested, etc.) and related records; – procedures/instructions for the identification and traceability of stored products and related records; – procedures/instructions for the traceability of picking operations and authorization for shipment to customers (finished products) and related records; – procedures/instructions for the definition of the criteria for the selection of transporters and the checks to be carried out on the means of transport (supply / service specifications) and related records; – operating instructions for issuing a transport document.
Notes	-

Sheet B5.2.m. QUALITY CONTROL SYSTEMS
***Conformity of the application of the GMP and claims management, corrective and preventive actions* (guideline CAST GMP → B5.2.2.6)**

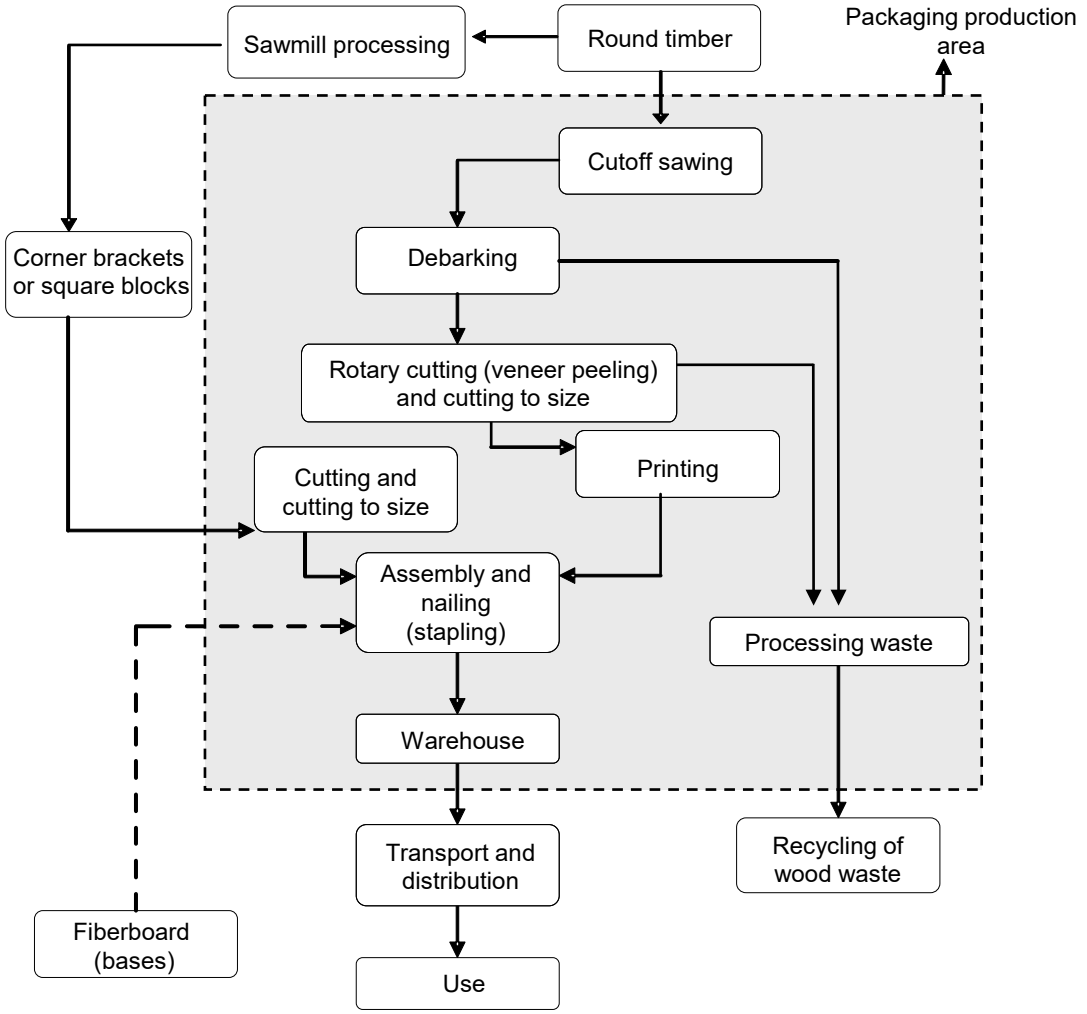
INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP. Such corrective measures shall be implemented without delay and made available to the Competent Authorities for inspections.*
Fulfilment	Instructions and procedures for monitoring the implementation of GMP standards.
Document type and description	The following should be defined: – procedures/operating instructions for carrying out internal audits; – procedures for the management of complaints and management of any non-conformities; – procedures for the implementation of corrective and preventive actions for the resolution of non-conformities, the latter procedure must provide for the verification of the effectiveness of the corrective/preventive actions implemented.
Notes	Internal audits are planned, carried out and appropriately recorded for all business areas involved in the implementation of GMP standards, in order to verify their correct implementation.

Sheet B5.2.n. DOCUMENTATION
***Documentation* (guideline CAST GMP → B5.2.2.6)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 2: *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant to the conformity and safety of materials and finished articles, and relating to the results of the Quality Control System.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by operators in the sector.*
Fulfilment	Preservation of QAS and Quality Control System (QCS) documentation. Constant adaptation and transposition of legislation.
Document type and description	They should be defined as: – procedures, operating instructions for the archiving and storage of documents relating to the QAS (procedures, specifications, formulations, etc.); – procedures, operating instructions for the archiving and storage of documents relating to the QCS (instructions, records of process and control data). The Quality Manual or other company document defines an adequate time for the storage of all documents pertinent to the implementation of GMP standards. Procedures/instructions must be defined to ensure continuous compliance with the regulatory requirements of current legislation.
Notes	Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/2004 as amended). Copies of the declarations of conformity issued are an integral part of the archive (art. 16 of Regulation (EC) 1935/2004 as amended).

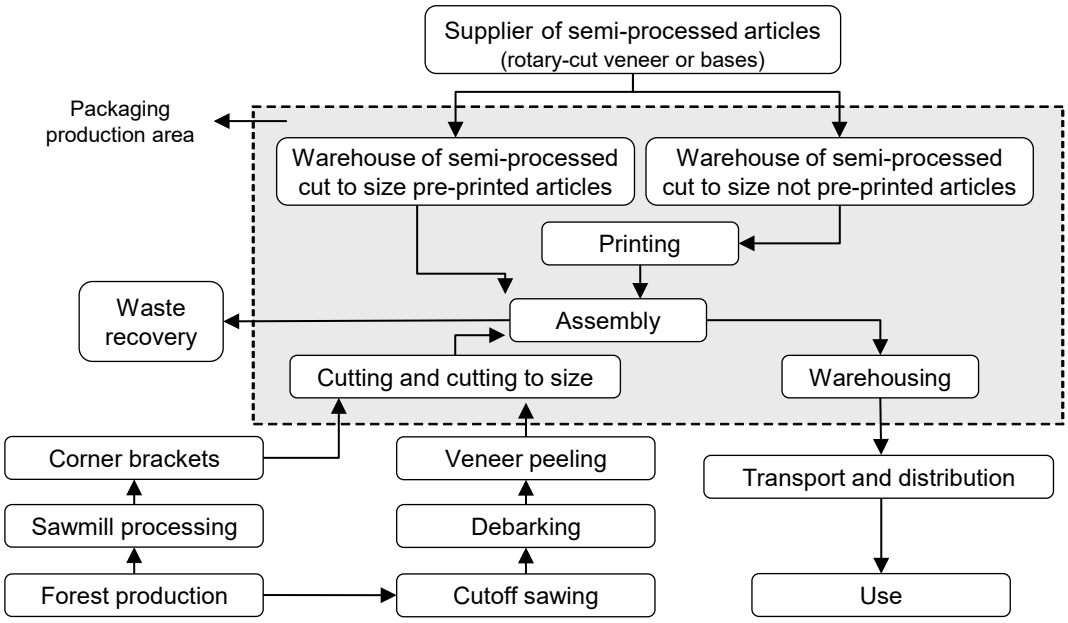
Annex B5.1.

Production flowchart for wooden boxes: complete flowchart



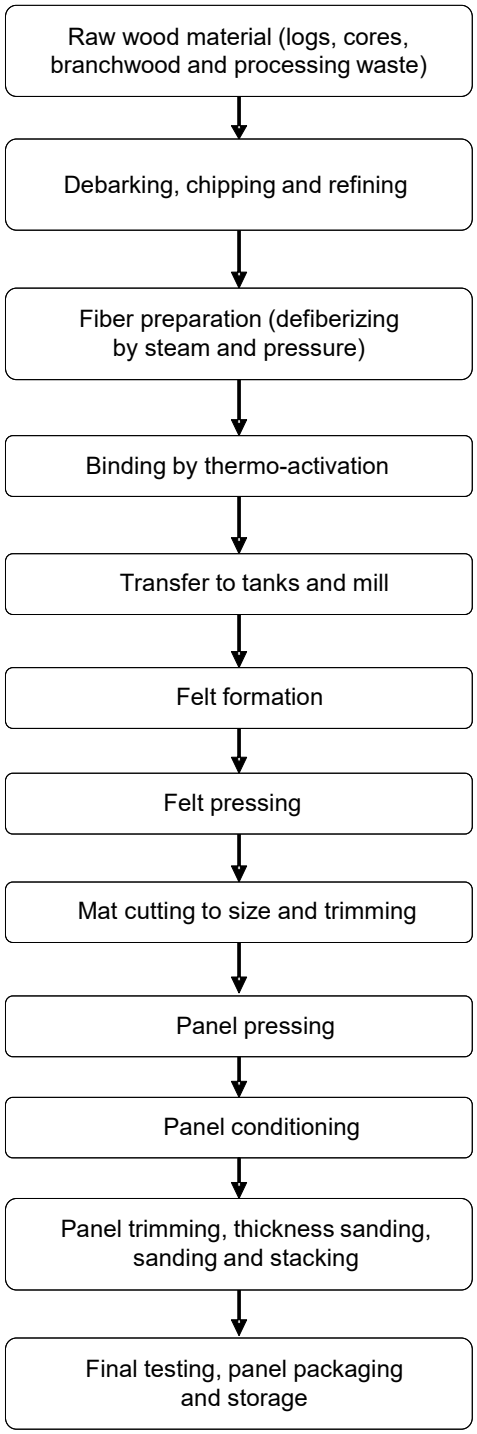
Annex B5.2.

Production flowchart wooden boxes: semi-finished products



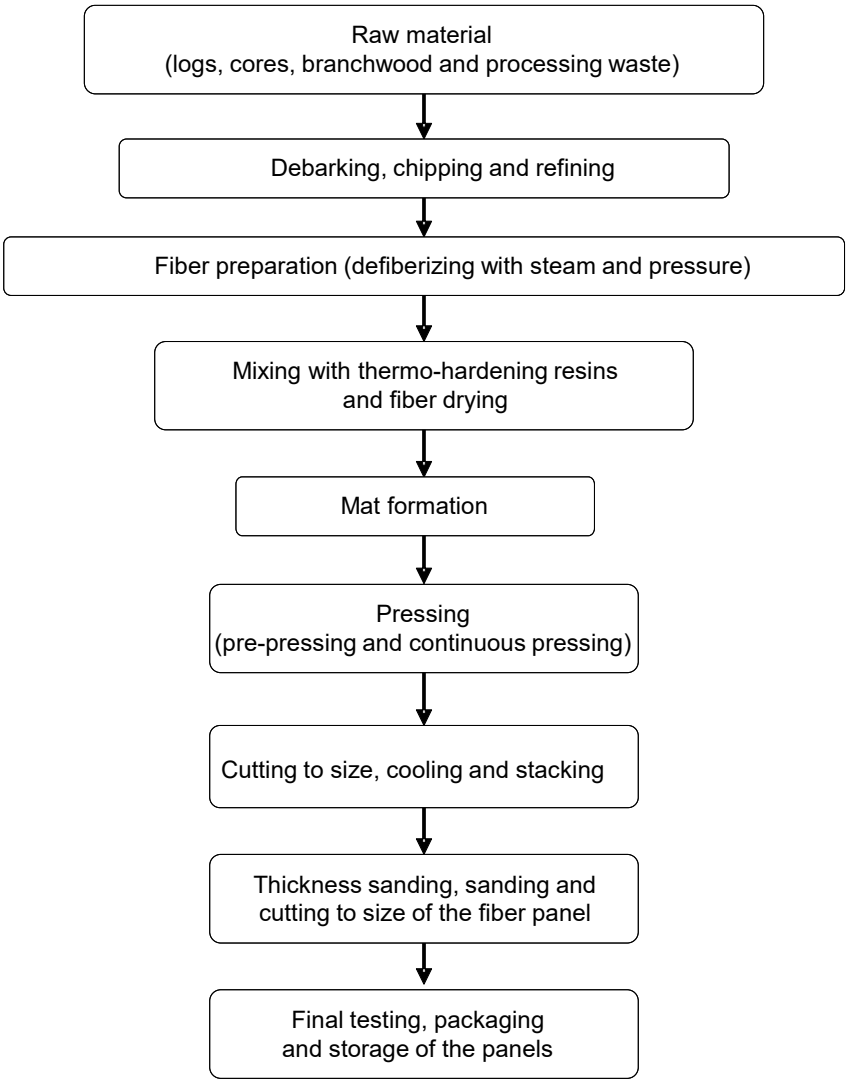
Annex B5.3.

Wood fibre panels using the wet method (Masonite)



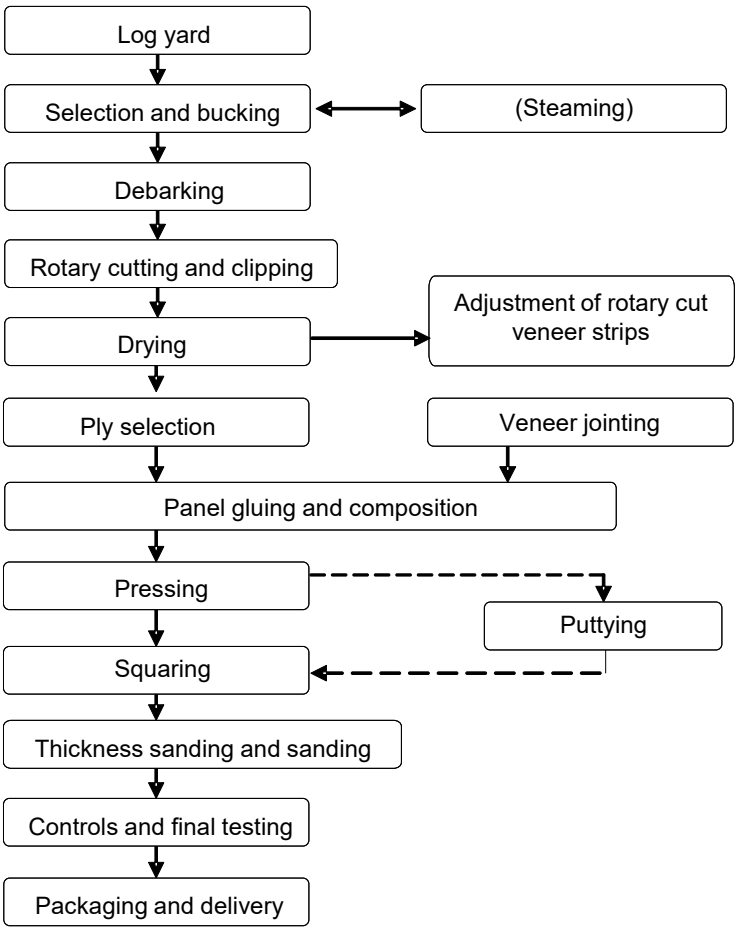
Annex B5.4.

Wood fibre panels using the dry method (MDF)



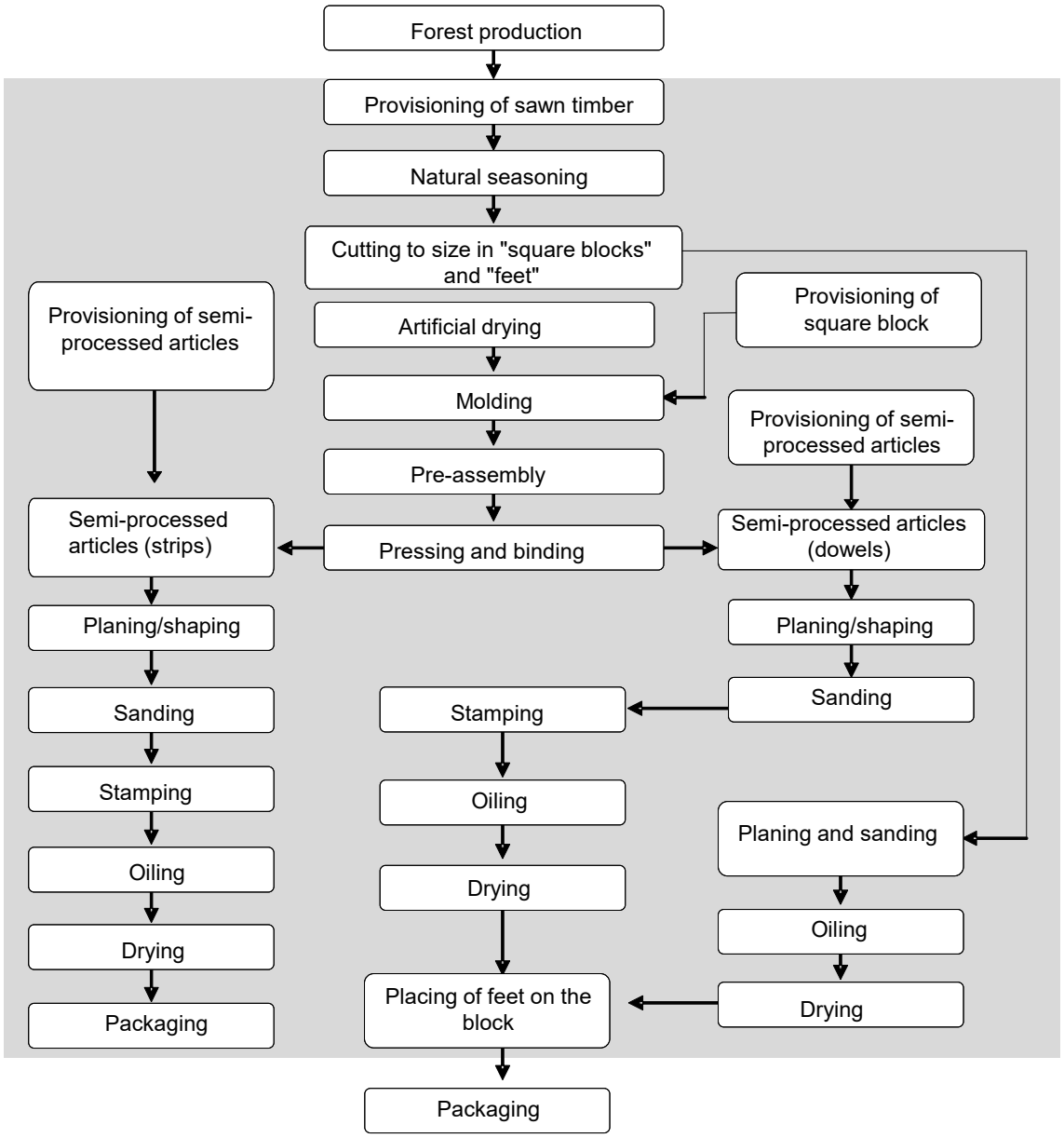
Annex B5.5.

Plywood panels and peeled wooden objects production flowchart



Annex B5.6.

Production flowchart for production of wood cutting boards, chopping blocks and boards



B6a. PLASTICS. POLYMER PRODUCTION AND MASTERBATCHES

B6a.1. Characterization of the sector

B6a.1.1. Field of application of the guideline

This guideline is applicable to all the companies operating within the plastic packaging production chain and dealing with food contact applications pursuant to article 1 of the Regulation (EC) 1935/2004 as amended. Production and conversion processes are included. Starting substances for the polymer production (additives, catalysts, monomers, etc.) are excluded from the GMP Regulation scope and hence from this guideline. Multi-material multilayer packaging (not in plastic material exclusively) is excluded as well from the scope of this guideline

B6a.1.2. Phases of the production process

The production flowchart is given in Annex B6a.1 at the end of this chapter. The summary description of the process steps is given in chapter B6.1.3 of the CAST GMP guideline.

B6a.2. Sheets for documental verification of the application of Regulation (EC) 2023/2006

This guideline defines the activities and documentation required to implement the provisions of Regulation (EC) 2023/2006 as amended concerning GMP standards for the production chain of plastic polymers[4].

Any other documents related to the legal provisions on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs) are included in separate documentation systems, such as the Supporting Documentation (SD).

Below are the sheets (B6a.2.a-B6a.2.n) for documental verification that describe the activities and/or measures that can be adopted by the Company to implement the provisions of Articles 5, 6 and 7 of Regulation (EC) 2023/2006 as amended.

The sheets provided are not binding for the supply chain discussed here, but their content must be considered a set of operational recommendations. The cards should always be used in conjunction with the CAST GMP guideline.

[4] The transformation sheets are dealt with in Chapter B6b.

Sheet B6a.2.a. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Quality Assurance Systems* (guideline CAST GMP → B6.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective. – documented. – appropriate to the size of the company.
Document type and description	The documentation relating to the QAS may consist of the Quality Manual, if available, or of other similar document demonstrating that the System is applied and implemented. The system must contain: – Regulation (EC) 2023/2006 as amended; – procedures, instructions and documents that define how the system is implemented and maintained; – roles and responsibilities within the Company itself. The Company should identify within its organization the function responsible for the application of Regulation (EC) 2023/2006 as amended.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended. Any certification by third parties (e.g. according to ISO 9001) could guarantee the adequacy of the QAS with respect to the size of the company. ISO 9001 quality management systems include multiple requirements also for GMP standards.

Sheet B6a.2.b. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Size of the business* (guideline CAST GMP → B6.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Organization of the necessary locations and equipment.
Document type and description	The organization of the offices and/or their structure should be described in the Quality Manual or in other specific company documentation. The following must be present: – documents relating to the adequacy of production equipment and the control of finished materials and articles; – manuals/production procedures/technical documentation of machinery and its calibration status, etc.
Notes	Manuals and technical documentation of machinery and equipment may be referenced, included, or attached to in the relevant Quality System documentation.

Sheet B6a.2.c. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Human resources and training* (guideline CAST GMP → B6.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 5, paragraph 1, letter a):* *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Adequacy of staff. Staff knowledge and skills.
Document type and description	Training is recorded and documented for example by: – procedures and/or instructions for the training and updating of personnel containing indications for verifying effectiveness; – specific training activities on GMP standards and on Food Contact Materials (FCMs); – specific training and refresher courses related to the assigned task; – the Company may define roles and responsibilities to explain the internal organization (e.g. job descriptions) and include them in documents such as the Quality Manual or other suitable documentation.
Notes	-

Sheet B6a.2.d. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Selection of the starting materials of the suppliers and/or services and/or third parties* (guideline CAST GMP → B6.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 5, paragraph 2:* *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Selection of raw materials and suppliers.
Document type and description	The Company should prepare documents relating to: – specifications of the raw materials, established in “technical sheet” that contain the indications of the physical and chemical parameters that identify the raw material; – procedures for the selection and qualification of suppliers of external goods, materials and services that define: - the criteria for evaluation and inclusion in the list of approved suppliers; - the operating methods to assess over time the ability of suppliers to maintain the required quality level over time; – the selection, qualification, listing and monitoring of qualified suppliers must be properly recorded.
Notes	-

Sheet B6a.2.e. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Production* (guideline CAST GMP → B6.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Production. Instructions and procedures for the production process.
Document type and description	Specific documents describing the operating procedures and relevant process parameters should be defined for each stage of the production process, for example: – manuals, procedures, instructions, technical standards; – records of relevant activities carried out; – adequate records of the trend of significant parameters, including any deviations.
Notes	A process flow chart can help identify critical process points that need operating instructions and or other documents necessary to maintain and demonstrate control of activities for FCMs and GMP compliance.

Sheet B6a.2.f. QUALITY CONTROL SYSTEMS
***Management of raw materials warehouses* (guideline CAST GMP→ B6.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Compliance of raw materials with defined specifications.
Document type and description	The following should be defined: – operating procedures/instructions for incoming inspections, according to any sampling plans, in order to verify the compliance of raw materials with specifications; – records of the results of both documentary and analytical inspections.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, internal methods, standard methods) with suitable and adequately calibrated instrumentation. The data resulting from quality control operations should be appropriately recorded in digital spreadsheets, databases, etc.

Sheet B6a.2.g QUALITY CONTROL SYSTEMS
***Production controls* (guideline CAST GMP → B6.2.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the production process.
Document type and description	The following should be defined: – operating procedures/instructions that describe the methods to ensure the controls and traceability of the product starting from the raw materials used through the various stages of production up to the delivery to the warehouse; – procedures/instructions for delivery to the warehouse.
Notes	The product can be stored and identified in various ways as “not shippable” until its quality level and/or compliance with all production requirements has been verified. Production controls must guarantee through appropriate records certifying that the material has been checked at all stages starting from the raw materials used through the production process.

Sheet B6a.2.h QUALITY CONTROL SYSTEMS
***Quality Control of finished products* (guideline CAST GMP→ B6.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art.6, paragraph 1: *Operators in the sector must establish and maintain an effective quality control system.*
Fulfilment	Development of a Quality Control System (QCS) suitable for its activity, structure, product.
Document type and description	The reference documents are, for example: – Quality Manual; – procedures and operating instructions that establish control methods (references to laws, standards, specifications, internal methods, etc.); – records of the activities of verification of conformity of products with their respective specifications, e.g. control sheets, digital tables.
Notes	The Quality Manual is not expressly required by Regulation (EC) 2023/2006 as amended.

Sheet B6a.2.i QUALITY CONTROL SYSTEMS
***Quality Control of finished products* (guideline CAST GMP → B6.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the production process.
Document type and description	Operating instructions or procedures for verifying the conformity of the quality of the finished product with the expected requirements should be defined and codified in the respective product specifications.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, standard methods) with suitable and adequately calibrated instrumentation. The data resulting from quality control operations should be recorded in digital spreadsheets, databases, etc.

Sheet B6a.2.l. QUALITY CONTROL SYSTEMS
***Management of finished products warehouses* (guideline CAST GMP → B6.2.2.4)**
***Distribution, shipment and delivery* (guideline CAST GMP → B6.2.2.5)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 5, paragraph 3:* *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the management of the finished products warehouse, for transport and delivery.
Document type and description	The following should be defined: – procedures/instructions for the storage of finished products (with identification of their status: material meeting the established specification, under test, contested, etc.) and related records; – procedures/instructions for the identification and traceability of stored products and related records; – procedures/instructions for the traceability of picking operations and authorization for shipment to customers (finished products) and related records; – procedures/instructions for the definition of the criteria for the selection of transporters and the checks to be carried out on the means of transport (supply / service specifications) and related records; – operating instructions for issuing a transport document.
Notes	-

Sheet B6a.2.m. QUALITY CONTROL SYSTEMS
***Conformity of the application of the GMP and claims management, corrective and preventive actions* (guideline CAST GMP → B6.2.2.6)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.*
Fulfilment	Instructions and procedures for monitoring the implementation of GMP standards.
Document type and description	The following should be defined: – procedures/operating instructions for performing internal audits. – procedures for the management of complaints and of any non-conformities; – procedures for the implementation of corrective and preventive actions for the resolution of non-conformities; the latter procedure must include verification of the effectiveness of the corrective/preventive actions implemented.
Notes	Internal audits are planned, carried out and recorded in order to verify the correct implementation of GMP standards for all business areas involved.

Sheet B6a.2.n. DOCUMENTATION
***Documentation* (guideline CAST GMP → B6.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 2: *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant for the conformity and safety of finished materials and articles, and relating to the results of the quality control system.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by operators in the sector.*
Fulfilment	Preservation of QAS and SCQ documentation Constant adaptation and transposition of legislation
Document type and description	The following should be defined: – procedures, operating instructions for the archiving and retention of documents relating to the QAS (procedures, specifications, formulations, etc.); – procedures, operating instructions for the archiving and retention of documents relating to the QCS (instructions, records of process and control data). The Quality Manual or other company document defines an adequate time for the retention of all documents pertinent to the implementation of the GMP system. Procedures/instructions must be defined to ensure continuous compliance with the regulatory requirements of applicable legislation.
Notes	Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/2004 as amended). Copies of the declarations of conformity issued are an integral part of the archive (art. 16 of Regulation (EC) 1935/2004 as amended).

Annex B6a.1.

Production flowchart for plastic packaging

Table 6.1. Production steps and processes related to raw materials

Manufacturing steps	Processes to obtain plastic packaging								
	Extrusion	**Thermo-forming**	**Injection moulding**	**Injection blow moulding**	**Extrusion and blow moulding**	**Extrusion, expansion and thermo-forming**	**Sintering moulding**	**Roto-moulding**	**Coated articles**
Raw material Starting physical shape	polymers pellet flakes powder	polymers pellet flakes powder	polymers pellet	polymers flakes pellet	polymers pellet	polymers pellet	polymers beads	polymers powder	polymers pellet flakes powder
Semifinished products Starting physical shape		sheets		preforms					sheets/ plastic films obtained by extrusion + plastisol
Possible additivation	X	X	X	X	X	X			X
Conversion process/processes	• extrusion/ coextrusion with or without orientation	• extrusion • thermo-forming	• injection moulding	• blow injection moulding	• extrusion and blow moulding • orientation by blowing	• extrusion/ expansion • thermo-forming	• pre-expansion • Seasoning/ maturation • sintering	• roto-moulding	• spreading
where necessary	decoration	decoration	decoration	decoration	decoration	decoration			
Examples	films, sheets, rolls, semifinished products for thermo-forming	yogurt cups, diary trays, punnets for fruit & vegetables, single use dishes and cutlery	bottles closures and caps; freezer food containers, individually packaged dessert cups	bottles for water and soft drinks	oil bottles	trays for meat, fresh food, cheese and vegetables	fish boxes, take-away ice cream trays	holding tanks	holding tanks made of/coated with thermo-setting resins

B6b. PLASTICS: PROCESSING: PRODUCTION OF SEMI-FINISHED PRODUCTS AND PACKAGING

B6b.1. Characterization of the sector

B6b.1.1. Field of application of the guideline

This guideline is applicable to all the companies operating within the plastic packaging production chain and dealing with food contact applications pursuant to article 1 of the Regulation (EC) 1935/2004 as amended. Production and conversion processes are included. Starting substances for the polymer production (additives, catalysts, monomers, etc.) are excluded from the GMP Regulation scope and hence from this guideline. Multi-material multilayer packaging (not in plastic material exclusively) is excluded as well from the scope of this guideline

B6b.1.2. Phases of the production process

The production flowchart is given in Annex B6.1 at the end of this chapter. The summary description of the process steps is given in chapter B6.1.3 of the CAST GMP guideline.

B6b.2. Sheets for documental verification of the application of Regulation (EC) 2023/2006

This guideline defines the activities and documentation required to implement the provisions of Regulation (EC) 2023/2006 as amended concerning GMP standards for the plastic polymer processing chain[5].

Any other documents related to the legal provisions on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs) are included in separate documentation systems, such as the Supporting Documentation (SD).

Below are the sheets (B6b.3.a-B6b.3.n) for documental verification that describe the activities and/or measures that can be adopted by the Company to implement the provisions of Articles 5, 6 and 7 of Regulation (EC) 2023/2006 as amended.

The sheets presented are not binding for the supply chain discussed here, but their content must be considered a set of operational suggestions. The worksheet should always be used in conjunction with the CAST GMP guideline.

[5] The polymer production sheets can be found in Chapter B6a.2

Sheet B6b.3.a. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Quality Assurance Systems* (guideline CAST GMP → B6.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 5, paragraph 1*: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective. – documented. – appropriate to the size of the company.
Document type and description	The documentation relating to the Quality Assurance System may consist of the Quality Manual, if available, or of another similar document demonstrating that the System is applied and implemented. The system must contain: – references to Regulation (EC) 1935/2004 as amended and supplemented and to Regulation (EC) 2023/2006 as amended; – procedures, instructions and organization chart with definition of roles and responsibilities within the Company. The Company should identify within its organization the function responsible for the application of Regulation (EC) 2023/2006 as amended.
Notes	The Quality Manual is not a mandatory requirement of Regulation (EC) 2023/2006 as amended. Quality management systems, including certified (es. ISO 9001), do not ensure compliance with the legal requirements of Regulation (EC) 2023/2006 as amended.

Sheet B6b.3.b. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Size of the business* (guideline CAST GMP→ B6.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Organization of facilities (identification of company roles and responsibilities). Organization of equipment.
Document type and description	Organization chart of company roles and documents indicating the names of the persons in charge (internal/external staff) with specific responsibilities. The company organization is illustrated in a specific section of the Quality Manual or in other suitable documentation or in specific company organizational communications. The attributions and tasks of the Personnel (definition of tasks) should be indicated in company documents (e.g. organizational manuals that explain roles and functions) Production manuals/procedures with descriptions of equipment and controls.
Notes	-

Sheet B6b.3.c. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Human resources and training* (guideline CAST GMP→ B6.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Adequacy of staff. Staff knowledge and skills.
Document type and description	The training of the worker is recorded and documented, for example, by: – procedures and/or instructions for the training and updating of personnel containing indications for verifying effectiveness; – specific training activities on GMP standards and FCMs; – specific training and refresher courses in relation to the assigned task.
Notes	The Company defines roles and responsibilities to clarify the internal organization explicit. The Company promotes training programs and courses, records the participation of personnel in training activities and can carry out an assessment of the skills of the personnel involved.

Sheet B6b.3.d. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Selection of the starting materials of the suppliers and/or services and/or third parties* (guideline CAST GMP→ B6.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Selection of raw materials and suppliers.
Document type and description	The Company should prepare documents relating to: – specifications of the raw materials, established in *"technical sheeet"* containing indications of the physical and chemical parameters that identify the raw material and its suitability for the production of materials and articles intended for contact with food; – procedures for the selection and qualification of suppliers of external goods, materials and services; – procedures that define the criteria for evaluation and inclusion in the list of approved suppliers; – operating methods to assess over time the ability of suppliers to maintain the required quality level over time.
Notes	The qualification of materials must be carried out in relation to specifications/specifications and other applicable requirements that may affect the conformity and safety of FCMs. The selection of suppliers must be made on the basis of their ability to provide the significant information to be able to determine the conformity of the finished product. The qualification of external services is made on the basis of their ability to maintain a working environment that complies with hygiene standards and GMP standards.

Sheet B6b.3.e. QUALITY CONTROL SYSTEMS
***Management of raw materials warehouses* (guideline CAST GMP→ B6.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Compliance of raw materials with defined specifications
Document type and description	The following should be defined: – operating procedures/instructions for incoming inspections, according to any sampling plans, in order to verify the compliance of raw materials with specifications; – records of the results of both documentary and analytical inspections.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, internal methods, standard methods) with suitable and adequately calibrated instrumentation. The data resulting from quality control operations should be appropriately recorded in digital sheets, databases, etc. According to good industrial practice, samples taken during acceptance are kept for an appropriate and predefined time.

Sheet B6b.3.f. QUALITY CONTROL SYSTEMS
***Production controls* (guideline CAST GMP→ B6.2.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures*
Fulfilment	Operations according to instructions and procedures.
Document type and description	Specific documents describing the operational procedures and relevant process parameters should be defined for each stage of the production process, for example: manuals, procedures, instructions, technical standards and records of the activities performed. Adequate records of the trend of significant parameters are maintained.
Notes	A process flow chart can help identify process steps that require operating instructions and/or other documents necessary to maintain and demonstrate control of activities for FCM and GMP compliance.

Sheet B6b.3.g. QUALITY CONTROL SYSTEMS
***Production controls* (guideline CAST GMP→ B6.2.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures*
Fulfilment	Instructions and procedures for the production process
Document type and description	the following should be defined: – operating procedures/instructions describing the methods for ensuring the traceability of the product starting from the raw materials used through the various stages of production up to delivery to the warehouse; – procedures/instructions for delivery to the warehouse.
Notes	The product can be stored and identified in various ways as “not shippable” until its quality level and/or compliance with all the requirements of the production phase is verified. Production controls must guarantee through appropriate records that the material has been checked at all required stages starting from the raw materials used through the production process.

Sheet B6b.3.h. QUALITY CONTROL SYSTEMS
***Quality Control of the finished product* (guideline CAST GMP→ B6.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the production process
Document type and description	The quality control system should include operating instructions or procedures to monitor product attributes that affect compliance.
Notes	The tests must be carried out according to codified test methods (standard methods, methods validated between laboratories or internally, internal methods) whit suitable and adequately calibrated instrumentation. The data resulting from quality control operations should be appropriately recorded in digital sheets, databases, etc. The quality control procedures applied during the process phases (in-line) guarantee the finished product the same expected requirements. The constancy of the controlled attributes (e.g. thickness) can ensure that the conformity of the finished product to the predefined specifications does not vary.

Sheet B6b.3.i. QUALITY CONTROL SYSTEMS
***Management of finished products warehouses* (guideline CAST GMP → B6.2.2.4)**
***Distribution, shipment and deliver* (guideline CAST GMP → B6.2.2.5)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 5, paragraph 3*: *The various operations must be carried out according to pre-established instructions and procedures*
Fulfilment	Finished products warehouse management.
Document type and description	The following documents should be defined: – procedures/instructions for the storage of finished products (with identification of the status: material meeting the established specification, under test, contested, etc.) and related records; – procedures/instructions for the identification/traceability of stored products and related records; – procedures/instructions for the traceability of picking operations and authorization for shipment to customers (semi-finished and finished products) and related records; – procedures/instructions for the definition of the criteria for the selection of transporters and the checks to be carried out on the means of transport (supply / service specifications) and related records; – operational instruction for issuing a transport document.
Notes	The procedures for the warehouse management and distribution of products must be such that they do not change their compliance with predefined specifications.

Sheet B6b.3.l. QUALITY CONTROL SYSTEMS
***Quality Control Systems* (guideline CAST GMP→ B6.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 6, paragraph 1: *Operators in the sector must establish and maintain an effective quality control system.*
Fulfilment	Effective Quality Control System.
Document type and description	The reference documents are, for example: – Quality Manual; – procedures and operating instructions that establish control methods (references to laws, standards, specifications, internal methods, etc.); – records of the activities to verify the conformity of the products with the respective specifications (e.g. control sheets, digital spreadsheet).
Notes	Companies could manage the control of GMP standards as an integral part of the verifications required by ISO 9000 standards (e.g. compliance with specifications). While quality management systems (e.g. ISO 9000, BRC) ensure that production is conducted according to specific documented procedures to achieve a predefined quality level, a GMP system according to Regulation (EC) 2023/2006 as amended is focused on measures and activities aimed at ensuring with specific legislative requirements on FCMs.

Sheet B6b.3.m. QUALITY CONTROL SYSTEMS
***Conformity of the application of the GMP and claims management, corrective and preventive actions* (guideline CAST GMP → B6.2.2.6)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.*
Fulfilment	Preventive and corrective measures. Non-compliance management.
Document type and description	The following documents should be defined: – operating procedures/instructions for the execution of internal audits functional to the control of documental findings, which may also include the monitoring of FCM obligations and compliance with Regulation (EC) 2023/2006 as amended. The following should also be formalised: – procedures for managing complaints; – procedures for the implementation of corrective and preventive actions; the latter procedure must provide for the verification of the effectiveness of the corrective/preventive actions implemented.
Notes	Internal audits are planned, carried out for all business areas involved in the implementation of GMP standards and duly recorded. A distinction must be made between non-conformities related to product performance requirements and non-conformities that have regulatory or legal implications.

Sheet B6b.3.n. DOCUMENTATION
***Documentation* (guideline CAST GMP→ B6.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 2: *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant for the conformity and safety of finished materials and articles, and relating to the results of the quality control system.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by the operators in the sector.*
Fulfilment	Preservation of QAS and Quality Control System (QCS) documentation Constant adaptation and transposition of legislation
Document type and description	They should be defined as: - procedures, operating instructions for the archiving and retention of documents relating to the QAS (procedures, specifications, formulations, etc.); - procedures, operating instructions for the archiving and retention of documents relating to the QCS (instructions, records of process and control data). The Quality Manual or other company document defines an adequate time for the retention of all documents pertinent to the implementation of GMP standards. Procedures/instructions must be defined to ensure continuous compliance with the regulatory requirements of current legislation.
Notes	Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/2004 as amended). Copies of the declarations of compliance issued are an integral part of the archive (art. 16 of Regulation (EC) 1935/2004 as amended).

Annex B6b.1.

Production flowchart for plastic packaging

Table 6.1. Production steps and processes related to raw materials

Manufacturing steps	**Processes to obtain plastic packaging**								
	Extrusion	**Thermo-forming**	**Injection moulding**	**Injection blow moulding**	**Extrusion and blow moulding**	**Extrusion, expansion and thermo-forming**	**Sintering moulding**	**Roto-moulding**	**Coated articles**
Raw material Starting physical shape	polymers pellet flakes powder	polymers pellet flakes powder	polymers pellet	polymers flakes pellet	polymers pellet	polymers pellet	polymers beads	polymers powder	polymers pellet flakes powder
Semifinished products Starting physical shape		sheets		preforms					sheets/ plastic films obtained by extrusion + plastisol
Possible additivation	X	X	X	X	X	X			X
Conversion process/processes	• extrusion/ coextrusion with or without orientation	• extrusion • thermo-forming	• injection moulding	• blow injection moulding	• extrusion and blow moulding • orientation by blowing	• extrusion/ expansion • thermo-forming	• pre-expansion • Seasoning/ maturation • sintering	• roto-moulding	• spreading
where necessary	decoration	decoration	decoration	decoration	decoration	decoration			
Examples	films, sheets, rolls, semifinished products for thermo-forming	yogurt cups, diary trays, punnets for fruit & vegetables, single use dishes and cutlery	bottles closures and caps; freezer food containers, individually packaged dessert cups	bottles for water and soft drinks	oil bottles	trays for meat, fresh food, cheese and vegetables	fish boxes, take-away ice cream trays	holding tanks	holding tanks made of/coated with thermo-setting resins

B7. METALS AND METAL ALLOYS, COATED AND NOT-COATED

B7.1. Characterisation of the sector

B7.1.1. Field of application of the guideline

This guideline is applicable to all the companies that produce materials and articles made of coated and not-coated metals intended to be used in contact with food products. This guideline deals with these items:

- 3-piece cans and aerosols with electro-welded body;
- caps and closures;
- 2-piece cans;
- crown closures;
- semirigid cans;
- flexible tubes (deformable).

B7.1.2. Phases of the production process: flowcharts and descriptions

The production flow diagrams are given in Annexes B7.1-B7.7 at the end of this chapter.

The summary description of the process steps is given in chapters B7.1.3.2, B7.1.3.4, B7.1.3.6, B7.1.3.8, B7.1.3.10, B7.1.3.12 and B7.1.3.14 of the CAST GMP guideline.

B7.2. Sheets for documental verification of the application of Regulation (EC) 2023/2006: 2-piece cans, 3-piece cans, etc.

This guideline defines the activities and documentation required to implement the provisions of Regulation (EC) 2023/2006 as amended relating to GMP standards for the production chain of coated and uncoated metal packaging. Any other documents related to the legal provisions on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs) are included in separate documentation systems, such as the Supporting Documentation (SD).

The following are the sheets (B7.2.a.-B7.2.n.)[6] for documental evidence describing the activities and/or implementations that may be implemented by the Company to implement the provisions of Articles 5, 6 and 7 of Regulation (EC) 2023/2006 as amended. The sheets presented are not binding for the supply chain discussed here, but their content must be considered a set of operational suggestions. The cards should always be used in conjunction with the CAST GMP guideline.

[6] The sheets for semi-rigid containers are in paragraph B7.3

Sheet B7.2.a. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Quality Assurance System* (guideline CAST GMP→ B7.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 5, paragraph 1*: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective. – documented. – appropriate to the size of the company.
Document type and description	The documentation relating to the Quality Assurance System may consist of the Quality Manual, if available, or another similar document demonstrating that the System is applied and implemented. The system must contain: – Regulation (EC) 1935/2004 as amended and supplemented and Regulation (EC) 2023/2006 as amended; – procedures, instructions and documents that define how the system is implemented and enforced; – roles and responsibilities within the Company itself. The Company should identify within its organization the Function responsible for the application of Regulation (EC) 2023/2006 as amended.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended. Any certification by third parties (e.g. according to ISO 9001) could guarantee the adequacy of the QAS with respect to the size of the company. ISO 9001 quality management systems include multiple requirements also for GMP standards.

Sheet B7.2.b. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Human resources and training* (guideline CAST GMP → B7.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Adequacy of staff. Staff knowledge and skills.
Document type and description	Training is recorded and documented for example by: – procedures and/or instructions for the training and updating of personnel containing indications for verifying effectiveness; – specific training activities on GMP standards and FCMs; – personal training sheets for training recording; – specific training and refresher courses in relation to the assigned task.
Notes	The Company can define roles and responsibilities to explain the internal organization (job description) and report them in documents such as the Quality Manual or other suitable document.

Sheet B7.2.c. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Human resources and training* (guideline CAST GMP→ B7.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Organization of the necessary locations and equipment
Document type and description	The organization of the offices, their structure, should be reported in the Quality Manual or in other specific company documentation. The following should be present: – documents relating to the adequacy of production equipment and control of finished materials and articles; – manuals/production procedures/technical documentation of machinery and its calibration status, etc.
Notes	-

Sheet B7.2.d. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Selection of the starting materials of the suppliers and/or services and/or third parties* (guideline CAST GMP → B7.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 5, paragraph 2:* *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Selection of raw materials and suppliers.
Document type and description	The Company should prepare documents relating to: – specifications of the raw materials, established in *"technical specifications"* that contain the indications of the characteristics that identify the raw material; – procedures for the selection and qualification of suppliers of external goods, materials and services that define: - the evaluation criteria and inclusion in the list of approved suppliers; - the operating methods to assess over time the ability of suppliers to maintain the required quality level. The selection, qualification, listing and monitoring of qualified suppliers must be properly recorded.
Notes	-

Sheet B7.2.e. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Production* (guideline CAST GMP→ B7.2.1.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the production process.
Document type and description	Specific documents describing the operational methods of verification and control and the relevant product parameters should be defined for each stage of the production process, for example: – procedures, instructions, technical specifications; – recording of the monitoring and control activities carried out. Adequate records of the trend of significant parameters, including any deviations.
Notes	A process flow chart can help identify critical points in the process that need operating instructions and or other documents necessary to maintain and demonstrate control of activities for the purposes of FCMs and GMP standards.

Sheet B7.2.f. QUALITY CONTROL SYSTEMS
***Quality Control Systems* (guideline CAST GMP → B7.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art.6, paragraph 1: *Operators in the sector must establish and maintain an effective quality control system.*
Fulfilment	Development of a Quality Control System suitable for its activity, structure, product.
Document type and description	The reference documents are, for example: – Quality Manual; – procedures and operating instructions that establish control methods (references to laws, standards, specifications, internal methods, etc.); – records of the activities of verification of conformity of products with their respective specifications, e.g. control sheets, computerized tables.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended.

Sheet B7.2.g. QUALITY CONTROL SYSTEMS
***Warehouse management for raw materials* (guideline CAST GMP→ B7.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Compliance of raw materials with defined specifications
Document type and description	The following should be defined: – procedures/operating instructions for acceptance checks, according to any sampling plans, in order to verify the compliance of raw materials with the specifications. – records of control results.
Notes	The tests must be carried out according to test methods suitably described through an internal procedure, by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be appropriately recorded in computerized tables, databases, etc.

Sheet B7.2.h. QUALITY CONTROL SYSTEMS
***Production Controls* (guideline CAST GMP→ B7.2.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3*:* *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions/procedures for the production process.
Document type and description	The following should be defined: – operating procedures/instructions to describe the methods for ensuring the controls and traceability of the product starting from the raw materials used through the various stages of production up to the delivery to the warehouse; – operating procedures/instructions for delivery to the warehouse.
Notes	Production controls must guarantee through appropriate records certifying that the material has been checked at all stages starting from the raw materials used through the production process.

Sheet B7.2.i. QUALITY CONTROL SYSTEMS
***Quality Control of finished product* (guideline CAST GMP→ B7.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions/procedures for the production process.
Document type and description	Operating instructions or procedures for verifying the conformity of the quality of the finished product with the expected requirements should be defined and codified in the respective product specifications.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, standards) by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be recorded in computerized tables, databases, etc.

Sheet B7.2.l. QUALITY CONTROL SYSTEMS
***Management of finished products warehouses* (guideline CAST GMP → B7.2.2.4)**
***Distribution, transport and delivery* (guideline CAST GMP → B7.2.2.5)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 5, paragraph 3*: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions/procedures for warehouse management of finished goods, transport and delivery.
Document type and description	Procedures/instructions and any records should be defined for: – management of the non-compliant product; – identification and traceability of stored products; – traceability of the picking and shipping operations of finished products; – definition of the criteria for selecting transporters and the checks to be carried out on means of transport; – issuance of transport document.
Notes	-

Sheet B7.2.m. QUALITY CONTROL SYSTEMS
***Conformity of the application of the GMP and claims management, corrective and preventive actions* (guideline CAST GMP→ B7.2.2.6)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 6, paragraph 2*: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.*
Fulfilment	Instructions and procedures for monitoring the implementation of GMP standards.
Document type and description	Procedures/operating instructions should be defined for: – execution of internal audits; – management of complaints and management of any non-conformities; – implementation of corrective and preventive actions for the resolution of non-conformities; the latter procedure must provide for the verification of the effectiveness of the corrective/preventive actions implemented.
Notes	Internal audits are planned, carried out and recorded in order to verify the correct implementation of GMP standards in all business areas involved

Sheet B7.2.n. DOCUMENTATION
***Documentation* (guideline CAST GMP → B7.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 2: *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant for the conformity and safety of finished materials and articles, and relating to the results of the quality control system.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by operators in the sector.*
Fulfilment	Preservation of QAS and Quality Control System (QCS) documentation. Constant adaptation and transposition of legislation.
Document type and description	Procedures/operating instructions for archiving and storing documents should be defined: – related to QAS (procedures, instructions, etc.); – related to the QCS (instructions, records of process and control data). The Quality Manual or other company document defines an adequate time for the storage of all documents pertinent to the implementation of GMP standards. Procedures/instructions must be defined to ensure continuous compliance with the regulatory requirements of current legislation.
Notes	Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/2004 as amenmded). Copies of the declarations of conformity issued (art. 16 of Regulation (EC) 1935/2004 as amended are an integral part of the archive.).

B7.3. Sheets for documental verification of the application of Regulation (EC) 2023/2006: semi-rigid articles

This guideline defines the activities and documentation required to implement the provisions of Regulation (EC) 2023/2006 as amended relating to GMP standards for the production chain of coated and non-coated metal packaging in relation to semi-rigid articles.

Any other documents related to the legal provisions on Food Contact Materials (FCMs) are included in separate documentation systems, such as the Supporting Documentation (SD).

The following are the sheets (B7.3.a.-B7.3.h.)[7] for documental evidence describing the activities and/or implementations that may be implemented by the Company to implement the provisions of Articles 5, 6 and 7 of Regulation (EC) 2023/2006 as amended.

The sheets presented are not binding for the supply chain discussed here, but their content must be considered a set of operational suggestions. The cards should always be used in conjunction with the CAST GMP guideline.

Sheet B7.3.a. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Quality Assurance Systems* (guideline CAST GMP→ B7.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective. – documented. – appropriate to the size of the company.
Document type and description	The Company may adopt a Manual for the management of the Quality System and/or special procedures to define how the system is implemented and enforced and the methods for consulting the company documentation with respect to Regulation (EC) 2023/2006 as amended. The Company should identify within its organization the Function responsible for the application of Regulation (EC) 2023/2006 as amended. (e.g. name organization chart).
Notes	The Quality Manual is not expressly required by Regulation (EC) 2023/2006 as amended. Any certification by third parties (e.g. according to ISO 9001) could guarantee the adequacy of the QAS with respect to the size of the company. ISO 9001 quality management systems include multiple requirements also for GMP standards.

[7] The sheets for metal containers (2-piece boxes, 3-piece boxes, etc.) are in paragraph B7.2

Sheet B7.3.b. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Human resources and training* (guideline CAST GMP → B7.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Adequacy of staff. Training of employees knowledge and skills.
Document type and description	Training is planned and documented, for example, by: – procedures and/or instructions for the training and updating of personnel containing indications for verifying effectiveness. Specific training activity on GMP standards and FCMs.
Notes	The Company can define roles and responsibilities to explain the internal organization (job description) and report them in documents such as the Quality Manual or other suitable document.

Sheet B7.3 c. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Selection of starting materials and suppliers* (guideline CAST GMP → B7.2.1.2)**
QUALITY CONTROL SYSTEMS
***Management of raw materials warehouses* (guideline CAST GMP → B7.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 5, paragraph 2:* *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Selection of raw materials and suppliers.
Document type and description	The Company should prepare documents relating to: – technical specifications/safety data sheets/any documentation of legislative compliance of the raw materials with reference to FCMs; – procedures for the selection and qualification of suppliers of external goods, materials and services relevant to compliance with FCMs legislation; – procedures and records relating to the evaluation of suppliers; – operating procedures/instructions for any acceptance checks in order to verify the compliance of raw materials with specifications; – records of control results.
Notes	Controls and storage arrangements should be defined on the basis of an assessment of the risks of contamination and/or deterioration of raw materials. The risk of contamination during warehouse storage in the case of plates and semi-finished rolls can be considered irrelevant. Acceptance checks may not be necessary for all raw materials, if not mandatory to ensure legislative compliance (e.g. radioactivity assessment for semi-finished plates and rolls and evaluation of the chemical composition of aluminium). In particular, for approved materials/suppliers, the Company may decide to release the goods into production without prior controls.

Sheet B7.3.d. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Production* (guideline CAST GMP → B7.2.1.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Production – Production System Compliance.
Document type and description	For each phase of the production process: order of raw materials, possible product design, production planning, production according to defined recipe, production controls, the specific operating methods for that operation and the necessary related records should be defined through appropriate documentation such as: – procedures, instructions; – records of relevant activities carried out.
Notes	-

Sheet B7.3.e. QUALITY CONTROL SYSTEMS
***Production controls* (guideline CAST GMP → B7.2.2.2)**
***Quality Control of finished product* (guideline CAST GMP → B7.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Production controls and quality control of finished products.
Document type and description	The following should be defined: – procedures/work instructions for process control to define: - the critical points of the process; - the checks to be carried out (measurements, tolerances, frequencies); - levels of responsibility. – product control procedures to define: - the critical parameters and reference values in relation to the specification of each product; - the control methods (tolerances/frequency); - the levels of responsibility for controls. – procedures/instructions describing the methods for ensuring the controls and traceability of the product starting from the raw materials used through the various stages of production up to the delivery to the warehouse; – procedures/instructions for delivery to the warehouse; – recording of process and product controls.
Notes	-

Sheet B7.2.f. QUALITY CONTROL SYSTEMS
***Management of finished products warehouses* (guideline CAST GMP → B7.2.2.4)**
***Distribution, shipment and delivery* (guideline CAST GMP → B7.2.2.5)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions/procedures for warehouse management of finished goods, transport and delivery.
Document type and description	Procedures/instructions and any records should be defined for: – management of the non-compliant product; – identification and traceability of stored products; – traceability of the picking and shipping operations of finished products; – definition of the criteria for selecting transporters and the checks to be carried out on means of transport; – issuance of transport document.
Notes	-

Sheet B7.3.g. QUALITY CONTROL SYSTEMS
***Conformity of the application of the GMP and claims management, corrective and preventive actions* (guideline CAST GMP→ B7.2.2.6)**

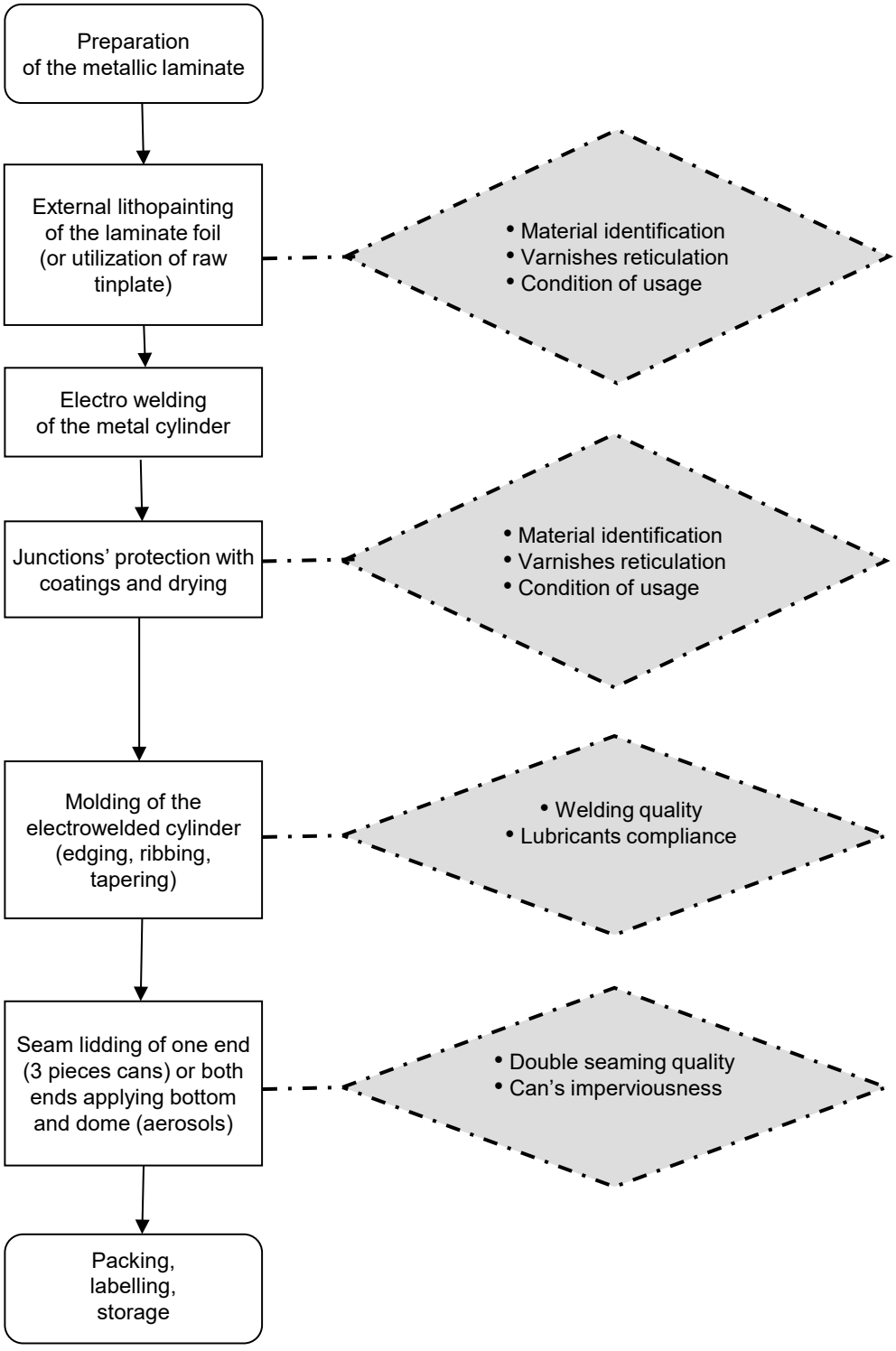
INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP. These corrective measures must be implemented without delay and made available to the Competent Authorities for inspections.*
Fulfilment	Instructions and procedures for monitoring the implementation of GMP standards.
Document type and description	Procedures/operating instructions should be defined for: – performing/implementation of internal audits; – management of complaints and management of any non-conformities; – implementation of corrective and preventive actions for the resolution of non-conformities, the latter procedure must provide for the verification of the effectiveness of the corrective/preventive actions implemented.
Notes	Internal audits are planned, carried out and recorded in order to verify the correct implementation of GMP standards in all business areas involved.

Sheet B7.3.h. DOCUMENTATION
***Documentation* (guideline CAST GMP → B7.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 2: *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant for the conformity and safety of finished materials and articles, and relating to the results of the quality control system.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by operators in the sector.*
Fulfilment	Preservation of QAS and QCS documentation. Continuous adaptation and transposition of legislation.
Document type and description	Procedures/operating instructions for archiving and storing documents should be defined: – related to QAS (procedures, instructions, etc.); – related to the QCS (instructions, records of process and control data). The Quality Manual or other company document defines an adequate time for the storage of all documents pertinent to the implementation of GMP standards. Procedures/instructions must be defined to ensure continuous compliance with the regulatory requirements of current legislation.
Notes	Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/2004 as amended). Copies of the declarations of compliance issued are an integral part of the archive (art. 16 of Regulation (EC) 1935/2004 as amended).

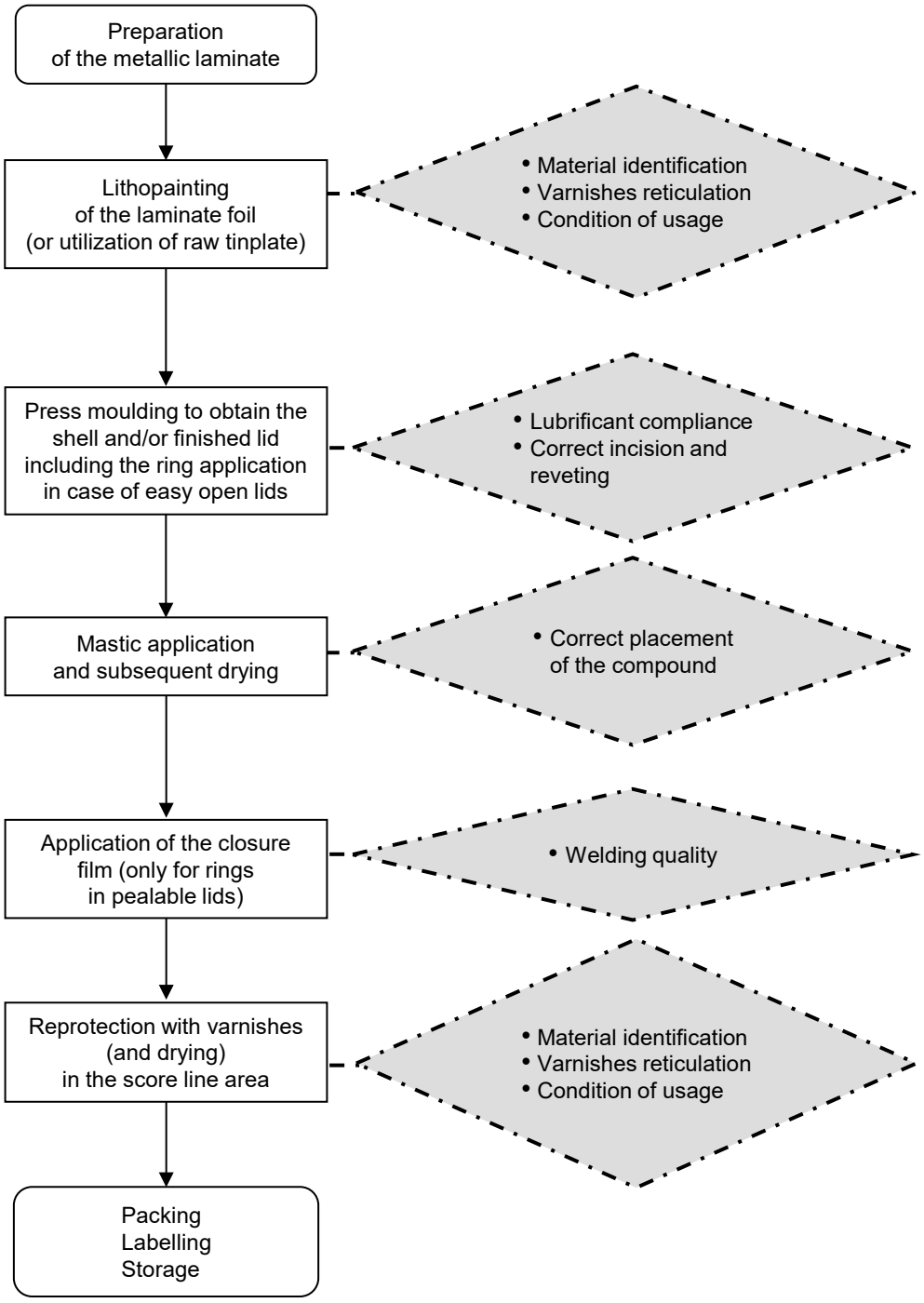
Annex B7.1.

Production flowchart of 3-piece cans and aerosol cans with electrowelded body



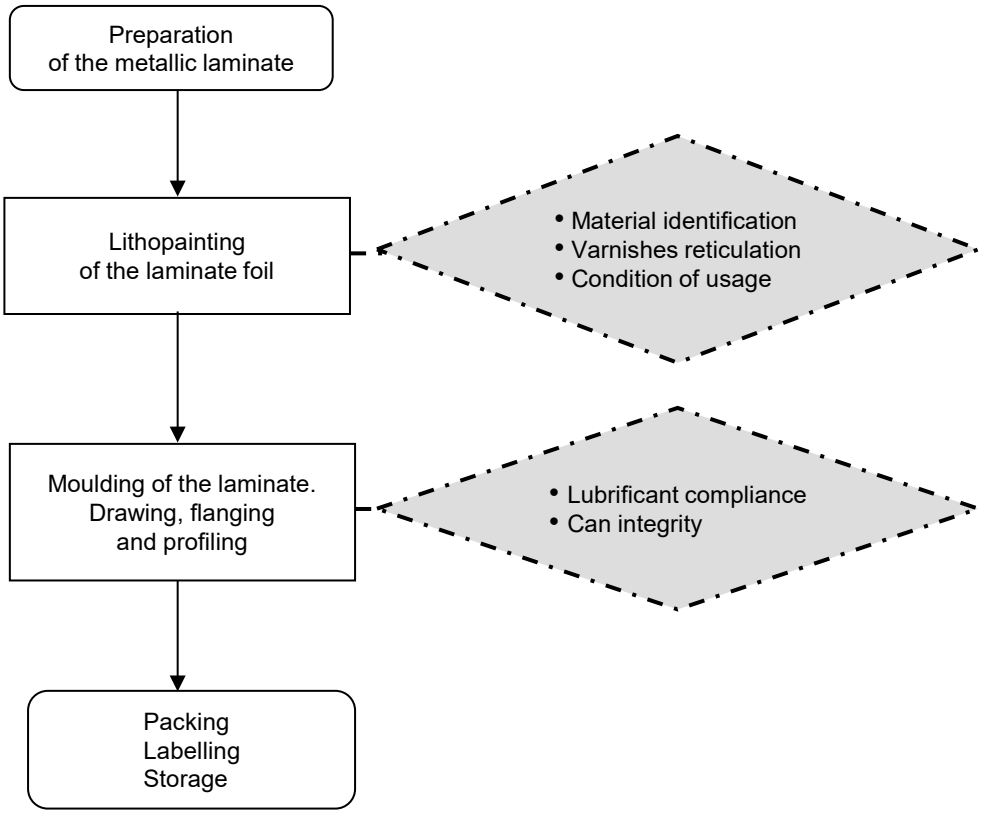
Annex B7.2.

Product flowchart of *open top*, *easy open* and peelable lids



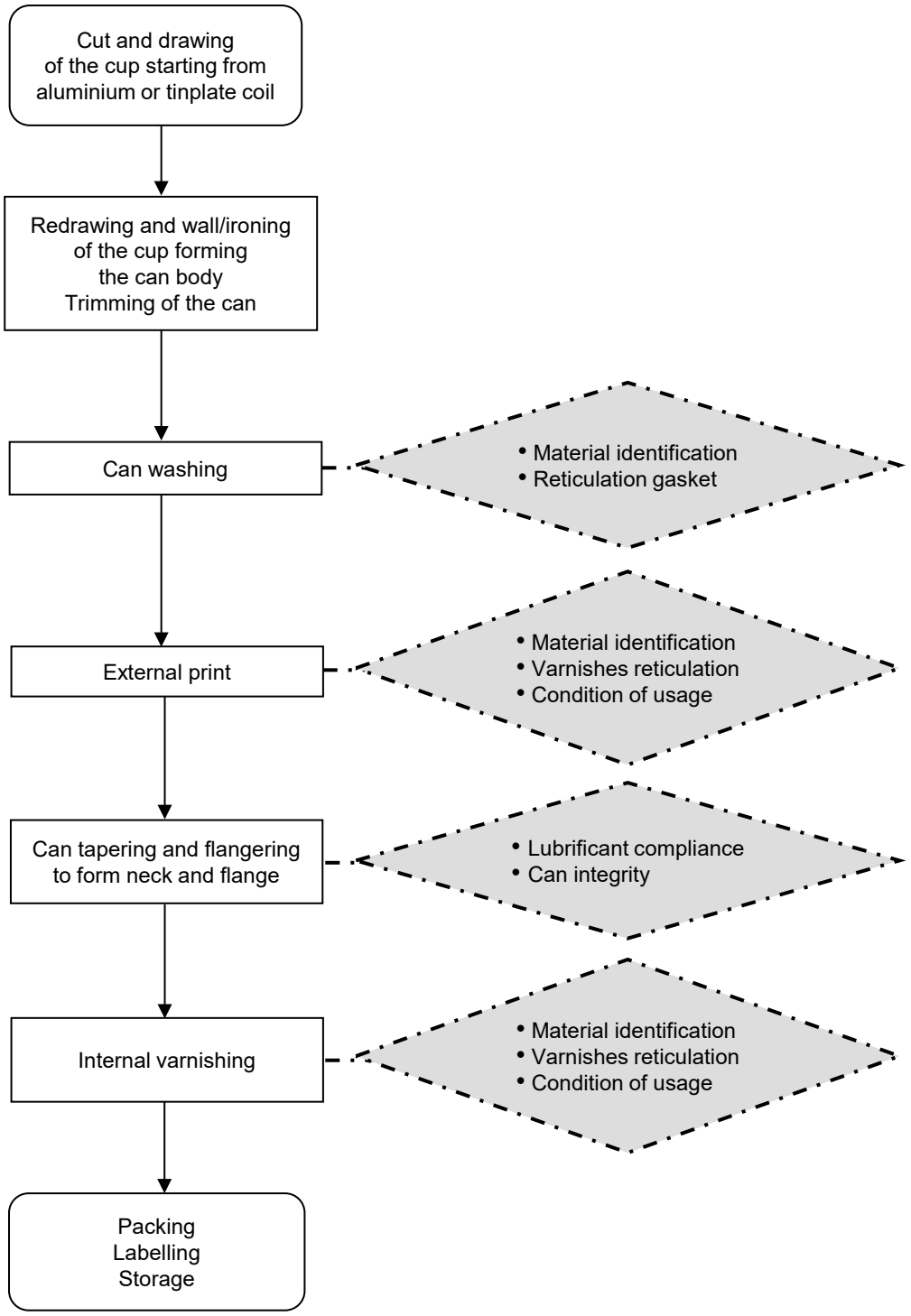
Annex B7.3.

Production flowchart of drawn and redrawn metal cans (2-pieces DRD cans)



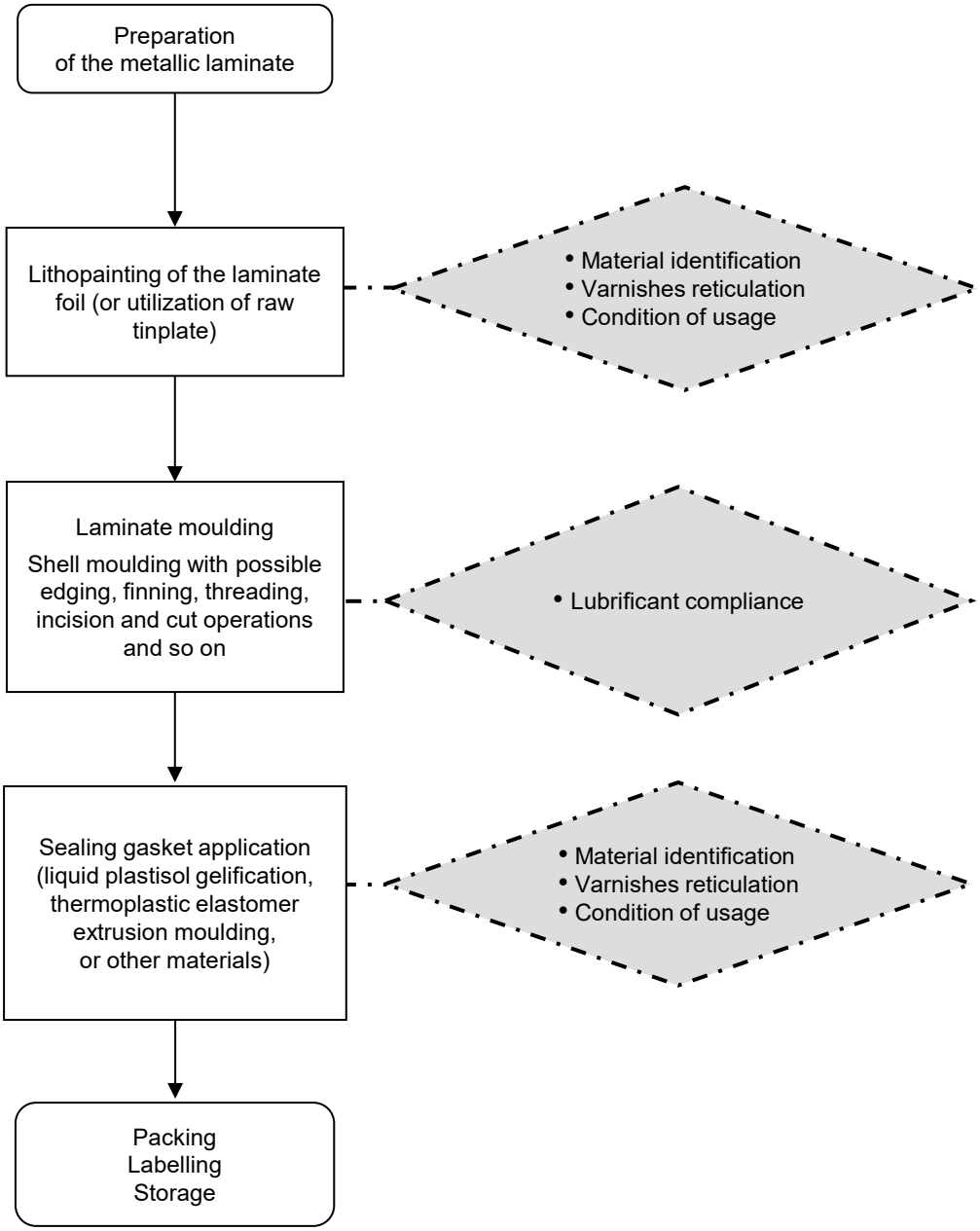
Annex B7.4.

Production flowchart of drawn and wall-ironed cans (2-pieces DWI cans)



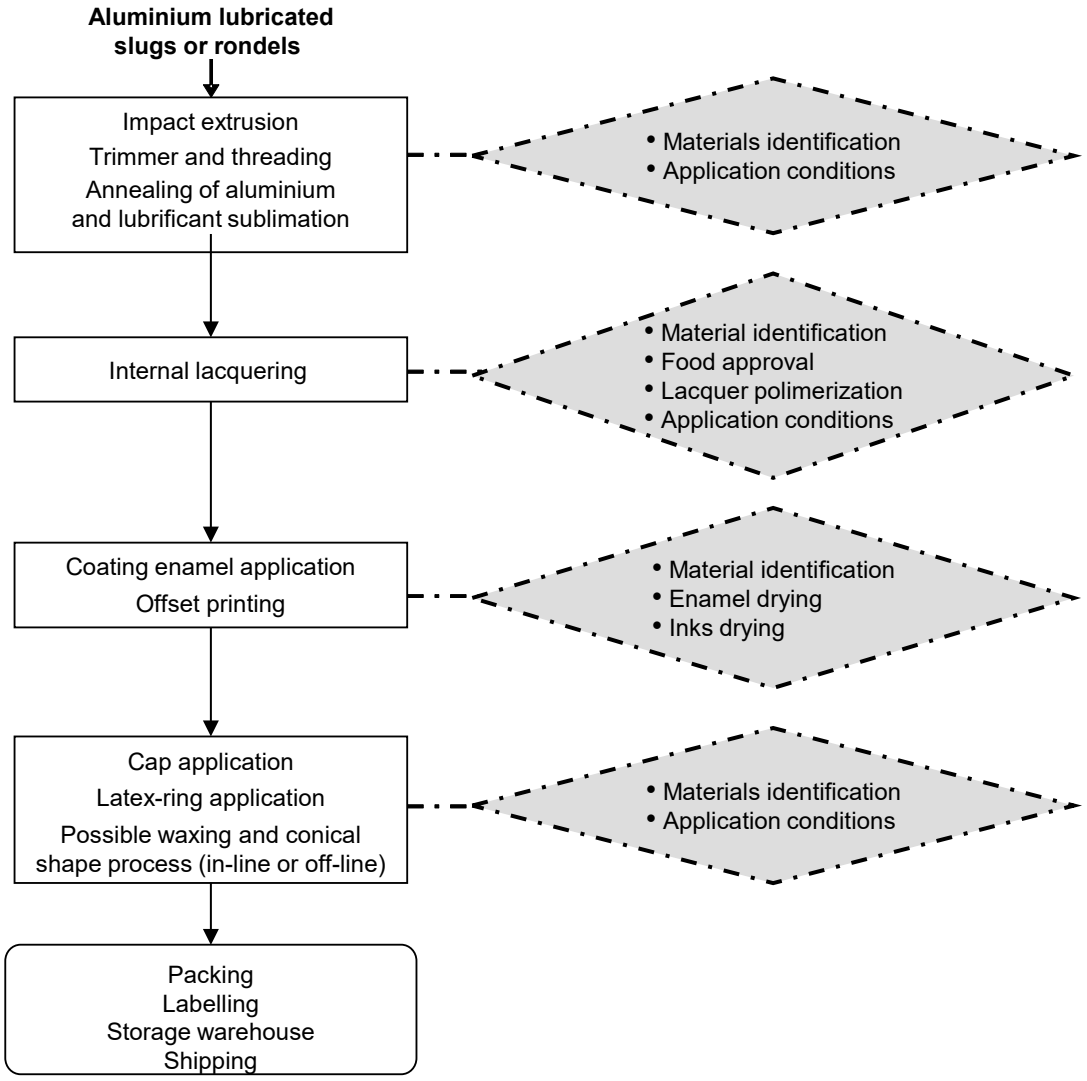
Annex B7.5.

Production flowchart of closures (capsules with fins, PT capsules, crown caps)



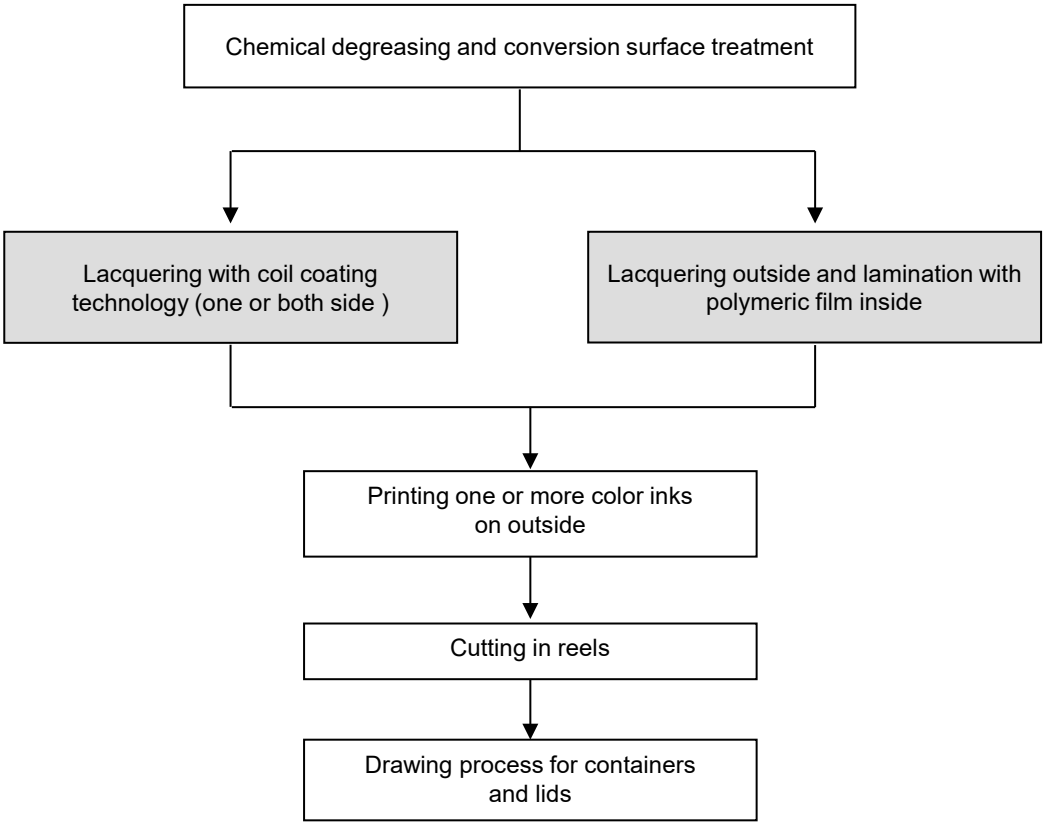
Annex B7.6.

Production flowchart: flexible tubes, not deformable



Annex B7.7.

Production flowchart of Semi-rigid containers lacquered or coupled with polymer films



B8. CORK: CORK STOPPERS

B8.1. Characterization of the sector

B8.1.1. Field of application of the guideline

This guideline applies to companies that manufacture cork stoppers or parts of cork stoppers or any other material or article for cork stoppers in which the main component is manufactured cork which, in the state of finished products, are intended to come into contact with food. Cork stoppers or cork parts of corks, in which the manufactured cork is at least 51%, fall within the scope of this guideline.[8] Exclusion from the scope of this guideline does not automatically entail exclusion from Regulation (EC) 2023/2006 as amended.

The cork part of corks may consist of a single piece, or of two or more pieces of cork, or granulated cork held together by means of glues, adhesives or other means.

For cork, intended for the production of articles intended for food contact, for starting material pursuant to Regulation (EC) 2023/2006 as amended. This refers to cork obtained decortication, which, after being stored in the forest and/or in the factory, has not yet undergone the first boiling.

The starting substances for the production of any additives are excluded from the scope of Regulation (EC) 2023/2006 as amended and therefore from this guideline.

B8.1.2. Phases of the production process: flowcharts and description

The production flow diagram is given in Annex B8.1 at the end of this chapter. A summary description of the process steps is given in chapter B8.1.3.2. of the CAST GMP guideline.

B8.2. Sheets for documental verification of the application of Regulation (EC) 2023/2006

This guideline defines the activities and documentation required to implement the provisions of Regulation (EC) 2023/2006 as amended concerning GMP standards for the cork stopper production chain.

Any other documents related to the legal provisions on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs) are included in separate documentation systems, such as the Supporting Documentation (SD).

Below are the sheets (B8.2.a.-B8.2.n.) for documental verification that describe the activities and/or implementations that can be implemented by the Company to implement the provisions of Articles 5, 6 and 7 of Regulation (EC) 2023/2006 as amended.

[8] The definition coincides with the definition in the "Appendix to Resolution ResAP(2004)2 on cork stoppers and other cork materials and articles intended to come into contact with foodstuffs". (Council of Europe, Committee of Ministers 1.12.2004)

The form presented are not binding for the supply chain discussed here, but their content must be considered a set of operational suggestions.

The cards should always be used in conjunction with the CAST GMP guideline.

Sheet B8.2.a. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Quality Assurance Systems* (guideline CAST GMP → B8.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective. – documented – appropriate to the size of the company.
Document type and description	The documentation relating to the QAS may consist of the Quality Manual if available or another similar document demonstrating that the system is applied and implemented. The system must contain: – Regulation (EC) 1935/2004 as amended and supplemented and Regulation (EC) 2023/2006 as amended; – procedures, instructions and documents that define how the system is implemented and enforced; – roles and responsibilities within the Company itself. The Company should identify within its organization the function responsible for the application of Regulation (EC) 2023/2006 as amended.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended. Any certification by third parties (e.g. according to ISO 9001 or Celiege's Systecode manufacturing code) could guarantee the adequacy of the QAS with respect to the size of the company. ISO 9001 quality management systems and the Systecode they include multiple requirements also provided for GMP standards.

Sheet B8.2.b. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Human Resources and Training* (guideline CAST GMP→ B8.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Adequacy of staff. Staff knowledge and skills.
Document type and description	Training is recorded and documented for example by: – procedures and/or instructions for the training and updating of personnel containing indications for verifying effectiveness; – specific training activities on GMP standards and on Food Contact Materials (FCMs); – specific training and refresher courses in relation to the assigned task.
Notes	The Company can define roles and responsibilities to explain the internal organization (job description) and report them in documents such as the Quality Manual or other suitable document.

Sheet B8.2.c. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Size of the business* (guideline CAST GMP → B8.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.* Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter b): *Be applied taking into account the size of the company, so as not to constitute an excessive burden on the company.*
Fulfilment	Organization of the necessary locations and equipment.
Document type and description	The organization of the offices, their structure, should be reported in the Quality Manual or in other specific company documentation. Documents relating to the adequacy of production equipment and control of finished materials and objects; manuals/production procedures/technical documentation of the machinery and its calibration status, etc. Manuals and technical documentation of machinery and equipment may be recalled/inserted/attached in the relevant Quality System documentation.
Notes	-

Sheet B8.2.d. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Production* (guideline CAST GMP→ B8.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the production process.
Document type and description	Specific documents describing the management operating modes and relevant process parameters should be defined for each stage of the production process, for example: – manuals, procedures, instructions, technical standards; – records of relevant activities carried out; – adequate records of the trend of significant parameters, including any deviations.
Notes	A process flow chart can help identify critical points that need operating instructions and or other documents necessary to maintain and demonstrate control of activities for the purposes of FCMs and GMP standards.

Sheet B8.2.e. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Selection of the starting materials of the suppliers and/or services and/or third parties* (guideline CAST GMP→ B8.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Selection of the starting materials of the suppliers and/or services and/or third parties
Document type and description	The Company should prepare documents relating to: – specifications of the raw materials, established in “technical specifications” that contain the indications of the characteristics that identify the raw material; – procedures for the selection and qualification of suppliers of external goods, materials and services that define: - the criteria for evaluation and inclusion in the list of approved suppliers, - the operating methods to assess over time the ability of suppliers to maintain the required quality level. The selection, qualification, listing and monitoring of qualified suppliers must be properly recorded.
Notes	-

Sheet B8.2.f. QUALITY CONTROL SYSTEMS
***Quality Control System* (guideline CAST GMP → B8.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 1: *Operators in the sector must establish and maintain an effective quality control system.*
Fulfilment	Development of a Quality Control System suitable for its activity, structure, product.
Document type and description	The reference documents are, for example: – Quality Manual; – procedures and operating instructions that establish control methods (references to laws, standards, specifications, internal methods, etc.); – records of the activities of verification of conformity of products with their respective specifications, e.g. control sheets, computerized tables.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended..

Sheet B8.2.g. QUALITY CONTROL SYSTEMS
***Management of raw materials warehouses* (guideline CAST GMP→ B8.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Compliance of raw materials/starting materials with defined specifications. Raw material warehouse management.
Document type and description	Procedures/operating instructions for acceptance checks, according to any sampling plans, should be defined in order to verify the compliance of raw materials with the specifications. Records of control results.
Notes	The tests must be carried out according to test methods suitably described through an internal procedure, by means of suitable instrumentation adequately calibrated. The data resulting from quality control operations should be appropriately recorded in computerized tables, databases, etc.

Sheet B8.2.h. QUALITY CONTROL SYSTEMS
***Production controls* (guideline CAST GMP→ B8.2.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 5, paragraph 3:* *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the production process
Document type and description	Procedures/operating instructions should be defined to describe how to ensure the controls and traceability of the product from the raw materials used through the various stages of production, including delivery to the warehouse
Notes	The product can be stored and identified in various ways as "*not shippable*" until its quality level and/or compliance with all the requirements of the production phase is ascertained

Sheet B8.2.i. QUALITY CONTROL SYSTEMS
***Quality control of the finished product* (guideline CAST GMP → B8.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the production process.
Document type and description	Operating instructions or procedures for verifying the conformity of the quality of the finished product with the expected requirements should be defined and codified in the respective product specifications.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, internal methods, standards) by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be appropriately recorded in computerized tables, databases, etc.

Sheet B8.2.l. QUALITY CONTROL SYSTEMS
***Management of finished products warehouses* (guideline CAST GMP → B8.2.2.4)**
***Distribution, shipment and delivery* (guideline CAST GMP → B8.2.2.5)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the management of the finished products warehouse, for transport and delivery.
Document type and description	The following should be defined: – procedures/instructions for the storage of finished products (with identification of the condition: material meeting the established specification, under test, contested, etc.) and related records; – procedures/instructions for the identification and traceability of stored products and related records; – procedures/instructions for the traceability of picking operations and authorization for shipment to customers (finished products) and related records; – procedures/instructions for the definition of the criteria for the selection of transporters and the checks to be carried out on the means of transport (supply / service specifications) and related records; – operating instructions for issuing a transport document.
Notes	-

Sheet B8.2.m. QUALITY CONTROL SYSTEMS
***Conformity of the application of the GMP and claims management, corrective and preventive actions* (guideline CAST GMP → B8.2.2.6)**

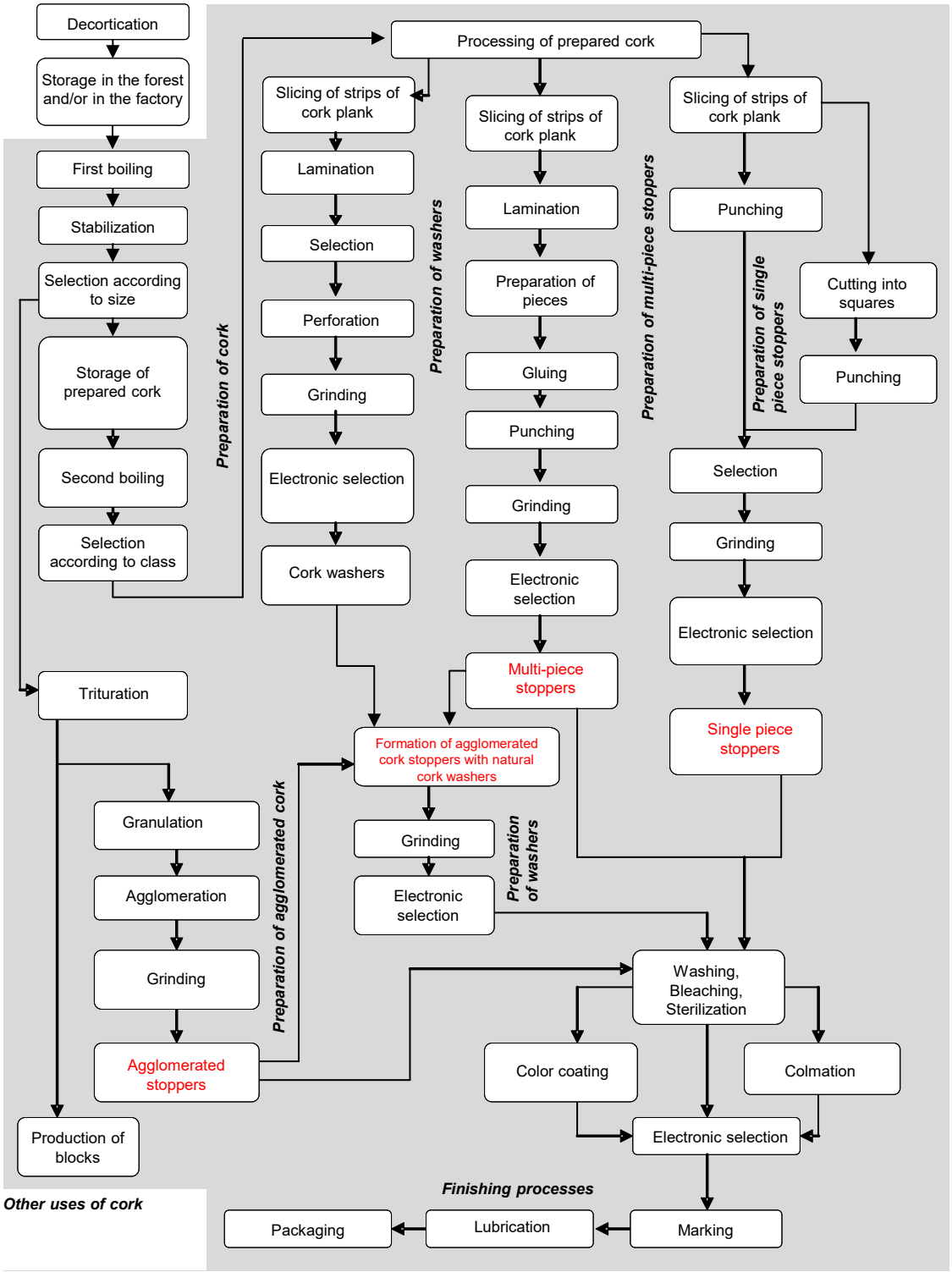
INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.*
Fulfilment	Instructions and procedures for monitoring the implementation of GMP standards.
Document type and description	The following should be defined: – procedures/operating instructions for carrying out internal audits; – procedures for the management of complaints and management of any non-conformities; – procedures for the implementation of corrective and preventive actions for the resolution of non-conformities; the latter procedure must provide for the verification of the effectiveness of the corrective/preventive actions implemented.
Notes	Internal audits are planned, carried out and appropriately recorded for all business areas involved in the implementation of GMP standards, in order to verify their correct implementation.

Sheet B8.2.n. DOCUMENTATION
***Documentation* (guideline CAST GMP→ B8.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 2: *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant for the conformity and safety of finished materials and articles, and relating to the results of the quality control system.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by operators in the sector.*
Fulfilment	Preservation of QAS and Quality Control System (QCS) documentation. Continuous adaptation and transposition of legislation.
Document type and description	The following should be defined: – procedures, operating instructions for the archiving and storage of documents relating to the QAS (procedures, specifications, formulations, etc.); – procedures, operating instructions for the archiving and storage of documents relating to the CSF (instructions, records of process and control data). The Quality Manual or other company document defines an adequate time for the storage of all documents pertinent to the implementation of GMP standards. Procedures/instructions must be defined to ensure continuous compliance with the regulatory requirements of current legislation.
Notes	Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/2004 as amended). Copies of the declarations of conformity issued (art. 16 of Regulation (EC) 1935/2004 as amended are an integral part of the archive.).

Annex B8.1.

Production flowchart of cork stoppers



B9. GLASS

B9.1. Characterization of the sector

B9.1.1. Field of application of the guideline

This guideline applies to the sector of glass containers designed for food contact.

These containers mainly consist of bottles (wine, oil, mineral water, pulped tomatoes, milk, beer, spirits, soft drinks, syrups, juices, vinegar, etc.), jars (ketchup, pulped tomatoes, mayonnaise, jams, pickles, yoghurt, baby food, etc.), bottles for diet-specific foods and tableware (plates, tumblers, stemware glasses, etc.).

The glass containers are produced industrially in a two-stage process by pressing and blowing the molten glass in moulds.

B9.1.2. Phases of the production process: flowchart and description

The production flow diagram is given in Annex B9.1 at the end of this chapter. The summary description of the process steps is given in chapter B9.1.3.2 of the CAST GMP guideline.

B9.2. Sheets for documental verification of the application of Regulation (EC) 2023/2006

This guideline outlines the activities and documentation required to implement the provisions of Regulation (EC) 2023/2006 as amended regarding GMP standards applicable for the supply chain of glass container manufacturers.

Any other documents related to the legal provisions on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs) are included in separate documentation systems, such as the Supporting Documentation (SD).

Below are the sheets (B9.2.a.-B9.2.r.) for documental verification that describe the activities and/or measures that can be adopted by the Company to implement the provisions of Articles 5, 6 and 7 of Regulation (EC) 2023/2006 as amended.

The form presented are not binding for the supply chain discussed here, but their content must be considered a set of operational suggestions. The cards should always be used in conjunction with the CAST GMP guideline.

The following abbreviations are present in the cards:

- MP: Management Procedure;
- O or WP: Operational or Work Procedure;
- RS: Requirements Sheet;
- RF: Registration Form.

Sheet B9.2.a. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Quality Assurance Systems* (guideline CAST GMP→ B9.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective. – documented. – appropriate to the size of the company.
Document type and description	The QAS, depending on the characteristics, size and type of organization, should have, for of example, one of the following organizational models: Model A: The Company has adopted a QAS document separate from its Quality Manual. Model B: The Company has integrated the practices, procedures and operating instructions constituting the QAS into its Quality Manual. Form C: The company has established a company-level organization chart that identifies and represents the various functions involved in the implementation of FCM legislation. Each function is associated with specific tasks, and the corresponding responsibilities are clearly defined. The Company has articulated its QAS in relation to the size of its organization. In particular, it has structured its QAS according to the following criteria: efficiency, streamlining, articulation of the company (single plant, or multiple plant). The Company should identify within its organization the Function responsible for the application of Regulation (EC) 2023/2006 as amended.
Notes	The Company has established the QAS, which concretely represents a set of practices, procedures and operating instructions, through which, with documental evidence, the Company itself is able to harmonize and monitor the parameters and process variables, so that the technical and organizational aspects, functional to the implementation and compliance with the provisions of Regulation (EC) 2023/2006 as amended on FCMs are well known to the company structure of reference and are fully monitored. The adequacy and efficiency of the QAS shall be subject to regular verification.

Sheet B9.2.b. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Size of the business* (guideline CAST GMP→ B9.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Implementing a QAS: – effective and documented; – appropriate to the size of the company.
Document type and description	The organization of the company is designed to enable verification of the conformity of the FCM product. This structure is equipped with suitable equipment, which is periodically checked, calibrated and maintained. Certain specialist checks may be entrusted to qualified external structures. The documentation concerning the organizational model, control procedures, and test and calibration certificates, along with the related findings archived by the Company, is defined.
Notes	-

Sheet B9.2.c. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Human resources and training* (guideline CAST GMP→ B9.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Adequacy of the staff. Staff knowledge and skills.
Document type and description	The company's human resources department takes care of and manages the selection and training of personnel. The Company Organization is illustrated in a paragraph of the QAS (or, in the Company Organization Chart). The roles and responsibilities of the Personnel are indicated in the company documents relating to the task. The training of the worker is recorded and documented.
Notes	In order for the Company to be sure that the staff is aware of the type of Company they are employed by and understand the level of commitment required, the Company provides an adequate training course for the worker.

Sheet B9.2.d. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Selection of raw materials* (guideline CAST GMP → B9.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Selection of raw materials and suppliers.
Document type and description	The raw materials are identified in relation to the formulation of the composition of the vitrifiable mixture, functional to the production of the FCM container. *[MP]* The characteristics of each raw material are defined by a Specification containing the type of raw material and the indications of the desired physical and chemical parameters. *[RS]* The supply of each raw material is recorded. [*RS]* Supplier selection is carried out in accordance with specific company procedures. Specific procedures are established to define the requirements for each supplier and to verify the ongoing compliance of those requirements with company specifications and production needs. [*MP + O or WP + RS]*
Notes	-

Sheet B9.2.e. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Selection of raw materials* (guideline CAST GMP→ B9.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Compliance of raw materials with specifications.
Document type and description	The raw materials are subjected to acceptance checks in order to verify their compliance with the specifications according to procedures defined in the QAS (periodicity, methods and parameters). [*MP + O or WP + RS]* The results are recorded and stored in company documents. *[RF]*
Notes	-

Sheet B9.2.f. QUALITY CONTROL SYSTEMS
***Quality Control System Quality Control System* (guideline CAST GMP→ B9.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 6, paragraph 1*: *Operators in the sector must establish and maintain an effective quality control system.*
Fulfilment	Implementation of an effective Quality Control System (QCS).
Document type and description	The Company has established the CSF, which concretely represents the set of control operations aimed at verifying compliance with the requirements of Regulation (EC) 2023/2006 as amended and the specific legislation related to FCMs.
Notes	With this System, the Company has also introduced and adopted measures aimed at correcting any non-compliance with the requirements of FCMs.

Sheet B9.2.g.QUALITY CONTROL SYSTEMS
***Quality Control System* (guideline CAST GMP→ B9.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 5, paragraph 3:* *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Operations according to instructions and procedures A) COMPOSITION
Document type and description	Raw Materials Control through a feedback module. *[RF]* Cullet control by means of a feedback module. *[RF]* Control of raw material dosages through automatic instrumental verification with data recording. *[RF]* Calibrations Scales for dosing raw materials through internal verification or by a third party. *[RF]*
Notes	-

Sheet B9.2.h. QUALITY CONTROL SYSTEM
***Quality Control System* (guideline CAST GMP→ B9.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 5, paragraph 3:* *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Operations according to instructions and procedures B) MERGER
Document type and description	Temperature control through continuous instrumental monitoring with data recording. *[RF]*
Notes	The controls and instrumental checks carried out in this phase of the production process are necessarily functional to verifying the correctness of the parameters of the process itself and do not affect the characteristics for the FCMs product.

Sheet B9.2.i. QUALITY CONTROL SYSTEMS
***Quality Control System* (guideline CAST GMP→ B9.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 5, paragraph 3:* *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Operations according to instructions and procedures C) MANUFACTURE
Document type and description	Temperature control of the glass in the droplet formation phase by instrumental verification with data recording. *[RF]* Control of the weight of the drop by instrumental verification with data recording. *[RF]*
Notes	The controls and instrumental checks carried out in this phase of the production process are mainly functional to verifying the correctness of the parameters of the process itself.

Sheet B9.2.l. QUALITY CONTROL SYSTEMS
***Quality Control System* (guideline CAST GMP→ B9.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 5, paragraph 3:* *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Operations according to instructions and procedures D) ANNEALING
Document type and description	See “notes” field
Notes	In the CAST GMP guidelines, the Annealing phase has been indicated and described, with the sole purpose of providing a complete overview of the process, a phase that does not affect the suitability of the container for food contact, but which influences the physical characteristics of the object in terms of resistance to mechanical stress and temperature changes and therefore to its intended use. This Sheet is therefore reported in this document only for the purpose of linking with the CAST GMP guidelines.

Sheet B9.2.m. QUALITY CONTROL SYSTEMS
Q*uality Control System* (guideline CAST GMP→ B9.2.2)

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Operations according to instructions and procedures E) PRODUCT CONTROL.
Document type and description	Global Migration Control (DM 21 March 1973 as amended) with the issuance of an annual certificate of analysis issued by an external laboratory or an internal test report. *[RF]* Specific migration control (Ministerial Decree of 21 March 1973 as amended) and for export ISO 7086/2000) with the issuance of three-year certificates of analysis issued by an external laboratory or internal test report (1). *[RF]* Chemical analysis of the glass with the issuance of a certificate of analysis issued by an external laboratory or an internal analysis report; *[RF]* Cold treatment control (2): – adjustment and fine-tuning of equipment by means of an operating procedure for equipment adjustment and fine-tuning personnel, *[O or WP];* – control of the product flow by means of an operating instruction; *[O or WP]* – control and dilution of the product by means of an operating instruction. *[O or WP + RS + RF]*
Notess	(1) - The glass industry carries out periodic checks on specific migration only to verify the consistency and consistency of the data. The glass industry has verified, through historical data and through a specific analytical study carried out by a third party, that the glass material has an insignificant release of heavy metals and is normally below the limits of instrumental detection. In addition, the Ministerial Decree of 21 March 1973 allows the use of Category C (Lead glass) crockery and glasses provided that the contact is short and repeated and that these objects comply with the 0.3 ppm lead release limit (Annex II – Section 5). (2) – The cold treatment is aimed at optimizing the sliding of the containers on the filling lines, through the application of specific products on the external surface of the same.

Sheet B9.2.n. QUALITY CONTROL SYSTEMS
***Product storage management* (guideline CAST GMP→ B9.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 5, paragraph 3:* *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Operations according to instructions and procedures F) MANAGEMENT OF FINISHED PRODUCTS IN THE WAREHOUSE.
Document type and description	Placing the finished product in stock according to the procedure with registration of the operation. *[O or WP + RF]* Shipment of the Finished Product according to the procedure with registration of the operation with issuance of a transport document. *[O or WP + RF]*
Notes	In implementation of the requirements of Regulation (EC) 1935/2004 as amended, art. 17, on traceability and traceability, glass companies adopt a label that exhaustively collects all the information necessary to identify the product placed on the market.

Sheet B9.2.o. QUALITY CONTROL SYSTEMS
***Quality Control System* (guideline CAST GMP→ B9.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP. Such corrective measures shall be implemented without delay and made available to the Competent Authorities for inspections.*
Fulfilment	Monitoring of implementation and compliance with GMP regulations.
Document type and description	The QCS is concretely and operationally composed of instructions *[O or WP]* and control procedures *[MP]*, checklists *[RS],* instrumental test certifications *[RF],* internal analysis reports *[RF],* related feedback data and recording of the same *[RF]*. The QCS identifies the company functions responsible for carrying out procedural controls and instrumental checks, so that compliance with the requirements of Regulation (EC) 2023/2006 as amended and the legislation relating to FCMs is constantly verified. In addition to this functionality, the procedures relating to the CSF provide for the communication of critical issues that require a modification of the procedures contained in the QAS, so that the company control apparatus can guarantee the full and constant efficiency and reliability of the system, without prejudice to the immediate application of the corrective action and the verification of its effectiveness.
Notes	The QCS is structured within the QAS, follows its organizational lines and company functional relations and includes all the control procedures and related documentary findings referred to in the previous sheets, functional to the monitoring of the obligations introduced by Regulation (EC) 2023/06 as amended on FCMs.

Sheet B9.2.p. QUALITY CONTROL SYSTEMS
***Quality Control System* (guideline CAST GMP→ B9.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.*
Fulfilment	Monitoring of implementation and compliance with GMP regulations
Document type and description	The QCS adopted by the glass companies includes procedures *[MP]* and controls *[O or WP]* such as to constantly monitor the process data that are critical with regard to GMP for the production of FCMs.
Notes	Any non-conformities detected throughout the process, in addition to determining an intervention for the rebalancing of the process parameters, can give rise to the revision of the procedures themselves with a view to continuous improvement. In the previous sheets, the controls, verifications and tests that make it possible to monitor the compliance of each phase of the process with the provisions of Regulation (EC) 2023/2006 as amended have been indicated and to identify any anomalies that require prompt intervention along the line and timely corrective action necessary to balance the parameters and the process. This prerogative of the glass process makes it possible to prevent non-conformities at the end of the line.

Sheet B9.2.q. QUALITY CONTROL SYSTEMS
***Adaptation and acknowledge of laws* (guideline CAST GMP → B9.2.2.2)**

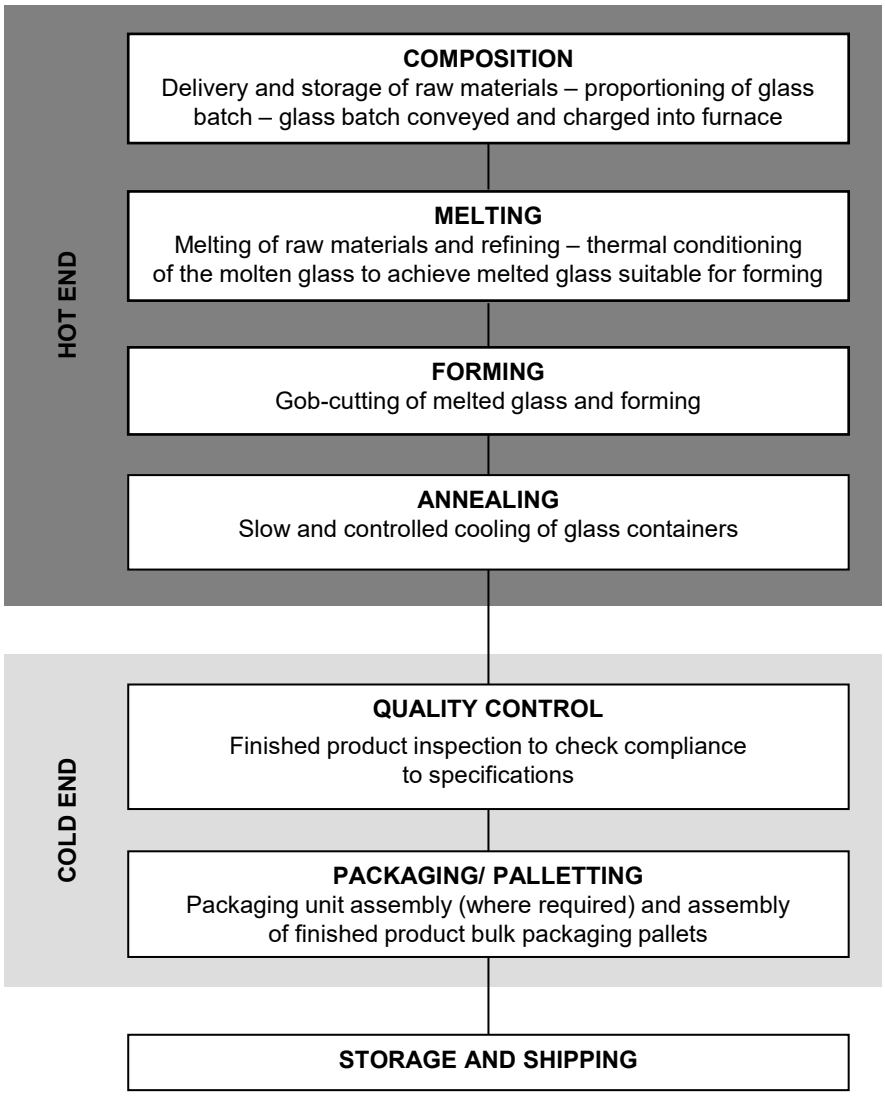
INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Adaptation and acknowledge of laws.
Document type and description	On the occasion of the adoption of new mandatory technical regulations or legislative provisions, both Italian and European, the competent company management will launch information initiatives and, if necessary, will implement training sessions aimed at the personnel concerned according to the various levels. The company equips a dedicated archive for all the legislative and regulatory provisions concerning FCMs that is accessible to interested personnel.
Notes	The company management responsible for the management of the QAS maintains continuous monitoring of the regulatory evolution concerning FCMs, both at national and European level, so that initiatives can be launched to adapt the QAS and the procedures provided for by it. This paragraph has been included in the CAST guidelines but for this activity there are neither direct and specific fulfilments nor obligations, but responds to a general obligation and as such managed in the QAS (see definition of GMP in Regulation (EC) 2023/2006 as amended art 3). The organization of the individual company is responsible for the adoption of a specific procedure.

Sheet B9.2.r. DOCUMENTATION
***Documentation* (guideline CAST GMP → B9.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 2: *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant to the conformity and safety of materials and finished articles, and relating to the results of the Quality Control System.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by operators in the sector.*
Fulfilment	Preparation of adequate documentation. Document recording and archiving. Preservation and archiving of the documental part.
Document type and description	In general, the documentation adopted consists of: formulations of the composition, product technical sheets, operating procedures and instructions, checklists and related records. The QAS contains a *procedure [MP]* with regard to the archiving and preservation of the specifications, formulations and process data constituting the documentation, as identified and indicated in these guidelines. This procedure will also include the archiving of records of the controls concerned. Production control involves the entire production process in its various phases: formulation of the vitrifiable mixture, design of the container, control of process parameters and verification of the finished product.
Notes	All the various data collected in the individual characteristic operations envisaged, relating to the various phases, are appropriately recorded and made available for consultation. Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/as amended). Copies of the declarations of conformity issued (art. 16 of Regulation (EC) 1935/2004 as amended are an integral part of the archive).

Annex B9.1.

Flowchart of production of glass containers



B10. COATING

B10.1. Characterization of the sector

B10.1.1. Field of application of the guideline

This guideline applies to coatings to be used for the internal protection of metal-based materials and articles intended for direct food contact, such as:

- glass jar capsules;
- 3-piece cans;
- one-piece and three-piece aerosol cans;
- 2-piece cans for food
- 2-piece cans for beverages;
- drums;
- thin films and laminates for aluminium trays;
- tubes;
- buckets with handle (pail).

Closures are also part of the sector as manufactured products:

- crown caps;
- aluminium closures (pilfer).

These articles, however, are not included in this guideline, as contact with the foodstuff only occurs with the plastic material of the seal.

B10.1.2. Phases of the production process: flowchart and description

The production flow diagram is given in Annexes B10.1 and B10.2 at the end of this chapter.

A summary description of the process steps is given in chapter B10.1.5.2. from the CAST GMP guideline.

B10.2. Sheets for documental verification of the application of Regulation (EC) 2023/2006

This guideline defines the activities and documentation required to implement the provisions of Regulation (EC) 2023/2006 as amended concerning GMP standards for the production chain of coatings intended for products in contact with food.

Any other documents related to the legal provisions on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs) are included in separate documentation systems, such as the Supporting Documentation (SD).

Below are sheets (B10.2.a.-B10.2.l.) for documental verification of activities and/or implementations that may be implemented by the Company to implement the provisions of Articles 5, 6 and 7 of Regulation (EC) 2023/2006 as amended.

The form presented are not binding for the supply chain discussed here, but their content must be considered a set of operational suggestions. The cards should always be used in conjunction with the CAST GMP guideline.

Sheet B10.2.a. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Quality Assurance System* (guideline CAST GMP → B10.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective; – documented; – appropriate to the size of the company.
Document type and description	The documentation relating to the QAS may consist of the Quality Manual, if available, or other similar document demonstrating that the System is applied and implemented. The system must contain: – explicit references to GMP standards; – procedures, instructions and organization chart with definition of roles and responsibilities within the Company. The Company should identify within its organization the Function responsible for the application of Regulation (EC) 2023/2006 as amended.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended. Any certification by third parties could guarantee the adequacy of the QAS with respect to the size of the company. ISO 9001 quality management systems include multiple requirements also for GMP standards.

Sheet B10.2.b. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Human resources and training* (guideline CAST GMP→ B10.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Adequacy of staff. Staff knowledge and skills.
Document type and description	Training is planned and documented, for example, by: – procedures and/or instructions for the training and updating of personnel containing indications for verifying effectiveness. – specific training activity on GMP standards.
Notes	The Company can define roles and responsibilities to explain the internal organization (job description) and report them in documents such as the Quality Manual or other suitable document.

Sheet B10.2.c. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Size of the business* (guideline CAST GMP→ B10.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, *art. 5, paragraph 1, letter a):* *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Organization of the necessary locations and equipment
Document type and description	The organization of the offices and their structure should be reported in the Quality Manual or in other specific company documentation. The QAS must include: – organization of the production site and production processes. – documents relating to the adequacy of production equipment, control processes and calibration of production tools. – manuals/production procedures/technical documentation of the machinery and its calibration status. – manuals and technical documentation of machinery and equipment should be recalled/inserted/attached in the QAS documentation.
Notes	-

Sheet B10.2.d. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
Selection of starting materials and suppliers and/or services and/or third parties
(guideline CAST GMP→ B10.2.1.2)

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, *art. 5, paragraph 2:* *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Selection of starting materials and suppliers
Document type and description	The Company should prepare documents relating to: – procedures for the selection and qualification of raw materials – procedures for the qualification and approval of raw material suppliers – documentation of raw materials, such as specifications, safety data sheets and declarations useful for conformity assessment for use in FCMs. A record of selections, supplier qualification and monitoring of suppliers must be available.
Notes	-

Sheet B10.2.e. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
Production **(guideline CAST GMP→ B10.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006**,** art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Production system compliance.
Document type and description	For each finished product, the following should be defined: – formulation – production procedure – production controls – product Specifications For each phase of the production process, records of the activities carried out are kept to ensure the traceability of the finished product. In addition , procedures should be defined for the prevention of contamination of finished products (cleaning plans, personnel hygiene, pest prevention).
Notes	-

Sheet B10.2.f. QUALITY CONTROL SYSTEMS
***Management of raw materials warehouses* (guideline CAST GMP→ B10.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, *art. 5, paragraph 2:* *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Compliance of raw materials with defined specifications
Document type and description	The following must be provided: – procedures to define any incoming checks to be carried out on raw materials/semi-finished products to identify any anomalies with respect to the specifications. – procedures for storage rules (approved, tested, contested material, etc.). the rules for the separation and segregation of non-compliant materials are important. – records of the results of both documental and analytical checks – procedures for sending it to production.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, internal methods, standards) by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be appropriately recorded in computerized tables, databases, etc.

Sheet B10.2.g. QUALITY CONTROL SYSTEMS
***Production controls* (guideline CAST GMP→ B10.2.2.2)**
***Quality Control of the finished product* (guideline CAST GMP→ B10.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Production Controls and Quality Control of the finished product
Document type and description	The following should be defined: – operating instructions or procedures aimed at identifying the product controls to be carried out during processing to verify compliance with product specifications (measurements, tolerances, frequencies) to authorize subsequent packaging procedures. – operating instructions or procedures aimed at verifying the conformity of the quality of the finished product with the expected requirements and codified in the respective product specifications for the purpose of contact with food. – procedures/instructions that describe the methods to ensure the controls and traceability of the product starting from the raw materials used through the various stages of production up to the delivery to the warehouse. – procedures/instructions for delivery to the warehouse. – recording of process and product controls.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, internal methods, standards) by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be appropriately recorded in computerized tables, databases, etc.

Sheet B10.2.h. QUALITY CONTROL SYSTEMS
***Management of finished products warehouses* (guideline CAST GMP→ B10.2.2.4)**
***Distribution, shipment and delivery* (guideline CAST GMP→B10.2.2.5)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the management of the finished products warehouse, for transport and delivery
Document type and description	The following should be defined: – procedures/instructions for the storage of finished products (with identification of the condition: material that meets the established specification, on trial, contested, etc.) and related records. – procedures/instructions for the identification and traceability of stored products. – procedures/instructions for the traceability of picking operations and authorization for shipment to customers (finished goods) and related records. – procedures/instructions for the definition of the criteria for the selection of transporters and the checks to be carried out on the means of transport (any supply/service specifications) and related records. – operating instructions for issuing a transport document.
Notes	-

Sheet B10.2.i. QUALITY CONTROL SYSTEMS
***Conformity of the application of the GMP and claims management, corrective and preventive actions* (guideline CAST GMP → B10.2.2.6)**

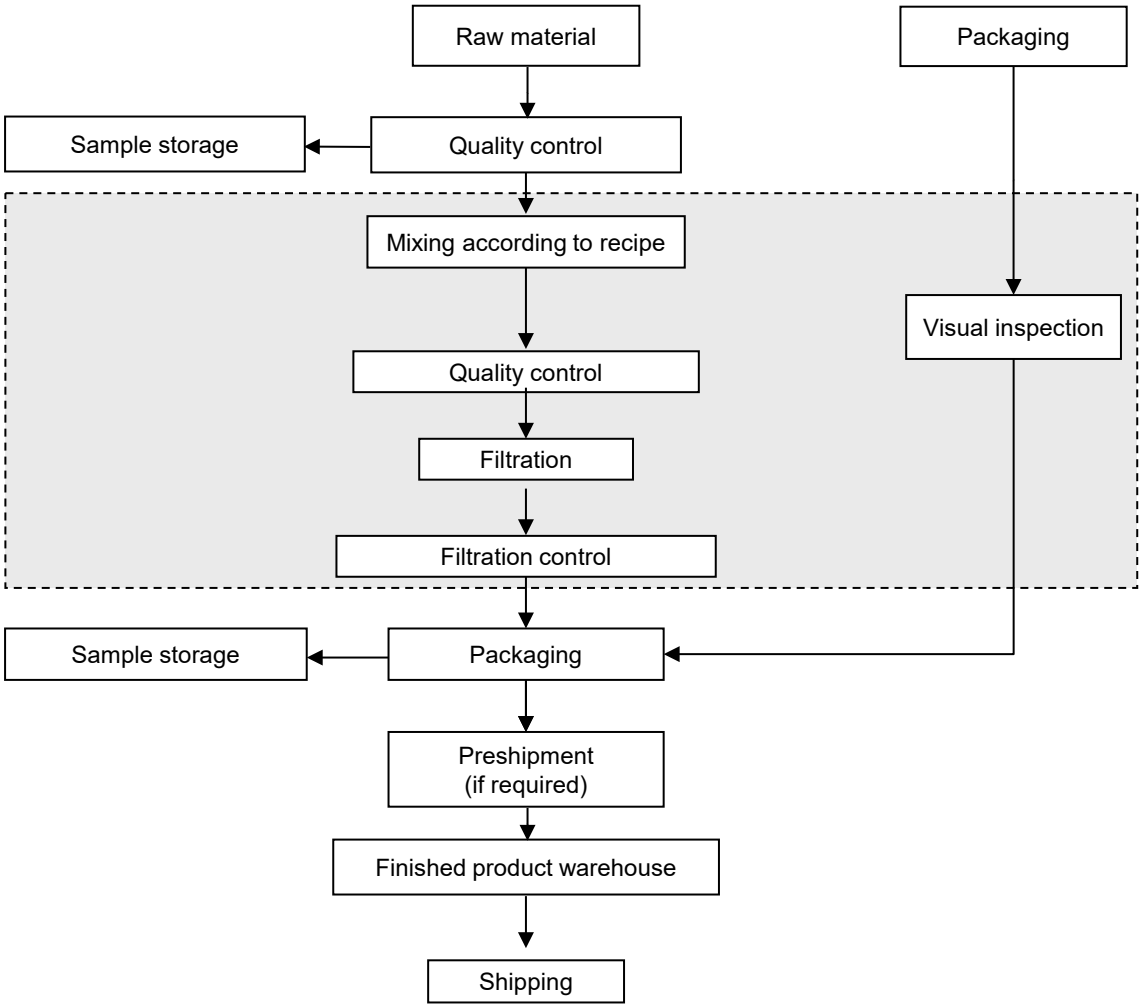
INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.*
Fulfilment	Instructions and procedures for monitoring the implementation of GMP standards.
Document type and description	The following should be defined: – procedures/operating instructions for the execution of internal and/or external audits. Internal audits are planned, carried out and appropriately recorded for all business areas involved in the implementation of GMP standards, in order to verify their correct implementation. – procedures for the management of complaints and management of any non-conformities. – procedures for the implementation of corrective and preventive actions for the resolution of non-conformities. The latter procedure must include the verification of the effectiveness of the corrective/preventive actions implemented.
Notes	-

Sheet B10.2.I. DOCUMENTATION
***Documentation* (guideline CAST GMP→ B10.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* Regulation (EC) 2023/2006, art. 7, paragraph 2: *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant for the conformity and safety of finished materials and articles, and relating to the results of the quality control system.* Regulation (EC) 2023/2006, art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by operators in the sector.*
Fulfilment	Preservation of QAS and Quality Control System (QCS) documentation Constant adaptation and transposition of legislation
Document type and description	The following should be defined: – procedures, operating instructions for the archiving and storage of documents related to the QAS (procedures, specifications, formulations, etc.) – procedures, operating instructions for the archiving and storage of documents relating to the SCQ (instructions, records of process and control data). The Quality Manual or other company document defines an adequate time for the storage of all documents pertinent to the implementation of GMP standards. Procedures/instructions must be defined to ensure continuous compliance with the regulatory requirements of current legislation.
Notes	Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/2004 as amended). Copies of the declarations of conformity issued (art. 16 of Regulation (EC) 1935/2004 as amended are an integral part of the archive).

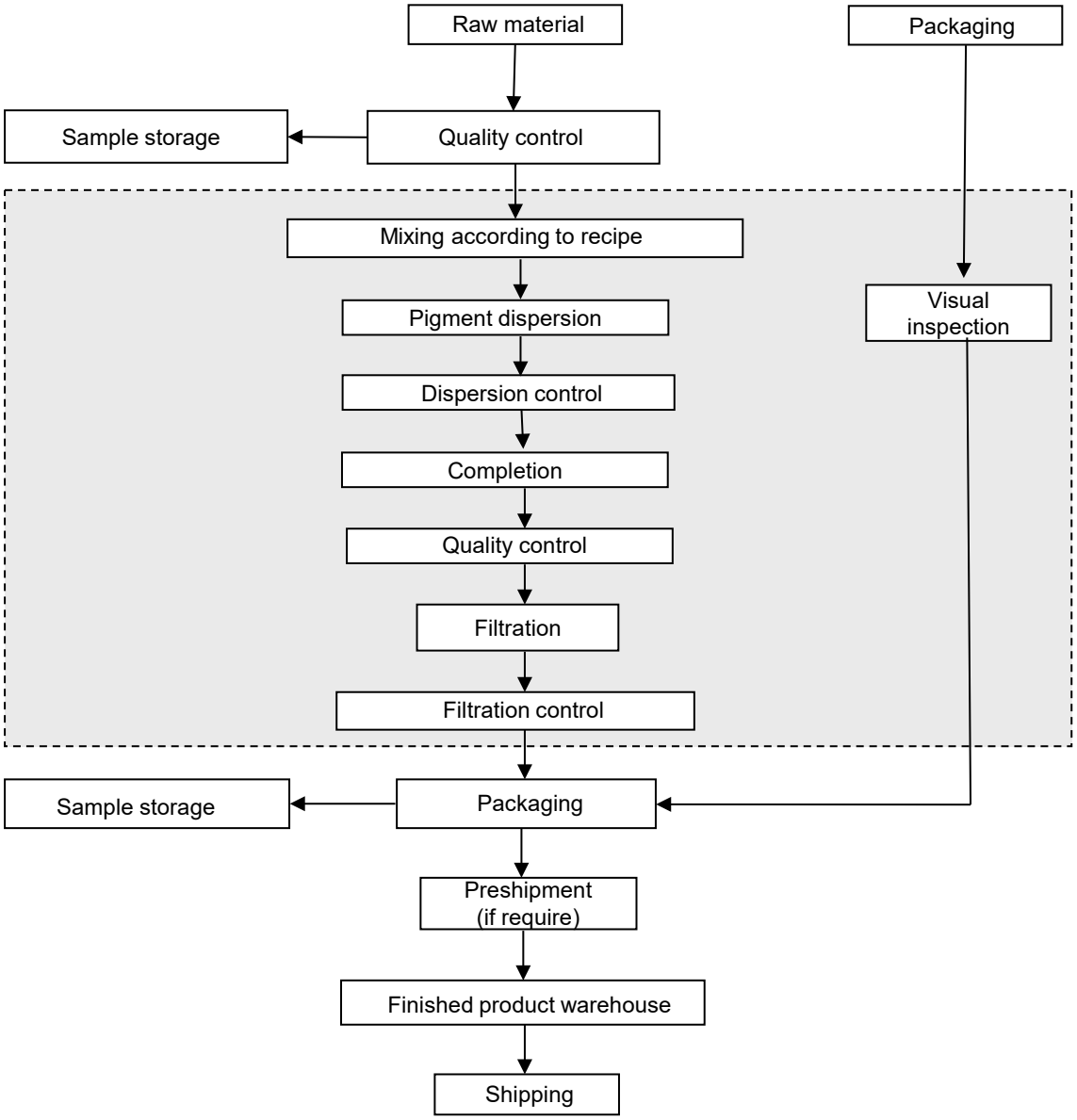
Annex B10.1.

Flowchart for the production of coated on metal (coating): paints



Annex B10.2.

Flowchart for the production of coated on metal (coating): enamels



B11. ADHESIVES AND SEALANTS

B11.1. Characterization of the sector

B11.1.1. Field of application of the guideline

Present guideline applies to all companies manufacturing adhesives and sealants used in the production of food-contact packaging

B11.1.2. Phases of the production process: flowchart and description

The production flow diagram is given in Annex B11.1 at the end of this chapter.

A summary description of the process steps is given in chapter B11.1.4.2. of the CAST GMP guideline.

B11.2. Sheets for documental verification of the application of Regulation (EC) 2023/2006

This guideline defines the activities and documentation required to implement the provisions of Regulation (EC) 2023/2006 as amended concerning GMP standards for the production chain of adhesives and sealants intended for products in contact with food.

Any other documents related to the legal provisions on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs) are included in separate documentation systems, such as the Supporting Documentation (SD).

Below are sheets (B11.2.a.-B11.2.l.) for documental verification of activities and/or implementations that may be implemented by the Company to implement the provisions of articles 5, 6 and 7 of Regulation (EC) 2023/2006 as amended.

The form presented are not binding for the supply chain discussed here, but their content must be considered a set of operational suggestions. The cards should always be used in conjunction with the CAST GMP guideline.

Sheet B11.2.a. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Quality Assurance System* (guideline CAST GMP → B11.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective. – documented. – appropriate to the size of the company.
Document type and description	The documentation relating to the QAS may consist of the Quality Manual, if available, or other similar document demonstrating that the System is applied and implemented. The system must contain: – explicit references to GMP standards; – procedures, instructions and organization chart with definition of roles and responsibilities within the Company. The Company should identify within its organization the Function responsible for the application of Regulation (EC) 2023/2006 as amended
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006.as amended Any certification by third parties could guarantee the adequacy of the QAS with respect to the size of the company. ISO 9001 quality management systems include multiple requirements also for GMP.

Sheet B11.2.b. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Human resources and training* (guideline CAST GMP→ B11.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Adequacy of staff. Staff knowledge and skills.
Document type and description	Training is planned and documented, for example, by: – procedures and/or instructions for the training and updating of personnel containing indications for verifying effectiveness. – specific training activity on GMP standards.
Notes	The Company can define roles and responsibilities to explain the internal organization (job description) and report them in documents such as the Quality Manual or other suitable document.

Sheet B11.2.c. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Size of the business* (guideline CAST GMP→ B11.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organization of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Organization of the necessary locations and equipment
Document type and description	The organization of the offices and their structure should be reported in the Quality Manual or in other specific company documentation. The QAS must include: – organization of the production site and production processes. – documents relating to the adequacy of production equipment, control processes and calibration of production tools. – manuals/production procedures/technical documentation of the machinery and its calibration status. – manuals and technical documentation of machinery and equipment should be recalled/inserted/attached in the QAS documentation.
Notes	-

Sheet B11.2.d. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Selection of starting materials and suppliers of goods and/or services and or subcontractors* (guideline CAST GMP → B11.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Selection of raw materials and suppliers
Document type and description	The Company should prepare documents relating to: – procedures for the selection and qualification of raw materials – procedures for the qualification and approval of raw material suppliers – documentation of raw materials, such as specifications, safety data sheets and declarations useful for conformity assessment for use in FCMs. A record of selections, supplier qualification and monitoring of suppliers must be available.
Notes	-

Sheet B11.2.e. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Production* (guideline CAST GMP → B11.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006**,** art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures*.
Fulfilment	Production system compliance.
Document type and description	For each finished product, the following should be defined: – formulation – production procedure – production controls – product Specifications For each phase of the production process, records of the activities carried out are kept to ensure the traceability of the finished product. In addition , procedures should be defined for the prevention of contamination of finished products (cleaning plans, personnel hygiene, pest prevention).
Notes	-

Sheet B11.2.f. QUALITY CONTROL SYSTEMS
***Management of raw materials warehouses* (guideline CAST GMP → B11.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Compliance of raw materials with defined specifications
Document type and description	The following must be provided: – procedures to define any incoming checks to be carried out on raw materials/semi-finished products to identify any anomalies with respect to the specifications. – procedures for storage rules (approved, tested, contested material, etc.). the rules for the separation and segregation of non-compliant materials are important. – records of the results of both documental and analytical checks – procedures for sending it to production.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, internal methods, standards) by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be appropriately recorded in computerized tables, databases, etc.

Sheet B11.2.g. QUALITY CONTROL SYSTEMS
***Production controls* (guideline CAST GMP → B11.2.2.2)**
***Quality Control of finished products* (guideline CAST GMP → B11.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Production Controls and Finished Product Quality Control
Document type and description	The following should be defined: – operating instructions or procedures aimed at identifying the product controls to be carried out during processing to verify compliance with product specifications (measurements, tolerances, frequencies) to authorize subsequent packaging procedures. – operating instructions or procedures aimed at verifying the conformity of the quality of the finished product with the expected requirements and codified in the respective product specifications for the purpose of contact with food. – procedures/instructions that describe the methods to ensure the controls and traceability of the product starting from the raw materials used through the various stages of production up to the delivery to the warehouse. – procedures/instructions for delivery to the warehouse. – recording of process and product controls.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, internal methods, standards) by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be appropriately recorded in computerized tables, databases, etc.

Sheet B11.2.h. QUALITY CONTROL SYSTEMS
***Management of finished products warehouses* (guideline CAST GMP → B11.2.2.4)**
***Distribution, shipment and delivery* (guideline CAST GMP → B11.2.2.5)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions/procedures for finished goods warehouse management, transport and delivery
Document type and description	The following should be defined: – procedures/instructions for the storage of finished products (with identification of the condition: material that meets the established specification, on trial, contested, etc.) and related records. – procedures/instructions for the identification and traceability of stored products. – procedures/instructions for the traceability of picking operations and authorization for shipment to customers (finished goods) and related records. – procedures/instructions for the definition of the criteria for the selection of transporters and the checks to be carried out on the means of transport (any supply/service specifications) and related records. – operating instructions for issuing a transport document.
Notes	-

Sheet B11.2.i. QUALITY CONTROL SYSTEMS
***Conformity of the application of the GMP and claims management, corrective and preventive actions* (guideline CAST GMP → B11.2.2.6)**

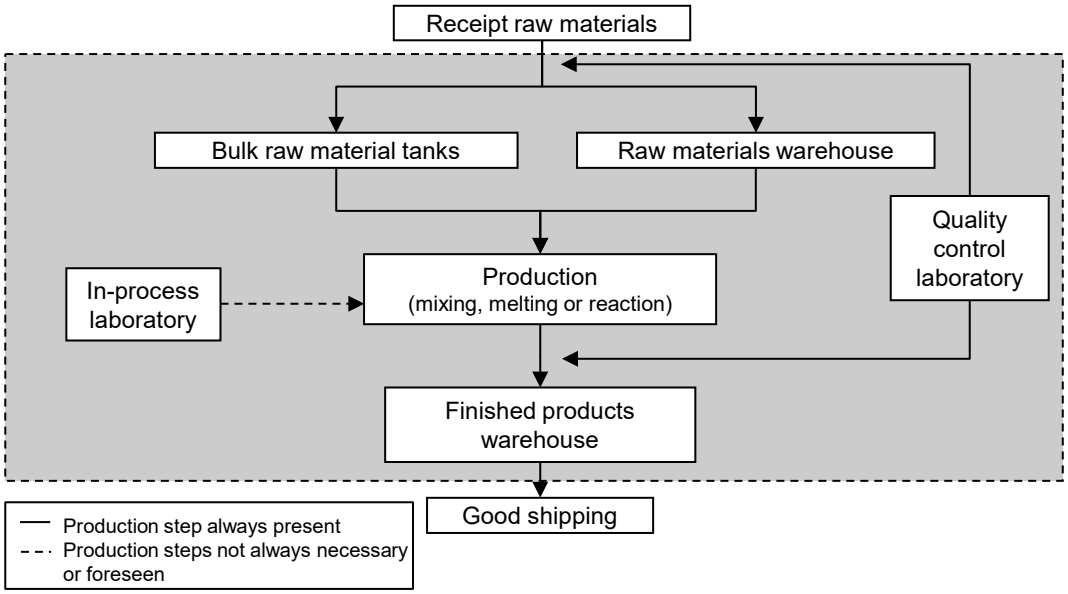
INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.*
Fulfilment	Instructions and procedures for monitoring the implementation of GMP standards.
Document type and description	The following should be defined: – procedures/operating instructions for the execution of internal and/or external audits. Internal audits are planned, carried out and appropriately recorded for all business areas involved in the implementation of GMP standards, in order to verify their correct implementation. – procedures for the management of complaints and management of any non-conformities. – procedures for the implementation of corrective and preventive actions for the resolution of non-conformities. The latter procedure must include the verification of the effectiveness of the corrective/preventive actions implemented.
Notes	-

Sheet B11.2.I. DOCUMENTATION
***Documentation* (guideline CAST GMP → B11.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 2: *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant for the conformity and safety of finished materials and articles, and relating to the results of the quality control system.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by operators in the sector.*
Fulfilment	Preservation of QAS and Quality Control System (QCS) documentation Constant adaptation and transposition of legislation
Document type and description	The following should be defined: – procedures, operating instructions for the archiving and storage of documents related to the QAS (procedures, specifications, formulations, etc.) – procedures, operating instructions for the archiving and storage of documents relating to the SCQ (instructions, records of process and control data). The Quality Manual or other company document defines an adequate time for the storage of all documents pertinent to the implementation of GMP standards. Procedures/instructions must be defined to ensure continuous compliance with the regulatory requirements of current legislation.
Notes	Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/2004 ac amended). Copies of the declarations of conformity issued (art. 16 of Regulation (EC) 1935/2004 as amended are an integral part of the archive).

Annex B11.1.

Production flowchart of adhesivies and sealant



B12. PRINTING INKS

B12.1. Characterization of the sector

B12.1.1. Field of application of the guideline

Present guideline applies to printing inks and auxiliaries (the printing process may require the use of printing auxiliaries) intended for external printing of food packaging, hereinafter referred to as printing inks.

B12.1.2. Phases of the production process: flowchart and description

The production flow diagram is given in Annex B12.1 at the end of this chapter.

A brief description of the process steps is given in chapter B12.1.4.2. from the CAST GMP guideline

B12.2. Sheets for documental verification of the application of Regulation (EC) 2023/2006

This guideline defines the activities and documentation required to implement the provisions of Regulation (EC) 2023/2006 as amended, concerning GMP standards for the supply chain of printing inks intended for the external printing of materials and articles in contact with foodstuffs (Food Contact Materials, FCMs).

Any other documents related to the legal provisions FCMs are included in separate documentation systems, such as the Supporting Documentation (SD).

Below are the sheets (B12.2.a.-B12.2.l.) for documental verification of activities and/or implementations that may be implemented by the Company to implement the provisions of Articles 5, 6 and 7 of Regulation (EC) 2023/2006as amended.

The form presented are not binding for the supply chain discussed here, but their content must be considered a set of operational suggestions. The cards should always be used in conjunction with the CAST GMP guideline.

Sheet B12.2.a. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Quality Assurance System* (guideline CAST GMP → B12.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system (QAS).*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective; – documented; – appropriate to the size of the company.
Document type and description	The documentation relating to the QAS may consist of the Quality Manual, if available, or other similar document demonstrating that the System is applied and implemented. The system must contain: – explicit references to GMP standards; – procedures, instructions and organization chart with definition of roles and responsibilities within the Company. The Company should identify within its organization the Function responsible for the application of Regulation (EC) 2023/2006 as amended
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended. Any certification by third parties could guarantee the adequacy of the QAS with respect to the size of the company. ISO 9001 quality management systems include multiple requirements also for GMP standards.

Sheet B12.2.b. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Size of the business* (guideline CAST GMP → B12.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Organization of the necessary locations and equipment
Document type and description	The organization of the locations and their structure should be reported in the Quality Manual or in other specific company documentation. The QAS must include: – organization of the production site and production processes; – documents relating to the adequacy of production equipment, control processes and calibration of production tools; – manuals/production procedures/technical documentation of the machinery and its calibration status; – manuals and technical documentation of machinery and equipment should be recalled/inserted/attached in the QAS documentation.
Notes	-

Sheet B12.2.c. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Human resources and training* (guideline CAST GMP → B12.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Adequacy of staff. Staff knowledge and skills.
Document type and description	Training is planned and documented, for example, by: – procedures and/or instructions for the training and updating of personnel containing indications for verifying effectiveness. – specific training activity on GMP standards.
Notes	The Company can define roles and responsibilities to explain the internal organization (job description) and report them in documents such as the Quality Manual or other suitable document.

Sheet B12.2.d. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Selection of starting materials, suppliers and/or services and/or third parties* (guideline CAST GMP → B12.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Selection of Raw Materials and Suppliers
Document type and description	The Company should prepare documents relating to: – procedures for the selection and qualification of raw materials – procedures for the qualification and approval of raw material suppliers – documentation of raw materials, such as specifications, safety data sheets and declarations useful for conformity assessment for use in FCMs. In addition, the following must be provided: – procedures to define any incoming checks to be carried out on raw materials / semi-finished products to identify any anomalies with respect to the specifications. – procedures for the identification of raw materials
Notes	Where necessary, raw materials deemed critical are analyzed internally with specific operating procedures and/or instructions.

Sheet B12.2.e. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Production* (guideline CAST GMP → B12.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Production system compliance.
Document type and description	For each finished product, the following should be defined: – formulation – production procedure – production controls – product specifications. For each phase of the production process, records of the activities carried out must be kept to ensure the traceability of the finished product. Since the activities are not subject to HACCP, procedures for the prevention of contamination of finished products can be implemented on a voluntary basis (cleaning plans, personnel hygiene, pest prevention)).
Notes	-

Sheet B12.2.f. QUALITY CONTROL SYSTEMS
***Management of raw materials warehouses* (guideline CAST GMP → B12.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Compliance of Raw Materials with Defined Specifications – Characteristics of Raw Material Storage
Document type and description	The following must be provided: – assessment of the suitability of storage rooms – procedures for storage rules, including separation and segregation of non-compliant materials – procedures for sending it to production (FIFO)
Notes	-

Sheet B12.2.g. QUALITY CONTROL SYSTEMS
***Production controls* (guideline CAST GMP→ B12.2.2.2)**
***Quality Control of the finished product* (guideline CAST GMP→ B12.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Production Controls and Finished Product Quality Control
Document type and description	The following must be defined: – operating instructions or procedures aimed at identifying the product controls to be carried out during processing to verify compliance with product specifications (measurements, tolerances, frequencies) to authorize subsequent packaging procedures. – operating instructions or procedures aimed at verifying the conformity of the quality of the finished product with the expected requirements and codified in the respective product specifications for the purpose of contact with food. – procedures/instructions that describe the methods to ensure the controls and traceability of the product starting from the raw materials used through the various stages of production up to the delivery to the warehouse. – procedures/instructions for delivery to the warehouse. – recording of process and product controls.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, internal methods, standards) by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be appropriately recorded in computerized tables, databases, etc.

Sheet B12.2.h. QUALITY CONTROL SYSTEMS
***Management of finished products warehouses* (guideline CAST GMP→ B12.2.2.4)**
***Distribution, shipment and delivery* (guideline CAST GMP→ B12.2.2.5)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the management of the finished products warehouse, for transport and delivery
Document type and description	The following must be defined: – procedures/instructions for the transfer of finished products to the warehouse (with identification of the status: material meeting the established specification, under test, contested, etc.) and related records. – procedures/instructions for identification and traceability of stored products. – procedures/instructions for the traceability of picking operations and authorization for shipment to customers (finished goods) and related records. – procedures/instructions for the definition of the criteria for the selection of transporters and the checks to be carried out on the means of transport (any supply/service specifications) and related records. – operating instructions for issuing a transport document.
Notes	-

Sheet B12.2.i. QUALITY CONTROL SYSTEMS

***Conformity of the application of the GMP and claims management, corrective and preventive actions* (guideline CAST GMP → B12.2.2.6)**

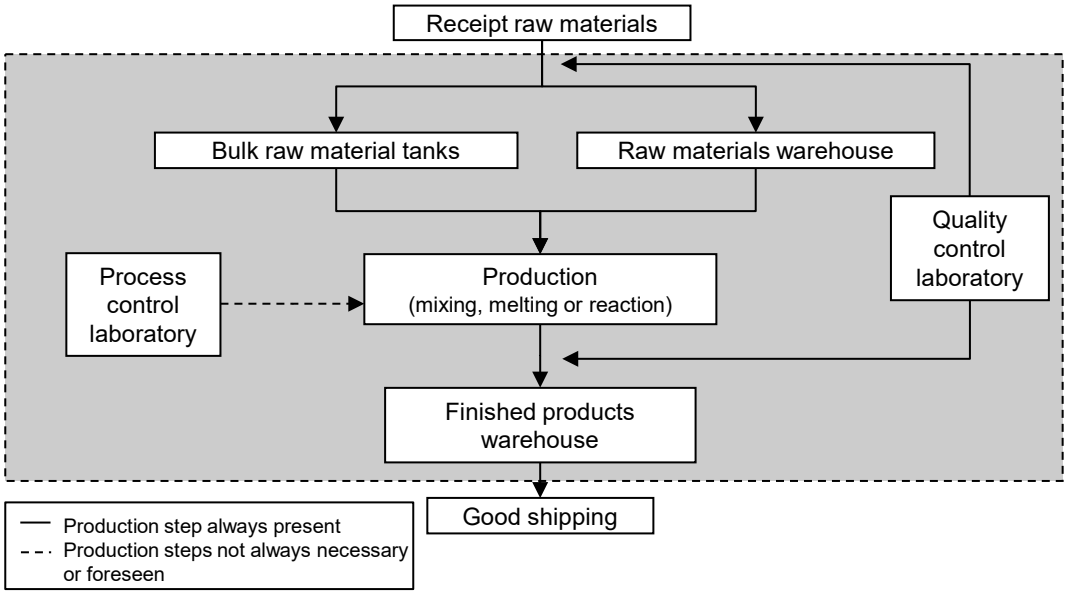
INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.*
Fulfilment	Instructions and procedures for monitoring the implementation of GMP standards.
Document type and description	The following must be defined: – procedures/operating instructions for the execution of internal and/or external audits. Internal audits are planned, carried out and appropriately recorded for all business areas involved in the implementation of GMP standards, in order to verify their correct implementation. – procedures for the management of complaints and management of any non-conformities. Procedures for the implementation of corrective and preventive actions for the resolution of non-conformities. The latter procedure must include the verification of the effectiveness of the corrective/preventive actions implemented.
Notes	-

Sheet B12.2.I. DOCUMENTATION
***Documentation* (guideline CAST GMP→ B12.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 2: *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant for the conformity and safety of finished materials and articles, and relating to the results of the quality control system.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by operators in the sector.*
Fulfilment	QAS Record-Keeping Constant adaptation and transposition of legislation
Document type and description	The following should be defined: – procedures, operating instructions for the archiving and storage of documents related to the QAS (procedures, specifications, formulations, instructions, records of process and control data). The Quality Manual, or other equivalent company document, defines an adequate time for the storage of all documents pertinent to the implementation of the GMP system. In addition, procedures/instructions must be defined to ensure continuous compliance with the regulatory requirements of current legislation.
Notes	Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/2004 as amended). Copies of the declarations of conformity issued are an integral part of the archive (art. 16 of Regulation (EC) 1935/2004 as amended).

Annex B12.1.

Flowchart for the production of printing inks



B13. COATED METAL ARTICLES INTENDED FOR COOKING

B13.1. Characterization of the sector

B13.1.1. Field of application of the guideline

This guideline applies to companies that produce objects for repeated use, made from a metal base, with a non-stick coating of different nature, intended for contact and cooking of food. The main articles covered by this guideline are:

- items for baking: for example, baking trays, roasting pan, moulds for cakes, pizzas, donuts, pies, biscuits, puddings, plum cakes;
- items for cooking on other heat sources (gas cookers, electric cookers, induction plates, etc.): for example, pots, pans, saucepans, casseroles, grills, milk boilers.

Disposable cooking items such as trays for baking in the oven referred to in chapter "B7. Metals and metal alloys, coated and not-coated" and coating products referred to in chapter "B10. Coating" are excluded from the field of application".

B13.1.2. Phases of the production process: flowcharts and description

The production flow diagrams are given in Annexes B13.1 to B13.3 at the end of this chapter. The summary description of the process steps is given in chapters B13.1.3.2., B13.1.3.4, B13.1.3.6 of the CAST GMP guideline.

B13.2. Sheets for documental verification of the application of Regulation (EC) 2023/2006

This guideline defines the activities and documentation required to implement the provisions of Regulation (EC) 2023/2006 as amended concerning GMP standards for the production chain of metal articles intended for cooking.

Any other documents related to the legal provisions on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs) are included in separate documentation systems, such as the Supporting Documentation (SD).

Below are the sheets (B13.2.a.-B13.2.n.) for documental verification that describe the activities and/or implementations that can be implemented by the Company to implement the provisions of Articles 5, 6 and 7 of Regulation (EC) 2023/2006 as amended.

The form presented are not binding for the supply chain discussed here, but their content should be considered a set of operational suggestions. The cards should always be used in conjunction with the CAST GMP guideline.

Sheet B13.2.a. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Quality Assurance System* (guideline CAST GMP→ B13.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective. – documented. – appropriate to the size of the company.
Document type and description	The documentation relating to the QAS may consist of the Quality Manual, if available, or other similar document demonstrating that the System is applied and implemented. The system must contain: – Regulation (EC) 1935/2004 as amended and Regulation (EC) 2023/2006 as amended; – procedures, instructions and documents that define how the system is implemented and enforced; – roles and responsibilities within the Company itself. The Company should identify within its organization the Function responsible for the application of Regulation (EC) 2023/2006 as amended.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended. Any certification by third parties (e.g. according to ISO 9001) could guarantee the adequacy of the QAS with respect to the size of the company. ISO 9001 quality management systems include multiple requirements also for GMP standards.

Sheet B13.2.b. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Human resources and training* (guideline CAST GMP → B13.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Adequacy of staff. Staff knowledge and skills.
Document type and description	Training is recorded and documented for example by: – procedures and/or instructions for the training and updating of personnel containing indications for verifying effectiveness; – specific training activities on GMP standards and FCMs; – personal training sheets for training recording; – specific training and refresher courses in relation to the assigned task.
Notes	The Company can define roles and responsibilities to explain the internal organization (job description) and report them in documents such as the Quality Manual or other suitable document.

Sheet B13.2.c. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Human resources and training* (guideline CAST GMP→ B13.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Organization of the necessary locations and equipment
Document type and description	The organization of the offices, their structure, should be reported in the Quality Manual or in other specific company documentation. The following should be present: – documents relating to the adequacy of production equipment and control of finished materials and articles; – manuals/production procedures/technical documentation of machinery and its calibration status, etc.
Notes	-

Sheet B13.2.d. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Selection of starting materials of the suppliers* (guideline CAST GMP → B13.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Selection of raw materials and suppliers.
Document type and description	The Company should prepare documents relating to: – specifications of the raw materials, established in "technical specifications" that contain the indications of the characteristics that identify the raw material; – procedures for the selection and qualification of suppliers of external goods, materials and services that define: - the evaluation criteria and inclusion in the list of approved suppliers; - the operating methods to assess over time the ability of suppliers to maintain the required quality level. The selection, qualification, listing and monitoring of qualified suppliers must be properly recorded.
Notes	-

Sheet B13.2.e QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Production* (guideline CAST GMP→ B13.2.1.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended*M.I.,* art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the production process.
Document type and description	Specific documents describing the operational methods of verification and control and the relevant product parameters should be defined for each stage of the production process, for example: – procedures, instructions, technical specifications; – recording of the monitoring and control activities carried out. Adequate records of the trend of significant parameters, including any deviations.
Notes	A process flow chart can help identify critical points in the process that need operating instructions and or other documents necessary to maintain and demonstrate control of activities for the purposes of FCMs and GMP standards.

Sheet B13.2.f. QUALITY CONTROL SYSTEMS
***Quality Control System* (guideline CAST GMP → B13.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art.6, paragraph 1: *Operators in the sector must establish and maintain an effective quality control system.*
Fulfilment	Development of a Quality Control System suitable for its activity, structure, product.
Document type and description	The reference documents are, for example: – Quality Manual; – procedures and operating instructions that establish control methods (references to laws, standards, specifications, internal methods, etc.); – records of the activities of verification of conformity of products with their respective specifications, e.g. control sheets, computerized tables.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended.

Sheet B13.2.g. QUALITY CONTROL SYSTEMS
***Management of raw materials warehouses* (guideline CAST GMP→ B13.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Compliance of Raw Materials with defined specifications
Document type and description	The following should be defined: – procedures/operating instructions for acceptance checks, according to any sampling plans, in order to verify the compliance of raw materials with the specifications. – records of the results of the controls.
Notes	The tests must be carried out according to test methods suitably described through an internal procedure, by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be appropriately recorded in computerized tables, databases, etc.

Sheet B13.2.h. QUALITY CONTROL SYSTEMS
***Production controls* (guideline CAST GMP→ B13.2.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions/procedures for the production process.
Document type and description	The following should be defined: – operating procedures/instructions to describe the methods for ensuring the controls and traceability of the product starting from the raw materials used through the various stages of production up to the delivery to the warehouse; – operating procedures/instructions for delivery to the warehouse.
Notes	Production controls must guarantee, through appropriate records, that the material has been checked at all stages starting from the raw materials used through the production process.

Sheet B13.2.i. QUALITY CONTROL SYSTEMS
***Quality control of finished product* (guideline CAST GMP→ B13.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions/procedures for the production process.
Document type and description	Operating instructions or procedures for verifying the conformity of the quality of the finished product with the expected requirements should be defined and codified in the respective product specifications.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, standards) by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be recorded in computerized tables, databases, etc.

Sheet B13.2.l. QUALITY CONTROL SYSTEMS
***Management of finished products warehouses* (guideline CAST GMP → B13.2.2.4)**
***Distribution, shipment and delivery* (guideline CAST GMP → B13.2.2.5)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions/procedures for warehouse management of finished goods, transport and delivery.
Document type and description	Procedures/instructions and any records should be defined for: – management of the non-compliant product; – identification and traceability of stored products; – traceability of the picking and shipping operations of finished products; – definition of the criteria for selecting transporters and the checks to be carried out on means of transport; – issuance of transport document.
Notes	-

Sheet B13.2.m. QUALITY CONTROL SYSTEMS
Conformity of the application of the GMP and claims management, corrective and preventive actions (guideline CAST GMP→ B13.2.2.6)

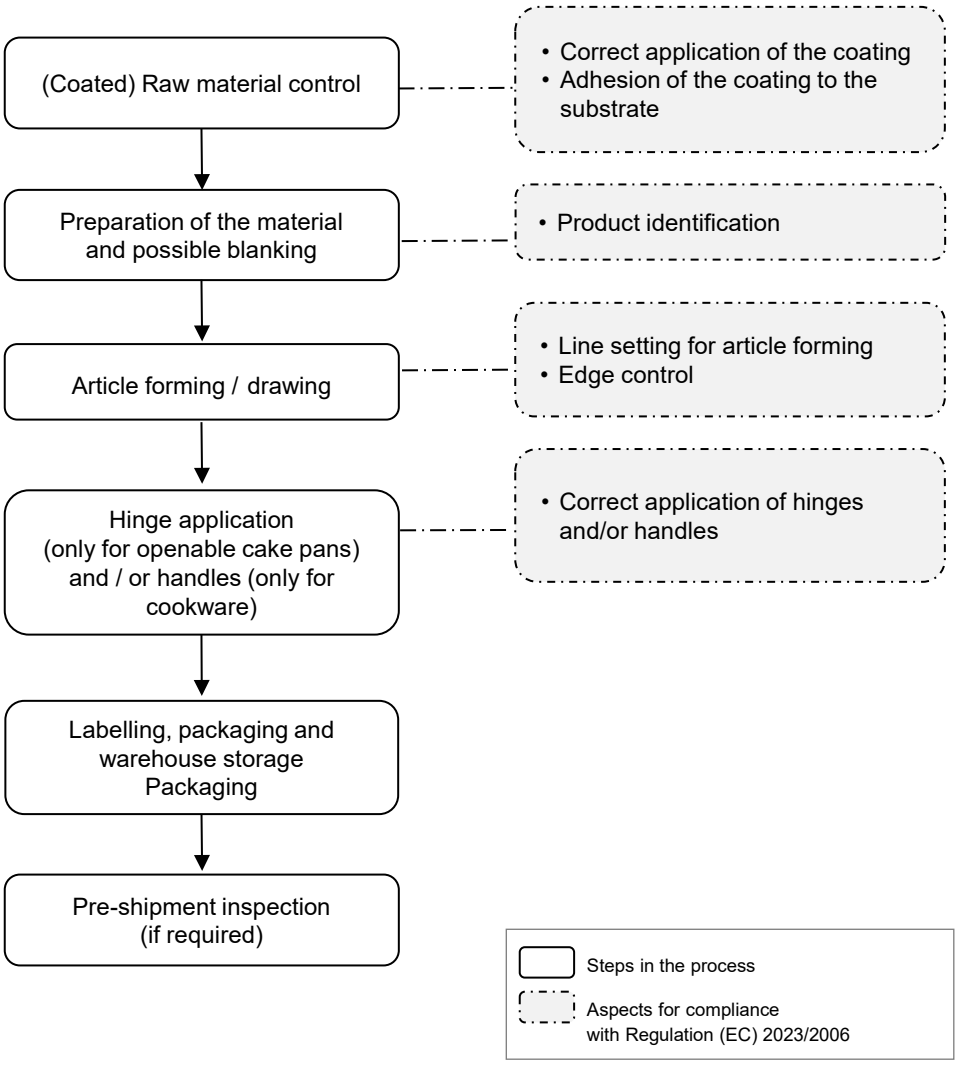
INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.*
Fulfilment	Instructions and procedures for monitoring the implementation of GMP standards.
Document type and description	Procedures/operating instructions should be defined for: – execution of internal audits; – management of complaints and management of any non-conformities; – implementation of corrective and preventive actions for the resolution of non-conformities; the latter procedure must provide for the verification of the effectiveness of the corrective/preventive actions implemented.
Notes	Internal audits are planned, carried out and recorded in order to verify the correct implementation of GMP standards in all business areas involved

Sheet B13.2.n. DOCUMENTATION
***Documentation* (guideline CAST GMP → B13.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 2: *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant for the conformity and safety of finished materials and articles, and relating to the results of the quality control system.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by operators in the sector.*
Fulfilment	Preservation of QAS and Quality Control System (QCS) documentation. Constant adaptation and transposition of legislation.
Document type and description	Operating procedures/instructions for archiving and storing documents should be defined – related to QAS (procedures, instructions, etc.); – related to the QCS (instructions, records of process and control data). The Quality Manual or other company document defines an adequate time for the storage of all documents pertinent to the implementation of the GMP system. Procedures/instructions must be defined to ensure continuous compliance with the regulatory requirements of current legislation.
Notes	Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/2004 as amended). Copies of the declarations of conformity issued are an integral part of the archive (art. 16 of Regulation (EC) 1935/2004 as amended).

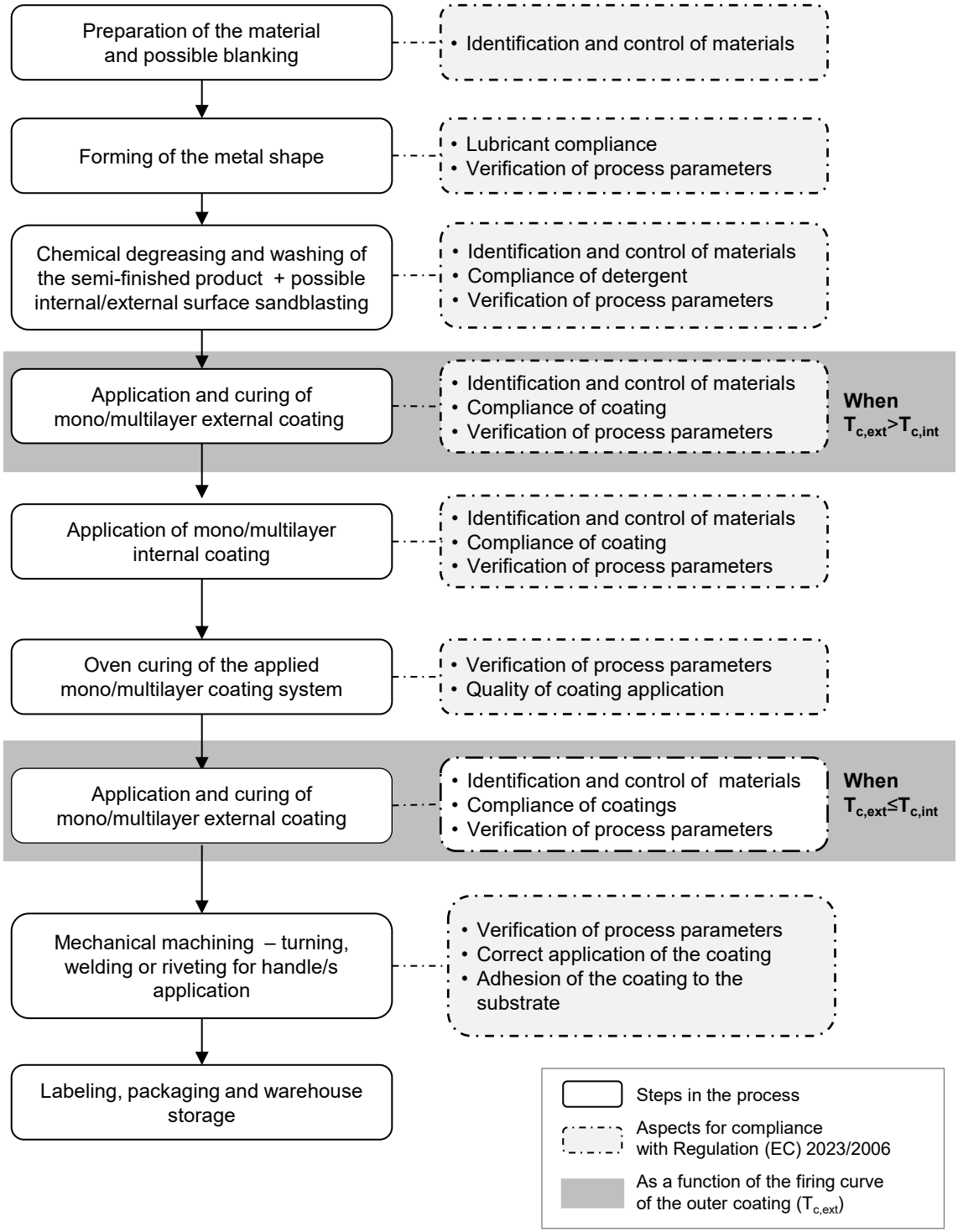
Annex B13.1.

Flowchart for the production of cooking items from non-stick coated raw material



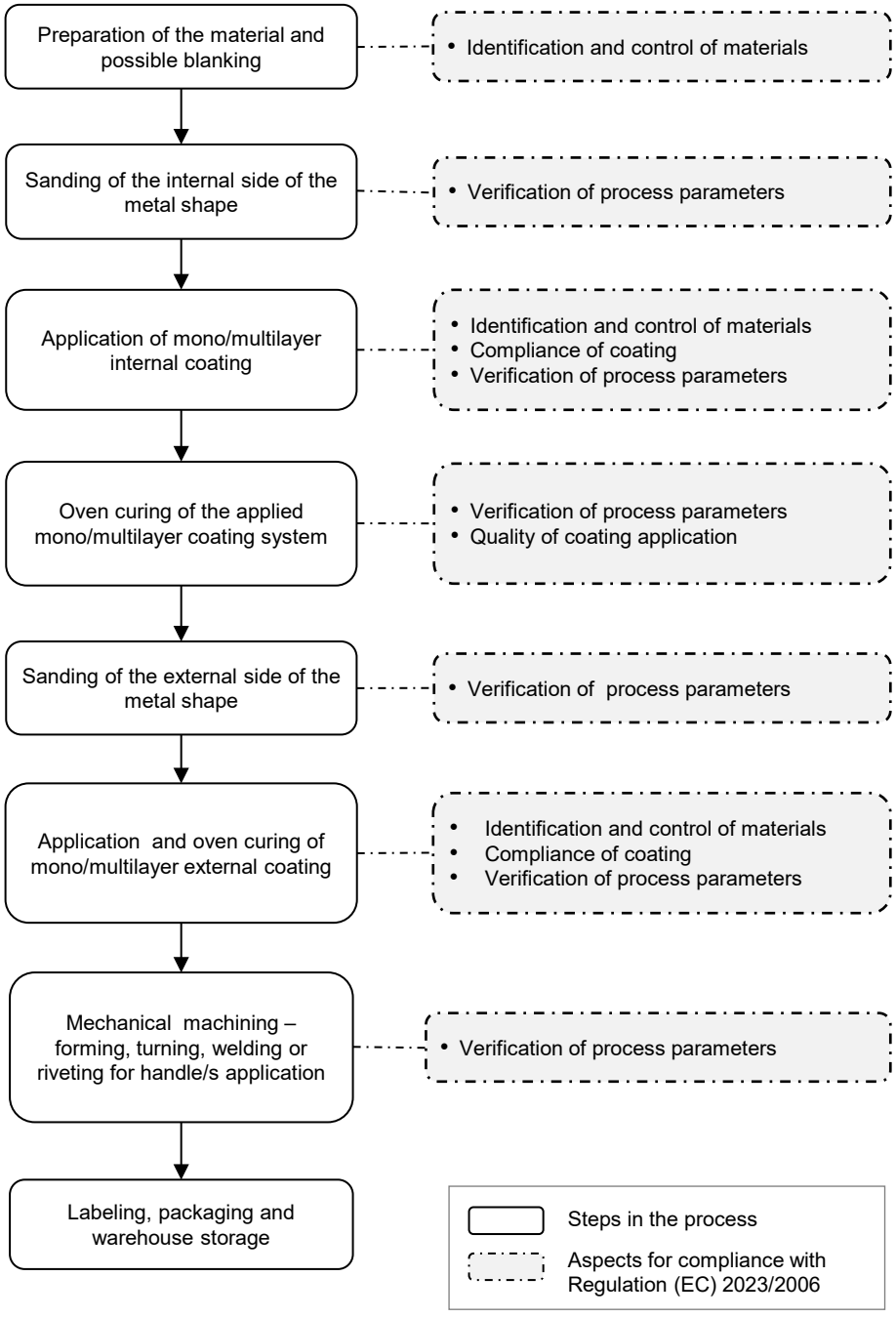
Annex B13.2.

Flowcharts of spray-coated metal cooking items with non-stick coating on the internal surface



Annex B13.3.

Flowcharts of roll-coated metal cooking items with non-stick coating on the internal surface production



B14.a. RUBBER. PRODUCTION OF ELASTOMERS, COMPOUNDS AND MASTERBATCHES

B14a.1. Characterization of the sector

B14a.1.1. Field of application of the guideline

The present guideline applies to all the companies operating within the supply chain of rubber articles intended to come in contact with foodstuff complying to article 1 of the Regulation (EC) 1935/2004 as amended.

Elastomers production and conversion processes are included. Starting substances for the production of elastomers (monomers, catalysts, additives, etc.) are excluded from the scope of Regulation (EC) 2023/2006 as amended and therefore from this guideline.

This includes the processes of mixing elastomers with fillers, oils and other additives to make rubber compounds (semi-finished products).

B14a.1.2. Phases of the production process: flowcharts and description

The production flow diagram is given in Annex B14.1 at the end of this chapter.

A summary description of the process steps is given in chapter B14.1.3.2. from the CAST GMP guideline.

B14a.2. Sheets for documental verification of the application of Regulation (EC) 2023/2006

This guideline defines the activities and documentation required to implement the provisions of Regulation (EC) 2023/2006 as amended concerning GMP standards for the production chain of elastomers, compounds and *masterbatches*[9].

Any other documents related to the legal provisions on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs) are included in separate documentation systems, such as the Supporting Documentation (SD).

Below are the sheets (B14a.2.a-B14a.2.n) for documental verification that describe the activities and/or implementations that should be carry out by the Company to implement the provisions of Articles 5, 6 and 7 of Regulation (EC) 2023/2006 as amended.

The form presented are not binding for the supply chain discussed here, but their content must be considered a set of operational suggestions. The sheet should always be used in conjunction with the CAST GMP guideline.

[9] The sheets relating to transformation are dealt with in this same chapter, but in point B14b.2.

Sheet B14a.2.a. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Quality Assurance Systems* (guideline CAST GMP → B14.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective. – documented. – appropriate to the size of the company.
Document type and description	The documentation relating to the QAS may consist of the Quality Manual, if available, or another similar document demonstrating that the System is applied and implemented. The system must contain: – Regulation (EC) 2023/2006 as amended; – procedures, instructions and documents that define how the system is implemented and enforced; – roles and responsibilities within the Company itself. The Company should identify within its organization the Function responsible for the application of Regulation (EC) 2023/2006 as amended.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended. Any certification by third parties (e.g. according to ISO 9001) could guarantee the adequacy of the QAS with respect to the size of the company. ISO 9001 quality management systems include multiple requirements also for GMP.

Sheet B14a.2.b. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Size of the business* (guideline CAST GMP → B14.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Organization of the necessary locations and equipment.
Document type and description	The organization of the offices and/or their structure should be reported in the Quality Manual or in other specific company documentation. The following should be present: – documents relating to the adequacy of production equipment and control of finished materials and articles; – manuals/production procedures/technical documentation of machinery and its calibration status, etc.
Notes	Manuals and technical documentation of machinery and equipment could be recalled/inserted/attached in the relevant documentation of the QAS.

Sheet B14a.2.c. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Human Resources and Training* (guideline CAST GMP → B14.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Adequacy of staff. Staff knowledge and skills.
Document type and description	Training is recorded and documented for example by: – procedures and/or instructions for the training and updating of personnel containing indications for verifying effectiveness; – specific training activities on GMP standards and on Materials and Objects in Contact with Food (FCM); – specific training and refresher courses in relation to the assigned task; The Company can define roles and responsibilities to explain the internal organization (job description) and report them in documents such as the Quality Manual or other suitable document.
Notes	-

Sheet B14a.2.d. QUALITY CONTROL SYSTEMS E SIZE OF THE BUSINESS
***Production* (guideline CAST GMP → B14.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Production. Instructions and procedures for the production process.
Document type and description	Specific documents describing the management operating modes and relevant process parameters should be defined for each stage of the production process, for example: – manuals, procedures, instructions, technical standards; – records of relevant activities carried out; – adequate records of the trend of significant parameters, including any deviations.
Notes	A process flow chart can help identify critical process points that need operating instructions and or other documents necessary to maintain and demonstrate control of activities for FCMs and GMP compliance.

Sheet B14a.2.e. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Selection of the starting materials, of the suppliers and/or services and/or third parties* (guideline CAST GMP → B14.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Selection of raw materials and suppliers.
Document type and description	The Company should prepare documents relating to: – specifications of the raw materials, established in *"specifications"* that contain the indications of the physical and chemical parameters that identify the raw material; – procedures for the selection and qualification of suppliers of external goods, materials and services that define: - the evaluation criteria and inclusion in the list of approved suppliers; - the operating methods to assess over time the ability of suppliers to maintain the required quality level. The selection, qualification, listing and monitoring of qualified suppliers must be properly recorded.
Notes	-

Sheet B14a.2.f. QUALITY CONTROL SYSTEMS
***Management of raw materials warehouses* (guideline CAST GMP→ B14.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 5, paragraph 2*: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Compliance of raw materials with defined specifications.
Document type and description	The following should be defined: – operating procedures/instructions for acceptance checks, according to any sampling plans, in order to verify the compliance of raw materials with specifications; – records of the results of both documental and analytical checks.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, internal methods, standards) by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be appropriately recorded in computerized tables, databases, etc.

Sheet B14a.2.g. QUALITY CONTROL SYSTEMS
***Production controls* (guideline CAST GMP → B14.2.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the production process.
Document type and description	The following should be defined: – operating procedures/instructions that describe the methods to ensure the controls and traceability of the product starting from the raw materials used through the various stages of production up to the delivery to the warehouse; – procedures/instructions for delivery to the warehouse.
Notes	The product can be stored and identified in various ways as “not shippable” until its quality level and/or compliance with all production requirements is ascertained. Production controls must guarantee through appropriate records certifying that the material has been checked at all stages starting from the raw materials used through the production process.

Sheet B14.2.h. QUALITY CONTROL SYSTEMS
***Quality control of finished product* (guideline CAST GMP→ B14.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art.6, paragraph 1: *Operators in the sector must establish and maintain an effective quality control system.*
Fulfilment	Development of a Quality Control System (QCS) suitable for its activity, structure, product.
Document type and description	The reference documents are, for example: – Quality Manual; – procedures and operating instructions that establish control methods (references to laws, standards, specifications, internal methods, etc.); – records of the activities of verification of conformity of products with their respective specifications, e.g. control sheets, computerized tables.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended.

Sheet B14a.2.i. QUALITY CONTROL SYSTEMS
***Quality control of the finished product* (guideline CAST GMP → B14.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the production process.
Document type and description	Operating instructions or procedures for verifying the conformity of the quality of the finished product with the expected requirements should be defined and codified in the respective product specifications.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, standards) by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be recorded in computerized tables, databases, etc.

Sheet B14a.2.l. QUALITY CONTROL SYSTEMS
***Management of finished products warehouses* (guideline CAST GMP → B14.2.2.4)**
***Distribution, shipment and delivery* (guideline CAST GMP → B14.2.2.5)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the management of the finished products warehouse, for shipment and delivery.
Document type and description	The following should be defined: – procedures/instructions for the storage of finished products (with identification of the condition: material meeting the established specification, under test, contested, etc.) and related records; – procedures/instructions for the identification and traceability of stored products and related records; – procedures/instructions for the traceability of picking operations and authorization for shipment to customers (finished products) and related records; – procedures/instructions for the definition of the criteria for the selection of transporters and the checks to be carried out on the means of transport (supply / service specifications) and related records; – operating instructions for issuing a transport document.
Notes	-

Sheet B14a.2.m. QUALITY CONTROL SYSTEMS
***Conformity of the application of the GMP and claims management, corrective and preventive actions* (guideline CAST GMP → B14.2.2.6)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.*
Fulfilment	Instructions and procedures for monitoring the implementation of GMP standards.
Document type and description	The following should be defined: – procedures/operating instructions for performing internal audits. – procedures for the management of complaints and management of any non-conformities; – procedures for the implementation of corrective and preventive actions for the resolution of non-conformities; the latter procedure must provide for the verification of the effectiveness of the corrective/preventive actions implemented.
Notes	Internal audits are planned, carried out and recorded in order to verify the correct implementation of the GMP system for all the business areas involved

Sheet B14a.2.n. DOCUMENTATION
***Documentation* (guideline CAST GMP → B14.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* Regulation (EC) 2023/2006 as amended, *art. 7, paragraph 2:* *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant for the conformity and safety of finished materials and articles, and relating to the results of the quality control system.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by operators in the sector.*
Fulfilment	Preservation of QAS and QCS documentation Constant adaptation and transposition of legislation
Document type and description	The following should be defined: – procedures, operating instructions for the archiving and storage of documents relating to the QAS (procedures, specifications, formulations, etc.); – procedures, operating instructions for the archiving and storage of documents relating to the QSC (instructions, records of process and control data). The Quality Manual or other company document defines an adequate time for the storage of all documents pertinent to the implementation of the GMP. Procedures/instructions should be defined to ensure continuous adaptation to the regulatory requirements of existing legislation.
Notes	Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/2004 as amended) Copies of the declarations of conformity issued are an integral part of the archive (art. 16 of Regulation (EC) 1935/2004 as amended).

B14.b. RUBBER. PROCESSING: PRODUCTION OF FINISHED ARTICLES

B14b.1. Characterization of the sector

B14b.1.1. Field of application of the guideline

The present guideline is applicable to all the companies operating within the supply chain of rubber articles intended to come in contact with foodstuff complying to article 1 of the Regulation (EC) 1935/2004 as amended.

Elastomers production and conversion processes are included. Starting substances for the production of elastomers (monomers, catalysts, additives, etc.) are excluded from the GMP Regulation scope and hence from this guideline.

This includes the processes of mixing elastomers with fillers, oils and other additives to make rubber compounds (semi-finished products).

B14b.1.2. Phases of the production process: flowcharts and description

The production flow diagram is given in Annex B14.1 at the end of this chapter.

A summary description of the process steps is given in chapter B14.1.3.2. from the guideline CAST GMP.

B14b.2. Sheets for documental verification of the application of Regulation (EC) 2023/2006

This guideline defines the activities and documentation required to implement the provisions of Regulation (EC) 2023/2006 as amended concerning GMP standards for the production chain of finished articles (transformation).

Any other documents related to the legal provisions on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs) are included in separate documentation systems, such as the Supporting Documentation (SD).

Below are the sheets (B14b.2.a-B14b.2.n) for documental verification that describe the activities and/or implementations that can be carry out by the Company to implement the provisions of Articles 5, 6 and 7 of Regulation (EC) 2023/2006 as amended.

The form presented are not binding for the supply chain discussed here, but their content must be considered a set of operational suggestions. The sheet should always be used in conjunction with the guideline CAST GMP.

Sheet B14b.2.a. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Quality Assurance Systems* (guideline CAST GMP → B14.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective. – documented. – appropriate to the size of the company.
Document type and description	The documentation relating to the QAS may consist of the Quality Manual, if available, or another similar document demonstrating that the System is applied and implemented. The system must contain: – Regulation (EC) 2023/2006 as amended; – procedures, instructions and documents that define how the system is implemented and enforced; – roles and responsibilities within the Company itself. The Company should identify within its organization the Function responsible for the application of Regulation (EC) 2023/2006 as amended.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended. Any certification by third parties (e.g. according to ISO 9001) could guarantee the adequacy of the QAS with respect to the size of the company. ISO 9001 quality management systems include multiple requirements also for GMP standards.

Sheet B14b.2.b. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Size of the business* (guideline CAST GMP → B14.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Organization of the necessary locations and equipment.
Document type and description	The organization of the offices and/or their structure should be reported in the Quality Manual or in other specific company documentation. The following should be present: – documents relating to the adequacy of production equipment and control of finished materials and articles; – manuals/production procedures/technical documentation of machinery and its calibration status, etc.
Notes	Manuals and technical documentation of machinery and equipment could be recalled/inserted/attached in the relevant documentation of the QAS.

Sheet B14b.2.c. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Human Resource and Training* (guideline CAST GMP → B14.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Adequacy of staff. Staff knowledge and skills.
Document type and description	Training is recorded and documented for example by: – procedures and/or instructions for the training and updating of personnel containing indications for verifying effectiveness; – specific training activities on GMP standards and on Materials and Objects in Contact with Food (FCM); – specific training and refresher courses in relation to the assigned task; The Company can define roles and responsibilities to explain the internal organization (job description) and report them in documents such as the Quality Manual or other suitable document.
Notes	-

Sheet B14b.2.d. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Production* (guideline CAST GMP → B14.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Production. Instructions and procedures for the production process.
Document type and description	Specific documents describing the management operating modes and relevant process parameters should be defined for each stage of the production process, for example: – manuals, procedures, instructions, technical standards; – records of relevant activities carried out; – adequate records of the trend of significant parameters, including any deviations.
Notes	A process flow chart can help identify critical process points that need operating instructions and or other documents necessary to maintain and demonstrate control of activities for FCMs and GMP compliance.

Sheet B14b.2.e. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Selection of the starting materials of the suppliers and/or services and/or third parties* (guideline CAST GMP → B14.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Selection of raw materials and suppliers.
Document type and description	The Company should prepare documents relating to: – specifications of the raw materials, established in *"specifications"* that contain the indications of the physical and chemical parameters that identify the raw material; – procedures for the selection and qualification of suppliers of external goods, materials and services that define: - the evaluation criteria and inclusion in the list of approved suppliers; - the operating methods to assess over time the ability of suppliers to maintain the required quality level. The selection, qualification, listing and monitoring of qualified suppliers must be properly recorded.
Notes	-

Sheet B14b.2.f. QUALITY ASSURANCE SYSTEMS
***Management of raw materials warehouses* (guideline CAST GMP→ B14.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 5, paragraph 2*: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Compliance of raw materials with defined specifications.
Document type and description	The following should be defined: – operating procedures/instructions for acceptance checks, according to any sampling plans, in order to verify the compliance of raw materials with specifications; – records of the results of both documental and analytical checks.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, internal methods, standards) by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be appropriately recorded in computerized tables, databases, etc.

Sheet B14b.2.g. QUALITY ASSURANCE SYSTEMS
***Production controls* (guideline CAST GMP → B14.2.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the production process.
Document type and description	The following should be defined: – operating procedures/instructions that describe the methods to ensure the controls and traceability of the product starting from the raw materials used through the various stages of production up to the delivery to the warehouse; – procedures/instructions for delivery to the warehouse.
Notes	The product can be stored and identified in various ways as “not shippable” until its quality level and/or compliance with all production requirements is ascertained. Production controls must guarantee through appropriate records certifying that the material has been checked at all stages starting from the raw materials used through the production process.

Sheet B14b.2.h. QUALITY ASSURANCE SYSTEMS
***Quality control of finished product* (guideline CAST GMP→ B14.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art.6, paragraph 1: *Operators in the sector must establish and maintain an effective quality control system.*
Fulfilment	Development of a Quality Control System (QCS) suitable for its activity, structure, product.
Document type and description	The reference documents are, for example: – Quality Manual; – procedures and operating instructions that establish control methods (references to laws, standards, specifications, internal methods, etc.); – records of the activities of verification of conformity of products with their respective specifications, e.g. control sheets, computerized tables.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended.

Sheet B14b.2.i. QUALITY ASSURANCE SYSTEMS
***Quality control of the finished product* (guideline CAST GMP → B14.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the production process.
Document type and description	Operating instructions or procedures for verifying the conformity of the quality of the finished product with the expected requirements should be defined and codified in the respective product specifications.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, standards) by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be recorded in computerized tables, databases, etc.

Sheet B14b.2.l. QUALITY ASSURANCE SYSTEMS
***Management of finished products warehouses (*guideline CAST GMP → B14.2.2.4)**
***Distribution, shipment and delivery (*guideline CAST GMP → B14.2.2.5)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the management of the finished products warehouse, for shipment and delivery.
Document type and description	The following should be defined: – procedures/instructions for the storage of finished products (with identification of the condition: material meeting the established specification, under test, contested, etc.) and related records; – procedures/instructions for the identification and traceability of stored products and related records; – procedures/instructions for the traceability of picking operations and authorization for shipment to customers (finished products) and related records; – procedures/instructions for the definition of the criteria for the selection of transporters and the checks to be carried out on the means of transport (supply / service specifications) and related records; – operating instructions for issuing a transport document.
Notes	-

Sheet B14b.2.m. QUALITY ASSURANCE SYSTEMS
***Conformity of the application of the GMP and claims management, corrective and preventive actions* (guideline CAST GMP → B14.2.2.6)**

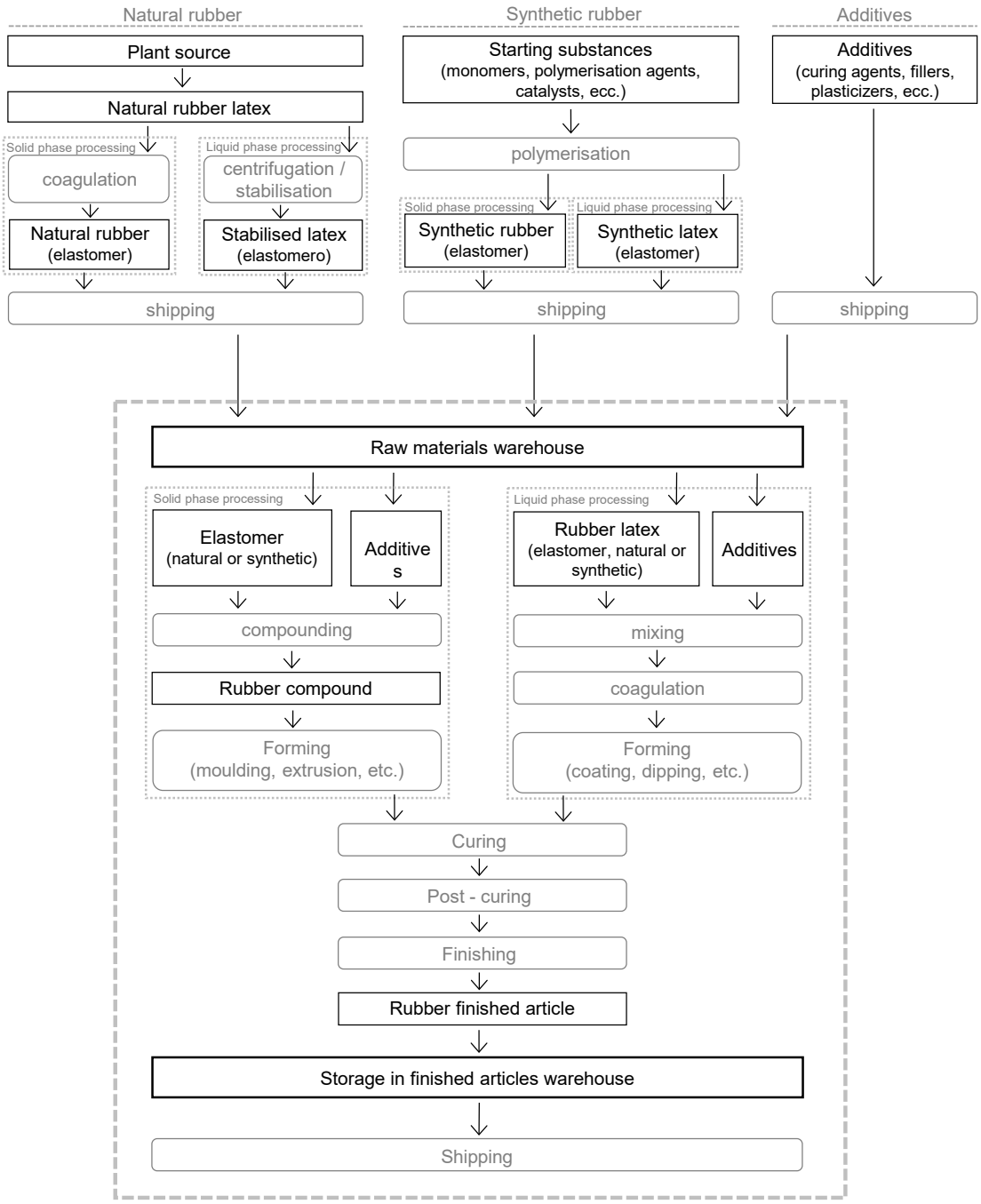
INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.*
Fulfilment	Instructions and procedures for monitoring the implementation of GMP standards.
Document type and description	The following should be defined: – procedures/operating instructions for performing internal audits. – procedures for the management of complaints and management of any non-conformities; – procedures for the implementation of corrective and preventive actions for the resolution of non-conformities; the latter procedure must provide for the verification of the effectiveness of the corrective/preventive actions implemented.
Notes	Internal audits are planned, carried out and recorded in order to verify the correct implementation of the GMP system for all the business areas involved

Sheet B14b.2.n. DOCUMENTATION
***Documentation* (guideline CAST GMP → B14.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* Regulation (EC) 2023/2006 as amended, *art. 7, paragraph 2:* *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant for the conformity and safety of finished materials and articles, and relating to the results of the quality control system.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by operators in the sector.*
Fulfilment	Preservation of QAS and QCS documentation Constant adaptation and transposition of legislation
Document type and description	They should be defined as: – procedures, operating instructions for the archiving and storage of documents relating to the QAS (procedures, specifications, formulations, etc.); – procedures, operating instructions for the archiving and storage of documents relating to the QCS (instructions, records of process and control data). The Quality Manual or other company document defines an adequate time for the storage of all documents pertinent to the implementation of the GMP. Procedures/instructions should be defined to ensure continuous adaptation to the regulatory requirements of existing legislation.
Notes	Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/2004 as amended) Copies of the declarations of conformity issued are an integral part of the archive (art. 16 of Regulation (EC) 1935/2004 as amended).

Annex B14.1.

Flowchart for the production of rubber Food Contact Materials (FCMs)



B15. FOOD PACKAGING MACHINES

B15.1. Characterization of the sector

B15.1.1. Field of application of the guideline

This guideline applies to companies that produce food packaging machines[10].

B15.1.2. Phases of the production process: flowcharts and description

The production flow diagrams are given in Annexes B15.1 at the end of this chapter. A summary description of the process steps is given in chapter B15.1.3.2. of the guideline CAST GMP.

B15.2. Sheets for documental verification of the application of Regulation (EC) 2023/2006

This guideline defines the activities and documentation required to implement the provisions of Regulation (EC) 2023/2006 as amended concerning GMP standards for the food packaging machinery supply chain.

Any other documents related to the legal provisions on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs) are included in separate documentation systems, such as the Supporting Documentation (SD).

Below are the sheets (B15.2.a.-B15.2.n.) for documental verification that describe the activities and/or implementations that can be implemented by the Company to implement the provisions of Articles 5, 6 and 7 of Regulation (EC) 2023/2006 as amended.

The form presented are not binding for the supply chain discussed here, but their content must be considered a set of operational suggestions. The cards should always be used in conjunction with the guideline CAST GMP.

[10]The term “machine” will be used to include plants and production lines.

Sheet B15.2.a. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Quality Assurance Systems* (guideline CAST GMP→ B15.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system.*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective. – documented. – appropriate to the size of the company.
Document type and description	The documentation relating to the QAS may consist of the Quality Manual, if available, or another similar document demonstrating that the System is applied and implemented. The system must contain: – Regulation (EC) 2023/2006 as amended; – procedures, instructions and documents that define how the system is implemented and enforced; – roles and responsibilities within the Company itself. The Company should identify within its organization the Function responsible for the application of Regulation (EC) 2023/2006 as amended.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended. Any certification by third parties (e.g. according to ISO 9001) could guarantee the adequacy of the QAS with respect to the size of the company. ISO 9001 quality management systems include multiple requirements also for GMP.

Sheet B15.2.b. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Size of the business* (guideline CAST GMP → B15.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Organization of the necessary locations and equipment.
Document type and description	The organization of the offices and/or their structure should be reported in the Quality Manual or in other specific company documentation. The following should be present: – documents relating to the adequacy of production equipment and control of finished materials and articles; – manuals/production procedures/technical documentation of machinery and its calibration status, etc.
Notes	Manuals and technical documentation of machinery and equipment could be recalled/inserted/attached in the relevant documentation of the QAS.

Sheet B15.2.c. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Human Resources and Training* (guideline CAST GMP → B15.2.1.1.)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Adequacy of staff. Staff knowledge and skills.
Document type and description	Training is recorded and documented for example by: – procedures and/or instructions for the training and updating of personnel containing indications for verifying effectiveness; – specific training activities on GMP standards and on Materials and Objects in Contact with Food (FCM); – specific training and refresher courses in relation to the assigned task; – the Company can define roles and responsibilities to explain the internal organization (job description) and report them in documents such as the Quality Manual or other suitable document.
Notes	The Company should define roles and responsibilities to make explicit the internal organization (job description) and report them in documents such as the Quality Manual or other suitable document.

Sheet B15.2.d. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Production* (guideline CAST GMP → B15.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Production. Instructions and procedures for the production process.
Document type and description	Specific documents describing the management operating modes and relevant process parameters should be defined for each stage of the production process, for example: – manuals, procedures, instructions, technical standards; – records of relevant activities carried out; – adequate records of the trend of significant parameters, including any deviations.
Notes	A process flow chart can help identify critical process points that need operating instructions and or other documents necessary to maintain and demonstrate control of activities for FCMs and GMP compliance.

Sheet B15.2.e. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Selection of the starting materials of the suppliers* (guideline CAST GMP → B15.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Selection of raw materials and suppliers.
Document type and description	The Company should prepare documents relating to: – specifications of the raw materials, established in *"specifications"* that contain the indications of the physical and chemical parameters that identify the raw material; Procedures for the selection and qualification of suppliers of external goods, materials and services that define: – the evaluation criteria and inclusion in the list of approved suppliers; – the operating methods to assess over time the ability of suppliers to maintain the required quality level. The selection, qualification, listing and monitoring of qualified suppliers must be properly recorded.
Notes	-

Sheet B15.2.f. QUALITY CONTROL SYSTEMS
***Quality Control System* (guideline CAST GMP → B15.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art.6, paragraph 1: *Operators in the sector must establish and maintain an effective quality control system.*
Fulfilment	Development of a Quality Control System suitable for its activity, structure, product.
Document type and description	The reference documents are, for example: – Quality Manual; – procedures and operating instructions that establish control methods (references to laws, standards, specifications, internal methods, etc.); – records of the activities of verification of conformity of products with their respective specifications, e.g. control sheets, computerized tables.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended..

Sheet B15.2.g. QUALITY CONTROL SYSTEMS
Management of raw materials warehouses **(guideline CAST GMP→ B15.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, *art. 5, paragraph 2*: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Compliance of raw materials with defined specifications.
Document type and description	The following should be defined: – operating procedures/instructions for acceptance checks, according to any sampling plans, in order to verify the compliance of raw materials with specifications; – records of the results of both documental and analytical checks.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, internal methods, standards) by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be appropriately recorded in computerized tables, databases, etc.

Sheet B15.2.h. QUALITY CONTROL SYSTEMS
Production controls **(guideline CAST GMP→ B15.2.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the production process.
Document type and description	The following should be defined: – operating procedures/instructions that describe the methods to ensure the controls and traceability of the product starting from the raw materials used through the various stages of production up to the delivery to the warehouse; – procedures/instructions for delivery to the warehouse.
Notes	Production controls must guarantee through appropriate records certifying that the material has been checked at all stages starting from the raw materials used through the production process.

Sheet B15.2.i. QUALITY CONTROL SYSTEMS
Quality control of finished product **(guideline CAST GMP→ B15.2.2.3)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the production process.
Document type and description	Operating instructions or procedures for verifying the conformity of the quality of the finished product with the expected requirements should be defined and codified in the respective product specifications.
Notes	The tests must be carried out according to codified test methods (methods validated between laboratories or internally, standards) by means of suitable, adequately calibrated instrumentation. The data resulting from quality control operations should be recorded in computerized tables, databases, etc.

Sheet B15.2.l. QUALITY CONTROL SYSTEMS
Management of finished products warehouses **(guideline CAST GMP → B15.2.2.4)**
Distribution, shipment and delivery **(guideline CAST GMP → B15.2.2.5)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the management of the finished products warehouse, for shipment and delivery.
Document type and description	Procedures/instructions and any records should be defined for: – management of the non-compliant product; – identification and traceability of stored products; – traceability of the picking and shipping operations of finished products; – definition of the criteria for selecting transporters and the checks to be carried out on means of transport; – issuance of transport document.
Notes	-

Sheet B15.2.m. QUALITY CONTROL SYSTEMS
***Conformity of the application of the GMP and claims management, corrective and preventive actions* (guideline CAST GMP→ B15.2.2.6)**

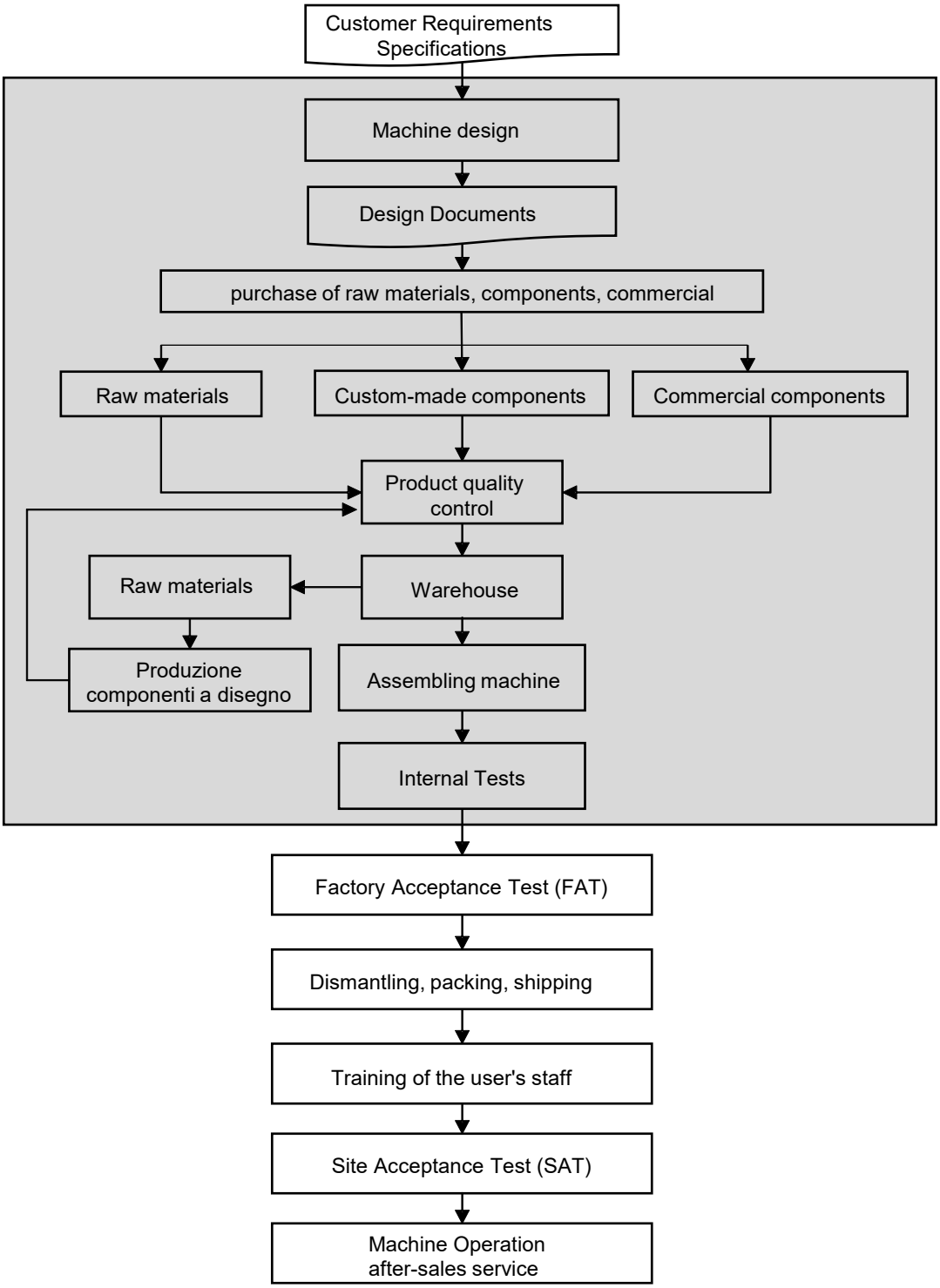
INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.*
Fulfilment	Instructions and procedures for monitoring the implementation of GMP standards.
Document type and description	The following should be defined: – procedures/operating instructions for performing internal audits. – procedures for the management of complaints and management of any non-conformities; – procedures for the implementation of corrective and preventive actions for the resolution of non-conformities; the latter procedure must provide for the verification of the effectiveness of the corrective/preventive actions implemented.
Notes	Internal audits are planned, carried out and recorded in order to verify the correct implementation of the GMP system for all the business areas involved

Sheet B15.2.n. DOCUMENTATION
***Documentation* (guideline CAST GMP → B15.2.3.)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 2: *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant for the conformity and safety of finished materials and articles, and relating to the results of the quality control system.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by operators in the sector.*
Fulfilment	Preservation of QAS and QSC documentation. Constant adaptation and transposition of legislation
Document type and description	Procedures/operating instructions for archiving and storage of documents relating to: – to the QAS (procedures, instructions, etc.); – to the QCS (instructions, records of process and control data). The Quality Manual or other company document defines an adequate time for the storage of all documents pertinent to the implementation of the GMP. Procedures/instructions should be defined to ensure continuous adaptation to the regulatory requirements of existing legislation.
Notes	Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/2004 as amended). Copies of the declarations of conformity issued are an integral part of the archive (art. 16 of Regulation (EC) 1935/2004 as amended).

Annex B15.1.

Flowchart for the construction of food packaging machines



B16. FOOD GASES DISTRIBUTION EQUIPMENT

B16.1. Characterization of the sector

B16.1.1. Field of application of the guideline

The present guideline applies to all manufacturing companies of food gases distribution equipment. A distribution equipment is formed by a set of components interconnected to each other so as to create a single and functional system with the aim of supplying the food additive gas to the point of use.

The manufacturing company can provide the equipment by committing to an installer the work of assembly of the equipment at the point of use. In this case it is necessary to distinguish the role of the *manufacturer*, namely the company responsible for marketing the equipment, from that of the outsourcing company, that is the *installer* who carries out the assembly of the components of the equipment at the user's site.

In cases where the manufacturing company also performs the installation, the manufacturer and the installer are the same.

In any case, the assembly of the equipment generally takes place at the user's site and not at the manufacturer's site.

The gas distribution equipment covered by this document is used in the food industry sector (Food and Beverage) mainly in the following food additive gases applications:

- Modified Atmosphere Packaging (MAP),
- freezing and cooling,
- beverage carbonation,
- inerting processes.

The main gases used are:

- nitrogen,
- argon,
- oxygen,
- carbon dioxide,

and mixtures thereof.

Gases can be used in gaseous, liquid or solid form depending on the user's food process and technological purposes.

B16.1.2. Phases of the production process: flowcharts and description

Production flow diagrams are given in Annexes B16.1 at the end of this chapter.

A summary description of the process steps is given in chapter B16.1.3.2. of the guideline CAST GMP.

B16.2. Sheets for documental verification of the application of Regulation (EC) 2023/2006

This guideline defines the activities and documentation required to implement the provisions of Regulation (EC) 2023/2006 as amended concerning GMP standards for the supply chain of food additive gas distribution systems.

Any other documents related to the legal provisions on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs) are included in separate documentation systems, such as the Supporting Documentation (SD).

Below are the sheets (B16.2.a.-B16.2.n.) for documental verification that describe the activities and/or implementations that can be implemented by the Company to implement the provisions of Articles 5, 6 and 7 of Regulation (EC) 2023/2006 as amended.

The form presented are not binding for the supply chain discussed here, but their content must be considered a set of operational suggestions. The cards should always be used in conjunction with the guideline CAST GMP.

Sheet B16.2.a. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Quality Assurance System* (guideline CAST GMP→ B16.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1: *Operators in the sector must establish, implement and enforce an effective and documented quality assurance system..*
Fulfilment	Implementation of a Quality Assurance System (QAS): – effective. – documented. – appropriate to the size of the company.
Document type and description	The documentation relating to the QAS may consist of the Quality Manual, if available, or other similar document demonstrating that the System is applied and implemented. The system must contain: – explicit references to GMP standards; – procedures, instructions and organization chart with definition of roles and responsibilities within the Company. The Company should identify within its organization the Function responsible for the application of Regulation (EC) 2023/2006 as amended
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended. Any certification by third parties (e.g. according to ISO 9001) could guarantee the adequacy of the QAS with respect to the size of the company. ISO 9001 quality management systems include multiple requirements also for GMP standards.

Sheet B16.2.b. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Size of the business* (guideline CAST GMP → B16.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Organization of the necessary locations and equipment.
Document type and description	The organization of the offices, their structure, should be reported in the Quality Manual or in other specific company documentation. The QAS must include: – organization of production sites and production processes. – documents relating to the adequacy of production equipment, control and calibration processes of measuring and control instruments.
Notes	-

Sheet B16.2.c. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Human resources and training* (guideline CAST GMP → B16.2.1.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 1, letter a): *That system must take into account the adequacy of the staff, their knowledge and skills, as well as the organisation of the premises and equipment necessary to ensure that the finished materials and articles comply with the standards applicable to them.*
Fulfilment	Adequacy of staff. Staff knowledge and skills.
Document type and description	Training is recorded and documented for example by: – procedures and/or instructions for the training and updating of staff containing indications for verifying effectiveness; – specific training activities on GMP standards, FCMs and in relation to the assigned task; – personal training cards for training recording.
Notes	Company can define roles and responsibilities to explain the internal organization (job description) and report them in documents such as the Quality Manual or other suitable document.

Sheet B15.2.d. QUALITY ASSURANCE SYSTEMS AND COMPANY SIZE
***Production* (guideline CAST GMP→ B16.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions and procedures for the manufacturing process of the food additive gas distribution equipment.
Document type and description	Specific documents describing the operational methods of assembly, control, testing and traceability of the components and the equipment should be defined for each stage of the equipment manufacturing process, for example: – procedures, instructions, technical specifications; – recording of manufacturing activities carried out.
Notes	A process flow chart can help identify critical points in the process that need operating instructions and or other documents necessary to maintain and demonstrate control of activities for the purposes of FCMs and GMP standards.

Sheet B16.2.e. QUALITY ASSURANCE SYSTEMS AND SIZE OF THE BUSINESS
***Selection of components and suppliers of goods and/or services and/or subcontractors* (guideline CAST GMP → B16.2.1.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Selection of components and suppliers.
Document type and description	The Company should prepare documents relating to: – procedures for the selection and qualification of components – procedures for the qualification of component suppliers – documentation of components such as: specifications, safety data sheets and declarations useful for conformity for FCM use Selection, qualification, listing of qualified suppliers and monitoring of qualified suppliers must be properly recorded.
Notes	-

Sheet B16.2.f. QUALITY CONTROL SYSTEMS
***Quality Control System* (guideline CAST GMP → B16.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 1: *Operators in the sector must establish and maintain an effective quality control system.*
Fulfilment	Development of a Quality Control System suitable for its activity and organisational structure.
Document type and description	The reference documents could include procedures, instructions and records related to quality/conformity checks during manufacturing processes, as well as the actions to be taken in the event of non-compliance.
Notes	The Quality Manual is not a requirement expressly required by Regulation (EC) 2023/2006 as amended.

Sheet B16.2.g. QUALITY CONTROL SYSTEMS
***Management of raw materials warehouses* (guideline CAST GMP→ B16.2.2.1)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 2: *The starting materials must be selected and must comply with the pre-established specifications, so as to ensure that the material or object complies with the standards applicable to it.*
Fulfilment	Compliance of components to the defined specifications
Document type and description	Input components intended as raw materials should be verified for: – compliance with the order; – presence of suitable protective packaging where required; – integrity conditions; – completeness of the accompanying documentation. In the event of non-compliance, the material must not be accepted and handled in accordance with company non-compliance procedures.
Notes	Particular attention must be paid to the storage and handling of the components to avoid damage that could render the material unusable.

Sheet B16.2.h. QUALITY CONTROL SYSTEMS
***Production Controls* (guideline CAST GMP→ B16.2.2.2)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions/procedures for the production process.
Document type and description	The control operations should be: – the verification of the integrity of the material received before the assembly operations of the equipment at the site of use; – the correspondence between the Bill of Materials (identification of the components) and the materials received; – correspondence to the *Piping and Instrumentation Diagram* (P&ID); – the execution of the pressure test with food gas.
Notes	Production controls must ensure through appropriate records that all stages of the manufacturing process are in accordance with the design. The components must be shipped to the user keeping the original packaging conditions intact and guaranteeing the conditions provided by the supplier.

Sheet B16.2.i. QUALITY CONTROL SYSTEMS
***Quality control of finished product* (guideline CAST GMP→ B16.2.2.3.)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions/procedures for the production process.
Document type and description	Operating instructions or procedures should be defined to verify the compatibility of the delivered equipment (finished product) with the design and its functionality for the use for which it is intended.
Notes	The operation tests of the system are carried out by testing to verify compliance with the specifications of use.

Sheet B16.2.l. QUALITY CONTROL SYSTEMS
***Management of finished products warehouses* (guideline CAST GMP → B16.2.2.4.)**
***Shipment and delivery* (guideline CAST GMP → B16.2.2.5)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 5, paragraph 3: *The various operations must be carried out according to pre-established instructions and procedures.*
Fulfilment	Instructions/procedures for the delivery of the system to the user.
Document type and description	By transmitting the manufacturing documents (test report, equipment delivery report and FCM Declaration of Compliance) to the user, the manufacturer formally “delivers” the equipment.
Notes	The manufacturing process does not involve warehouse storage and transport of the finished product as the equipment is assembled directly at the site of use.

Sheet B16.2.m. QUALITY CONTROL SYSTEMS
***Conformity of the application of the GMP and claims management, corrective and preventive actions* (guideline CAST GMP→ B16.2.2.6)**

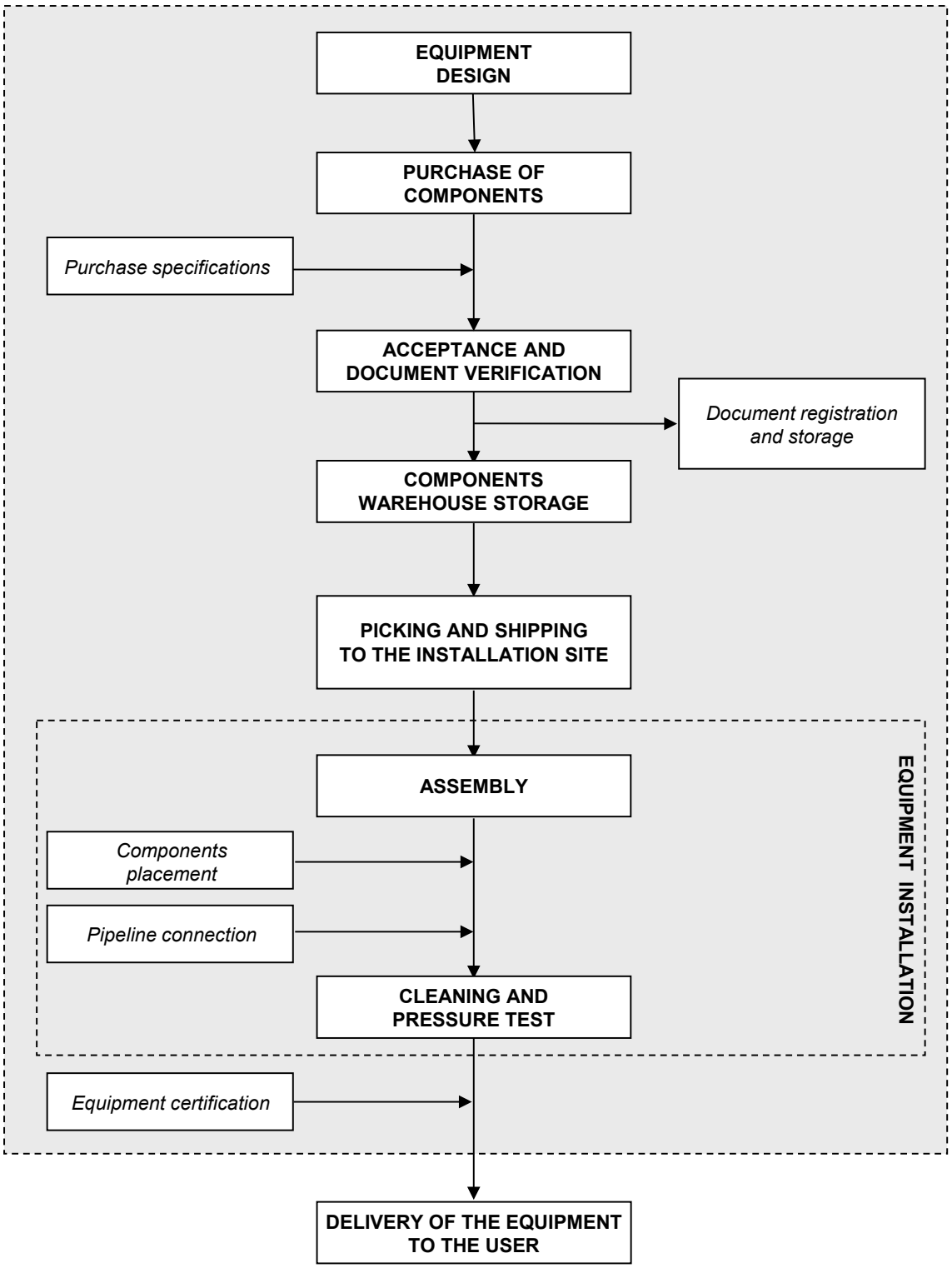
INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 6, paragraph 2: *The quality control system must include monitoring the implementation and full compliance with GMP and must identify measures to correct any non-compliance with GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.*
Fulfilment	Instructions and procedures for monitoring the implementation of GMP standards.
Document type and description	Procedures/operating instructions should be defined for: – execution of internal audits; – management of complaints and management of any non-conformities; – implementation of corrective and preventive actions for the resolution of non-conformities; the latter procedure must provide for the verification of the effectiveness of the corrective/preventive actions implemented.
Notes	Internal audits are planned, carried out and recorded in order to verify the correct implementation of GMP standards in all business areas involved

Sheet B16.2.n. DOCUMENTATION
***Documentation* (guideline CAST GMP → B16.2.3.)**

INDICATION	DESCRIPTION
Legislative reference	Regulation (EC) 2023/2006 as amended, art. 7, paragraph 1: *Operators in the sector must develop and maintain appropriate documentation on paper or in electronic format concerning specifications, formulations and manufacturing processes that are relevant for the conformity and safety of finished materials and articles.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 2: *Operators in the sector must develop and maintain adequate documentation, on paper or in electronic format, relating to the records of the various manufacturing operations carried out that are relevant for the conformity and safety of finished materials and articles, and relating to the results of the quality control system.* Regulation (EC) 2023/2006 as amended, art. 7, paragraph 3: *The documentation must be made available to the competent authorities, if they request it, by operators in the sector.*
Fulfilment	Processing and storage of QAS and Quality Control System (QCS) documentation. Constant adaptation and transposition of legislation.
Document type and description	Operating procedures/instructions for archiving and storing documents should be defined – related to QAS (procedures, instructions, etc.); – related to the QCS (instructions, records of process and control data). It is possible to provide additional company documentation that defines an adequate time for the storage of all documents pertinent to the implementation of the GMP system. Procedures/instructions must be defined to ensure continuous compliance with the regulatory requirements of current legislation.
Notes	Documents that guarantee traceability must also be appropriately archived and stored (art. 17 Regulation (EC) 1935/2004 as amended). Copies of the declarations of conformity issued are an integral part of the archive (art. 16 of Regulation (EC) 1935/2004 as amended).

Annex B16.1.

Flowchart for the production of food gases distribution equipment



REFERENCES

1. Cinzia Gesumundo, Maria Rosaria Milana, Fabiana Vanni, Giorgio Padula, Silvia Giamberardini, Massimo Denaro, Michele Massara, Marco De Felice, Roberta Feliciani, Veruscka Mannoni (Ed.). *Progetto CAST (Contatto Alimentare Sicurezza e Tecnologia). Linea guida per il riscontro documentale sull'applicazione del Regolamento (CE) 2023/2006.* Edizione 2024. Roma: Istituto superiore di Sanità; 2024. (Rapporti ISTISAN 24/36).
2. Milana MR, Denaro M, Feliciani R, Maggio A, Maini A *Linee guida per l'applicazione del Regolamento (CE) 2023/2006 alla filiera dei materiali e oggetti destinati al contatto con gli alimenti*. Roma: Istituto Superiore di Sanità; 2009. (Rapporti ISTISAN 09/33).
3. Milana MR, Denaro M, Feliciani R, Maggio A, Maini A, Padula G (Ed.). *CAST Project. Guidelines for the application of the Regulation (EC) 2023/2006 to the supply chain of materials and articles intended to come into contact with food*. Roma: Istituto Superiore di Sanità; 2011. (Rapporti ISTISAN 11/37).
4. Milana MR, Denaro M, Feliciani R, Gesumundo C, Maggio A, Mannoni V, Panico O, Padula G (Ed.). *Linea guida per il riscontro documentale sull'applicazione del Regolamento (CE) 2023/2006. Roma: Istituto Superiore di Sanità; 2013.* (Rapporti ISTISAN 13/14).
5. Milana MR, Denaro M, Feliciani R, Gesumundo C, Maggio A, Mannoni V, Panico O, Padula G (Ed.). *Progetto CAST (Contatto Alimentare Sicurezza e Tecnologia). Linee guida per l'applicazione del Regolamento (CE) 2023/2006 alla filiera di produzione di vernici, adesivi e inchiostri da stampa per materiali a contatto con alimenti*. Roma: Istituto Superiore di Sanità; 2016. (Rapporti ISTISAN 16/42).
6. Milana MR, Denaro M, Feliciani R, Gesumundo C, Maggio A, Mannoni V, Panico O, Padula G (Ed.). *Progetto CAST (Contatto Alimentare Sicurezza e Tecnologia). Linea guida per il riscontro documentale sull'applicazione del Regolamento (CE) 2023/2006. Vernici, adesivi e inchiostri da stampa*. Roma: Istituto Superiore di Sanità; 2016. (Rapporti ISTISAN 16/43).
7. Milana MR, Denaro M, Feliciani R, Gesumundo C, Maggio A, Mannoni V, Panico O, Padula G (Ed.). *Linea guida sulla documentazione di supporto per la dichiarazione di conformità alla legislazione sui materiali e oggetti a contatto con alimenti.* Roma: Istituto Superiore di Sanità; 2018. (Rapporti ISTISAN 18/24).
8. Gesumundo C, Milana MR, Padula G, Giamberardini S, Vanni F, De Felice M, Denaro M, Feliciani R, Massara M, Mannoni V (Ed.). *Progetto CAST (Contatto Alimentare Sicurezza e Tecnologia). Linea guida sulla documentazione di supporto per la dichiarazione di conformità alla legislazione sui materiali e oggetti a contatto con alimenti*. Edizione 2023. Roma: Istituto Superiore di Sanità; 2024. (Rapporti ISTISAN 24/29).
9. Gesumundo C, Milana MR, Mannoni V, Giamberardini S, Vanni F, De Felice M, Denaro M, Feliciani R, Massara M, Padula G (Ed.). *Linee guida per l'applicazione del Regolamento (CE) 2023/2006 alla filiera di produzione dei materiali e oggetti destinati a venire in contatto con gli alimenti.* Edizione 2023. Roma: Istituto Superiore di Sanità; 2023. (Rapporti ISTISAN 23/4 Rev., aggiornamento giugno 2024).
10. Gesumundo C, Milana MR, Mannoni V, Giamberardini S, Vanni F, De Felice M, Denaro M, Feliciani R, Massara M, Padula G (Ed.). *CAST Project. Guidelines for the application of the Regulation (EC) 2023/2006 to the supply chain of materials and articles intended to come into contact with food*. Edition 2023. Roma: Istituto Superiore di Sanità; 2024 (Rapporti ISTISAN 24/8).

ACKNOWLEDGEMENTS

We would like to thank the participants who contributed to the elaboration of the documents of the CAST Project:

Abbà F.
Acanfora A.
Adversi G.
Aglio M.
Aldrigo D.
Alessi A.
Amato G.
Arduini A.
Badomer E.
Barbieri C.
Barani L.
Barbuio M.
Barenghi D.
Basi A.
Bassi S.
Belinghieri F.
Bergaglio P.
Bergamini M.
Bertolotti F.
Betelli R.
Bianchini G.
Bianco A.
Biatta A.
Biavati E.
Boccardelli M.
Boffa V.
Bonacina R.
Bottura M.
Bruscella A.
Buonauro G.
Buondonno M.
Bonuomo M.
Busi P.
Caburlotto D.
Calabretti L.
Calderan F.
Calsana M.
Castagna G.
Cantoni M.
Canulli A.
Cappelli G.
Carosi P.L.
Carpanelli E.
Cavalli E.
Cella A.
Cerullo S.
Chiozza F.
Conca R.
Corradetti D.
Cozzi L.
Dabiankov D.
Dagostino G.
Dainelli D.
Dallavalle M.G.
Da Riz W.
De Boni B.
De Felice M.
De Giovanni G.
De Lorenzi L.
Denaro M.
Di Bernardo M.
Eusebio R.
Fabiani R.
Fancinelli M.
Fava E.
Favaro N.
Feliciani R.
Feola A.
Ferdenzi C.
Ferron J.
Ferrari G.
Fieschi A.
Finazzi C.
Finazzi E.
Forni G.
Fragnelli G.
Galliena S.
Gaggino A.
Gammacurta F.
Gavioli L.
Gesumundo C.
Ghibaudo M.
Ghizzoni R.
Giamberardini S.
Graziadio D.
Grisai L.
Guardini M.
Incocciati L.
Lamperti M.
Laporta M.
Legrenzi F.
Lena P.
Lentini P.
Levratto M.

Lovisotto G.
Lucchese E.
Lugli S.
Maggio A.
Maggio M.
Maggioni A.
Magri N.
Maini A.
Maloberti A.
Mannoni V.
Marchetti E.
Marchegiani M.
Marmiroli G.
Masciotta P.
Massara M.
Masotto P.
Mastrototaro M.
Mazzocchi C.
Mecacci M.
Mencarelli M.
Medugno M.
Milana M.R.
Minardi S.
Montereali S.
Orlandi V.
Padula G.
Panico O.
Pantano S.
Papagni P.
Parizzi D.
Pasquarelli O.
Pellegrini P.
Perego A.
Perizzolo F.
Petri C.
Piana M.
Pierini M.
Piovan A.
Pitzanti G.
Polini D.
Poncini M.
Ramunni M.
Ravasio A.
Reggiani C.
Ripa A.
Rizzo L.
Romano M.
Rosati G.
Ruggero A.
Sachet M.
Sala A.
Salinetti S.
Scarpa, M.
Sicco G.
Scopolino D.
Sentimenti A.
Sicco G.
Sinagra C.
Simone F.
Sirotti M.
Stanghellini P.
Soana M.
Soldi M.
Stanghellini P.
Taraschi I.
Tarozzo S.
Tincani M.
Tralongo A.
Tonazzo M.
Tosini M.
Vailati I.
Vanni F.
Veltri F.
Vinciguerra S.
Visca E.
Visentin D.
Volpe R.
Zambon F.
Zancanella C.
Zaninotto S.
Zannier P.
Zanni V.
Zollo M.

Serie Rapporti ISTISAN
numero di gennaio 2026

Stampato in proprio
Servizio Comunicazione Scientifica – Istituto Superiore di Sanità

Roma, marzo 2026