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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

English version of Rapporto ISTISAN 23/4 Rev.

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

AMBIENTE E SALUTE

ISTITUTO SUPERIORE DI SANITÀ

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Edited by
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2024, xviii, 328 p. Rapporti ISTISAN 24/8

In the frame of the CAST Project (*Contatto Alimentare Sicurezza e Tecnologia:* Food Contact Safety and Technology) general and specific guidelines for the application of the Regulation (EC) 2023/2006 on good manufacturing practice in the supply chain of materials and articles intended to come into contact with food were developed. 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. These guidelines update and supplement the documents *Rapporti ISTISAN* 09/33 and 16/42.
Key words: Regulation (CE) 2023/2006; Good manufacturing practice; Materials; Contact; Food

Istituto Superiore di Sanità
Progetto CAST. 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. Versione inglese del Rapporto ISTISAN 23/4 Rev.
A cura di Cinzia Gesumundo, Maria Rosaria Milana, Veruscka Mannoni, Silvia Giamberardini, Fabiana Vanni, Marco De Felice, Massimo Denaro, Roberta Feliciani, Michele Massara, Giorgio Padula
2024, xviii, 328 p. Rapporti ISTISAN 24/8 (in inglese)

Nell'ambito del Progetto CAST (Contatto Alimentare Sicurezza e Tecnologia) sono state sviluppate linee guida per l'applicazione del Regolamento (CE) 2023/2006 sulle buone pratiche di fabbricazione nella filiera di produzione dei materiali e oggetti destinati a venire in contatto con gli alimenti. 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. Queste linee guida aggiornano e integrano i *Rapporti ISTISAN* 09/33 e 16/42.
Parole chiave: Regolamento (CE) 2023/2006; Buone pratiche di fabbricazione; Materiali; Contatto; Alimenti

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The following associations took part in the present CAST project:

ANFIMA
Associazione Nazionale fra i Fabbricanti di Imballaggi Metallici e Affini
Italian Association of Manufacturers of Metal Packaging and like products (Milan)

Assocarta
Italian Association of Paper, Board and Paper Pulp Industrialists (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
Italian Association of non-ferrous metal industries / 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
Italian Federation of the chemical industry

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
National Union of Italian Plastic Converters (Milan)

The following associations collaborated in the drafting of the guidelines published in the previous volumes (Rapporti ISTISAN 09/33 and Rapporti ISTISAN 16/42):

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

AIDI
Associazione Industrie Dolciarie Italiane
Italian Association of Confectionery 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
Associazione Nazionale fra i Fabbricanti di Imballaggi Metallici e Affini
Italian Association of Manufacturers of Metal Packaging and like products (Milan)

ASSOBIBE
Associazione Italiana tra gli Industriali delle Bevande analcoliche
Italian Association of Soft Drinks Industrialists (Rome)

Assocarta
Italian Association of Paper, Board and Paper Pulp Industrialists (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)

GIFASP - Assografici
Gruppo Italiano Fabbricanti Astucci e Scatole Pieghevoli
Italian Group of Folding Case and Box Manufacturers (Milan)

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

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

ConLegno
Wood-Cork Service Consortium (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)

Federalimentare
Italian Food Industry Federation (Rome)

Unionplast – Federazione Gomma Plastica
National Union of Italian plastic converters (National Federation of the Rubber, Electrical Cables and Related Industries - 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)

PVC Information Centre (Milan)

Unionzucchero
National Union of Sugar Industrialists (Rome)

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PREFACE TO THE ENGLISH VERSION

This document is the English version of “Progetto CAST (Contatto Alimentare Sicurezza e Tecnologia). Linee guida per l’applicazione del Regolamento (CE) 2023/2006 alla filiera dei materiali e oggetti destinati al contatto con gli alimenti”, published in 2023 in the series *Rapporti ISTISAN* (Rapporti ISTISAN 23/4 Rev.).

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 implementation of the Regulation (EC) 2023/2006 on GMP (Good Manufacturing Practice).

The CAST GMP 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 to help implementation of Regulation (EC) 2023/2006 as amended especially for SME (Small and Medium Enterprises), but in the meantime offering a valid tool to the Public Inspectors to 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 GMP 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 Food Contact Materials (FCMs).

The project name reflects this objective and the innovative approach taken to merge knowledge and knowhow of the public and private stakeholders in order to:

- improve the technical application of the rules;
- 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.

The Project explores the issues of conformity to current legislation governing FCMs, based on joint activities of the various stakeholders in the food sector, under the technical guidance of the Istituto Superiore di Sanità (ISS, the National Institute of Health in Italy) and 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 activities of the Industrial associations as individual player and cover the supply chain from producers of materials to packaging converters and ultimately the food companies.

The project was made up of separate working groups to cover the various supply chains:

- aluminium;
- paper and board (in separate groups to cover production and converting);
- flexible packaging;
- wood or wood-based fibre;
- plastic packaging;
- metals and metal alloys, coated and not-coated;
- cork;
- glass;
- coating;
- adhesives and sealants;
- printing inks;
- coated metal articles intended for cooking;
- rubber;
- food packaging machines;
- food gases distribution equipment.

Each Working group has drawn up a guideline document for the application of the Regulation (EC) 2023/2006 as amended regarding GMP in the FCM sector.

The various materials and items which fall under these guidelines, as well as the components at various stages of production of such items, have been covered in great detail so that the business operators can easily recognise the common ground.

The basic idea in developing these guidelines has been to exploit what already existed at company and sector level and finalising the most common systems of management in respect of the Regulation (EC) 2023/2006 as amended.

Special attention has been paid to the small and medium-sized enterprises, with the objective of constituting a base for making the most practical operational choices.

The drafting of the initial guidelines, published in 2009 (*Rapporti ISTISAN* 09/33) (1), involved the participation of various sectors, including aluminium, paper and cardboard, flexible packaging, plastics, wood and wood-based materials, coated and uncoated metals and alloys, cork,

and glass. The guidelines were subsequently published in English in 2011 (*Rapporti ISTISAN* 11/37) (2).

In addition to the aforementioned guidelines, the Project on Documentary Verification Sheets for the Implementation of GMP Regulations in various sectors (*Rapporti ISTISAN* 13/14) (3) was developed, along with a subsequent guideline on essential aspects of supporting documentation (*Rapporti ISTISAN* 18/24) (4).

Later, the sectors of paints, adhesives, sealants, and printing inks joined the Working Group of the CAST Project. This led to the publication of additional guidelines on the application of Regulation (EC) 2023/2006 (*Rapporti ISTISAN* 16/42) (5) and documentary verification sheets for the implementation in these sectors (*Rapporti ISTISAN* 16/43) (6).

This document represents a further advancement of the CAST guidelines on GMP for FCMs (materials and objects intended to come into contact with food). New sectors added to the project include coated metal articles for cooking, rubber, food packaging machinery, and facilities for distributing food additives. Consequently, the guidelines for the application of GMP regulations on FCMs (materials and objects intended to come into contact with food) have been updated, consolidated with references to legislative and regulatory frameworks, and integrated with the new sectors. They are now presented in a single document resulting from a comprehensive review within the Working Groups of the CAST Project.

Throughout the development of the guidelines, it became evident from the project's inception that, regardless of individual achievements and operational choices made by each stakeholder, the correct implementation of GMP cannot overlook a genuine dialogue among all stakeholders in the *food packaging* industry and, more broadly, in the materials and objects intended to come into contact with food and the food industry itself. This is evident both in the proper selection of starting materials and in the transfer of a set of specific information for each stage (e.g., declarations of conformity, composition statements, usage indications, etc.) that truly enable the flow and maintenance of necessary information throughout the supply chain to ensure product conformity and continuous improvement of food product safety.

The contributors to this edition of the guideline include:

- ANFIMA (*Associazione Nazionale fra i Fabbricanti di Imballaggi Metallici e Affini,* Italian Association of Manufacturers of Metal Packaging and like products);
- Assocarta (Italian Association of Paper, Board and Paper Pulp Industrialists);
- 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);
- Italian Federation of the chemical industry;

- 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 (National Union of Italian Plastic Converters);

The present document is divided into three parts:

- *Part A.*
  General guidelines for the application of the Regulation (EC) 2023/2006
  containing the analysis of the Regulation and the applications from a general point of view.
- *Part B.*
  Specific guidelines for the application of the Regulation (EC) 2023/2006
  containing the implementations that the packaging chains, considered in the present guideline, make to guarantee conformity to the requisites of the Regulation.
- *Appendix.*
  Other aspects connected to food safety in the practices of the food packaging segments
  containing some aspects that, while not directly regarding the field of application of the Regulation (EC) 2023/2006 as amended are closely connected to the practice of the food packaging chain.

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

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materiali a contatto con alimenti. Roma: Istituto Superiore di Sanità; 2016. (Rapporti ISTISAN 16/42).

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PART A
General guideline
for the application of the Regulation (EC) 2023/2006

A1. GENERAL ASPECTS

A1.1. Purpose of the guideline

The present guideline provides instructions for the application of the Regulation (EC) 2023/2006 as amended by the Commission on December 22nd, 2006, on good manufacturing practice for materials and articles intended to come into contact with food* to the production chain of materials and articles intended for food contact.

This guideline is not legally binding, but it can be a useful tool for the various players in the supply chain that, regardless of their place in this chain, will be able to find technical and applicative orientation for the implementation or for the finalisation of the systems that conform to the requirements of the Regulation (EC) 2023/2006 as amended.

A1.2. Field of application of the guideline

The present guideline applies to materials and articles produced in the manufacturing supply chains listed below. The details of each typology and relevant application of the guideline can be found in the specific chapters for each chain. The chapters are:

- B1. Aluminium;
- B2. Paper and board: production;
- B3. Paper and board: converting;
- B4. Flexible packaging;
- B5. Wood or wood-based fibre;
- B6. Plastic 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. Rubber;
- B15. Food packaging machines;
- B16. Food gases distribution equipment.

* Regulation published in *Official Journal of the European Union* L384/75-78, December 29, 2006.

A1.3. General legislation on materials and articles in contact with foodstuffs

All materials and articles that come in contact with foodstuffs are subject to general regulations which are harmonized at a community level and are applicable to all sectors and to all the stages 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.[1]

- *Italian legislation*
  - Decree of the Italian 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.
  - Italian Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
  - Italian 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 objects intended to come into contact with food.

[1] It replaced the Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

A2. DEFINITIONS

The following definitions illustrate the most important terms used in the present text (when present, these definitions are dealt with textually in the Regulation (EC) 1935/2004 as amended and Regulation (EC) 2023/2006 as amended):

- *Good Manufacturing Practice or 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).

- *Materials and articles in Contact with Foodstuffs (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).

- *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).[2]

- *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.

[2] 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.

- *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.

A3. APPLICATION OF THE REGULATION (EC) 2023/2006 ON GOOD MANUFACTURING PRACTICE

A3.1. Introduction

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 FCMs, 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.

A3.2. Analysis of the articles

The following text illustrates the key concepts of the Regulation (EC) 2023/2006 as amended, presented singularly for each article, illustrating the practical implications for the businesses. To

facilitate the reading, the text of the article has been entered, or the part in discussion, keeping the same numerical sequence found in the Regulation:

Article 1: Object

Art. 1 reads:

> "This Regulation lays down the rules on good manufacturing practice (GMP) for the groups of materials and articles intended to come into contact with food (hereafter referred to as materials and articles) listed in Annex I to Regulation (EC) No 1935/2004 and combinations of those materials and articles or recycled materials and articles used in those materials and articles."

Regulation (EC) 2023/2006 as amended applies to the production of products and articles for food contact constituted by:

- materials entered in Annex I of Regulation (EC) 1935/2004 as amended;
- possible combinations of the said materials;
- recycled materials and articles.

Article 2: Field of application

Art. 2 reads:

> "This Regulation shall apply to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances. The detailed rules set out in the Annex shall apply to the relevant individually mentioned processes, as appropriate".

All production phases in all production sectors have to be carried out under GMP excluding the production of the starting substances.

Currently within the Regulation (EC) 2023/2006 as amended, specific dispositions are defined for processes concerning the use of printing inks and the use of recycled plastic materials (Regulation (EC) 1616/2022 that repealed Regulation (EC) 282/2008).

Note. Art. 15 of the repealed Regulation (EC) 282/2008 amended Regulation (EC) 2023/2006 by inserting a specific annex "Specific rules on good manufacturing practices", part B of which "Quality assurance system for plastic recycling processes referred to in Regulation (EC) 282/2008 on recycled plastic materials and articles intended to come into contact with food and amending Commission Regulation (EC) 2023/2006" is specifically dedicated to the Quality Assurance System of recycling processes for plastics intended for the preparation of FCMs.

Article 3: Definitions

Art. 3 reads:

> "For the purpose of this Regulation, the following definitions shall apply:
>
> a) 'good manufacturing practice (GMP)' means those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure

> conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof".

The GMP is the body of the *modus operandi* adopted for managing the process so as to guarantee the conformity to the rules and quality requisites applicable as well as to the legislative prescriptions in force for materials and articles for food contact.

> "b) 'quality assurance system' means 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;"

The QAS (Quality Assurance System) is the body of practises and procedures for managing the entire process. The Quality Assurance System has to be based on objective documentary evidence and registrations capable of proving conformation to the pertinent legislative and regulatory requisites applied so as to guarantee the conformity of the FCMs produced.

> "c) 'quality control system' means 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".

The Quality Control System has to comprehend documented activities for monitoring and maintaining the specifications laid down by the Quality Assurance System

Article 4: Conformity to GMP

Art. 4 reads:

> The business operator shall ensure that the manufacturing operations are carried out in accordance with:
> a) the general rules on GMP, as provided for in Article 5, 6 and 7;
> b) the detailed rules on GMP as set out in the Annex.

The business operators have to set up and maintain at least:
- a Quality Assurance System,
- a Quality Control System,

providing
- the drawing up of the relative documentation;
- the storage of the operative and recorded documents.

Article 5: Quality Assurance System

First part

Art. 5, paragraph 1, reads:

> "1. The business operator shall establish, implement and ensure adherence to an effective and documented quality assurance system. That system shall:

> a) take account of the adequacy of personnel, their knowledge and skills, and the organisation of the premises and equipment such as is necessary to ensure that finished materials and articles comply with the rules applicable to them;
>
> b) be applied taking into account the size of the business run by the operator, so as not to be an excessive burden on the business."

The business operator has to set up and maintain an effective Quality Assurance System, that should be managed via documented objective evidence and records pertinent to the various phases of the process. The Quality Assurance System has to at least be responsible for:

- personnel training, in particular as far as the role within the GMP system and the respective tasks and responsibilities are concerned;
- organization suited to the entire production and logistic system;
- equipment suited for the creation of FCMs conforming to the standards in force.

The business operator is the Responsible of the Quality Assurance System. He may avail himself of internal or external resources to carry out the operations of the same.

The Quality Assurance System (QAS) demanded and finalised in the Regulation (EC) 2023/2006 as amended must *always* be applied, whatever the size of the Business. The same Business has the task of suiting the QAS to its own technical and human resources and to the complexity of the production activity.

The system should at any rate guarantee the creation of finished materials or products conforming to the legislation in force on FCMs.

Second part

Art. 5, paragraph 2, reads:

> "2. Starting materials shall be selected and comply with pre-established specifications that shall ensure compliance of the material or article with the rules applicable to it".

Regulation (EC) 1935/2004 as amended demands that the compliance of finished product for food contact is guaranteed, not mentioning the production process, but only generally indicating the term good manufacturing practice (art. 3 Regulation (EC) 1935/2004).

Regulation (EC) 2023/2006 as amended introduces the novelty of the process control: to obtain the guarantee demanded by Regulation (EC) 1935/2004 as amended the control and knowledge of the production activity and the working procedures that, starting from the ingoing raw materials, enable the attainment of finished products conforming to the standards in force governing FCMs.

This knowledge for example includes chemical processes, the processing machines used, the working conditions, the treatment of products and can be considered the nucleus of the GMP. The starting materials have to be appropriately selected on the basis of the knowledge and control of one's own processes.

This leads to the concepts of selection of the materials and selection and qualification of the supplier, extremely important both due to their deep influence on both the management of the production process, as well as on the economic-financial balance of the business operator.

Third part

Art. 5, paragraph 3, reads:

> "3. The different operations shall be carried out in accordance with pre-established instructions and procedures".

Regulation (EC) 2023/2006 as amended lays down that, for the management of the GMP system, it is indispensable that the business operator prepares and enacts documented procedures, that at least describe the operations pertinent to the maintaining of the Quality System.

This means that the legal obligations only demand the proceduralization of the operations covering the management of the FCMs and that they influence the conformity to the legislation pertinent to the subject of food contact.

However, the multiplicity of processes and activities within a company and their interconnection may be such that documents cannot easily be drawn up technical-managerial that concern only a part of such as to not easily permit the drawing up of technical-managerial documents that only cover a part of these practises; thus, in many cases the Quality System is constructed to cover all the processes.

It is also underlined that the Regulation does not explicitly demand the drawing up of a *Quality Manual* or a *GMP Manual* as commonly understood in the quality management systems, all the same this can be a useful management tool, as well as in the event of a control from the Competent Authorities.

For example, in the case of a small company, the enunciations of a quality policy as well as the operative documentation can be conveniently gathered in one document. Against this the composition specifications, formulations, the manufacturing processes etc or that is, the documents required to demonstrate the conformity of the finished materials and articles could be collected separately and made available to the Competent Authorities on demand or shown to the customers for bilateral voluntary agreements. The separation of the two documentations, that should all the same be conveniently and unequivocally correlated, would enable some part of the process or information that the business operator wishes to keep as reserved information to be kept secret.

Article 6: Quality Control Systems

Art. 6 reads:

> "1. The business operator shall establish and maintain an effective quality control system.
> 2. The quality control system shall include monitoring of the implementation and achievement of GMP and identify measures to correct any failure to achieve GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.

For *effectiveness* it must be here understood *suitability to the purpose.* The Quality Control System*,* in the context of the Regulation, also covers the aspects of monitoring and checking the parameters that contribute to the correct management of the process.

Indeed, the activities of the Quality Control System have to obligatorily also provide for activities for the checking "of the implementation and achievement of the GMP".

For the carrying out of the said activities the Regulation does not lay down the obligation of designating responsible figures inside the company. All the same documented evidence proving the application of the Regulation should be available.

The Quality Control System has to hence be organized so as:

- to be able to intervene on the production process in the event that it has to resolve the conditions that caused the non-respect of the required specifications;
- in the event of serious deviations from conformity to the standards, to be able to identify corrective measures to enable the speedy implementation of the same (*without delay*) and

it should if called upon be able to illustrate and demonstrate the effectiveness of the measures to the *competent authorities for the audits*.

It must be underlined that the GMP Regulation has not attributed to the Quality Control System the responsibility of implementing the corrective measures, but only their identification.

Obviously, the Quality Control System has to also monitor the implementation of the corrective measures applied.

Hence it would be advisable, in the light of the obligations to supply documentary evidence of the actions carried out, to establish procedures for documenting the identification of any corrective measures and for monitoring their correct implementation.

Article 7: Documentation

Art. 7 reads:

> "1. The business operator shall establish and maintain appropriate documentation in paper or electronic format with respect to specifications, manufacturing formulae and processing which are relevant to compliance and safety of the finished material or article.
> 2. The business operator shall establish and maintain appropriate documentation in paper or electronic format relative to the registration of the various manufacturing operations carried out which are relevant to compliance and safety of the finished material or article, and relative to the results of the Quality Control System.
> 3. The documentation shall be made available by the business operator to the competent authorities at their request."

Regulation (EC) 2023/2006 as amended, lays down the institution of a complete documental system. The documentation demonstrating the conformity of the business operator's GMP system to the demands of the Regulation (EC) 2023/2006 as amended must be established obligatorily. Hence registration and operative documents must be established obligatorily.

Below is a non-exhaustive list of the documents that the Operator should have at his disposal:

- *Supporting documentation*
  demanded by Regulation (EC) 1935/2004 as amended under art. 16. The obligation is what is more reiterated in art. 7 paragraph 1 of the Regulation (EC) 2023/2006 as amended. It should comprise organized collections, containing the specification of composition and procurement, the certification/declaration of compliance issued by the supplier, when applicable, the test reports on starting material, raw materials, semi processed and/or finished articles, etc, or that is all that enables the business operator to demonstrate to the Competent Authorities that what their company produces conforms to the rules on FCMs.
- *Operative documentation of the business*
  or that is operating procedures, instructions, forms, etc., required in creating the FCM.

It might be useful to define a brief list of the documented procedures that should make up the "minimum issue" of a GMP system conforming to the Regulation (EC) 2023/2006 as amended (see art. 5, paragraph 2).

These procedures can include:

- *Selection of materials*
  The procedure describes the mode of selection of the materials, so as to ensure compliance to the specifications laid down. This procedure generally implies the preventive selection of suppliers capable of satisfying the said demands, that should always be laid down in

detail in special contractual agreements, where the responsibilities of the supplier and the business operator are clearly defined.

- *Registration of production data*
  The procedure describes the type of production data management, or that is the registration of products during the manufacture of the materials and/or articles, so as to enable an easy identification. The registrations should be collected and preserved in an organized, ordered manner.
- *Production controls*
  The procedure defines and describes the type of planning and control of the production activities, through the availability of specifications that define the characteristics of the products and the enactment of suited control or verification activities that guarantee a correct execution of the production process.
- *Procedure for corrective actions*
  The procedure defines and describes responsibilities and modes of operation governing the activity with which the Corrective Actions (CA) are defined, carried out and made available to the competent authorities for inspection. The CAs have the function of correcting any non-conformities highlighted in the continuous monitoring that the Quality Control System has to carry out to verify the correct implementation and application of the GMP regulations.
- *Controls on the finished product*
  The procedure defines and describes responsibilities and modes of operation covering the activity of tests and controls on the finished product as established in order to provide products that comply with the pre-established requirements and therefore with the applicable legislation.
- *Training and information of the personnel*
  The procedure describes the mode with which the training of the personnel involved in the manufacture of the materials and/or articles for food contact is controlled, for the purpose of guaranteeing the continuous update both in terms of the Regulations (laws, rules, circulars etc.) and regarding the latest technical and analytical knowledge.
- *Storage management*
  The purpose of the procedure is that of defining the operations required for a correct management of the storage facilities defining the different phases of identification, handling, packaging, storage and transport of the raw material and/or semi processed articles and/or final products.
- *Distribution, shipment and transport*
  The purpose of the procedure is that of describing the modes adopted for guaranteeing the correct management of the distribution, shipping and transport phases of the materials and/or finished products to the final customer, so as to prevent possible alterations that can make the product no longer suitable for its destined use or even endanger hygienic safety as under the relative legislation.

The adopting of further procedures or an extension of existing procedures is the faculty of the business or company, this in consideration of the chain type it belongs to and to its position within the same.

The specific chapters within the present guidelines describe the implementations that the production chain of the single material and articles make to guarantee conformity to the requisites as under Regulation (EC) 2023/2006 as amended.

A4. QUESTIONS AND ANSWERS ON REGULATION (EC) 2023/2006

Q1 *What does GMP mean?*

It is short for Good Manufacturing Practice.

Q2 *How is the GMP defined?*

GMP is defined as "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".

Q3 *What is Regulation (EC) 2023/2006?*

This is a legislative tool adopted by the EU to defend the consumers in application as under art. 3 of the Regulation (EC) 1935/2004 as amended covering materials and objects for contact with food products.

Q4 *What does art. 3 of Regulation (EC) 1935/2004 establish?*

This article lays down that the materials and articles, comprising active and intelligent materials and articles, have to be produced conforming to GMP so that, under normal or foreseeable conditions of use, they do not transfer to the food product components in quantities that they might:

a) endanger human health;
b) bring about an unacceptable change in the composition of the food;
or c) bring about a deterioration of the organoleptic characteristics thereof.

Q5 *What is the field of application of the Regulation (EC) 2023/2006?*

The present Regulation applies to all sectors and all the phases of production, processing and distribution of materials and objects for contact with foodstuffs up to and excluding the production of starting materials.

Q6 *What are the production chains of the different materials?*

The production chains are the total sum of industrial processes that from the production of the raw materials lead to the obtaining of the finished article and its distribution.

Q7 *Who has to ensure the application of the GMP?*

All the actors in the production chain of materials and articles for food contact are bound to guarantee the observance of what is laid down by the GMP in function of their positioning in the self-same supply chain.

Q8 *Can one demand the application of the Regulation (EC) 2023/2006 applied to the production of semi processed articles or finished products from countries outside the EU?*

Yes. Inter EU trade only occurs via the circulation of goods compliant with EU laws, hence a producer from outside the EU has to follow Regulation (EC) 2023/2006 as amended.

Q9 *What are the quality management systems?*

The Quality Assurance System defines the sum total of 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.

Q10 *Do businesses have to be certified?*

No. Regulation (EC) 2023/2006 as amended does not lay down any obligation of system or product certification.

Q11 *Are the GMP necessary if my company is already ISO 9000 and BRC certified?*

Yes. While the quality management systems ensure that production is carried out following specific documented procedures to obtain a preset quality level, a GMP system is focussed on measures for the purpose of fulfilling the specific legislative requirements on materials and objects in contact with foodstuffs.

Q12 *Can you graft a GMP system into a certified quality scheme?*

Yes. A certified Quality System (i.e., EN ISO 9000, BRC) is an excellent basis for the implementation of GMP, that all the same should not be confused with the Quality System in itself. Some systems can include the GMP, but cannot in themselves be considered a sufficient condition.

Q13 *If the business is small, are the obligations as laid down in the Regulation (EC) 2023/2006 still the same?*

The obligations laid down in the Regulation (EC) 2023/2006 as amended do not consider the size of the business but, in the foreword (paragraph 6) it is stated that "The rules on GMP should be applied proportionately to avoid undue burdens for small businesses". As well as that, in art. 5 ("Quality assurance system" requires that "That system shall: […] be applied taking into account the size of the business run by the operator, so as not to be an excessive burden on the business".

Q14 *What is FCM traceability?*

Traceability (defined in art. 17 of the Regulation (EC) 1935/2004 as amended) is the possibility to reconstruct and follow the route that materials and articles follow through the processing, converting and distribution phases. The traceability of the FCMs has the aim of food safety, facilitating the handling of emergencies, enabling the recall of defective products from the market, tracing the causes of non-conformity and locating the responsibilities in the single phases.

Q15 *How do you ensure an adequate hygiene level?*

Every actor in the production chain must ensure an adequate level of cleanliness and/or hygiene in relation to his/her own position in the supply chain.

Q16 *How do you prevent contamination?*

Contamination can be prevented through knowledge of and the current application of the GMP, in particular the control of the critical phases of the entire process and the application of all the measures suited to the prevention of potential contamination**.**

Q17 *Are the requisites the same along the entire production chain?*

No. The GMP should be applied according to the positioning of the single actor within the supply chain.

Q18 *Does one have to involve all company personnel?*

Yes, the personnel must be aware of the fact that the product is intended for food contact.

Q19 *What should one ensure in training the staff to observe the GMP?*

For the correct application of the GMP the staff must receive adequate training and precise instructions on the way of working.

Q20 *Who is responsible for the implementation and enactment of the company GMP system?*

The business operator is responsible for the management of resources and the activities necessary to guarantee that Regulation (EC) 2023/2006 as amended is understood and applied at all levels in the company organization.

Q21 *Does Regulation (EC) 2023/2006 require the creation of a specific figure responsible for the QAS and/or GMP?*

No, the Regulation demands that the business operator guarantees that Regulation (EC) 2023/2006 as amended is understood and applied at all levels of the company organisation in order to obtain FCMs conforming to the applicable legislation. Every company can organize its activities best befitting its size and activity, on condition that the system is effective, implemented, maintained and documented and that products conforming to the applicable legislation are obtained.

Q22 *What does one need to do for the documentation?*

The documentation and its correct management and updating is a key aspect, what is more obligatory, for the maintenance of a system in GMP. As well as the documentation of the suppliers a documentation enabling the tracing of the production phases should be prepared.

Q23 *If the business has not drawn up a manual but it limits itself to registering its own management system via the relevant documentation, is this enough to demonstrate conformity to Regulation (EC) 2023/2006?*

Yes. In the Regulation (EC) 2023/2006 as amended no mention is made of the obligation to draw up a manual but in art. 7 mention is made of "appropriate documentation in paper or electronic format".

Q24 *What should one do to manage GMP of raw materials?*

The supplier documentation is to be handled so as to connect each lot of raw material to a specific batch of finished product, to ensure the full traceability within a certain sector of the segment. This duly considering the technological feasibility, so as to enable the controlling of the companies that supplied the materials, the articles and, if the case has it, the substances and products used in the processing.

Q25 *How does one manage the change?*

Any variation in a given process that has influence on the conformity and requisites on FCMs (i.e., the use of a new raw material, a new formulation, or a new machine) should be evaluated

before the implementation. The GMP system should be re-evaluated at each change to check any need for a potential review of the system. Documentary traces of any changes should be kept.

Q26 *How does one correctly manage handling, transport and storage?*

The handling, transport and storage conditions have to always be such as to avoid adulterations and contaminations both of raw materials, as well as semi processed and finished articles.

Q27 *How does one manage activities carried out by third parties?*

Each job contracted to third parties has to be subordinated to a written contract and has to be carried out in accordance with the GMP, in any case at a level comparable to that applied for the processes placed at the same level in the production chain on the contractor's premises.

Q28 *How does one check the effectiveness of the GMP?*

The Quality Control System has to be organized to include verification activities for the implementation and total respect of the GMP. The effectiveness is also checked through controls on finished products.

Q29 *Who checks the application of the GMP?*

The implementation of controls as to the application of the GMP, in the Regulation (EC) 2023/2006 as amended is entrusted to the Quality Control System of the Business. The verifications by the Competent Authorities are carried out as under the Discipline of the Official Control of Food Products (Regulation (EC) 882/2004 of the European Parliament and the Council 29th April 2004/EC).

Q30 *Where does one find clarification on the responsibility of the producers of materials and object intended for food contact and for the food industry?*

The Italian ministry of Health has issued Circular 24th January 2006 "Materials and objects intended for food contact: responsibility of the Enterprises and the Food Industry". The Circular can be found at the web address:
https://www.trovanorme.salute.gov.it/normsan-pdf/0000/20977_1.pdf

PART B
Specific guidelines
for the application of the Regulation (EC) 2023/2006

INTRODUCTION

In this Part B, the specific chapters describe the implementations that the packaging chain, considered in the present guideline, has to make to guarantee conformity to the requirement of the Regulation (EC) 2023/2006 as amended.

The description is divided into separate and independent chapters for each chain, in order to reflect and respect the peculiarities of the same.

Yet, for clear reading and interpretation, where possible a homogenous structure and terminology throughout has been maintained.

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 fibre;
- B6. Plastic 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. Rubber;
- B15. Food packaging machines;
- B16. Food gases distribution equipment.

Each specific guideline includes a description of:

- the production process, both in flowchart and in summary description;
- the applicable legislation;
- the fulfilments deriving from the application of the GMP Regulation;
- a technical glossary.

Where necessary a section of frequent questions and answers has been included along with a useful list of bibliographic references.

B1. ALUMINIUM

B1.1. Characterization of the sector

B1.1.1. Field of application of the guideline

This guideline is applicable to manufacturers of thin foil and foil intended for the production of alufoil trays.

B1.1.2. Applicable legislation

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.[3]

Italian legislation

- Decree of the Italian 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.
- Italian Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- Italian 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 objects intended to come into contact with food.
- Italian Ministerial Decree No. 76/2007 on regulation regarding the hygienic discipline of materials and articles of aluminium and aluminium alloys intended to come into contact with foodstuffs.

[3] It replaced the Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

B1.1.3. Phases of the production process: flowchart and description

B1.1.3.1. Production flowchart

Figure B1.1 illustrates the flowchart to produce thin foil and foil for containers intended for the manufacture of alufoil trays (the dashed part is complaint with the GMP Regulation (EC) 2023/2006 as amended).

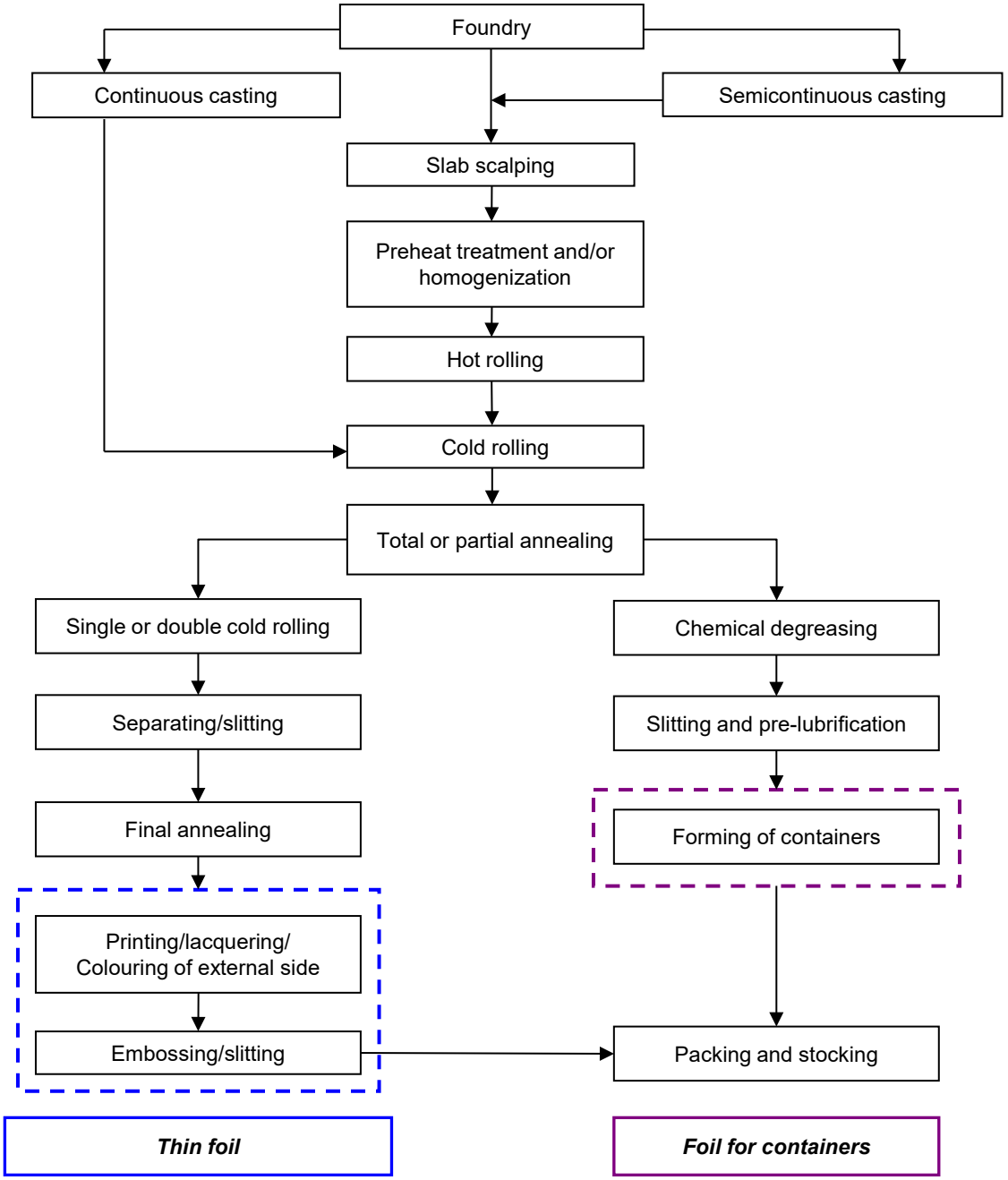

Figure B1.1. Production flowchart of thin foil and foil for containers

B1.1.3.2. Brief description of process phases

Foundry: slab casting

Metal is molten in furnaces at about 800°C, where primary metal ingots or Tbars are charged, at times together with scraps from the production process (selected according to the chemical composition). The phases of the process can be divided as follows:

- charging;
- alligation;
- slagging;
- bath rest;
- degassing;
- filtration;
- refining.

Semicontinuous casting

In the process of direct chill semicontinuous casting, the molten metal is channelled towards the water-cooled casting bed, and it solidifies in the shape of slab for the following plastic transformation.

Continuous casting

In the process of continuous casting, the molten metal is channelled and passes through two water-cooled rollers solidifying. The result of the process is a tape with a thickness of some mm, already coiled for the following cold working.

Slab scalping

In this process some millimetres of material are removed from the surface of the slab in order to eliminate oxides and impurities (segregations).

Preheat treatment and/or homogenization

After the scalping the slab undergoes a heat treatment at a temperature between 550 and 600°C. The purpose of this treatment is to homogenize aluminium and the alloying elements through a diffusive process and to make the slabs plastically deformable.

Hot rolling

After having been preheated, the slab undergoes the process of thickness reduction. Thanks to many passes through the rollers of the hot rolling mill, the slab is worked into to a coiled foil with a thickness between 3.0 and 8.0 mm.

An emulsion of oil and water is usually used as lubricant-refrigerant fluid to reduce friction, helping in the *passes* through the rollers and in the process of *thickness reduction* at every pass, and, at the same time, to cool the rollers.

The final temperature at which the hot rolled material is coiled has to allow the complete evaporation of the emulsion from the surface.

Cold rolling

After having been hot rolled and then cooled at room temperature, the foil undergoes a new process of thickness reduction passing though the rollers of the cold rolling mill. The final

thickness is normally between 0.4 and 0.7 mm, when cold rolling for thin foil follows, or it is ≥ 0.035 mm, usually for trays.
Also in the cold rolling stage, a lubricant-refrigerant fluid is used with the same aim as in the hot rolling. The chemical-physical characteristics of the fluid should allow the elimination of the residual fluid during the following heat treatments.

Total or partial annealing

Thanks to the heat treatment in ovens carried out at the right temperature/time, the foil acquires physical and mechanical characteristics (as hardness, ultimate tensile strength, yield strength and elongation, etc.), which make it suitable for following processes, both for thin foil production, as well as for containers.

Single or double cold rolling

After having been hot rolled and then cooled at room temperature, the foil undergoes a new process of thickness reduction passing though the rollers of the cold rolling mill until the final thickness is reached. For very thin thicknesses (usually < 50 μm) the last pass is carried out rolling two foils at the same time (in jargon called "double rolling"). Doubling can take place both at the "entry" of the rolling mill or on a separate doubling machine.
Also in this case, a lubricant-refrigerant fluid is used to control the friction between the foil and the rollers and the heat due to the plastic deformation. The chemical-physical characteristics of the fluid shall allow the evaporation of the fluid itself during the final annealing in the oven.

Separating/slitting

The doubled coils are first separated in different reels on a specific separating machine, then slit to the required dimensions.
The single rolled coils are directly slit into tapes of the required dimensions.

Final annealing

The reels undergo a final heat treatment in ovens which, carried out at the right times/temperatures, gives the foil the physical-mechanical characteristics according to the customers' requests (as ultimate tensile strength, yield strength and elongation).
This heat treatment is essential to the evaporation of the lubricant-refrigerant fluid still present on the foil after the cold rolling.

Chemical degreasing

In the production run of the foil for the production of trays, there can be also a final chemical degreasing to assure that possible residues from the different production phases are removed.
This operation is carried out by letting the foil go through baths containing water solutions additivated with acid or alkaline surface-active, degreasing substances. The foil is then rinsed in demineralised water.
The machines allow a superficial cleaning of the foil by synergistically exploiting both the chemical effect created by the degreasing solution used and the hydro-mechanical effect.
The foil remains in contact with the solutions normally for few seconds. Then the tape is "squeezed" by passing through rubberized rollers (*squeeze-roll* system) in order to eliminate most product from the surface. The foil is then rinsed in demineralised water in different, consecutive tanks.

In the end, the foil passes through a hot air-drying tunnel, where it is completely dried from any liquid residue.
This operation brings advantages both from the point of view of "smell" as well as "surface cleaning".

Pre-lubrication and slitting

Once all the above-described phases are completed, the *master coils* are normally sent to the longitudinal slitting unit. Thanks to circular blades the material is slit into smaller and narrower reels. In this way, the final customer forming the containers will have less scrap. The foil is wound on cores (metallic, in cardboard or PVC) which can be placed on the customer's unwinding reels.
The aluminium foil supplied by the manufacturer can be already pre-lubricated, that means lubricated with a pre-established quantity of oil (classified as "processing aid" according to the Italian Ministerial Decree No. 76 of 18.04.07) suitable for continuous food contact, which allows the forming of the containers without having to do it on the press.
Oil can be applied either using photoengraved rollers (indirect gravure system) or through electrostatic application.
According to GMP, in the production of trays for food and their lidding it is possible to use lubricating oils as processing aids (art. 4 par. 2 of Italian Ministerial Decree No. 76 of 18.04.2007).

Tray forming

The forming or the moulding of a metallic sheet is normally carried out using a male/female forming mould, which gives the sheet a variable deformation degree according to the final shape of the object.
As a consequence, the stress resulting on the material is the addition of the forming strength, which is transmitted from the forming mould to the material, and of the skin friction between them.
It is clear that the skin friction is an important limit to the possible deformation, as the ultimate tensile strength is inevitably limited and cannot assume values higher than those specific of the metal. Moreover, the friction between the forming mould and the material causes the continuous wear of the forming mould and the abrasion of the foil. It is therefore absolutely necessary to use a lubricant – processing aid – which has the task of:

- establishing a balance between the reduction of the friction and the braking action of the pressure bar;
- creating a film between the foil and the forming moulds in order to avoid scratching and seizing the formed part;
- minimizing die and punch wear;
- making the distribution of the deformations uniform;
- removing heat from the working area;
- helping the release of the formed piece;
- protecting the formed piece and the forming mould from corrosion.

The forming moulds for the production of trays are normally made of steel of different composition and hardness; the parts which are most subject to wear can be treated with a process of surface hardening (casehardening and tempering; nitriding, etc.).
The forming mould can have one or more cavities; this means that one or more pieces can be formed for each stroke in order to implement the productivity for the most required models.

The latest plants also have transportation and automated stacking systems and sometimes there are also automated packaging machines. This equipment allows a lower incidence of the cost of labour and brings advantages from the point of view of hygiene, as it avoids the physical contact between trays and operators, thus strongly reducing the risk of microbiological contaminations.

B1.2. Fulfilments deriving from the application of the Regulation (EC) 2023/2006

In this part are described the activities and the implementation enacted by the manufacturers of materials and articles of aluminium for thin foil and foil for the production of trays to conform to the Regulation (EC) 2023/2006 as amended. Since this Regulation was laid down when the quality assurance systems had already become a daily work tool in most of the manufacturing businesses, it is likely that these businesses already produce in conformity with technical specifications laid down by themselves.

All the same, should it be necessary, the Quality Assurance System and the Quality Control System should be extended to ensure:

> "[...] that the materials and articles are constantly manufactured and controlled, to ensure their conformity to 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" (art. 3 paragraph a Regulation (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006 as amended. Every paragraph is hence the response of the manufacturers of materials and articles of aluminium for thin foil and foil for the production of trays to the requirements of the article in question. To facilitate reading, the paragraphs keep the same title as the article considered, while the subparagraphs indicate specific subjects.

B1.2.1. Quality Assurance Systems (Regulation (EC) 2023/2006, art. 5) and Size of the business

Quality Assurance Systems

The producer of materials and articles of aluminium for thin foil and not-coated foil for the production of trays (hereafter referred to as "the producer") should establish and maintain a Quality Assurance System capable of ensuring the achievement of the objectives laid down by the Regulation and described in the general guideline.

The Quality Assurance System should be documented so as to enable control by the competent authorities.

The Quality Assurance System should establish rules and procedures that regulate the company activity, at least concerning the following points:

- conformity to the requisites of the legislation in force;
- human resources and training:
- raw materials and suppliers including suppliers of goods and services and third parties working under contract;
- production;

- quality control;
- storage, handling and shipment;
- complaints and corrective and preventive actions.

The system must ensure that the future legislative changes are adopted in all the phases of the company process also including the specifications and any contracts with qualified suppliers.
It is recommended to implement a procedure which enables the company to adopt the changes deriving from updates of the applicable legislation on FCMs.

Size of the business

Independently from the business size, it should at any rate be guaranteed that the Quality Assurance System, as demanded and finalised by the Regulation (EC) 2023/2006 as amended, is always applied.
The system should be established, implemented and run taking into account the actual size and complexity of the company as well as the technical and human resources available.
On its own premises the business has to at any rate be capable of guaranteeing the application and running of the Quality Assurance and Quality Control System in order to obtain finished materials and products in compliance with the legislation in force on FCMs.

B1.2.1.1. Human resources and training

The *Business operator,* in compliance with the objectives of the Regulation (EC) 1935/2004 as amended and the Regulation (EC) 2023/2006 as amended is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 as amended is applied at all levels of their organization.

The operative aspects relating to the application of the provisions laid down in the Regulation (EC) 2023/2006 as amended can be entrusted by the Business operator to competent and adequately trained people that have to at any rate have at their disposition adequate means to ensure that the requisites of the Regulation (EC) 2023/2006 as amended are respected.

The *company organization* has to at any rate enable the location of the functions to enable inspection by the Competent Authorities.

All *company personnel* potentially involved, including the highest management levels, has to be informed on the principles of GMP, on the obligations that derive from the Regulation (EC) 2023/2006 as amended, on its objectives and on the policy for applying the Regulation.

The *Business* should operate and implement procedures for identifying personnel training requirements and has to see to the training of all staff regarding the tasks that might affect the compliance to the said Regulation.

The *personnel* assigned to GMP control activities should be qualified on the basis of the training and the experience acquired.

An appropriate registration of the training process of all personnel must be kept.

B1.2.1.2. Production

The company production phase extends from design and planning to storage of the finished product.

The production process includes all the company phases that combine to guarantee that the end product complies with the legislative, technical and performance requisites laid down at the planning phase to guarantee the suitability for intended use.

Hence the Quality Assurance System should comprise procedures that regulate all the phases listed hereafter:

- Design and development of the product;
- Suppliers and start up materials selection;
- Raw material arrival and storage;
- Raw materials/start up materials Quality Control;
- Production processes and traceability;
- Process parameters controls;
- Quality Control during production;
- Quality Control and storage of finished product.

Design and development of the product

The most important concept implied by the GMP is that of a product designed to be compliant to the legislative requisites on materials and articles intended for food contact (FCMs).

Distinctions can be made between the design of a product and the adaptation of a product to the requirements of a customer, who may have a product developed for a specific use subsequently suited to the precise and different demands of a customer.

In any case the packaging material produced must:

- comply with the performances for the final use it is intended for;
- comply with the requisites of the legislation in force for materials intended for food contact.

To this purpose the product has to be produced with raw materials that, subject to controls, guarantee, in all the process phases, the compliance to use the same are intended for and the legislative requisites covering food contact. To enable the development of a project of a packaging compliant to customer requisites the following information has to be known and available:

- nature of the food product to be packed;
- shelf life of the product to be packed;
- thermal preservation or cooking processes that the pack along with its content will be subjected to.

When an already existing packaging material is adapted to the requisites of a new product launch the initial project has to be recontroled and verified to make sure it complies to the new use.

To ensure that the project of conformity of a packaging item remains valid for the new use the necessary information has to at least include the data described above.

All the modifications on the original project have to be verified to control any undesired effects on the conformity of the product.

The requisites of the new packaging must be suitably documented.

The producer has to indicate to the customer any possible changes that might in some way undermine the material's correspondence to the demanded requisites.

Selection of the starting materials and the suppliers of goods and/or services

The producer is called upon to use only approved starting materials or that is that for which he has all the necessary data guaranteeing the conformity of the packaging produced to the legal requisites, including the restrictions due to conditions of use, this by way of information from the supplier and/or through controls and checks made during the design phase.

Observance of the following requisites should also be ensured:

- declaration of compliance according to what has been established by the applicable European and/or Italian legislation;

- traceability according to the Framework Regulation (EC) 1935/2004 as amended (where applicable);
- conformity to the Regulation (EC) 2023/2006 as amended (where applicable). Any supply of starting material has to be kept under adequate control.

It is good practise that the starting materials/raw materials are procured from qualified suppliers. By qualification is meant a pre-established, organized and documented process that can also include supply contracts.

It is advised to verify, also through periodical visits of inspection (audits), the Quality Assurance System of the supplier of starting materials or third parties to ascertain whether it is compliant with the requisites as laid down by the Regulation (EC) 2023/2006 as amended, where applicable.

In case the supplier is not under a GMP regime, the producer must ensure that raw materials or semi-finished products to be used will be appropriate to produce materials and articles suitable to contact with food; this verification, which is at producer's costs, could be carried out by means of checking of the compositional certification given by the suppliers, and by carrying out appropriate technical and analytical evaluations.

Process conformity

The production process has to be kept under adequate control with a Quality Assurance System that has to be conceived so as to be able to guarantee and document that the product responds to the relevant technical specifications and that these specifications comply with the product design.

The Quality Assurance System has to be adapted so as to proffer sufficient attention to the more critical points of the production system that might endanger the attainment of both legislative, technical and qualitative conformity of the end product.

Documentation of procedure/instructions

Every production phase related to the GMP Regulation has to be regulated through adequate documentation. Examples of documentation can be: manuals, procedures, working instructions, technical rules and registrations. The documentation required to perform the activity must be at the disposition of the appointed personnel, must be kept updated and the distribution of the same must be controlled, so that non updated information is speedily withdrawn.

B1.2.2. Quality Control System (Regulation (EC) 2023/2006, art. 6)

The producer should establish and maintain an effective Quality Control System capable of ensuring the respect of the conformity to the Regulation as laid down in the general guideline.

The system should include procedures that envisage all the necessary controls, the relative registrations and actions to be carried out in the event of lack of conformity.

All the documentation has to be available for the Competent Authorities that demand to see it in accordance with the Regulation (EC) 2023/2006 as amended.

The rules and the procedures have to cover the entire production process, as described in paragraph B1.2.1.2, also including a part that deals with the handling of any non-conformities and corrective actions.

B1.2.2.1. Management of raw materials warehouses

The approved starting materials from qualified suppliers must be clearly separated from other starting materials that have not yet been homologated or that are from suppliers who are undergoing qualification or who have not been qualified.

For the latter materials a procedure must be established that authorizes their use in production only after the function laid down under the Quality Control System has confirmed the suitability of the material for use in production.

Any raw material subject to contestation has to be stored in a predefined area and clearly identified pending the clarification of the problem. Only the function as established under the Quality Control System is enabled to authorize any use of these materials.

The conditions of the environment, of the storage and handling of the storage areas must be such as to guarantee that there is no risk of deterioration of the material.

Particular attention must be paid about raw materials handling in order to avoid damaging which may make the materials unusable.

B1.2.2.2. Production controls

The Quality Control System has to be regulated by suitable procedures that guarantee that during the production process all the necessary controls are carried out to guarantee that the product conforms to the legal, technical and quality specifications defined during the design phase.

The traceability of the products through suitable registration of the raw material lots used, by the machine conditions set and registered during production and the quality controls also carried out on intermediate products and semi processed articles must be guaranteed.

The storage of the finished product and the shipment to the customer should only be enacted against procedures that enable the unequivocal documentation that the material has been controlled in all the established phases and that the final controls have ascertained the conformity of the same to all the requisites laid down in the design phase.

This conformity should be ascertained via the comparison between the control data collected and the values and/or tolerances entered in the product technical specifications or the specific legislation.

As an example, some characteristic parameters that can be kept under control are listed:

- mechanical features (UNI EN 546 part 2);
- dimensional tolerances (UNI EN 546 part 3);
- special property requirements (UNI EN 546 part 4);

A special attention must be paid to the control of possible contaminations. Suitable procedures must take this risk into account and must document how it can be prevented (orderly machine and tools cleaning, hygiene of the personnel and of the workplace, prevention against bugs and rodents, etc.).

B1.2.2.3. Quality Control of finished products

The Quality Control System has to dispose of suitable procedures for controlling the finished product. In verifying the conformity of the finished product, the function laid down under Quality Control System has to use the information available on raw materials and on the process applied to highlight any limitations and restrictions of use for food contact. Control evidences must be appropriately recorded.

The goals achievable through controls of finished products are the following:

- conformity of packaging materials to the applicable legislation for food contact;

– in absence of specific legislative parameters, when elements to assess the product are available, the conformity to performance requirements agreed during the negotiation phase.

B1.2.2.4. Management of finished products warehouses

The Quality Assurance System should establish a procedure to authorize the storage of finished products. The authorization for storage of the products and for their delivery to customers should be given by the function laid down under the Quality Control System, after performing all the controls provided for by the relevant procedures to ascertain the suitability of finished products for their intended use.

The approved finished products should be clearly separated, or in any case clearly labelled from those that still have to be controlled or subject to further controls as to their suitability.

For any products that are declared as unsuited, a procedure should be available to block the progress of production step pending the definition of the problem. Any derogations are only to be authorized by the function established under the Quality Control System.

The unsuited products, clearly identified, should be kept separated in a predefined area in order to impede their storage, or they should be in any case clearly labelled.

Any finished products returned by customers due to non-conformity, should be kept in a predefined area and clearly identified, or in any case clearly labelled, pending the definition of the contestation. Segregation of non-compliant material may also be accomplished through system constraints other than physical segregation in a specially engaged area (i.e., informatics' block via IT system). Only the function laid down under the Quality Control System is allowed to authorize any use of these materials.

The environmental conditions of storage of the areas in question have to be such as to guarantee that there is no risk of deterioration of the material.

Special attention should be paid during handling operations in order to avoid damaging that may make the material useless.

B1.2.2.5. Distribution, shipment and delivery

The producer, if responsible for the transport and the delivery of the material to its destination, has to also guarantee that this phase is regulated by instructions and procedures that guarantee the quality of the material preserving it from any damage and contamination risk that might compromise its use or suitability.

If the means of transport are the property of the packaging producer, it must be ensured, also by periodic checks, that these are suited for transporting goods and that maintain the requisites of safety and hygiene required to guarantee the integrity of the product.

If the delivery is via external couriers, a procedure should be established that qualifies the courier and a technical contract should be defined that sets the minimum requisites to be respected to eliminate possible risks (i.e., damage, contamination, etc.).

B1.2.2.6. Conformity of the application of the GMP and claims management, corrective and preventive actions

The Quality Control System has to enact suitable procedures so as to monitor the correct implementation and total respect of the GMP.

The Quality Control System has to enact procedures for documenting the identification of lack of conformity, the enacting of any corrective measures and the monitoring of the implementation of the said measures, with particular attention to the time frame envisaged to implement the measures.

The Quality Assurance System of the Business should therefore be implemented to include periodical verification and control plans on conformity to pre-established parameters and specifications, relevant to compliance with legislation on FCMs; procedures for managing non conformities and corrective measures should be implemented.

B1.2.3. Documentation (Regulation (EC) 2023/2006, art. 7)

All the documents concerning the Quality Assurance System (procedures, specifications, formulations, etc.) and all the activity of the Quality Control System (instructions, registrations of control data, machine setup data, tolerances and measurements, etc.) have to be organized so as to constitute a paper or electronic archive, immediately accessible and easily consultable on request by the Competent Authorities.

The documents guaranteeing the traceability will also constitute an integral part of the same, as under art. 17 of the Regulation (EC) 1935/2004 as amended, the copies of the declarations of compliance issued by the customers in observance of the applicable national dispositions, and the supporting documentation. This documentation will also include any conditions for tests, calculations and analyses, carried out by internal and external laboratories, that serve to demonstrate conformity.

B1.2.4. References

Technical norms

UNI EN 602. *Alluminio e leghe di alluminio - Semilavorati - Composizione chimica dei semilavorati utilizzati nella fabbricazione di oggetti destinati al contatto con gli alimenti.* Milano: Ente Nazionale Italiano di Unificazione, 2007.

UNI EN 546-1. *Alluminio e leghe di alluminio – Foglio sottile – Parte 1: Condizioni tecniche di fornitura e di collaudo.* Milano: Ente Nazionale Italiano di Unificazione, 2007.

UNI EN 546-2: *Alluminio e leghe di alluminio – Foglio sottile - Parte 2: Caratteristiche meccaniche.* Milano: Ente Nazionale Italiano di Unificazione, 2007.

UNI EN 546-3. *Alluminio e leghe di alluminio – Foglio sottile - Parte 3: Tolleranze dimensionali.* Milano: Ente Nazionale Italiano di Unificazione, 2007.

UNI EN 546-4. *Alluminio e leghe di alluminio – Foglio sottile - Parte 4: Caratteristiche particolari*. Milano: Ente Nazionale Italiano di Unificazione, 2007.

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Sinagra C, Priola E. Ruolo del lubrificante nei processi di stampaggio delle vaschette in alluminio per alimenti. Criteri di scelta dei lubrificanti alimentari utilizzati come coadiuvanti tecnologici. *Italia Imballaggio* 2007;5:145-52.

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Annex B1.1

Technical glossary

Alloying: Adding of metallic chemical elements to get alloys of controlled composition.

Aluminium foil: Aluminium thin strip obtained for cold rolling having a thickness ≤ 0.20 mm.

Aluminium alloy: Aluminium containing metallic elements in its chemical composition of alloying in which mass quantities of Al predominates.

Casting machine: Water-cooled equipment in use in the semi-continuous casting process, for the solidification of liquid aluminium and the formation of typical Slab for rolling process.

Chemical degreasing: Operation washing the surfaces of rolled strip by contact of the water solutions, acidic or alkaline and / or surfactants, and then washed in demineralized water. Drying takes place by "squeezing-rollers" and subsequent drying in a hot air tunnel. This operation is technologically feasible only for thickness ≥ 35μm.

Cold rolled: Product of the cold rolling with consequent strain hardening metal machining.

Cold rolling mill: System technology which reduces the thickness of cold-rolled by repeated passages through two rollers through which the crushing force is exerted necessary. The technologies currently in use provides several system solutions: two, four or multi-roll (six or over) mill, reversible or unidirectional rolling to one or more cages.

Cold rolling: Thickness reduction operation performed through cold rolling mills.

Container "smooth wall": Container obtained in a mould with plastic deformation processes characterized by smooth walls and a flat top of a few millimetres that allows using thermal bonding of a film for closure.

Container "wrinkle wall": Container that is obtained in a mould but without a real process of drawing. The container, although geometry defined, does not have smooth walls but numerous folds or wrinkles.

Containers foil: Aluminium thin strip obtained for cold rolling having a thickness ≥ 35 μm, with or without a final heat treatment normally used for forming semi rigid containers, trays and lids.

Continuous casting: The liquid metal is fluxed in between two water cooled rolls through which the liquid become solid and exit in the shape of a strip few mm thick wrapped immediately on Coils.

Converter foil (for flexible packaging): Aluminium thin strip obtained for cold rolling having a thickness around 5-8 μm, degreased thermally, intended to be printed, embossed, lacquer and/or coupled with other materials such as paper, plastic films, etc.

Dedrossing: Mechanical operation of dross elimination from the surface of the liquid before casting.

Degassing: Blowing gas inside the liquid metal for the removal of hydrogen and other unwanted impurities from the aluminium bath.

Doubling: Preparatory phase to final step of thin foil rolling passes, it consists of coiling together (doubled) two aluminium foils to be rolled together in the last finishing pass. The operation can be realized with special machine as parted work step or directly by the unwinding devices in the entry side of the finishing foil mill.

Emulsion for hot rolling: Fluid lubro-cooler obtained by emulsifying specific oil in water. It has the task of cool work roll and create the necessary lubrication conditions in the hot rolling process.

Filtering (ref. to casting process): Filtering operation performed on liquid metal during casting by passing the same through ceramic filters having a controlled porosity.

Final annealing: Heat-treatment carried out on the final thickness, with the aim of get the mechanical properties required and to perform thermal degreasing.

Folded container: Container with smooth walls with only corners folded geometrically.

Holding time: Stage prior to casting in which molten metal is left at rest in order to facilitate the separation of impurities removed with the dross by a skimming operation (dedrossing).

Homogenisation and/or pre-heating: Heat treatment run on plaques by rolling to appropriate temperatures in order to homogenize the metal structure and prepare the material to the next phase of hot rolling and cold.

Hot mill: Technological system that allows the reduction of thickness of hot plates by repeated passages through two rollers through which the crushing force is exerted necessary. The technologies currently in use provides several system solutions: Duo Mill or fourth, or one-way reversible rolling mill, one or more cages.

Hot rolling: Product lamination realized at a temperature higher than that of recrystallization typical metal machining

Intermediate annealing: Heat-treatment carried out on the cold rolled obtained by cold rolling mill, which restores the deformability conditions.

Primary aluminium: Aluminium not alloyed, obtained by electrolysis method from alumina and with a title of Al not less than 99.7%.

Refinement: Controlling grain size during solidification made by adding during the casting of an alloy of Al-TiB

Rolled product: Product of lamination of coil wrapped around a core.

Rolling in double: Operation especially thin lamination performed in the last step to final thickness directly on two sheets of aluminium dubbed together.

Rolling oil: Fluid lubro-cooler used in cold rolling composed of a mixture of kerosene with appropriate additives designed to cool properly the work rolls, allowing a better control of flatness of the rolled strip and create the necessary lubrication conditions during the rolling process itself.

Semi-continuous casting: The liquid metal is fluxed in an appropriate water-cooled ingot mould in which metal solidifies and take typical shape of a Slab for rolling process.

Separating: Separating and cutting the double rolled foil for obtaining the individual foil wrapped reel with the final dimensional requirements.

Slab for rolling: Product of parallelepiped size obtained via semi-continuous casting process in water and used in the next phase of hot rolling.

Slab scalping: Mechanical operation by removing depth variable on the external surfaces of the slab for the elimination of oxides, casting defects or other anomalies metallurgically linked to the semi-continuous casting process.

Thermal degreasing: Operation of evaporation of the rolling fluid through a final heat treatment.

Work-hardening (or strain hardening): Metallurgical phenomenon that leads to a hardening of the metal when it is cold forming.

Annex B1.2

Frequently asked questions

Q1 *What is meant by aluminium and aluminium alloys?*

In the DM 76 of 18 April 2007 the term aluminium includes both aluminium products containing the 99,0% minimum weight of aluminium (annex 1 of DM) and aluminium alloys that contain lower amounts of aluminium in conjunction with other alloying elements (annex 2 of DM).

Q2 *Is it allowed to use oils on aluminium foil and containers?*

Yes, it is. The DM 76 of 18 April 2007 in paragraph 4 allows the use of lubricants as processing aids for mechanical forming (via drawing press). For the choice of lubricants, refer to paragraph B1.1.3

Q3 *Is it allowed to use lubricants containing MCT (medium Chain Triglycerides) including the glyceroltricaprylate?*

Yes, it is. The possibility of safe use of lubricants including glyceroltricaprylate was reiterated by the Ministry of Health in the press release no. 22 of March 18, 2006 https://www.salute.gov.it/imgs/C_17_comunicati_906_testo.rtf

Q4 *What is it meant for coated aluminium?*

Coated aluminium means an article where aluminium is not in direct contact with food because of a coating with other materials.

Q5 *Which legislation applies to coated aluminium?*

The applicable legislation varies depending on the type of the applied coating. In fact only the layer directly in contact with food should meet the requirements of the applicable legislation

Q6 *Overall migration tests with the simulants should apply to articles of not-coated aluminium?*

The DM 76, April 18, 2007 provides that the compliance of the material in contact with food must be ensured by controlling through control of the chemical composition of aluminium and alloys as reported in the same DM.

Q7 *How do you choose a lubricant?*

Lubricants for use must not alter the organoleptic properties of food (article 3 of the Regulation (EC) 1935/2004 of 27 October 2004 as amended) and can be chosen from the following types:

1. paraffinic medicinal grade (satisfying the specifications of the official pharmacopoeia, latest edition) both semisolids (Vaseline) and liquids (oil Vaseline);
2. natural, synthetics esters obtained by reaction of natural acids and poly-alcohols or by modifying glycerides-or mixtures thereof.

For synthetic esters are esters of natural origin which may have undergone chemical processes trans-esterification or re-esterification in order to eliminate undesirable compounds that can impart negative attributes that come into contact with food. In practice these processes are indispensable to eliminate easily oxidizable compounds which may cause rancidity of oil.

To ensure this last feature such substances must exceed the 100-hour Rancimat® test (EN ISO 6886:2008) at 100°C and must not alter the organoleptic characteristics of food in accordance with the requirements of the European Regulation on materials and articles intended to come into contact with foodstuffs.

Q8 *Are there other reference documents for the production of thin and laminated sheets intended for the manufacture of aluminium trays?*

- Yes, the following documents may be useful:

- UNI EN 16773:2016 Guideline for the production of semi-thin sheet intended for the production of food trays and lids;
- UNI EN 15593: 2008 Packaging - Hygiene management in the production of packaging for food products - Requirements

B2. PAPER AND BOARD: PRODUCTION

B2.1. Characterization of the sector

B2.1.1. Field of application of the guideline

This guideline is applicable to companies producing paper and board from virgin fibre or paper for recycling until the development of sheet and its setting up in reels or sheets.

B2.1.2. Applicable legislation

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.[4]

Italian legislation

- Decree of the Italian 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.
- Italian Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- Italian 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 objects intended to come into contact with food.
- Ministerial Decree of 21st March 1973 on hygiene requirements of packages, containers and tools destined to come into contact with food or substances for personal use and following changes and integrations.

The following reference may be helpful:

- Ministry for Health Circular 24th January 2006 on materials and articles intended to come into contact with food: companies and food industry responsibilities.[5]

[4] It replaced the Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

[5] The circulars of the Italian Ministry for Health are tools issued in support of particular legislative aspects.

B2.1.3. Phases of the production process: flowchart and description

B2.1.3.1. Production flowchart

Figure B2.1 illustrates the flowchart to produce paper and board intended for sheet manufacturing and preparation in reels or sheets (the dashed part is compliant with the GMP Regulation (EC) 2023/2006 as amended).

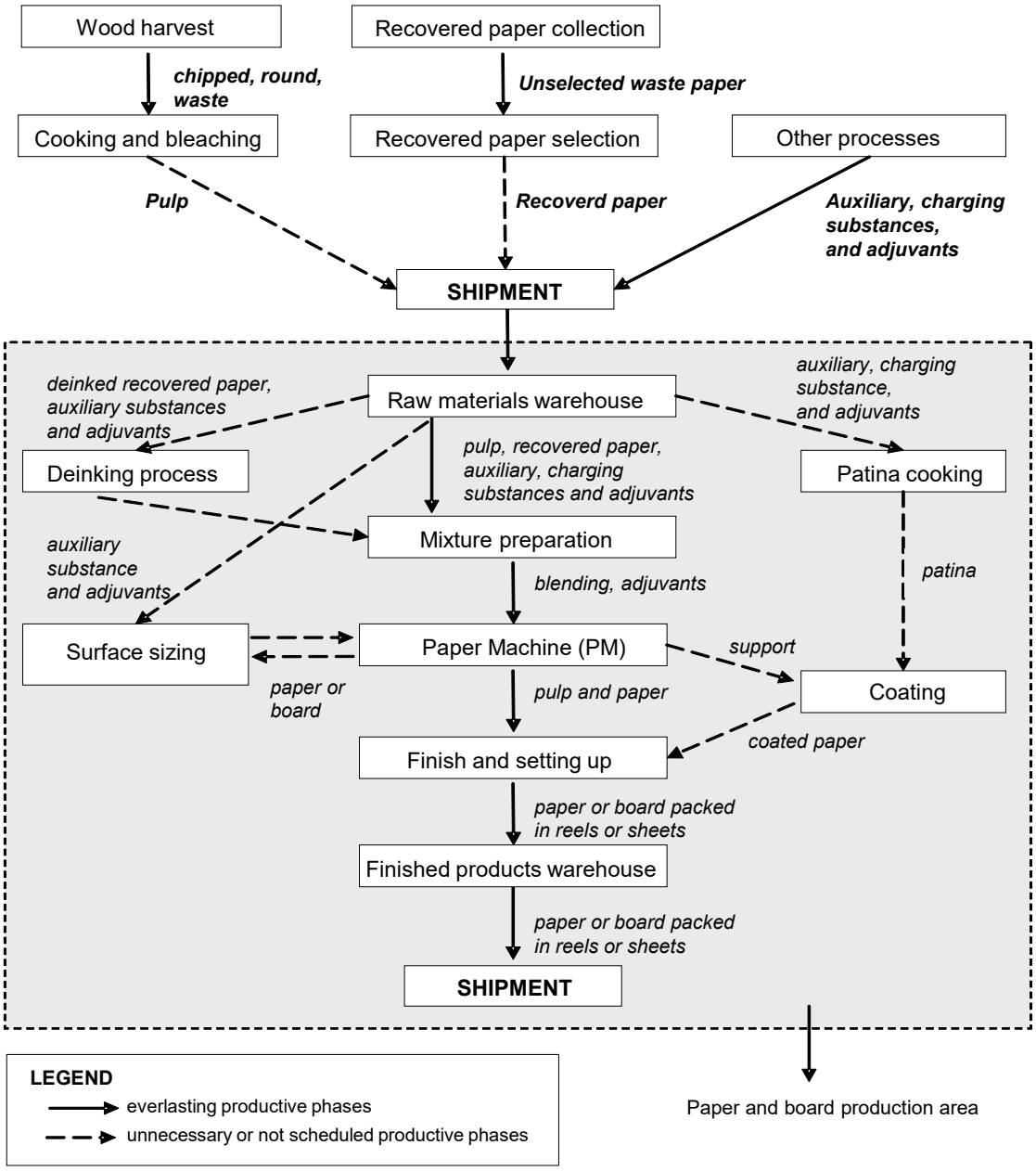


Figure B2.1. Production flowchart paper and board intended for sheet manufacturing and preparation in reels or sheets

B2.1.3.2. Brief description of process phases

Raw materials warehouse

Raw materials (pulp, selected paper for recycling, auxiliary substances, charging and adjuvant substances) getting to the paper mill are checked to verify that they correspond to accompanying documents, do not result damaged even partially and that were packed following supplier request.

Once in the mill, raw materials are identified per grade and stored in the raw material warehouse, while quantities data and location of storage site are registered. Unsuitable material is properly identified and stored in a specific area left at this purpose.

Raw material ready for production is then taken out from raw material warehouse and sent to the mixing (mixture) division in accordance with quantity and quality required for specific productive grade.

Mixing (mixture) department

In the mixture division fibrous raw materials are duly treated to make them suitable to be used and then mixed amongst themselves and with auxiliary and charging substances on the basis of the proportion pointed out in the "formula". Pulp and/or paper for recycling is firstly sent to the pulper where pulp fibres are crumbled and suspended into water.

Then, fibres are sent to refiners where, through friction, raising of fibrils of pulp surface is obtained, so to allow fibres to increase capacity of binding when forming the sheet.

When using paper for recycling, refining is not always necessary but, in this case, the mixture is submitted to one or more cleaning (purge) phases, to remove impurities through proceedings mainly mechanical (filters and centrifugal purgers). Water suspension of fibres is therefore added with right proportions of auxiliary substances, such as mass adhesive and colouring agents, retentives and charging substances, necessary to mould the mixture ready for forthcoming preparation of paper sheet with required characteristics.

Deinking

For some grades of recycled papers, paper for recycling is submitted to one more step, called deinking where, due to the action of surfactants, a removal of inks is obtained. Then, bleaching action with oxidant agents can be carried out the so obtained fibre is ready to be used for the preparation of the mixture.

Paper machine

The mixture duly diluted is sent to the afflux case, which takes care of spreading it out with homogeneousness on a continuously moving band (wire section) on which fibres lay down and join while water drains in the below area. Then, the sheet is taken to a further and deep dehydration through pressing between rotating cylinders (wet press) just before being dried in the dry end, composed by a number of high temperature cylinders in which paper sheet passes by accompanied by two felts. When coming out the dry end, uninterrupted sheet is rolled up on a cylinder (pope), forming the paper reel.

Surface gluing

For some paper grades paper machine is equipped with a further phase called "size press", in which already formed sheet undergoes a surface gluing treatment to increase characteristics of mechanical strength and stiffness.

Coating cooking and coating

Some grades of paper are exposed to a further coating treatment, that can be performed in the same paper machine (coating on line) or afterwards (coating off line). Coating is a surface treatment on a paper sheet (support) laid down by deposition, on one or both sides, of one or more lays of pigments, so to allow a better aspect and printability. Coating that is prepared in its specific cooking, is a water dispersion of mineral pigments, binders and auxiliary substances mixed in right proportions.

Patina cooking and coating

Some grades of paper are exposed to a further coating treatment, that can be performed in the same paper machine (coating on line) or afterwards (coating off line). Coating is a surface treatment on a paper sheet (support) laid down by deposition, on one or both sides, of one or more lays of pigments, so to allow a better aspect and printability. Patina that is prepared in its specific cooking, is a water dispersion of mineral pigments, ligand and auxiliary substances mixed in right proportions.

Finish and setting up

Reels such as come out from paper machine can be directly addressed to the finished products warehouse or undergo to further processing.

With calendaring, sheet is to suffer a strong pressure amongst a series of coupling cylinders (one of rigid metal, the other made of flexible material) so paper can be smoothed and made lighter and homogeneous on the surface.

Embossing, instead, impresses a surface deformation to the sheet to make it possible a specific relief drawing.

With the respool, paper ribbon is wrapped up again on-board tubes and, eventually, cut in small reels.

Such lower reels can be finally cut in size, that is in sheets for the consignment to customer.

Reels, small reels or sheets, as for customer request, are finally wrapped-up, labelled, sometimes palletized ready to be sent to the finished products warehouse ready to be delivered to customer.

Finished products warehouse

Finished product, duly labelled, is stored in the finished products warehouse. Data on quantity and location of stored material are registered. Material which does not comply is duly identified and stored in a predefined place.

Delivery

Finished product ready for the delivery is taken out from the finished products warehouse as requested in the delivery plan and loaded on means of transport, accompanied by necessary documentation.

B2.2. Fulfilments deriving from the application of the Regulation (EC) 2023/2006

In this part are described the activities and the implementation enacted by paper and board production chain to conform to the Regulation (EC) 2023/2006 as amended. Since this Regulation was laid down when the quality assurance systems had already become a daily work tool in most of the manufacturing businesses, it is likely that paper companies already produce in conformity with technical specifications laid down by themselves.

All the same, should it be necessary, the Quality Assurance System and the Quality Control System should be extended to ensure:

> "[...] that the materials and articles are constantly manufactured and controlled, to ensure their conformity to 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" (art. 3 paragraph a Regulation (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006 as amended. Every paragraph is hence the response of the manufacturers of paper and board production chain to the requirements of the article in question. To facilitate reading, the paragraphs keep the same title as the article considered, while the subparagraphs indicate specific subjects.

B2.2.1. Quality Assurance Systems (Regulation (EC) 2023/2006, art. 5) and Size of the business

Quality Assurance Systems

Paper and board producer (paper mill) should establish and maintain a Quality Assurance System capable of ensuring the achievement of the objectives laid down by the Regulation and described in the general guideline.

The Quality Assurance System should be documented so as to enable control by the competent authorities.

The Quality Assurance System should establish rules and procedures that regulate the company activity, at least concerning the following points:

- conformity to the requisites of the legislation in force;
- human resources and training:
- raw materials and suppliers including suppliers of goods and services;
- production;
- quality control;
- storage, handling and shipment;
- complaints and corrective and preventive actions.

The system must ensure that the future legislative changes are adopted in all the phases of the company process also including the specifications and any contracts with qualified suppliers.

It is recommended to implement a procedure which enables the company to adopt the changes deriving from updates of the applicable legislation on FCMs for instance through the relevant industrial associations.

Size of the business

Independently from the business size, it should at any rate be guaranteed that the Quality Assurance System, as demanded and finalised by the Regulation (EC) 2023/2006 as amended, is always applied.

The system should be established, implemented and run taking into account the actual size and complexity of the company as well as the technical and human resources available.

On its own premises the business has to at any rate be capable of guaranteeing the application and running of the Quality Assurance and Quality Control System in order to obtain finished materials and products in compliance with the legislation in force on FCMs.

B2.2.1.1. Human resources and training

The *Business operator,* in compliance with the objectives of the Regulation (EC) 1935/2004 as amended and the Regulation (EC) 2023/2006 as amended is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 as amended is applied at all levels of their organization.

The operative aspects relating to the application of the provisions laid down in the Regulation (EC) 2023/2006 as amended can be entrusted by the Business operator to competent and adequately trained people that have to at any rate have at their disposition adequate means to ensure that the requisites of the Regulation (EC) 2023/2006 as amended are respected.

The *company organization* has to at any rate enable the location of the functions to enable inspection by the Competent Authorities.

All *company personnel* potentially involved, including the highest management levels, has to be informed on the principles of GMP, on the obligations that derive from the Regulation (EC) 2023/2006 as amended, on its objectives and on the policy for applying the Regulation.

The *business* should operate and implement procedures for identifying personnel training requirements and has to see to the training of all staff regarding the tasks that might affect the compliance to the said Regulation.

The *personnel* assigned to GMP control activities should be qualified on the basis of the training and the experience acquired.

An appropriate registration of the training process of all personnel must be kept.

B2.2.1.2. Production

The company production phase extends from planning of the formula to storage of the finished product.

This guideline is referred to the production of paper and board and therefore does not include successive transformation processes, such as corrugation, print, punching, coupling with other materials, filming, paraffinizing or bath with acids. If inside paper mills, also transformation works would be carried out, it will be necessary to make reference to specific guidelines, always realized within the CAST Project.

The production process includes all the company phases that combine to guarantee that the end product complies with the legislative, technical and performance requisites laid down at the planning phase to guarantee the suitability for intended use.

Hence the Quality Assurance System should comprise procedures that regulate all the phases listed hereafter:

- Planning of formula;
- Raw materials and goods and/or services suppliers selection;
- Raw materials arrival and storage;

- Control of raw materials;
- Manufacturing processes;
- Process parameters control;
- Production cycle control;
- Finished product and storage control.

The system should include a risk evaluation in each phase of productive cycle which may have an influence on suitability of material for contact with food.

Possible causes of contamination of the material when storing, working or moving has to be identified, kept under control, minimized or taken off where possible, through appropriate interventions. In the specific instance, the Council of Europe Resolution includes a list of possible hazards and relating prevention measures connected with the production of paper and board (i.e., Technical Document no. 4 for wrapping papers and boards).

Planning of formula

The most important concept implied by the GMP is that of a product designed to be compliant to the legislative requisites on materials and articles intended for food contact (FCMs).

Paper and board produced by mills should:

- meet with performances requirements for their final destination of use;
- meet with applicable legislative requirements on materials and articles intended for food contact.

To this aim, they have to be produced in accordance with a formula which considers only raw materials that, through control, guarantee in any phase of the process respect for final use and legislative requirements on materials and articles intended for food contact.

In a particular manner, raw materials, auxiliary and charging substances such as technological adjuvants must be in conformity with Ministerial Decree 21st March 1973 and following amendments and integrations.[6]

The formula has to be duly proved with documents. When an already existing formula is modified for the production of a new kind of paper and board intended to come into contact with food, the new formula will have to be checked and verified to prove its conformity.

Finally, paper mill has to show to customers possible changes that could modify the suitability to the use of supplied paper and board. It however stands responsibility of same customer to previously inform paper mill about what kind of use it is intended for purchased paper.

Raw materials and goods and/or services suppliers' selection

Paper mill is called upon to use only approved raw materials for which, through supplier information and/or inspections and tests, it has all the necessary data guaranteeing the conformity of the paper and board produced to the legislative requirements, including the restrictions due to conditions of use.

It is particularly important to select correctly virgin fibres and paper for recycling as a function of the destination of use of produced papers and boards.

Each supply of raw material has to be kept under adequate control.

It is good practise that the starting materials are procured from qualified suppliers. By qualification is meant a pre-established, organized and documented process that can also include supply contracts.

Furthermore, it is also suggested to verify, even through questionnaires or periodical inspective visits of inspections (audits), the Quality Assurance System for raw materials suppliers.

[6] This decree applies only in Italy.

Process conformity

The production process has to be kept under adequate control with a Quality Assurance System that has to be conceived so as to be able to guarantee and document that the produced paper and board responds to the relevant technical specifications.

The Quality Assurance System has to be finalized so as to proffer sufficient attention to the most critical points of the production system that might endanger the attainment of both legislative, technical and qualitative conformity of the end product.

Documentation of procedure/instructions

Every production phase has to be regulated through adequate documentation. Examples of documentation can be: manuals, procedures, working instructions, technical rules and registrations. The documentation required to perform the activity must be at the disposition of the appointed personnel, must be kept updated and the distribution of the same must be controlled, so that non updated information is speedily withdrawn.

B2.2.2. Quality Control System (Regulation (EC) 2023/2006, art. 6)

Paper and board producer (paper mill) should establish and maintain an effective Quality Control System capable of ensuring the respect of the conformity to the Regulation as laid down in the general guideline.

The system should include procedures that envisage all the necessary controls, the relative registrations and actions to be carried out in the event of lack of conformity.

All the documentation has to be available for the Competent Authorities that demand to see it in accordance with the Regulation (EC) 2023/2006 as amended.

The rules and the procedures have to cover the entire production process, as described in paragraph B2 1.3, also including a part that deals with the handling of any non-conformities and corrective actions.

B2.2.2.1. Management of raw materials warehouses

The approved raw materials from qualified suppliers must be clearly separated from other raw materials that have not been homologated or that are from suppliers who are undergoing qualification or who have not been qualified.

For the latter materials a procedure must be established that authorizes their use in production only after the function laid down under the Quality Control System has confirmed the suitability of the material for use in production.

Any non-compliant raw material subject to contestation has to be segregated in a predefined area and clearly identified pending suitable inspection or downgraded for a use other than food contact.

Only the function as established under the Quality Control System is enabled to authorize any use of these materials.

The conditions of the environment, of the storage and handling of the storage areas must be such as to guarantee that there is no risk of deterioration of the characteristics of the material which allow use for the production of articles intended to come into contact with food.

B2.2.2.2. Production controls

The Quality Control System has to be regulated by suitable procedures that guarantee that during the production process all the necessary controls are carried out to guarantee that the product conforms to the legal, technical and quality specifications defined during the design phase.

The traceability of the products through suitable registration of the machine conditions set and registered during production and the quality controls also carried out on intermediate products and semi processed articles must be guaranteed.

The storage of the finished product and the shipment to the customer should only be enacted against procedures that enable the unequivocal documentation that the material has been controlled in all the established phases and that the final controls have ascertained the conformity of the same to all the requisites laid down in the design phase.

This conformity should be ascertained via the comparison between the control data collected and the values and/or tolerances entered in the product technical specifications or the specific legislation.

Process phases to be kept under control are to be identified on the basis of a risk analysis and with reference to the legislative requirements applicable to FCMs.

B2.2.2.3. Quality Control of finished products

The Quality Control System has to dispose of suitable procedures for controlling the finished product. In verifying the conformity of the finished product, the function laid down under Quality Control System has to use the information available on raw materials and on the process applied to highlight any limitations and restrictions of use for food contact. Control evidences must be appropriately recorded.

The analyses must always be carried out using validated methods of analysis. If these methods do not exist, an analytical method with performance characteristics adapted to the specified limits may be used pending the drawing up of a validated method.

Measurement and analysis instruments are to be duly calibrated, and this operation is to be properly registered.

The goals achievable through controls of finished products are the following:

- conformity of paper and board to the applicable food contact legislation;
- in absence of specific legislative parameters, when elements to assess the product are available, the conformity to performance requirements agreed during the negotiation phase.

B2.2.2.4. Management of finished product warehouses

The Quality Assurance System should establish a procedure to authorize the storage of finished products. The authorization for storage of the products and for their delivery to customers should be given by the function laid down under the Quality Control System, after performing all the controls provided for by the relevant procedures to ascertain the suitability of finished products for their intended use.

The approved finished products should be clearly separated, or in any case clearly labelled from those that still have to be controlled or subject to further controls as to their suitability.

For any products that are declared as unsuited, a procedure must be prepared that prevents their storage pending the definition of the problem, or their downgrading. Any derogations are only to be authorized by the function established in the Quality Control System.

The unsuited products, clearly identified, should be kept separated in a predefined area in order to impede their storage, or they should be in any case clearly labelled.

Any finished products returned by customers due to non-conformity, should be kept in a predefined area and clearly identified, or in any case clearly labelled, pending the definition of the contestation. Only the function laid down under the Quality Control System is allowed to authorize any use of these materials.

The environmental conditions of storage of the areas in question have to be such as to guarantee that there is no risk of contamination of the materials.

Special attention should be paid during handling operations of the raw materials in order to avoid damaging that may make the material useless.

B2.2.2.5. Distribution, shipment and delivery

The paper mill, if responsible for the transport and the delivery of the material to its destination, has to also guarantee that this phase is regulated by instructions and procedures that guarantee the quality of the material preserving it from any contamination hazard that might compromise its suitability for food contact.

If the means of transport are the property of the customer, he will be called to ensure that these are suited for transporting goods and that maintain the requisites of safety and hygiene required to guarantee the integrity of the product.

If the delivery is via external couriers, a procedure should be established that qualifies the courier and a technical contract should be defined that sets the minimum requisites to be respected to eliminate possible hazards that may affect the conformity for food contact of the shipped paper and board.

B2.2.2.6. Conformity of the application of the GMP and claims management, corrective and preventive actions

The Quality Control System has to enact suitable procedures so as to monitor the correct implementation and total respect of the GMP.

The Quality Control System has to enact procedures for documenting the identification of lack of conformity, the enacting of any corrective measures and the monitoring of the implementation of the said measures, with particular attention to the time frame envisaged to implement the measures.

The Quality Assurance System of the business should therefore be implemented to include periodical internal verification and control plans on conformity to pre-established parameters and specifications, relevant to compliance with legislation on FCMs; procedures for managing nonconformities and corrective measures should be implemented.

B2.2.3. Documentation (Regulation (EC) 2023/2006, art. 7)

All the documents concerning the Quality Assurance System (handbooks, procedures, operating instructions, formulas, etc.) and all the activity of the Quality Control System (registration of data process, measurement etc.) have to be organized so as to constitute a paper or electronic archive, immediately accessible and easily consultable on request by the Competent Authorities.

The documents guaranteeing the traceability will also constitute an integral part of the same, as under art. 17 of the Regulation (EC) 1935/2004 as amended, the copies of the declarations of compliance issued by the customers in observance of art. 16 of the Regulation (EC) 1935/2004 as amended, the applicable national regulations, and the supporting documentation. This documentation will also include any conditions for tests, calculations and analyses, carried out by internal and external laboratories, that serve to demonstrate conformity.

In the event of substantial changes in production liable to change the essential requirements regarding compliance, or when the legislative benchmarks are modified and/or updated, it should be verified whether the documentation relating to the Regulation (EC) 2023/2006 as amended should be updated.

Annex B2.1

Technical glossary

Auxiliary and adjuvants substances: Ensemble of non-fibrous chemical substances, mainly of natural origin, used to give specific properties to paper or as technological adjuvants of process.

Charging substances (mineral pigments): Mineral substances mainly of natural origin such as carbonates, oxides and silicates, reduced in particles. They are used to regulate opacity, smoothness and capacity of absorbing inks both in paper and patination.

Formula: Proportion between different raw materials (pulp, auxiliary and charging substances) which are to be measured out during productive process to give paper requested characteristics.

Paper and board: Material in reels or sheets made out of fibres, mostly pulp (cellulose), with o without the addition of auxiliary substances and adjuvants, produced starting from a paper mixture for removal of water (rarely instead of water an organic solvent is used) through a chain links and subsequent drying process. It is instead preferred to call of board, usually, when grams of sheet exceed 225 gr. for square metre.

Pulp fibre: One of the main constituents of vegetables, in significant quantities in wood and annual plants. Fibre is constituted of a hollowed tube containing pulp developing while plant is growing. As for paper use, they are mainly divided in long fibres (prevailing in conifers) and short fibres (prevailing in broad-leaved). Other main element for wood is the lignin.

Pulp (more commonly called "cellulose"): Cellulose fibres, usually in form of rough, pressed and wrapped in bales sheets. In common meaning it is referred only to virgin fibres, even if it also gathers recovery fibres.

Recovered (paper): First raw material for recovery of cellulose fibre for the production of paper. Paper obtained with recovery fibres is called "recycled paper". Paper for recycling is classified below UNI EN Standard 643/2000 for their same composition and origin. It may be subject to selection treatment or directly selected at the origin.

Reel: Paper ribbon wrapped up on itself around a tube (core).

Virgin fibre: Pulp fibre obtained directly from wood and other seasonal plants with chemical or mechanical processes in which there is a separation of fibres and possible removal of lignin. Such removal take place through chemical disintegration. Presence of lignin is therefore unsteady depending on kind of process used (sulphate chemical pulp, or kraft, sulphite chemical pulp, semi-chemical pulp, chemo-thermomechanical pulp, thermomechanical pulp, mechanical pulp). Fibre can be exposed to a later stage of bleaching to get white quality.

Annex B2.2

Frequently asked questions

Q1 *Where is it possible to find reference on typical hazards connected with paper process related to compliance for food contact?*

In Technical Document nr. 4 of the Council of Europe Resolution on wrapping paper "Policy Statement concerning paper and board materials and articles intended to come into contact with foodstuffs", Version 1 (19.12.2002), a list regarding paper and board materials and articles intended to come into contact with food is provided, with connected hazards and relating prevention measures for wrapping paper and board production. Such list is approximate and cannot be considered exhaustive, as other hazards may be present related to specific manufacturing or, vice versa, some other hazards presented may not appear. As for tissue papers for food contact, one reference is chapter 8.4 of "Policy Statement concerning tissue paper kitchen towels and napkins", Version 1 (22.09.2004).

Q2 *When can we talk of "starting material"?*

With starting material is intended wood (rounds, chips, sawmill waste, etc.), pulp or paper for recycling.

Q3 *Where does GMP start for paper and board intended to come into contact with food?*

For paper, GMP obligation starts with phase of mixture preparation.

Q4 *Until where has paper and board for food contact traceability to get?*

For paper and board traceability has obligatory to get until first reel (parent reel).

Q5 *Is GMP to be applied also to tissue papers?*

For tissue papers, GMP is to applied when such products are realized for food contact and, for that use, identified in conformity with laws in act terms.

B3. PAPER & BOARD: CONVERTING

B3.1. Characterization of the sector

B3.1.1. Field of application of guideline

This guideline is applicable to all businesses that produce packaging in paper and cardboard independently of the materials that comprise the same. The paper and cardboard packaging cycle comprises the converting of paper and cardboard used on their own or in combination with primary and/or secondary packaging intended for contact with foodstuffs. For the starting raw materials reference should be made, where existing, to the guidelines of the specific material (plastic film, paper, aluminium, etc.).

B3.1.2. Applicable legislation

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.[7]

Italian legislation

- Decree of the Italian 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.
- Italian Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- Italian 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 objects intended to come into contact with food.
- Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, for contact with foodstuffs or substances for personal use as amended.

[7] It replaced the Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

The following reference may be helpful:

– Circular of the Italian Ministry of Health of 24th January 2006 on materials and articles intended for contact with food products: responsibility of the enterprises and the food industry[8].

B3.1.3. Phases of the production process: flowcharts and descriptions

B3.1.3.1. Production flowchart: Flat cardboard cartons

Figure B3.1 illustrates the flowchart to produce cardboard boxes (the dashed part is compliant with the GMP Regulation (EC) 2023/2006 as amended).

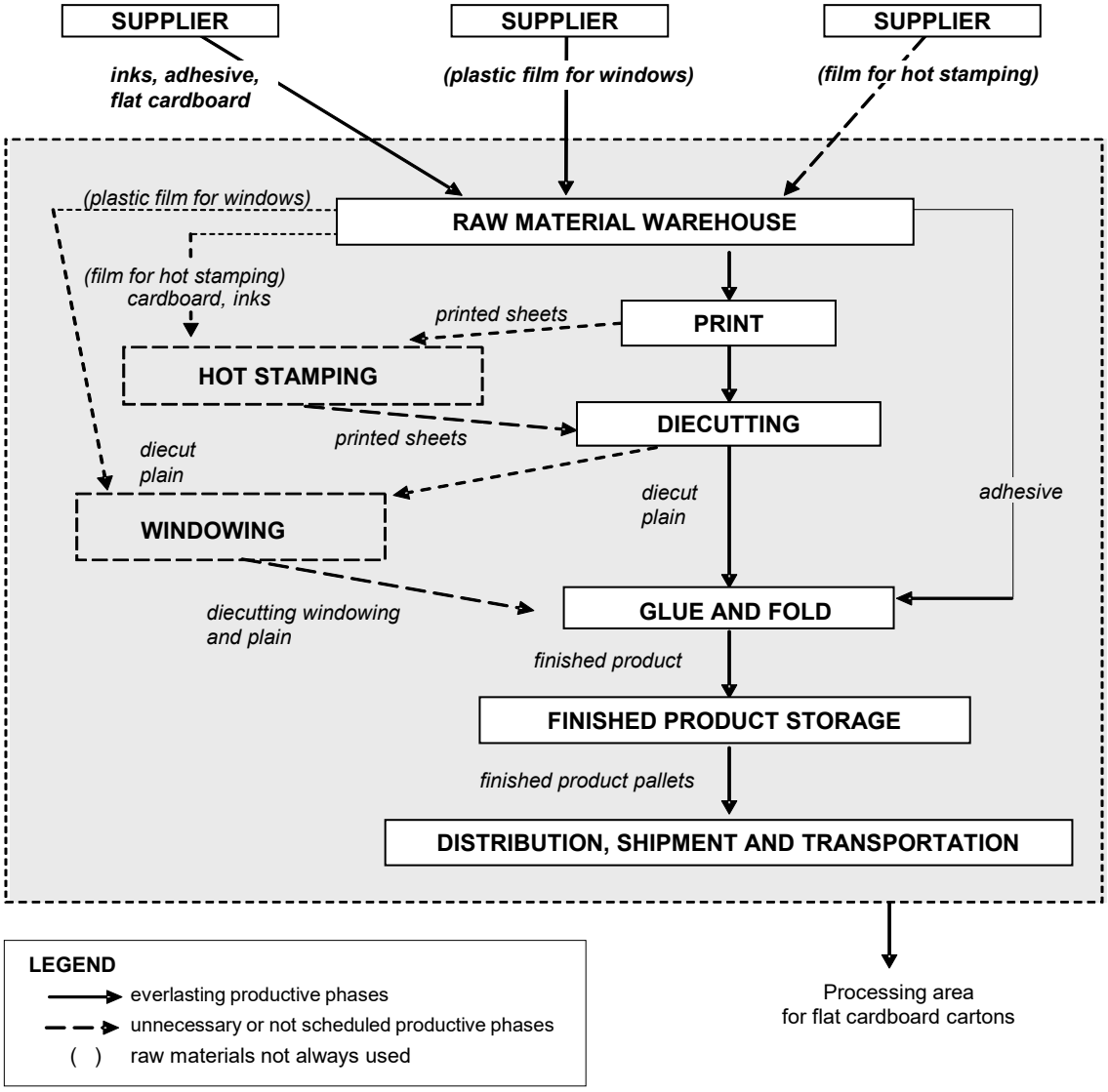


Figure B3.1. Production flowchart for cardboard boxes

[8] The circulars of the Italian Ministry for Health are tools issued in support of particular legislative aspects.

B3.1.3.2. Brief description of the process phases

Raw material warehouse

The raw materials that reach the converter are controlled to check whether they comply with the accompanying documents, are not damaged and they are packed according to the specifications agreed upon with the supplier. Samples of materials are taken to be handled over to Quality Control for the established controls. Any reservation as to incoming material is to be reported in written form on the product delivery note, in the copy that is left with the carrier. The pallets received, suitably identified in terms of type, format, thickness, etc. are to be stored in the raw material storage area according to the rules laid down in company procedures. The data regarding quantity and location are inserted in the operating system.
Should the shipment be blocked by Quality Control, the suitably identified and marked material, should be stored in the area for non-compliant raw materials up to the definitive solution of the problem.
When the material, not blocked by Quality Control, is transferred to the manufacturing section for processing, the protective packaging should be removed. Thus, just before using the carton, this has to be freed from the stretch film that wraps the same and any other type of packaging, except for the pallet that is required for handling. The material should be suitably identified to ensure that it is used correctly in production for the job it is intended for.

Offset printing

Offset implies a system of indirect printing, or that is without contact between the plate (matrix) and the print substrate, thanks to the interposition of a special cylinder covered with a rubberised fabric (caoutchouc) that transfers the ink graphisms from the plate (flexible zinc, aluminium or plastic plate) to the print substrate.
The print cycle includes a plate wetting phase – during which the wetting rollers distribute a watery solution that is retained in thin layer by the non-print hydrophilic metal parts (counter graphisms) – and a subsequent inking phase, via inking rollers that deposit the inks on the lipophilic parts forming the graphisms of the offset plate.
For some time now printing with UV inks has taken hold, inks that are polymerised via UV lamps placed after the print elements or at the end of the machine after the coating. Offset printing is essentially rotary printing using sheetfed or web offset or roto-offset. Roto-offset can be broken down into 'coldset' i.e. with cold drying and 'heatset' (normally used for printing packaging) with drying via hot air oven with gas or oil burners.

Flexographic printing

Flexographic printing is a direct print procedure via which cardboard sheets are printed (sheet flexo). Via the drip tanks that supply the colour, the cylinders (sleeves) mounted on the flexographic print machine transfer the ink to the substrate to be printed.
With multicolour printing and working on different substrates the printer can choose from numerous inks that differ in terms of pigment (colour) and polymeric matrix (depending on the print substrate). The print techniques differ depending on the type of inks that have been chosen:

– *water based inks*: the water is the solvent that keeps the ink liquid for its transfer to the substrate. The water needs to be stripped away after the print process and this is done using hot air ovens;
– *solvent based inks*: the solvent (generally ethyl acetate or mixes of alcohols) helps to keep the system liquid at the right viscosity. The highly volatile solvent fulfils the task of

facilitating the drying of the colour (and hence its fixing onto the substrate) in little time. Here too hot air ovens are used to strip the solvent.

Due to the greater surface tension of the substrate compared to the engraved plate the ink transfers to the substrate. Once the print operation has been terminated the cylinders (sleeves) are dismounted and after a thorough washing are stored away for reuse in the event of a reprint. The substrate printed in this manner can then be sent for subsequent processing.

Die-cutting and glue-n-fold

After printing the sheets are passed through a die-cutting machine in order to be cut, creased and subsequently folded in order to obtain the finished product. The print and die-cutting systems range from the single hand-operated machine to completely automated in-line processes.

The blank obtained can be directly supplied to the customer or transferred to glue-n-fold machines to obtain a vast range of cases and boxes.

Finished product storage

After the Quality Controls the final product, packed according to the specifications agreed upon with the customer, is allocated to the finished product storage according to the procedures that regulate the storage of finished products, so that the identification of the same is univocal. The data as to the quantity of product, its location in the storage area and any notations by Quality Control are inserted in the company's information system.

Distribution, shipment and transportation

Having established the delivery plan with the customer and that no blockages exist imposed by quality assurance, the final product, accompanied by the correct documentation (transport document, certificate of conformity etc.) is sent to its final destination via the use of carriers that must be part of the approved list of suppliers.

If the customer sees to retrieving the goods, except for the accompanying documents that are laid down by law, the responsibilities as to the homologation of the shipper come under the obligations of the final customer.

Note. Additional processes are generally not of a functional nature but are only to embellish the item. The only operation that needs be considered is the windowing, or that is the process that enables the application of a window in transparent plastic gluing the same on the inner side that is intended for food contact. In this case it is necessary that the plastic material corresponds to all the legal requisites regulating food contact for polymeric materials.

B3.1.3.3. Manufacturing flowchart: Corrugated cardboard boxes

Figure B3.2 illustrates the flow diagram for the production of corrugated cardboard boxes (the dashed part is compliant with the GMP Regulation (EC) 2023/2006 as amended).

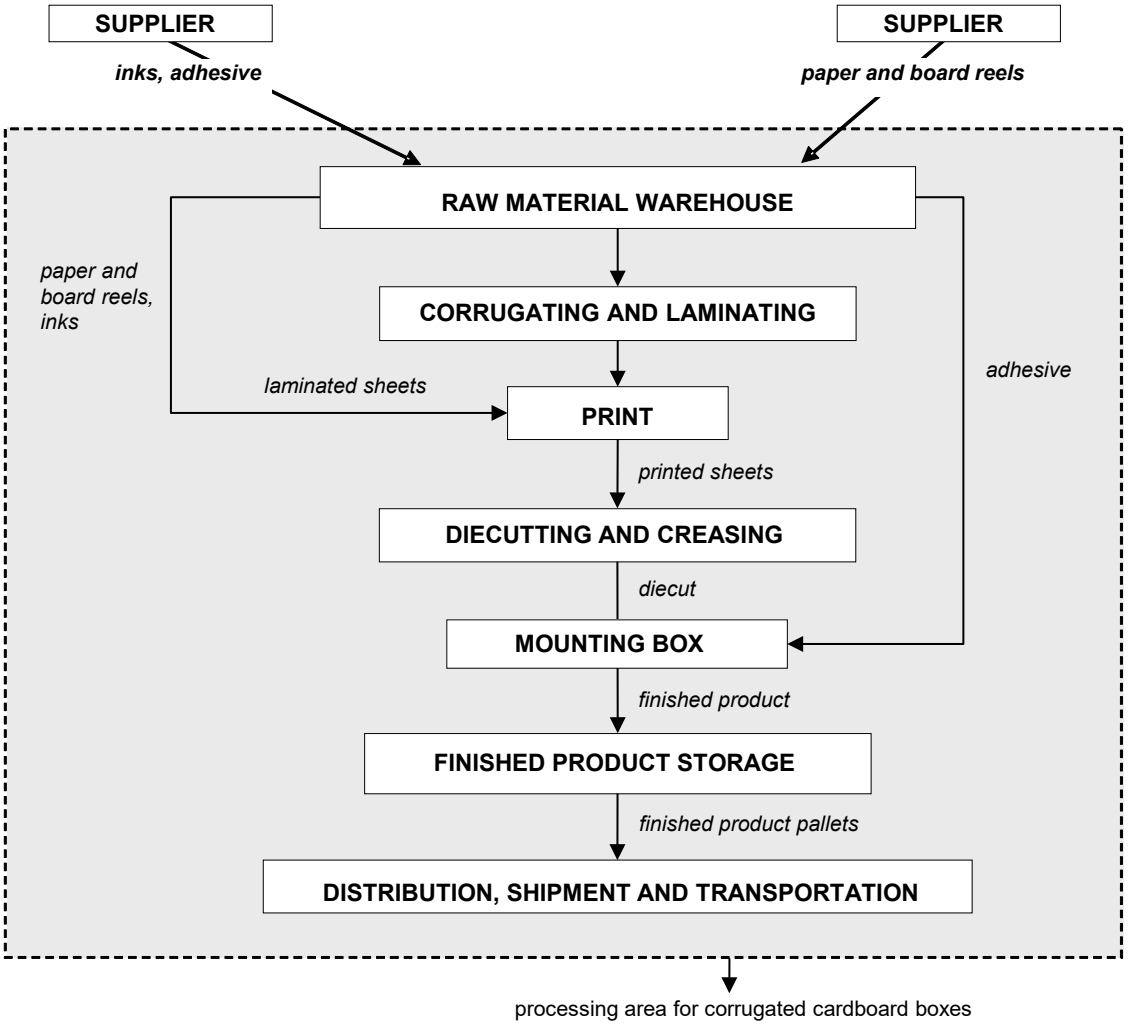


Figure B3.2. Production flowchart for corrugated cardboard boxes

B3.1.3.4. Basic description of the processing phases

Raw material warehouse

The raw materials that reach the converter are controlled to check whether they comply with the accompanying documents, are undamaged and packed according to the specifications agreed upon with the supplier. Samples of materials are taken to be handed over to Quality Control for the established controls. Any reservations as to incoming material have to be reported in written form on the product delivery note, in the copy that is left with the carrier.
The pallets received, suitably identified in terms of type, format, thickness, etc. are to be stored in the raw material storage area according to the rules laid down in company procedure. The data regarding quantity and location are inserted in the operating system.
Should the shipment be blocked by Quality Control, the suitably identified and marked material, should be stored in the area for non-compliant raw materials up to the definitive solution of the problem.

When the material, not blocked by Quality Control, is transferred to the manufacturing section for processing, the protective packaging should be removed. Thus, just before using the carton, this has to be freed from the stretch film that wraps the same and any other type of packaging except for the pallet that is required for handling. The material should be suitably identified to ensure that is used correctly in production for the job it is intended for.

Corrugating and laminating

Corrugated cardboard is produced with papers called Fluting, Medium and Liner that are combined with each other. Rolls of Fluting, Medium and Liner are "fed" into a machine that operates continuously and that is called a corrugator. The Fluting and Medium papers are conditioned using heat and steam and subsequently passed on two corrugator cylinders that give the paper the corrugate shape required (this station in the production system being commonly defined as "corrugator"). Applying starch-based glues on the tip of the corrugate and pressing the same on a liner a continuous strip of flute/liner is obtained. The corrugate/liner thus obtained is conveyed towards a hot surface gluer, that applies the glue on the uncovered corrugates, that are pressed by the hot surface onto the external liner of the corrugated cardboard. Several corrugate/liner strips can be glued together to obtain double or triple corrugated cardboard.

Print

Generally, the most typical print process used for producing corrugated cardboard boxes and containers is flexography, but offset print can also be used. Both the sheet processes have already been described for flat board. In the case of corrugated cardboard, the machines need to be reset for working with heavier, thicker and stiffer materials than card.

Die-cutting and creasing

As already described die-cutting is that process by which the shape of the box is obtained from the printed sheet through a process of cutting with a die that cuts the sheet of corrugated cardboard following a defined profile that corresponds to the box itself. Given the stiffness of the material, often during the die-cutting the sheet is creased, that is in some parts the cut stops short of penetrating the entire thickness to facilitate the folding during the subsequent stage of mounting the box. The die-cutters can be manual (here on more often speaks of platens) or automatic (called die-cutters or auto platens).

Mounting the box

After having removed the swarf from the die-cut piece or pieces (operation known as flaking) the same go on to the mounting phase that can be entirely manual, entirely mechanised (with fold-n-glue machines) or can be partially automated and partially manual.
The operation though always consists in glue spreading phases (water based vinylic) or a hot melt glue of phases of folding and subsequent gluing phases. At the end of this one has the box, not completely mounted, that though has all the characteristics of the finished product.

Finished product storage

After the Quality Controls the final product, packed according to the specifications agreed upon with the customer, is allocated to the finished product storage according to the procedures that regulate the storage of finished products so that the identification of the same is univocal.

The data as to the quantity of product, its location in the storage area and any notations by Quality Control are inserted in the company information system.

Distribution, shipment and transportation

Having established the delivery plan with the customer and that no blockages exist imposed by quality assurance, the final product, accompanied by the correct documentation (transport document, certificate of conformity etc.) is sent to its final destination via the use of shippers that must be part of the approved list of suppliers.

If the customer sees to retrieving the goods, except for the accompanying documents that are laid down by law, the responsibilities as to the homologation of the shipper come under the obligations of the final customer.

B3.1.3.5. Manufacturing flowchart: Paper bags

Figure B3.3 illustrates the flow diagram to produce paper bags (the dashed part is compliant with the GMP Regulation (EC) 2023/2006 as amended).

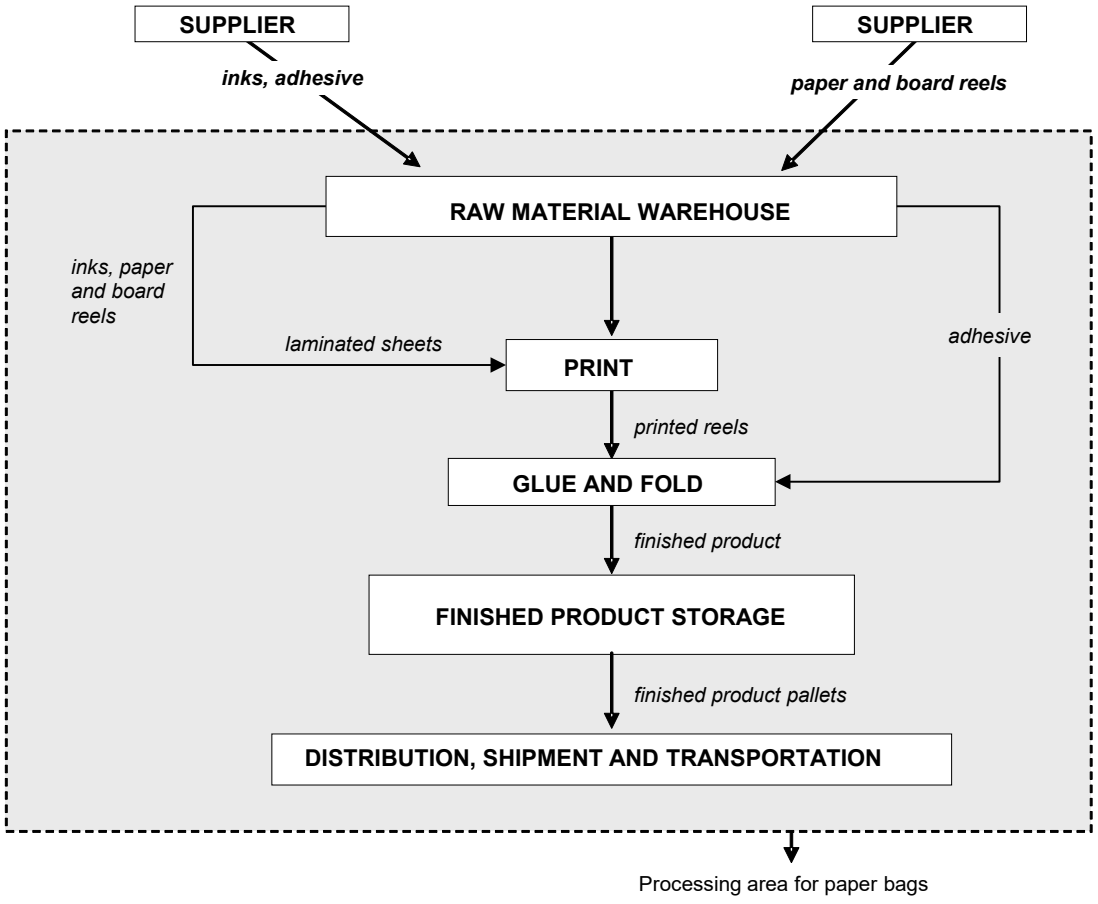


Figure B3.3. Production flowchart for paper bags

B3.1.3.6. Basic description of the processing phases

Raw material warehouse

The raw materials that reach the converter are controlled to check whether they comply with the accompanying documents, are undamaged and packed according to the specifications agreed upon with the supplier. Samples of materials are taken to be handed over to Quality Control for the established controls. Any reservations as to incoming material have to be reported in written form on the product delivery note, in the copy that is left with the shipper.
The pallets received, suitably identified in terms of type, format, thickness, etc. are to be stored in the raw material storage area according to the rules laid down in company procedure. The data regarding quantity and location are inserted in the operating system.
Should the shipment be blocked by Quality Control, the suitably identified and marked material, should be stored in the area for non-compliant raw materials up to the definitive solution of the problem.
When the material, not blocked by Quality Control, is transferred to the manufacturing section for processing, the protective packaging should be removed. Thus, just before using the carton, this has to be freed from the stretch film that wraps the same and any other type of packaging except for the pallet that is required for handling. The material should be suitably identified to ensure that is used correctly in production for the job it is intended for.

Print

In this case work is no longer from sheets but from paper rolls that are printed using a continuous flexographic system, hence a winder for producing rolls of printed paper is positioned at the machine outfeed.

Glue-n-fold

The printed rolls are processed using special automatic machine that see to the forming of the bag through a process that includes glue phases with naturally based (deriving from casein) or water-based glues and folding and cutting phases. Stacks of bags are collected at the end of the line using automatic or manual systems.

Finished product storage

After the Quality Controls the final product, packed according to the specifications agreed upon with the customer, is allocated to the finished product storage according to the procedures that regulate the storage of finished products, in order that the identification of the same is univocal. The data as to the quantity of product, its location in the storage area and any notations by Quality Control is inserted in the company information system.

Distribution, shipment and transportation

Having established the delivery plan with the customer and that no blockages exist imposed by quality assurance, the final product, accompanied by the correct documentation (transport document, certificate of conformity etc.) is sent to its final destination via the use of carriers that must be part of the approved list of suppliers.
If the customer sees to retrieving the goods, except for the accompanying documents that are laid down by law, the responsibilities as to the homologation of the shipper come under the obligations of the final customer.

B3.2. Fulfilments deriving from the application of the Regulation (EC) 2023/2006

In this part are described the activities and the implementation enacted by paper and board converting chain to conform to the Regulation (EC) 2023/2006 as amended. Since this Regulation was laid down when the quality assurance systems had already become a daily work tool in most of the manufacturing businesses, it is likely that these businesses already produce in conformity with technical specifications laid down by themselves.

All the same, should it be necessary, the Quality Assurance System and the Quality Control System should be extended to ensure:

> "[...] that the materials and articles are constantly manufactured and controlled, to ensure their conformity to 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" (art. 3 paragraph a Regulation (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006 as amended. Every paragraph is hence the response of the manufacturers of the paper and board converting chain to the requirements of the article in question. To facilitate reading, the paragraphs keep the same title as the article considered, while the subparagraphs indicate specific subjects.

B3.2.1. Quality Assurance Systems (Regulation (EC) 2023/2006, art. 5) and Size of the business

Quality Assurance Systems

The producer of packaging in paper or board (producer) should establish and maintain a Quality Assurance System capable of ensuring the achievement of the objectives laid down by the Regulation and described in the general guideline.

The Quality Assurance System should be documented so as to enable control by the competent authorities.

The Quality Assurance System should establish rules and procedures that regulate the company activity, at least concerning the following points:

- conformity to the requisites of the legislation in force;
- human resources and training:
- raw materials and suppliers including suppliers of goods and services;
- production;
- quality control;
- storage, handling and shipment;
- complaints and corrective and preventive actions.

The system must ensure that the future legislative changes are adopted in all the phases of the company process also including the specifications and any contracts with qualified suppliers.

Size of the business

Independently from the business size, it should at any rate be guaranteed that the Quality Assurance System, as demanded and finalised by the Regulation (EC) 2023/2006 as amended, is always applied.

The system should be established, implemented and run taking into account the actual size and complexity of the company as well as the technical and human resources available.

On its own premises the business has to at any rate be capable of guaranteeing the application and running of the Quality Assurance and Quality Control System in order to obtain finished materials and products in compliance with the legislation in force on FCMs.

B3.2.1.1. Human resources and training

The *Business operator,* in compliance with the objectives of the Regulation (EC) 1935/2004 as amended and the Regulation (EC) 2023/2006 as amended is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 as amended is applied at all levels of their organization.

The operative aspects relating to the application of the provisions laid down containing in the Regulation (EC) 2023/2006 as amended can be entrusted by the Business operator to competent and adequately trained people that have to at any rate have at their disposition adequate means to ensure that the requisites of the Regulation (EC) 2023/2006 as amended are respected.

The *company organization* has to at any rate enable the location of the functions to enable inspection by the Competent Authorities.

All *company personnel* potentially involved have to be informed on the principles of GMP, on the obligations that derive from the Regulation (EC) 2023/2006 as amended, on its objectives and on the policy for applying the Regulation.

The *business* should operate and implement procedures for identifying personnel training requirements and has to see to the training of all staff regarding the tasks that might affect the compliance to the said Regulation.

The *personnel* assigned to GMP control activities should be qualified on the basis of the training and the experience acquired.

An appropriate registration of the training process of all personnel must be kept.

B3.2.1.2. Production

The company production phase extends from design and planning to storage of the finished product.

The production process includes all the company phases that combine to guarantee that the end product complies with the legislative, technical and performance requisites laid down at the planning phase to guarantee the suitability for intended use.

Hence the Quality Assurance System should comprise procedures that regulate all the phases listed hereafter:

- Design and development of the product;
- Selection of starting material and suppliers including suppliers of goods and services;
- Arrival of raw material and storage;
- Control of raw material;
- Production processes and traceability of the raw materials used;
- Control of process parameters;
- Control during production;
- Control of the finished product and placing in storage.

During all the phases listed above an evaluation of the risks of contamination should be made identifying the potential sources and the actions to prevent the same.

Design and development of the product

The most important concept implied by the GMP is that of a product designed to be compliant to the legislative requisites on materials and articles intended for food contact (FCMs).

Distinctions can be made between the design of a product and the adaptation of a product to the requirements of a customer, who may have a product developed for a specific use subsequently suited to the precise and different demands of a customer.

If a producer develops a product compliant to a project for conformity of use, then packaging material produced must:

- comply with the performances for the final use it is intended for;
- comply with the requisites of the legislation in force for materials intended for food contact.

To this purpose the product has to be produced with raw materials that, subject to controls, guarantee, in all the process phases, the compliance to use the same are intended for and the legislative requisites covering food contact. To enable the development of a project of a packaging compliant to customer requisites the following information has to be known and available:

- nature of the food product to be packed;
- surface/volume ratio;
- shelf life of the product to be packed;
- filling, closure and preservation techniques of the final pack;
- thermal preservation processes that the pack along with its contents will be subjected to.

When an already existing packaging material is adapted to the requisites of a new product launch the initial project has to be recontroled and verified to make sure it complies to the new use.

To ensure that the project of conformity of a packaging item remains valid for the new use the necessary information has to at least include the data described above.

All the modifications on the original project have to be verified to control any undesired effects on the conformity of the product.

The requisites of the new packaging must be suitably documented.

Lastly, the producer has to indicate to the customer any possible changes that might in some way undermine the material's correspondence to the demanded requisites.

Selection of the starting materials and the suppliers of goods and/or services and/or third parties

The producer is called upon to use only approved starting material for which he has all the necessary data guaranteeing the conformity of the packaging produced to the legal requisites, including the restrictions due to conditions of use, this by way of information from the supplier and/or through controls and checks made during the design phase.

Observance of the following requisites should also be ensured:

- declaration of compliance according to what has been established by the applicable European and/or Italian legislation;
- traceability according to the Framework Regulation (EC) 1935/2004 as amended (where applicable);
- conformity to the Regulation (EC) 2023/2006 as amended (where applicable).

Any supply of starting material has to be kept under adequate control.

It is good practise that the starting materials are procured from qualified suppliers. By qualification is meant a pre-established, organized and documented process that can also include supply contracts. One is also advised to verify, also through periodical visits of inspection (audits) the Quality Assurance System of the supplier of starting materials or third parties to ascertain whether it is compliant with the requisites as laid down by the Regulation (EC) 2023/2006 as amended, where applicable.

Conformity of the production system

The production process has to kept under adequate control with a Quality Assurance System that has to be conceived so as to be able to guarantee and document that the product responds to the relevant technical specifications and that these specifications comply with the product design.

The Quality Assurance System has to be finalised so as to proffer sufficient attention to the most critical points of the production system that might endanger the attainment of both legislative, technical and qualitative conformity of the end product.

Documentation of procedure/instructions

Every production phase has to be regulated through adequate documentation. Examples of documentation can be: manuals, procedures, working instructions, technical rules and registrations. The documentation required to perform the activity must be at the disposition of the appointed personnel, must be kept updated and the distribution of the same must be controlled, so that non updated information is speedily withdrawn.

B3.2.2. Quality Control System (Regulation (EC) 2023/2006, art. 6)

The producer should establish and maintain an effective Quality Control System capable of ensuring the respect of the conformity to the Regulation as laid down in the general guideline.

The system should include procedures that envisage all the necessary controls, the relative registrations and actions to be carried out in the event of lack of conformity.

All the documentation has to be available for the Competent Authorities that demand to see it in accordance with the Regulation (EC) 2023/2006 as amended.

The rules and the procedures have to cover the entire production process, as described in paragraph B3 2.1.2., also including a part that deals with the handling of any non-conformities and corrective actions

B3.2.2.1. Management of raw materials warehouses

If not specified otherwise, the raw material should be used on the basis of the “first in first out” principle (rule of rotation by which the oldest material is the first to be used).

The approved starting materials from qualified suppliers must be clearly separated from other starting materials that have not been homologated or that are from suppliers who are undergoing qualification or who have not been qualified.

For the latter materials a procedure must be established that authorizes their use in production only after the function laid down under the Quality Control System has confirmed the suitability of the material for use in production.

Any non-compliant raw material and raw material subject to contestation has to be segregated in a predefined area and clearly identified pending suitable inspection.

The segregation of non-compliant material can also be carried out through system procedures other than that of physical separation in an especially defined area (IT blocking).

Only the function as established under the Quality Control System is enabled to authorize any use of these materials.

The conditions of storage must be such as to guarantee that there is no risk of contamination or deterioration of the material.

B3.2.2.2. Production controls

The Quality Control System has to be regulated by suitable procedures that guarantee that during the production process all the necessary controls are carried out to guarantee that the product conforms to the legal, technical and quality specifications defined during the design phase.

The traceability of the products through suitable registration of the raw material lots used, by the machine conditions set and registered during production and the quality controls also carried out on intermediate products and semi processed articles must be guaranteed.

The storage of the finished product and the shipment to the customer should only be enacted against procedures that enable the unequivocal documentation that the material has been controlled in all the established phases and that the final controls have ascertained the conformity of the same to all the requisites laid down in the design phase.

This conformity should be ascertained via the comparison between the control data collected and the values and/or tolerances entered in the product technical specifications or the specific legislation.

As an example, some characteristic parameters that can be kept under control are listed:

- size (print pitch, etc.);
- colour measure (density, etc.);
- print machine conditions;
- set-off.

B3.2.2.3. Quality Control of finished products

The Quality Control System has to dispose of suitable procedures for controlling the finished product. In verifying the conformity of the finished product, Quality Control has to use the information available on raw materials and on the process applied to highlight any limitations and restrictions of use for food contact.

Particular attention should also be paid to the test conditions used for carrying out the controls, which have to be suited to the verifications of the intended final use of the material.

The analyses must always be carried out using validated methods of analysis. If these methods do not exist, an analytical method with performance characteristics adapted to the specified limits may be used pending the drawing up of a validated method.

B3.2.2.4. Management of finished product warehouses

The approved finished products must be clearly separated from those that still have to be controlled or subject to further controls as to their suitability.

For any products that are declared as unsuited, a procedure must be prepared that prevents their storage pending the definition of the problem. Segregation of non-compliant material may also be accomplished through system constraints other than physical segregation in a specially engaged area (i.e., informatics' block via IT system). Any derogations are only to be authorized by the function established in the Quality Control System. The unsuited products, clearly

identified, must be segregated in a predefined area, different to that for the storage for the suited products.

Any finished products returned by customers due to non-conformity, have to be segregated in a predefined area and clearly identified pending the definition of the contestation.

It is advised that a procedure for managing non-compliant materials is set up also providing for their disposal or the destruction of the same.

The environmental conditions of storage of the areas in question have to be such as to guarantee that there is no risk of deterioration and/or contamination of the material.

B3.2.2.5. Distribution, shipment and delivery

The producer, if responsible for the transport and the delivery of the material to its destination, has to also guarantee that this phase is regulated by instructions and procedures that guarantee the quality of the material preserving it from any damage and contamination risk that might compromise its use or suitability.

If the means of transport are the property of the packaging producer, it must be ensured, also by periodic checks, that these are suited for transporting goods and that maintain the requisites of safety and hygiene required to guarantee the integrity of the product.

If the delivery is via external couriers, a procedure should be established that qualifies the courier and a technical contract should be defined that sets the minimum requisites to be respected to eliminate possible risks (i.e., damage, contamination, etc.).

B3.2.2.6. Conformity of the application of the GMP and claims management, corrective and preventive actions

The Quality Control System has to enact suitable procedures so as to periodically monitor the correct implementation and total respect of the GMP.

The Quality Control System has to enact procedures for documenting the identification of lack of conformity, the enacting of any corrective measures and the monitoring of the implementation of the said measures, with particular attention to the time frame envisaged.

B3.2.3. Documentation (Regulation (EC) 2023/2006, art. 7)

All the documents concerning the Quality Assurance System (procedures, specifications, formulations, etc.) and all the activity of the Quality Control System (instructions, registrations of control data, machine setup data, tolerances and measurements etc.) have to be organized so as to constitute a paper or electronic archive, immediately accessible and easily consultable on request by the Competent Authorities.

The documents guaranteeing the traceability will also constitute an integral part of the same, as under art. 17 of the Regulation (EC) 1935/2004 as amended, the copies of the declarations of compliance issued by the customers in observance of art. 16 of the Regulation (EC) 1935/2004 as amended and the applicable national regulations, and the supporting documentation. This documentation will also include any conditions for tests, calculations and analyses, carried out by internal and external laboratories, that serve to demonstrate conformity.

In the event of substantial changes in production liable to change the essential requirements regarding compliance, or when the legislative benchmarks are modified and/or updated, it should be verified whether the documentation relating to the Regulation (EC) 2023/2006 as amended should be updated.

Annex B3.1

Technical glossary

Basis weight: The weight of the cardboard expressed in grams per square metre (g/m2). The paper with a basis weight above 160 g/m2 is normally called cardboard, because this is the threshold after which a fibrous material has the sturdiness and stiffness that makes it suitable for constructing packaging. Most cardboard packaging has a basis weight of from 160 to 500 g/m2. The strip of corrugate/liner thus obtained is conveyed to a hot surface gluing device, that applies the glue to the exposed flutes, that are pressed via the hot surfaces on the external liner of the corrugated cardboard.

Coatings: There are different types of coatings, each of which has different properties and advantages. A cardboard surface is usually coated to preserve it from scratches or dirt. The coating can also be used to emphasize the brilliancy of the design or of a given detail. It can be applied directly on the cardboard during printing, or subsequently, during a separate process.

Compression resistance: When packaging articles are stored on top of each other, the lower layer naturally bears the greatest weight. To avoid collapse, the cardboard must have a good compressions resistance.

Corrugated cardboard: Corrugated cardboard is produced with papers called Fluting, Medium and Liner combined together. Several corrugate/liner strips can be laminated to each other to obtain double or triple corrugate.

Corrugator: The Fluting and Medium papers, fed from a roll; they are conditioned by heat and steam and subsequently posed on two corrugating cylinders that give the paper the required corrugate shape. By subsequently applying starch-based glues on the crest of the corrugate and pressing the same on a liner and continuous strip of corrugate/liner is obtained. The corrugate/liner thus obtained is conveyed towards a hot surface gluing machine, that applies the glue to the exposed corrugates, that are pressed using the hot surfaces on the external liner of the corrugated cardboard.

Creasing: To facilitate the folding of cardboard, a fold or crease line is created on the same. A perfect crease can be compared to a hinge and its purpose is that of producing the shape and function required for a given packaging article or other printed material.

Die-cutting: Die-cutting is that process by which the shape of the box is obtained from the printed sheet through a process of cutting with a die that cuts the sheet of corrugated cardboard following a defined profile that corresponds to the box itself. Given the stiffness of the material, often during the die-cutting the sheet is creased, that is in some parts the material is not cut all the way through, to facilitate folding during the subsequent stage of mounting the box. The die-cutters can be manual (here one more often speaks of platens) or automatic (called die-cutters or auto platens).

Dimensional stability: Resistance of the cardboard to dimensional modification due to the varying of some properties such as for example, humidity content. The dimensional stability is important during the print and converting stages, to avoid imperfections such as problems of register (see also “register”).

Embossing: This is a process that enables the cardboard to be permanently shaped according to a pattern or form in relief. Prior to embossing, the sheet of cardboard is often printed or laminated. If the relief is convex, it is defined as “positive”; if the process is by impression (concave), it is defined as “negative”. If the embossing is carried out without the piece being first printed, one speaks of blind embossing. The pattern or form created by the embossing can cover the entire surface of the piece.

Flatness: The capacity of the cardboard to remain flat (maintain its shape) during the print and converting processes.

Folding without creasing: this is when the cardboard sheet is folded without a crease line being traced beforehand. This operation is usually performed by a folding machine.

Folding/erecting: the operation via which, a previously die-cut and creased blank is assembled into a container or carton (from the blank to the box).

Gloss: The greater the quantity of light reflects by the surface of the board, the greater its gloss. This can be obtained with different types of coating.

Glue-n-fold: Automatic machine that enables the spreading of the blue (water based vinylic) or a hot melt adhesive after the die folding phase. The glued folding cartons are stacked at the end of line and compacted inside a corrugated cardboard box before being sent to storage.

Gluing/bonding: Uniting or more sheets of cardboard with an adhesive substance so as to create a single unit.

Grades of smoothness: It is the measure of the grade of smoothness of the surface of the cardboard. A smooth service is important for obtaining satisfactory printing and coating results.

Hot impression: A wording or design in metal lamina is applied using heat, often combined with embossing.

Lamination: the printed sheet is covered with a thin protective layer in plastic-metallic material, the laminate. Laminates can be shiny, matt and can be applied thanks to a special laminating machine. A laminate offers excellent protection against dirt, damp and wear. The same can also be for offering an aesthetic finish.

Machine direction: During the cardboard manufacturing process, the fibres are aligned parallel to the direction of the conveyor belt. This means that the cardboard is stiffer and sturdier in that direction. Hence the machine direction lies at a right angle to the width of the belt. In terms of creasing, creasing running across the machine direction is preferable to one parallel to the machine direction.

Opacity: Is the measure of the capacity of the cardboard, expressed in percent, to obscure that which is hidden behind it. A high percentage means cardboard with low transparency (high opacity). A cardboard sheet with 100% opacity is completely opaque. The degree of opacity depends how the light is diffused and absorbed by the material. A high opacity is important if the cardboard is to be printed on both sides.

Printing ink: Coloured pigment that is transferred to the print area with the aid of a transporting vehicle and hence fixed to the surface of the cardboard by fixing agents such as resins.

Printing with halftones: Print in which the colour images are formed by small dots (called halftone dots, that create a screen). The size of the dots determines the intensity of the colour. The combination of different colours creates the entire colour range.

Register: The situation that occurs when all the print inks are perfectly lined up in respect to each other (i.e., as in the case of four different coloured images in a four coloured print, or in the die-cutting, cutting and embossing sequence). Hence the print is out of register when the four coloured images are not perfectly overlapping, in that the resulting image is not clear and has colour blurred edges. To avoid problems of register it is important that the cardboard sheet is dimensionally stable.

Rigidity or stiffness: Stiffness is one of the most important characteristics of cardboard. The demand for stiffness or rigidity is constant along the entire chain, from shipping up to the positioning of the same on the shelf for the consumer. The cardboard can offer high rigidity per unit of weight. Without stiffness, the cardboard could not perform its primary function, that is protect the content of the packaging.

Screening: also called “screen frequency” or “resolution”; it indicates the number of lines of screen per unit of length, measured in lines per inch (lpi). The greater this is, the more detailed the picture. The type of cardboard and the choice of print method determines the screening that can be used during the print process.

Surface resistance: Is the capacity of the cardboard to withstand wear on its surface, such as for example that of the ink viscosity during printing: in fact, the cardboard surface should not be abrased during printing by the ink used during the process.

Tear resistance: Is the force needed to tear a sheet of cardboard along an existing engraved line. It is a property that is for example important in packaging with tear opening systems.

Thickness: The distance between the two surfaces of a sheet of cardboard, measured in microns (μ). The material used mostly for cardboard packaging has a thickness that varies between 300 and 800.

UV coatings: These are spread directly during the printing, as well as during a subsequent lacquering phase. It gives the surface gloss.

B4. FLEXIBLE PACKAGING

B4.1 Characterisation of the sector

B4.1.1. Field of application for the guideline

This guideline is applicable to all the companies that produce flexible packaging independently of the materials that comprise the same. For the starting raw materials reference should be made, where present, to the guidelines for the specific material (plastic films, paper, aluminium etc.). The flexible packaging chain includes paper, plastic film, regenerated cellulose, aluminium foil that are used on their own or in combination for primary and/or secondary packaging intended to be used in contact with food products. This definition specifically excludes stretch and heat shrink film used for secondary packaging of palletised products, shopping bags, supermarkets self-service bags, sealable neutral bags and big bags for transporting loose products. PVC films and other polymers sold for domestic use are also excluded, the same as aluminium foil sold directly to the consumers. The paper or cardboard based polylaminates for packaging liquid products do not come under the definition of flexible packaging.

B4.1.2. Applicable legislation

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.[9]
- Regulation (EC) 1895/2005 on the restriction of the use of certain epoxy derivates in materials and articles intended to come into contact with food.

Italian legislation

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

[9] It replaced the Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

- Italian 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 objects intended to come into contact with food.
- Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, intended to come into contact with food or substances for personal use as amended.

The following references may be helpful:

- Regulation (UE) 10/2011 on plastic materials and articles intended to come into contact with food.
- Circular of the Italian Ministry of Health of 24th January 2006 on materials and objects intended for contact with food products: responsibility of the enterprises and the food industry[10].

B4.1.3. Phases of the production process: flowchart and descriptions

B4.1.3.1. Production flowchart

Figure B4.1 illustrates the flowchart for the production flexible packaging (the dashed part is compliant with the GMP Regulation (EC) 2023/2006 as amended).

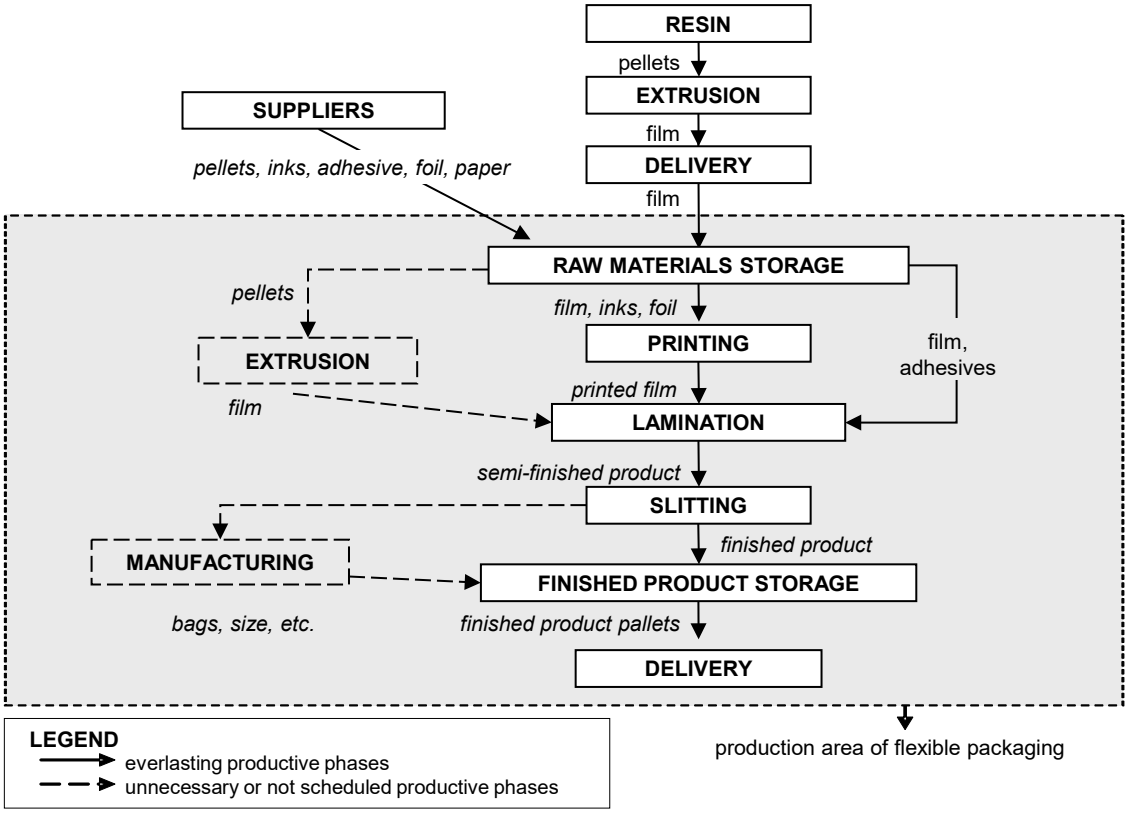


Figure B4.1. Production flowchart for flexible packaging

[10] The circulars of the Italian Ministry for Health are tools issued in support of particular legislative aspects.

B4.1.3.2. Brief description of the process phases

Raw material storage

The raw materials that reach the converter are controlled to check whether they comply with the accompanying documents, are not damaged and they are packed according to the specifications agreed upon with the supplier. If controls are laid down, samples are taken to be handed over to Quality Control.
Any reservations as to incoming material have to be reported in written form on the product delivery note, in the copy that is left with the carrier.
The starting material, suitably identified per type, dimensions etc, is to be stored in the raw material storage facilities according to the dispositions laid down by company procedures. Data regarding quantity and placement are to be inserted into the operating system.
In the event a raw material is blocked by Quality Control, this should be stored in the area for non-compliant raw materials up to the definitive solution of the problem.

Note*:* as far as the production of raw materials is concerned, see the production process described in the guidelines specific to the material (plastic, aluminium, paper, etc.)

Production phase

The print process for producing flexible packaging lays down the two possible print alternatives cited below.

Gravure printing

The essential elements for gravure printing are the substrate and the ink:

Substrate: a material that comes in web or roll form, of various formats and various thicknesses according to the type of product to be printed;

Inks: dealing with multicolour printing (up to 10 or 11 colours) also involving different substrates, the printer can choose from numerous inks that differ in terms of pigment (colour), polymeric matrix (depending on the print substrate); all inks are diluted with a solvent (generally ethyl acetate) that keeps the liquid system at the right viscosity. A highly volatile solvent facilitates the drying of the colour (hence the fixing to the substrate) in a brief period of time.

The engraved cylinders, one for each print unit, during production rotate on a shaft taking the ink from an underlying tray; a doctor blade (sharp steel blade) removes the excess ink so that it only remains in the engraved cell wells; the cylinder comes into contact with the substrate that unrolls across the print units and is kept in contact with the cylinders by a pressure roller. Due to the higher surface tension of the substrate in comparison with to the engraved and chromium plated cylinder, the ink transfers from the cells to the substrate.
Each print unit has a drying oven which, after being printed, the substrate enters, and the ink is dried and definitively attaches itself to the self-same substrate.

Flexographic printing

The cylinders (sleeves), complete with engraved plates, mounted on the flexographic print machine via the pans that supply the colour, transfer the ink to the substrate to be printed.
Dealing with multicolour printing (up to 10 colours) also involving different substrates the printer can choose from numerous inks that differ in terms of pigment (colour) and polymeric

matrix (depending on the print substrate) and per type of solvent used (water, organic solvent that is generally ethyl acetate or mixes of alcohols).
Due to the higher surface tension of the substrate compared to the engraved plate, the ink transfers to the substrate. The machine has a drying oven where the printed substrate enters and the solvent is "stripped" drying the ink.

Lamination

Lamination is the operation by which the printed film is laminated using an adhesive to one or more films that are normally of a polymeric nature. In the case of three or more layers the intermediate layer is aluminium foil.
In the flexible packaging sector, the lamination phase can be done in line with printing, if the machine has a laminating unit, or otherwise out of line, subsequently, on a second machine called a laminator.
The adhesive, normally bicomponent, can be solvent based (ethyl acetate) or solventless. For the solvent adhesives after the spreading on the substrate, via an engraved cylinder with very deep cells, an oven is used to strip the solvent and to start up the polymerisation of the adhesive proper. With the solventless adhesives polymerisation is via the mixing of the two components.
One of the films used for the lamination, of a polymeric nature, can be extruded by the company itself if the same has the right machine (extruder). This technique is described in the guidelines for plastic packaging.

Slitting

The rolls, if laminated after the suitable time for the maturing of the adhesive has passed (that can also be in a hot chamber with controlled humidity and temperature) are sent to the slitting section where the daughter rolls are constituted.
The said rolls are packed, labelled, palletized and sent to storage ready to be delivered to the customer.

Further processing

In some cases, the daughter rolls are worked on automatic machines in order to obtain bags of different types (flat bottomed, gusseted, etc.), heat formed containers (tubs and trays) or formats of different sizes (i.e., wrappings for easter eggs) that will be delivered to the customer as a final product.

Storage

After the Quality Controls the final product, packed according to the specifications agreed upon with the customer, is allocated to the finished product warehouse according to the procedures that regulate the storage of finished products, so that the identification of the same is univocal. The data as to the quantity of product, its location in the storage area and any notations by Quality Control are inserted in the company's information system.

Shipment

Having established the delivery plan with the customer and that no blockages exist imposed by Quality Assurance, the final product, accompanied by the correct documentation (transport document, certificate of conformity etc.) is sent to its final destination via the use of carriers that must be part of the approved list of suppliers.

If the customer sees to retrieving the goods, except for the accompanying documents that are laid down by law, the responsibilities as to the homologation of the carrier come under the obligations of the final customer.

B4.2. Fulfilments deriving from the application of the Regulation (EC) 2023/2006

In this part are described the activities and the implementation enacted by flexible packaging chain to conform to the Regulation (EC) 2023/2006 as amended. Since this Regulation was laid down when the quality assurance systems had already become a daily work tool in most of the manufacturing businesses, it is likely that converters already produce in conformity with technical specifications laid down by themselves.

All the same, should it be necessary, the Quality Assurance System and the Quality Control System should be extended to ensure:

> "[...] that the materials and articles are constantly manufactured and controlled, to ensure their conformity to 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" (art. 3 paragraph a Regulation (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006 as amended. Every paragraph is hence the response of the manufacturers of the flexible packaging chain to the requirements of the article in question. To facilitate reading, the paragraphs keep the same title as the article considered, while the subparagraphs indicate specific subjects.

B4.2.1. Quality Assurance Systems (Regulation (EC) 2023/2006, art. 5) and Size of the business

Quality Assurance Systems

The flexible packaging producer (converter) should establish and maintain a Quality Assurance System capable of ensuring the achievement of the objectives laid down by the Regulation and described in the general guideline.

The Quality Assurance System should be documented so as to enable control by the competent authorities.

The Quality Assurance System should establish rules and procedures that regulate the company activity, at least concerning the following points:

- conformity to the requisites of the legislation in force;
- human resources and training:
- raw materials and suppliers including suppliers of goods and services and third parties working under contract;
- production;
- quality control;
- storage, handling and shipment;
- complaints and corrective and preventive action.

The system must ensure that the future legislative changes are adopted in all the phases of the company process also including the specifications and any contracts with qualified suppliers.

Size of the business

Independently from the business size, it should at any rate be guaranteed that the Quality Assurance System, as demanded and finalised by the Regulation (EC) 2023/2006 as amended, is always applied.

The system should be established, implemented and run taking into account the actual size and complexity of the company as well as the technical and human resources available.

On its own premises the business has to at any rate be capable of guaranteeing the application and running of the Quality Assurance and Quality Control System in order to obtain finished materials and products in compliance with the legislation in force on FCMs.

B4.2.1.1. Human resources and training

The *Business operator,* in compliance with the objectives of the Regulation (EC) 1935/2004 as amended and the Regulation (EC) 2023/2006 as amended is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 as amended is applied at all levels of their organization.

The operative aspects relating to the application of the provisions laid down in the Regulation (EC) 2023/2006 as amended can be entrusted by the Business operator to competent and adequately trained people that have to at any rate have at their disposition adequate means to ensure that the requisites of the Regulation (EC) 2023/2006 as amended are respected.

The *company organization* has to at any rate enable the location of the functions to enable inspection by the Competent Authorities.

All *company personnel* potentially involved have to be informed on the principles of GMP, on the obligations that derive from the Regulation (EC) 2023/2006 as amended, on its objectives and on the policy for applying the Regulation.

The Business operator should operate and implement procedures for identifying personnel training requirements and has to see to the training of all staff regarding the tasks that might affect the compliance to the said Regulation. The personnel assigned to GMP control activities should be qualified on the basis of the training and the experience acquired.

An appropriate registration of the training process of all personnel must be kept.

B4.2.1.2. Production

The company production phase extends from design and planning to storage of the finished product.

The production process includes all the company phases that combine to guarantee that the end product complies with the legislative, technical and performance requisites laid down at the planning phase to guarantee the suitability for intended use.

Hence the Quality Assurance System should comprise procedures that regulate all the phases listed hereafter:

- Design and development of the product;
- Selection of starting material and suppliers;
- Arrival of raw material and storage;
- Control of raw material;
- Production processes and traceability of the raw materials used;
- Control of process parameters;

- Control during production;
- Control of the finished product and placing in storage.

During all the phases listed above an evaluation of the risks of contamination should be made identifying the potential sources and the actions to prevent the same.

Design and development of the product

The most important concept implied by the GMP is that of a product designed to be compliant to the legislative requisites on materials and articles intended for food contact (FCMs).

Distinctions can be made between the design of a product and the adaptation of a product to the requirements of a customer, who may have a product developed for a specific use subsequently suited to the precise and different demands of a customer.

In the event that a converter develops a product compliant to a project for conformity of use, that packaging material produced must:

- comply with the performances for the final use it is intended for;
- comply with the requisites of the legislation in force for materials intended for food contact.

To this purpose the product has to be produced with raw materials that, subject to controls, guarantee, in all the process phases, the compliance to use the same are intended for and the legislative requisites covering food contact. To enable the development of a project of a flexible packaging compliant to customer requisites the following information has to be known and available:

- nature of the food product to be packed;
- surface/volume ratio;
- shelf life of the product to be packed;
- filling, closure and preservation techniques of the final pack;
- thermal preservation processes that the pack along with its contents will be subjected to.

When an already existing packaging material is adapted to the requisites of a new product launch the initial project has to be recontroled and verified to make sure it complies to the new use.

To ensure that the project of conformity of a packaging item remains valid for the new use the necessary information has to at least include the data described above.

All the modifications on the original project have to be verified to control any undesired effects on the conformity of the product.

The requisites of the new packaging must be suitably documented.

Lastly, the converters have to indicate to the customer any possible changes that might in some way undermine the material's correspondence to the requisites demanded.

Selection of the starting materials and the suppliers of goods and/or services and/or third parties working under contract

The converter is called upon to use only approved starting material for which he has all the necessary data guaranteeing the conformity of the packaging produced to the legal requisites, including the restrictions due to conditions of use, this by way of information from the supplier and/or through controls and checks made during the design phase.

Observance of the following requisites should also be ensured:

- declaration of compliance according to what has been established by the applicable European and/or Italian legislation;
- traceability according to the Framework Regulation (EC) 1935/2004 as amended (where applicable);
- conformity to the Regulation (EC) 2023/2006 as amended (where applicable).

Any supply of starting material has to be kept under adequate control.
It is good practise that the starting materials are procured from qualified suppliers. By qualification is meant a pre-established, organized and documented process that can also include supply contracts.
It is advised to verify, also through periodical visits of inspection (audits), the Quality Assurance System of the supplier of starting materials or third parties to ascertain whether it is compliant with the requisites as laid down by the Regulation (EC) 2023/2006 as amended, where applicable.

Conformity of the production system

The production process has to be kept under adequate control with a Quality Assurance System that has to be conceived so as to be able to guarantee and document that the product responds to the relevant technical specifications and that these specifications comply with the product design.
The Quality Assurance System has to be finalized so as to proffer sufficient attention to the more critical points of the production system that might endanger the attainment of both legislative, technical and qualitative conformity of the end product.

Documentation of procedure/instructions

Every production phase has to be regulated through adequate documentation. Examples of documentation can be: manuals, procedures, working instructions, technical rules and registrations. The documentation required to perform the activity must be at the disposition of the appointed personnel, must be kept updated and the distribution of the same must be controlled, so that non updated information is speedily withdrawn.

B4.2.2. Quality Control System (Regulation (EC) 2023/2006, art. 6)

The flexible packaging producer (converter) should establish and maintain an effective Quality Control System capable of ensuring the respect of the conformity to the Regulation as laid down in the general guideline.

The system should include procedures that envisage all the necessary controls, the relative registrations and actions to be carried out in the event of lack of conformity.

All the documentation has to be available for the Competent Authorities that demand to see it in accordance with the Regulation (EC) 2023/2006 as amended.

The rules and the procedures have to cover the entire production process, as described in paragraph B4 2.1.2., also including a part that deals with the handling of any non-conformities and corrective actions.

B4.2.2.1. Management of raw materials warehouses

If not specified otherwise, the raw material should be used on the basis of the “first in first out” principle (rule of rotation by which the oldest material is the first to be used).

The approved starting materials from qualified suppliers must be clearly separated from other starting materials that have not been homologated or that are from suppliers who are undergoing qualification or who have not been qualified.

For the latter materials a procedure must be established that authorizes their use in production only after the function laid down under the Quality Control System has confirmed the suitability of the material for use in production.

Any non-compliant raw material and raw material subject to contestation has to be segregated in a predefined area and clearly identified pending suitable inspection.

The segregation of non-compliant material can also be carried out through system procedures other than that of physical separation in an especially defined area (IT blocking).

Only the function as established under the Quality Control System is enabled to authorize any use of these materials.

The conditions of storage must be such as to guarantee that there is no risk of contamination or deterioration of the material.

B4.2.2.2 Production controls

The Quality Control System has to be regulated by suitable procedures that guarantee that during the production process all the necessary controls are carried out to guarantee that the product conforms to the legal, technical and quality specifications defined during the design phase.

The traceability of the products through suitable registration of the raw material lots used, by the machine conditions set and registered during production and the quality controls also carried out on intermediate products and semi processed articles must be guaranteed.

The storage of the finished product and the shipment to the customer should only be enacted against procedures that enable the unequivocal documentation that the material has been controlled in all the established phases and that the final controls have ascertained the conformity of the same to all the requisites laid down in the design phase.

This conformity should be ascertained via the comparison between the control data collected and the values and/or tolerances entered in the product technical specifications or the specific legislation.

As an example, some characteristic parameters that can be kept under control are listed:

- size (gauges, web width, set print repeat, etc.);
- print machine conditions (temperature, tack, pressure, ink viscosity etc.);
- stoicometric ratios (for bi-component adhesives and/or inks);
- global and/or specific migrations (when called for);
- solvent residue (when called for);
- physical and mechanical properties (bond adhesion between layers, COF and slipperiness, sealability, etc.)
- set-off.

B4.2.2.3. Quality Control of finished products

The Quality Control System has to dispose of suitable procedures for controlling the finished product. In verifying the conformity of the finished product, Quality Control has to use the information available on raw materials and on the process applied to highlight any limitations and restrictions of use for food contact.

Particular attention should also be paid to the test conditions used for carrying out the controls, which have to be suited to the verifications of the intended final use of the material.

The analyses must always be carried out using validated methods of analysis. If these methods do not exist, an analytical method with performance characteristics adapted to the specified limits may be used pending the drawing up of a validated method.

B4.2.2.4. Management of finished products warehouses

The approved finished products must be clearly separated from those that still have to be controlled or subject to further controls as to their suitability.

For any products that are declared as unsuited, a procedure must be prepared that prevents their storage pending the definition of the problem. Any derogations are only to be authorized by the function established in the Quality Control System. The unsuited products, clearly identified, must be segregated in a predefined area, different to that for the storage for the suited products.

Any finished products returned by customers due to non-conformity, have to be segregated in a predefined area and clearly identified pending the definition of the contestation.

It is advised that a procedure for managing non-compliant materials is set up also providing for their disposal or the destruction of the same.

The environmental conditions of storage of the areas in question have to be such as to guarantee that there is no risk of deterioration and/or contamination of the material.

B4.2.2.5. Distribution, shipment and delivery

The converter, if responsible for the transport and the delivery of the material to its destination, has to also guarantee that this phase is regulated by instructions and procedures that guarantee the quality of the material preserving it from any damage and contamination risk that might compromise its use or suitability. If the means of transport are the property of the packaging producer, it must be ensured, also by periodic checks, that these are suited for transporting goods and that maintain the requisites of safety and hygiene required to guarantee the integrity of the product.

If the delivery is via external couriers, a procedure should be established that qualifies the courier and a technical contract should be defined that sets the minimum requisites to be respected to eliminate possible risks (i.e., damage, contamination, etc.).

B4.2.2.6. Conformity of the application of the GMP and claims management, corrective and preventive actions

The Quality Control System has to enact suitable procedures so as to periodically monitor the correct implementation and total respect of the GMP.

The Quality Control System has to enact procedures for documenting the identification of lack of conformity, the enacting of any corrective measures and the monitoring of the implementation of the said measures, with particular attention to the time frame envisaged.

B4.2.3. Documentation (Regulation (EC) 2023/2006, art. 7)

All the documents concerning the Quality Assurance System (procedures, specifications, formulations, etc.) and all the activity of the Quality Control System (instructions, registrations of control data, machine setup data, tolerances and measurements etc.) have to be organized so as to constitute a paper or electronic archive, immediately accessible and easily consultable on request by the Competent Authorities.

The documents guaranteeing the traceability will also constitute an integral part of the same, as under art. 17 of the Regulation (EC) 1935/2004 as amended, the copies of the declarations of compliance issued by the customers in observance of art. 16 of the Regulation (EC) 1935/2004 as amended and the applicable national regulations, and the supporting documentation. This documentation will also include any conditions for tests, calculations and analyses, carried out by internal and external laboratories, that serve to demonstrate conformity.

In the event of substantial changes in production liable to change the essential requirements regarding compliance, or when the legislative benchmarks are modified and/or updated, it should be verified whether the documentation relating to the Regulation (EC) 2023/2006 as amended should be updated.

Annex B4.1

Technical glossary

Cellophane: A thin, transparent material comprising cellulose hydrate. The material is still used in some instances for packaging and wrapping food products even if in time it has been replaced by other polymers that offer the same performance and are easier to process and more economical.

Further processing: In some cases, after cutting, the material wound on a roll is further worked on special machines to obtain ready-made bags or set sizes (i.e., wrapping for easter eggs). These operations are here defined as further processing.

Lamination: Process via which a film (printed or neutral) is definitively laminated to a second film via the use of a suitable adhesive that is spread on one of the two substrates. The operation is carried out in a machine called a laminator that can be in line with the print machine or can constitute a separate stand-alone machine. In this case the laminator may also have two laminating stations so that a structure made up of three laminated films (triplex) can be obtained in one run.

Printing: Process by which a gravure or flexographic machine continuously transfers a liquid ink from a tray or pan to a matrix (print cylinder or plate) and from this to a substrate that runs in the machine in the form of a continuous strip (film). The graphism on the matrix determines the subject to be printed.

Slitting: Operation that is carried out on special machines called slitting machines that consist in deriving, through an action of cutting (with blades or knives), several daughter rolls from a parent roll. The daughter rolls differ from the parent rolls in terms of size (width and length of the film wound on the shaft). During the cutting operation print trimmings are also removed.

Starting materials (raw materials): These are the materials that are always used to produce flexible packaging; in terms of substrates these are plastic films of various nature (PP, PE, PA, PET, etc.) and/or aluminium foil, and/or paper, while inks and lamination adhesives are required for printing and laminating.

Third party (working on contract): Company that manufactures FCMs under contract from a customer company that maintains the overall responsibility.

Annex B4.2

Frequently asked questions

Q1 *Do other print processes exist for producing flexible packaging as well as those cited in the guidelines?*

Yes, lately different solutions have been tried out such as printing with UV inks or digital printing.

B5. WOOD OR WOOD-BASED 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. Applicable Legislation

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.[11]

Italian legislation

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

[11] It replaced the Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

B5.1.3. Phases of the production process: flowcharts and description

B5.1.3.1. Production flowchart: Packaging and/or wooden objects, and/or wood fibre, and/or plywood

Wood from various botanical species is utilized in the production of solid wood packaging and objects. For boxes, the most commonly used wood species are poplar, beech, and fir; however, other species can also be employed.

Production can be the result of different production flows that can be grouped into two main typologies:

- complete production flow;
- semi-processed production flow.

B5.1.3.1.1. Complete production flowchart

Figure B5.1 illustrates the flowchart to produce wooden boxes (the dashed part is compliant with the GMP Regulation (EC) 2023/2006 as amended).

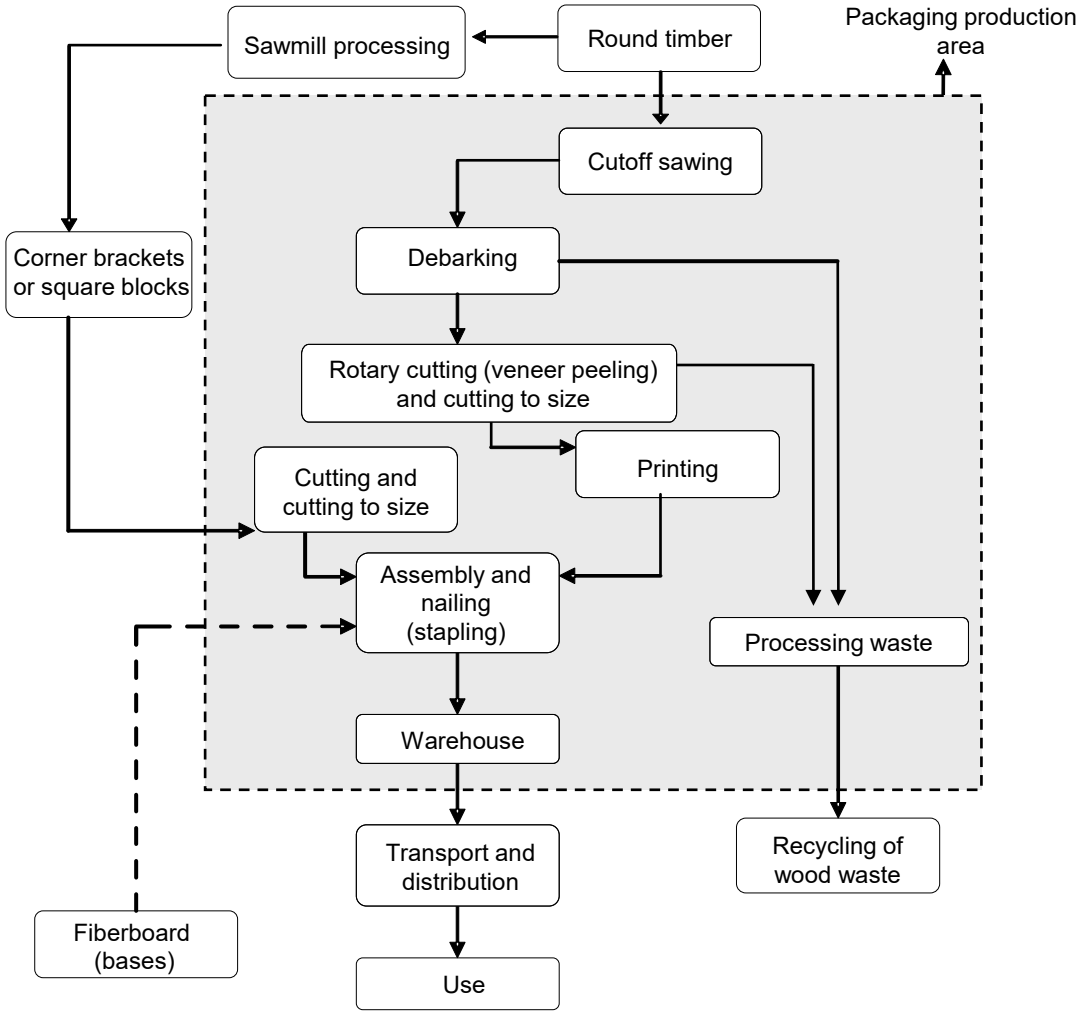


Figure B5.1. Production flowchart for wooden boxes – complete flowchart

B5.1.3.1.2. Brief description of stages in the complete flowchart

Integrated companies cover all the stages of the production process. From the woods or the facility, the wood logs go in two directions: one is the sawmill where the logs undergo the necessary processing to obtain certain physical components of the packaging, the corner brackets or square blocks; the other direction consists in the production of semi-processed articles from logs by:

- *Cutoff sawing* → cutting in a direction perpendicular to the wood fibre to produce;
- *Debarking*
- *Rotary cutting (veneer peeling) and cutting to size* → rotary cutting is performed on regular-sized logs that are suited for this kind of treatment. The product obtained is a kind of wood sheet of varying thicknesses which, once cut in the desired size, will give rise to the strips (or at the most the bases of the boxes).

The semi-processed product that is obtained is printed: during this stage promotional messages (at the request of the customer) are printed, as is all compulsory information on package weight etc. as required by the regulations in force. Printing is performed using ink applied to the non-food-contact side of the packaging.

The square blocks (or corner brackets), after being cut and cut to size, are assembled with the semi-processed products (after printing) using nails, magnetizable metal staples or iron wire for staplers (assembly using staples).

The boxes that are produced are placed in the warehouse, ready for transportation and distribution whereas the processing waste is collected for possible recycling. After use, the packaging can end its life cycle in a dump (controlled or not) or be recycled or used for energy recovery.

B5.1.3.1.3. Semi-processed articles production flowchart

Figure B5.2 illustrates the flow diagram to produce wooden boxes using semi-finished products as starting materials (the dashed part is compliant with the GMP Regulation (EC) 2023/2006 as amended).

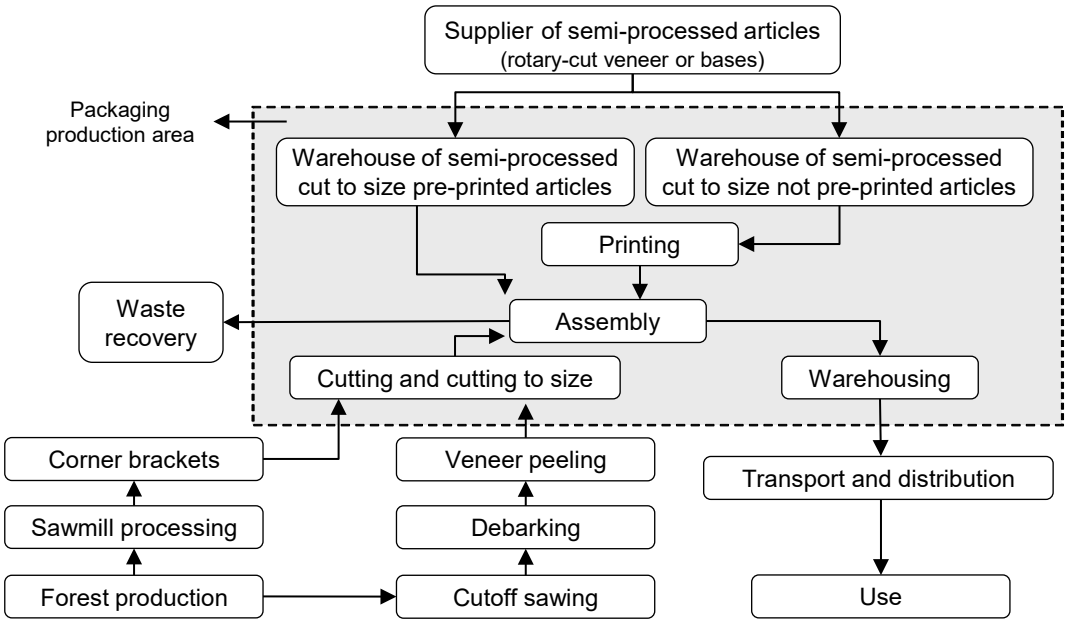


Figure B5.2. Production flowchart wooden boxes – semi-finished products

B5.1.3.1.4. Brief description of stages in the semi-processed articles procedure

The flow leading to the construction of fruit & vegetable wood packaging can be shorter than the complete flow if there is a supplier of semi-processed articles (pre-printed or to be printed): the semi-processed products needed for assembly are purchased directly and warehoused (no cutoff sawing, debarking, rotary cutting and cutting to size is required).

The semi-processed articles are made of solid wood, or wood fibre panels (using the wet or dry method) or plywood panels only.

The extreme case is a company that assembles only, i.e. that buys all the components from a producer and assembles them.

B5.1.3.1.4.1. Wood fibre panels: production flowchart

Under standard EN 316, wood fibre panels are classified according to the type of production process used (the wet or dry method) and in relation to the intended use (Table B5.1).

Table B5.1. Classification of wood fibre panels

Production process	Volumic mass (kg/m^3)	Description	Symbol
Wet method	$\rho \geq 900$	Hard panels	HB
	$400 \leq \rho < 900$	Medium – hard panels	MB
	$400 \leq \rho < 560$	Medium – hard low-density panels	MBL
	$560 \leq \rho < 900$	Medium - hard high-density panels	MBH
	$230 \leq \rho < 400$	Porous panels	SB
Dry method	$\rho \geq 450$	Panels produced using the dry method	MDF
	$\rho \geq 800$		HDF
	$\rho \leq 650$		Light MDF
	$\rho \leq 500$		Extra-light MDF

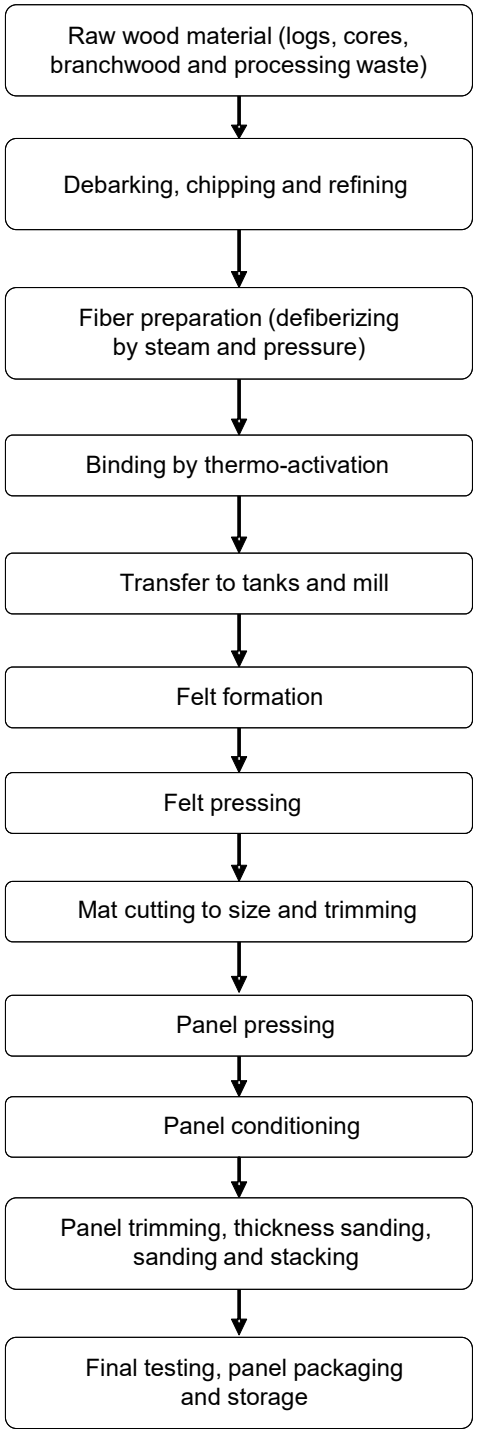
(from UNI EN 316:2009 - Wood fibre panels. Definition, classification and symbols)

Wood fibre panels are obtained by defiberising the raw wood material which becomes lignocellulosic fibres when heat and/or pressure are applied.

During this process, wood chips are inserted in a container and steam at 170°C is introduced through a valve to produce a pressure of approx. 7 atmospheres; the steam is released through a valve (made of two overlapping plates with parallel sliding slits) and causes a real explosion of the material whose cohesion, among other things, is reduced by the plastifying effect of the heat on the lignin.

The result is a mass of fibre aggregates and, only partially, of isolated fibres suspended in a black liquor made of products deriving from the thermo-hydrolysis of the cellulose.

B5.1.3.4.1a. Wood fibre panels using the wet method (Masonite)

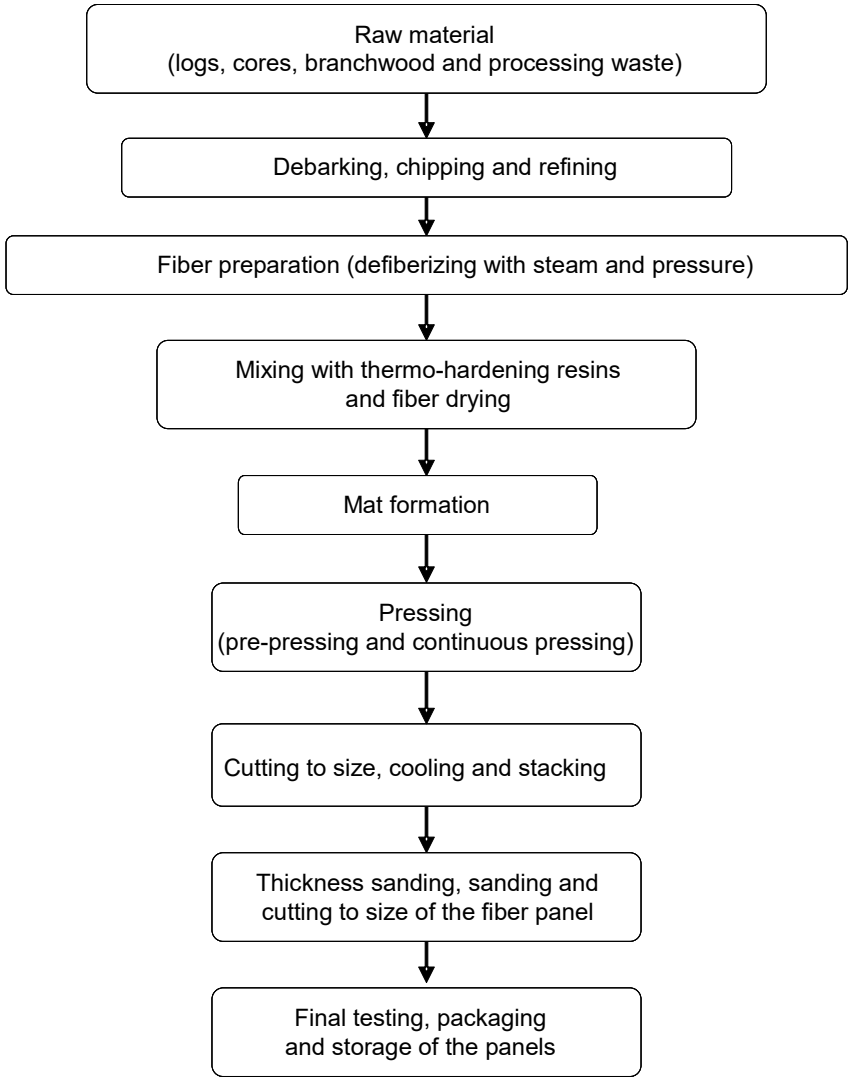


Brief description of the phases of the wet process

Defiberising creates a mass of fibre aggregates and, only partially, of isolated fibres suspended in a black liquor made of products deriving from the thermo-hydrolysis of the cellulose. As a result of the presence of these substances and a kind of thermo-activation[12] of the adhesive properties of lignin during the heating phase, this mass gives rise to a product that has a cohesive power after drying without any further addition of binding mixes.
If the lignocellulosic fibres contain a sufficient percentage of lignin and if the latter does not alter during the defiberising operations (by hydrolysis), it acts as a natural binding agent, transforming itself under the action of the heat and pressure into a thermoplastic adhesive.
The mass thus obtained is sent to special tanks to eliminate any lumps and remove any portions of wood fibre that have not been penetrated by the steam and which, as a result, are not defiberised. It is then homogenized in cone mills and collected in special containers.
This is followed by felt formation during which the mix of fibres and water is laid on a permeable continuous belt that is generally made of a fine metal mesh. The combined action of a number of pressing rollers acting on the felt surface and suction aspiration system acting below the mat removes the excess water from the felt.
The mat obtained is cut to size by automatic saws or shears and trimmed on the edges.
The panels are loaded in single- or multi-compartment presses and pressed several times. The first stage generally consists in applying high pressure (up to 160 kg/cm^2) for 90 seconds in order to eliminate most of the water and bring the panel close to its final thickness.
The pressure is then reduced to 25 kg/cm^2 for a few minutes to allow for expansion and steam release (degassing).
Last, the pressure is brought back to high levels, up to 120 kg/cm^2, for 5 minutes at a high temperature (higher than 210°C) according to the desired final density of the panel.
The metal mesh that helps remove the excess water and on which one side of the fibre panels lies, gives the bottom side its typical texture, in contrast with a smooth upper side which is directly in contact with the steel plate of the press.
After pressing, the panels have a very low moisture content, less than 1.5%, and require a period of conditioning in a controlled atmosphere to reach a well-balanced moisture content close to 8%.
The panels are then trimmed, thickness sanded, sanded and stacked in areas that are possibly well ventilated.

[12] The ability of lignin or rather of lignins to plasticize with steam and high temperatures without affecting cohesion is used here. Lignins are a family of polymorphous polymers of phenolic acids bonded to each other through a variety of different bonds and are the main component of the cellular walls of wood.

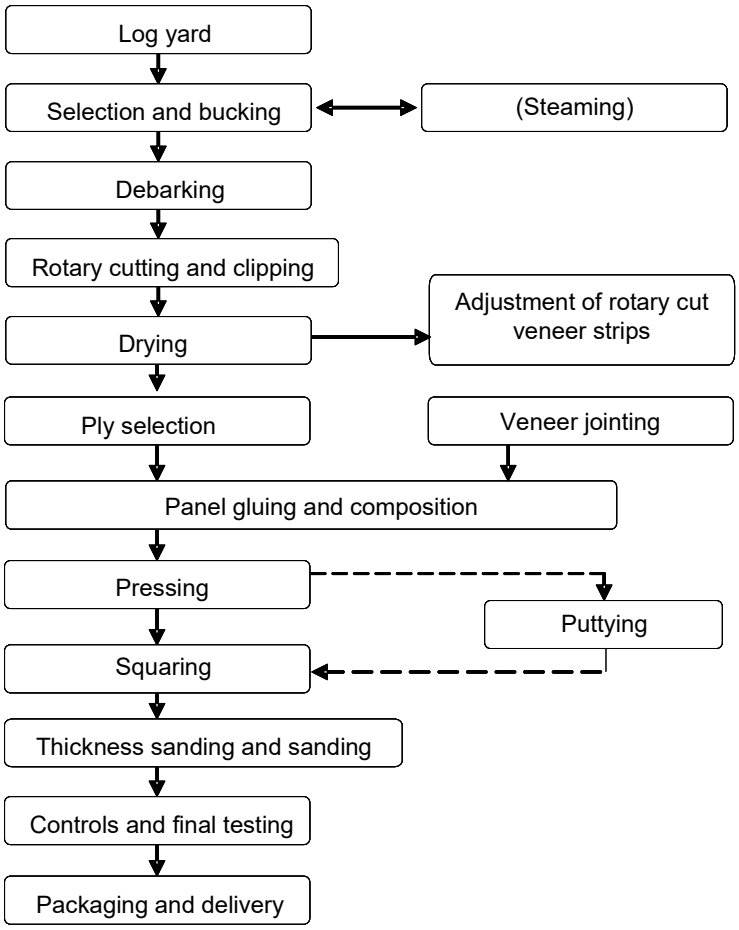
B5.1.3.4.1b. Wood fibre panels using the dry method (MDF)



Brief description of the phases of the dry process

The dry method produces fibreboard with a lower volumic mass and excellent mechanical characteristics, called MDF (*Medium Density Fibreboard*).
In the "dry" manufacture of MDF panels, the fibres are dried before forming the "mat" (the moisture content of the fibres is less than 20% in the felting phase) and pressed at lower temperatures than when pressing "wet" felts.
In this case – since fibre cohesion by means of the natural wood components only, particularly the adhesive properties of lignin, is not sufficient – for dry process production of fibreboard it is necessary to add a binding mix of thermo-hardening synthetic resin.

B5.1.3.1.4.2. Plywood panels and peeled wooden objects production flowchart



Brief description of stages in the process

Plywood panel production begins with the provisioning of round timber which, after being stored in sawmill warehoused or yards undergoes cross cutting. The bolts that are obtained undergo steaming to facilitate the next processing stages. After drying the bark is removed (debarking), the bolt is steamed and centred and undergoes rotary cutting: after a first phase of "rounding", during which the bolt is made perfectly cylindrical (and during which strips or "laths" of narrow rotary cut veneer can be obtained) a continuous strip of veneer of the desired thickness is obtained until the bolt diameter reaches a minimum size (core). In plywood production, this strip is therefore "clipped", that is, cut to size parallel to the fibre to obtain sheets of the same size as the finished panels.

The plies produced from the clipping are then stacked separately according to size, quality and moisture content (ply selection).

Each sliced veneer sheet and peeled strip (the latter after being trimmed) is temporarily jointed (veneer jointing) together to form a surface of the same size as the finished panel for easier composition (panel gluing and composition).

The pressing that follows is essential for excellent binding while any defects are eliminated by applying putty (puttying). Squaring allows the panel edges to be straightened and obtain the

final size. Thickness sandpapering is performed to obtain an even panel thickness, and usually comes before the sandpapering (which confers smooth surfaces). The controls and final testing are the last stage before the panel is packed and shipped.
Through a processing cycle similar to that used for plywood production, limited to the production of veneered wood, it is possible, using specific cutting and/or die-cutting systems, to obtain elements that can subsequently be dried and then shaped in special hot presses. This process allows for the production of disposable wooden cutlery or containers for certain types of food (such as cheeses and fruits).

B5.1.3.2. Production flowchart: wood cutting boards, chopping blocks and boards

Figure B5.3 illustrates the flowchart for the production of wood cutting boards, chopping blocks and boards (the part in grey is compliant with the GMP Regulation (EC) 2023/2006 as amended).

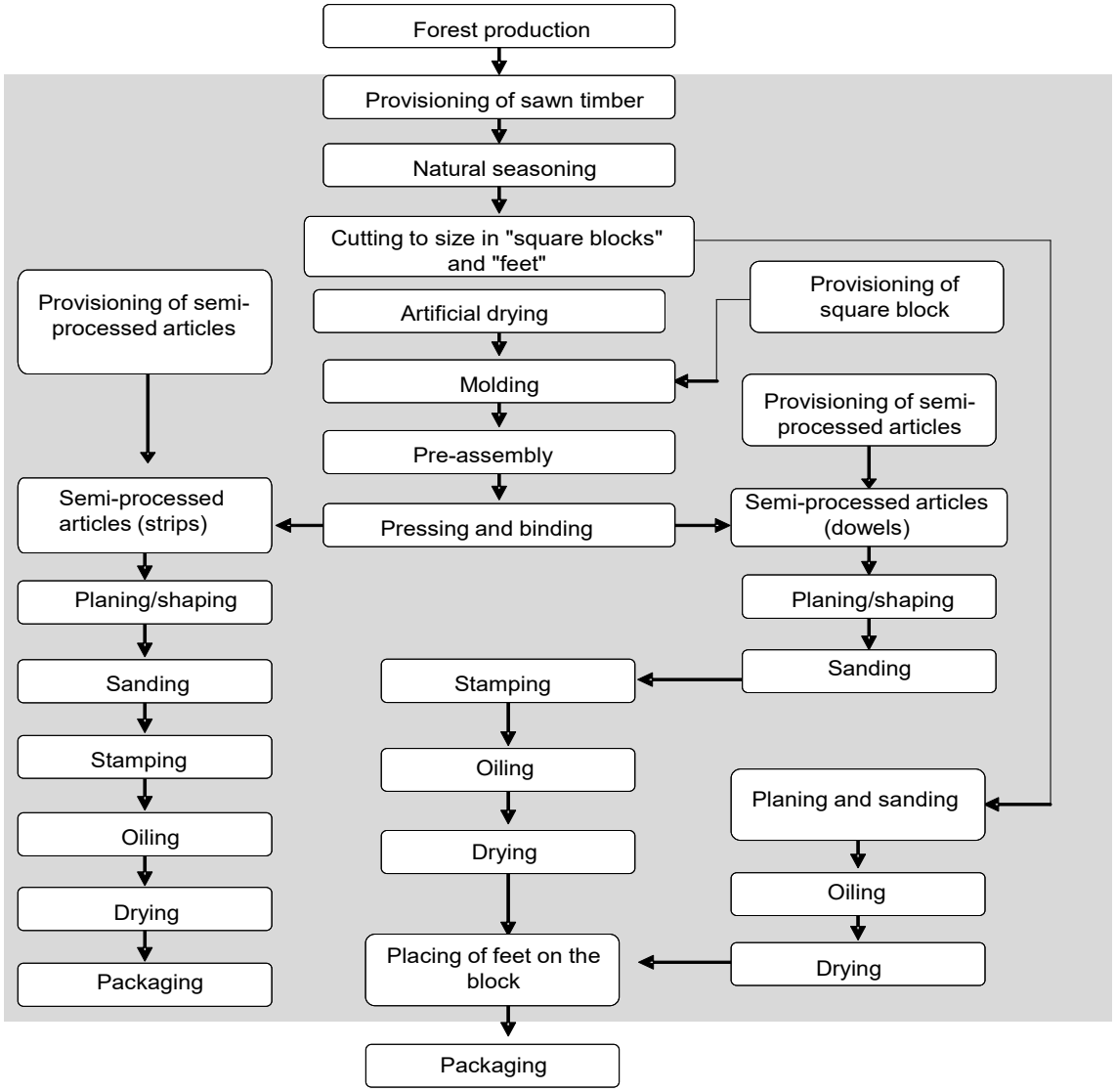


Figure B5.3. Production flowchart for wood cutting boards, chopping blocks and boards

5.1.3.2.1. Brief description of stages in the process

Wood cutting boards, chopping blocks and boards for food processing are made by a large number of manufacturers on the market, using a variety of methods.

The wood species used to make the two types of surfaces (cutting board or chopping block/board) are usually broadleaf trees, that is hardwood. The most used are hornbeam (*Carpinus betulus* L.), beechwood (*Fagus sylvatica*), sycamore maple (*Acer pseudoplatanus* L.), black locust (*Robinia pseudoacacia* L.), cherrywood (*Prunus avium* L.), walnut (*Juglans regia* L.).

The most used in Italy to produce professional cutting boards are:

- hornbeam;
- sycamore maple;
- beechwood;
- black locust.

These species have proven to be particularly suited for obtaining surfaces of the appropriate hardness and with a closed porosity, especially hornbeam and sycamore maple which have no resin and are very hard. However, other wood species can also be used.

Natural seasoning

The production process begins with the purchase of wood logs or sawn timber in the form of boards during the winter which undergo natural seasoning. The company may also purchase semi-processed, already dried products (called "square blocks") at the same time (or as an alternative).

Cutting to size and artificial drying

The proper production process begins with the cutting of the wood into pieces of various widths and lengths: the "square blocks" and the "feet" (the feet only for the manufacture of chopping blocks). These pieces can be further dried in vacuum drying units. When the desired moisture content is obtained, the wood is left to rest.

Molding and pre-assembly

The blocks obtained after cutting to size (and those that are purchased) are dried and fed through a moulding machine, then prepared for assembly on a flat hot press. Before pressing, pre-assembly is performed manually (which can also include the initial use of glue), during which the shape and size of the cutting board is formed, and everything is placed on a roll for gluing: a raw semi-processed article is obtained for finishing (many companies directly purchase similar semi-processed articles).

Pressing and gluing

The semi-processed article that is purchased from a supplier or pre-assembled by the company, is pressed in the hot press to glue the elements.

Production of blockboard cutting boards (cutting to size, sandpapering, oiling)

For the production of blockboard cutting boards, the semi-processed article (consisting in a flat piece of wood) is cut to size and its edges are shaped (for handles, if any) or alternatively, is shaped on a CNC machine and the flat and vertical surfaces are sanded. Fire branding is then followed by a final oil spray or immersion treatment, drying and heat-shrink packing.

Production of an end-grain block
(cutting to size, block pressing, planning, sandpapering, oiling)

For the production of an end-grain block with inserts, the flat piece of wood is cut to size in flat pieces corresponding to the thickness of the block to be assembled. These flat pieces are placed one over the other in a press and assembled to form an end-grain block. The semi-processed block is planned to final size or shaped on a CNC machine, then sanded; branding is followed by oil spray treatment and drying. At this point, the "feet" are assembled on the chopping block which is packed in cardboard boxes.

Finally, there are a variety of items crafted with various, more or less artisanal techniques, such as spoons, ladles, spatulas, and solid wood plates. In practice, these items are produced through transformation processes that focus solely on the volumetric reduction of the initial sawn material (cutting, turning, milling, and sandpapering).

B5.2. Fulfilments deriving from the application of the Regulation (EC) 2023/2006

In this part are described the activities and the implementation enacted by the production chain of wood articles to conform to the Regulation (EC) 2023/2006 as amended. Since this Regulation was laid down when the quality assurance systems had already become a daily work tool in most of the manufacturing businesses, it is likely that these businesses already produce in conformity with technical specifications laid down by themselves.

All the same, should it be necessary, the Quality Assurance System and the Quality Control System should be extended to ensure:

> "[...] that the materials and articles are constantly manufactured and controlled, to ensure their conformity to 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" (art. 3 paragraph a Regulation (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006 as amended. Every paragraph is hence the response of the manufacturers of wood articles to the requirements of the article in question. To facilitate reading, the paragraphs keep the same title as the article considered, while the subparagraphs indicate specific subjects.

B5.2.1. Quality Assurance Systems (Regulation (EC) 2023/2006, art. 5) and Size of the business

Quality Assurance Systems

The producer of fruit & vegetable packaging and wood cutting boards (hereafter called the producer) should establish and maintain a Quality Assurance System capable of ensuring the achievement of the objectives laid down by the Regulation and described in the general guideline. The Quality Assurance System should be documented so as to enable control by the competent authorities.

The Quality Assurance System should establish rules and procedures that regulate the company activity, at least concerning the following points:

- conformity to the requisites of the legislation in force;
- human resources and training:
- raw materials and suppliers including suppliers of goods and services and third parties working under contract;
- production;
- quality control;
- storage, handling and shipment;
- complaints and corrective and preventive action.

The system must ensure that the future legislative changes are adopted in all the phases of the company process also including the specifications and any contracts with qualified suppliers.
It is recommended to implement a procedure which enables the company to adopt the changes deriving from updates of the applicable legislation on FCMs.

Size of the business

Independently from the business size, it should at any rate be guaranteed that the Quality Assurance System, as demanded and finalised by the Regulation (EC) 2023/2006 as amended, is always applied.
The system should be established, implemented and run taking into account the actual size and complexity of the company as well as the technical and human resources available.
On its own premises the business has to at any rate be capable of guaranteeing the application and running of the Quality Assurance and Quality Control System in order to obtain finished materials and products in compliance with the legislation in force on FCMs.

B5.2.1.1. Human resources and training

The *Business operator,* in compliance with the objectives of the Regulation (EC) 1935/2004 as amended and the Regulation (EC) 2023/2006 as amended is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 as amended is applied at all levels of their organization.

The operative aspects relating to the application of the provisions laid down in the Regulation (EC) 2023/2006 as amended can be entrusted by the Business operator to competent and adequately trained people that have to at any rate have at their disposition adequate means to ensure that the requisites of the Regulation (EC) 2023/2006 as amended are respected.

The *company organization* has to at any rate enable the location of the functions to enable inspection by the Competent Authorities.

All *company personnel* potentially involved, including the highest management levels, has to be informed on the principles of GMP, on the obligations that derive from the Regulation (EC) 2023/2006 as amended, on its objectives and on the policy for applying the Regulation.

The *Business* should operate and implement procedures for identifying personnel training requirements and has to see to the training of all staff regarding the tasks that might affect the compliance to the said Regulation.

The *personnel* assigned to GMP control activities should be qualified on the basis of the training and the experience acquired.

An appropriate registration of the training process of all personnel must be kept.

B5.2.1.2. Production

The company production phase extends from design and planning to storage of the finished product.

The production process includes all the company phases that combine to guarantee that the end product complies with the legislative, technical and performance requisites laid down at the planning phase to guarantee the suitability for intended use.

Hence the Quality Assurance System should comprise procedures that regulate all the phases listed hereafter:

- Product planning and development;
- Selection of starting materials and suppliers;
- Arrival of raw materials and storage;
- Raw material control;
- Production processes and traceability of starting materials;
- Process parameter control;
- Production control;
- Finished product and storage control.

During all the phases listed above an evaluation of the risks of contamination should be made identifying the potential sources and the actions to prevent the same.

Product planning and development

The most important concept implied by the GMP is that of a product designed to be compliant to the legislative requisites on materials and articles intended for food contact (FCMs).

Distinctions can be made between the design of a product and the adaptation of a product to the requirements of a customer, who may have a product developed for a specific use that is subsequently suited to the precise and different demands of a customer.

If a producer develops a product compliant to a project for conformity of use, the packaging material produced must:

- comply with the performances for the final use it is intended for;
- comply with the requisites of the legislation in force for materials intended for food contact.

To this purpose the product has to be produced with raw materials that, subject to controls, guarantee, in all the process phases, the compliance to use the same are intended for and the legislative requisites covering food contact.

Selection of starting materials and suppliers of goods and/or services and/or subcontractors

The producer is called upon to use only approved starting material for which he has all the necessary data guaranteeing the conformity of the packaging produced to the legal requisites, including the restrictions due to conditions of use, this by way of information from the supplier and/or through controls and checks made during the design phase.

Observance of the following requisites should also be ensured:

- declaration of compliance according to what has been established by the applicable European and/or Italian legislation;
- traceability according to the Framework Regulation (EC) 1935/2004 as amended (where applicable);
- conformity to the Regulation (EC) 2023/2006 as amended (where applicable).

Any supply of starting material has to be kept under adequate control.

It is good practise that the starting materials are procured from qualified suppliers. By qualification is meant a pre-established, organized and documented process that can also include supply contracts.

It is advised to verify, also through periodical visits of inspection (audits), the Quality Assurance System of the supplier of starting materials or third parties to ascertain whether it is compliant with the requisites as laid down by the Regulation (EC) 2023/2006 as amended, where applicable.
In case the supplier is not under a GMP regime, the producer must ensure that raw materials or semi-finished products to be used will be appropriate to produce materials and articles suitable to contact with food; this verification, which is at producer's costs, could be carried out by means of checking of the compositional certification given by the suppliers, and by carrying out appropriate technical and analytical evaluations.

Process conformity

The production process has to be kept under adequate control with a Quality Assurance System that has to be conceived so as to be able to guarantee and document that the product responds to the relevant technical specifications and that these specifications comply with the product design.
The Quality Assurance System has to be finalized so as to proffer sufficient attention to the more critical points of the production system that might endanger the attainment of both legislative, technical and qualitative conformity of the end product.

Documentation of procedure/instructions

Every production phase has to be regulated through adequate documentation. Examples of documentation can be: manuals, procedures, working instructions, technical rules and registrations. The documentation required to perform the activity must be at the disposition of the appointed personnel, must be kept updated and the distribution of the same must be controlled, so that non updated information is speedily withdrawn.

B5.2.2. Quality Control System (Regulation (EC) 2023/2006, art. 6)

The producer should establish and maintain an effective Quality Control System capable of ensuring the respect of the conformity to the Regulation as laid down in the general guideline.

The system should include procedures that envisage all the necessary controls, the relative registrations and actions to be carried out in the event of lack of conformity.

All the documentation has to be available for the Competent Authorities that demand to see it in accordance with the Regulation (EC) 2023/2006 as amended.

The rules and the procedures have to cover the entire production process, as described in paragraph B5 2.1.2., also including a part that deals with the handling of any non-conformities and corrective actions.

B5.2.2.1. Management of raw materials warehouses

If not specified otherwise, the raw material should be used on the basis of the "first in first out" principle (rule of rotation by which the oldest material is the first to be used).

The approved starting materials from qualified suppliers must be clearly separated from other starting materials that have not been homologated or that are from suppliers who are undergoing qualification or who have not been qualified.

For the latter materials a procedure must be established that authorizes their use in production only after the function laid down under the Quality Control System has confirmed the suitability of the material for use in production.

Any raw materials that are the subject of disputes have to be segregated in a predefined area and clearly identified pending the problem is solved. The segregation of non-compliant material can also be performed through restrictions other than physical segregation in a specially assigned area (IT block).

Only the Quality Control is enabled to authorize any use of these materials.

The conditions of the environment, of the storage and handling of the storage areas must be such as to guarantee that there is no risk of deterioration of the material.

Special attention should be given to the storage, warehousing and handling of raw materials to avoid any damage that can make the materials unusable.

B5.2.2.2. Production controls

The Quality Control System has to be regulated by suitable procedures that guarantee that during the production process all the necessary controls are carried out to guarantee that the product conforms to the legal, technical and quality specifications defined during the design phase.

The traceability of the products through suitable registration of the raw material lots used, by the machine conditions set and registered during production and the quality controls also carried out on intermediate products and semi processed articles must be guaranteed.

The storage of the finished product and the shipment to the customer should only be enacted against procedures that enable the unequivocal documentation that the material has been controlled in all the established phases and that the final controls have ascertained the conformity of the same to all the requisites laid down in the design phase.

This conformity should be ascertained via the comparison between the control data collected and the values and/or tolerances entered in the product technical specifications or the specific legislation.

Special attention must be paid to the control of possible contamination. A procedure should be in place to assess this risk and actions established to prevent this should be documented (e.g., regular cleaning of machinery and equipment, hygiene in the workplace, prevention against insects and rodents, etc.).

B5.2.2.3. Quality Control of finished products

The Quality Control System has to dispose of suitable procedures for controlling the finished product. In verifying the conformity of the finished product, Quality Control has to use the information available on raw materials and on the process applied to highlight any limitations and restrictions of use for food contact.

Particular attention should also be paid to the test conditions used for carrying out the controls, which have to be suited to the verifications of the intended final use of the material, taking into account the position in the supply chain.

The analyses, whenever necessary must always be carried out using validated methods of analysis. If these methods do not exist, an analytical method with performance characteristics adapted to the specified limits may be used pending the drawing up of a validated method.

The goals achievable through controls of finished products are the following:

- conformity of packaging materials to the applicable legislation for food contact;
- in absence of specific legislative parameters, when elements to assess the product are available, the conformity to performance requirements agreed during the negotiation phase.

B5.2.2.4. Management of finished products warehouses

The Quality Assurance System should establish a procedure to authorize the storage of finished products. The authorization for storage of the products and for their delivery to customers should be given by the Quality Control System, after performing all the controls provided for by the relevant procedures to ascertain the suitability of finished products for their intended use.

The approved finished products should be clearly separated, or in any case clearly labelled from those that still have to be controlled or subject to further controls as to their suitability.

For any products that are declared as unsuited, a procedure must be prepared that prevents their storage pending the definition of the problem, or their downgrading. Any derogations are only to be authorized by the Quality Control.

The unsuited products, clearly identified, should be kept separated in a predefined area in order to impede their storage, or they should be in any case clearly labelled.

Any finished products returned by customers due to non-conformity, should be kept in a predefined area and clearly identified, or in any case clearly labelled, pending the definition of the contestation. Only the Quality Control is allowed to authorize any use of these materials.

It is advised that a procedure for managing non-compliant materials is set up also providing for their disposal or the destruction of the same.

The environmental conditions of storage and of the warehouses should be such as to guarantee that there is no risk of deterioration of the materials.

Special attention should be paid during handling operations of the raw materials in order to avoid damaging that may make the material useless.

B5.2.2.5. Distribution, shipment and delivery

The producer, if responsible for the transport and the delivery of the material to its destination, has to also guarantee that this phase is regulated by instructions and procedures that guarantee the quality of the material preserving it from any damage and contamination risk that might compromise its use or suitability.

If the means of transport are the property of the packaging producer, it must be ensured, also by periodic checks, that these are suited for transporting goods and that maintain the requisites of safety and hygiene required to guarantee the integrity of the product.

If the delivery is via external couriers, a procedure should be established that qualifies the courier and a technical contract should be defined that sets the minimum requisites to be respected to eliminate possible risks (i.e., damage, contamination, etc.).

B5.2.2.6. Conformity of the application of the GMP and claims management, corrective and preventive actions

The Quality Control System has to enact suitable procedures so as to monitor the correct implementation and total respect of the GMP.

The Quality Control System has to enact procedures for documenting the identification of lack of conformity, the enacting of any corrective measures and the monitoring of the implementation of the said measures, with particular attention to the time frame envisaged to implement the measures.

The Quality Assurance System of the Business should therefore be implemented to include periodical verification and control plans on conformity to pre-established parameters and specifications, relevant to compliance with legislation on FCMs; procedures for managing non conformities and corrective measures should be implemented.

B5.2.3. Documentation (Regulation (EC) 2023/2006, art. 7)

All the documents concerning the Quality Assurance System (procedures, specifications, formulations, etc.) and all the activity of the Quality Control System (instructions, registrations of control data, machine setup data, tolerances and measurements, etc.) have to be organized so as to constitute a paper or electronic archive, immediately accessible and easily consultable on request by the Competent Authorities.

The documents guaranteeing the traceability will also constitute an integral part of the same, as under art. 17 of the Regulation (EC) 1935/2004 as amended, the copies of the declarations of compliance issued by the customers in observance of art. 16 of the Regulation (EC) 1935/2004 as amended and the applicable national regulations, and the supporting documentation. This documentation will also include any conditions for tests, calculations and analyses, carried out by internal and external laboratories, that serve to demonstrate conformity.

In the event of substantial changes in production liable to change the essential requirements regarding compliance, or when the legislative benchmarks are modified and/or updated, it should be verified whether the documentation relating to the Regulation (EC) 2023/2006 as amended should be updated.

B5.2.4. References

Studio legno – Wood Consulting. *Imballaggi ortofrutticoli: linea guida per la caratterizzazione delle prestazioni e lo sviluppo di un sistema di rintracciabilità.* Milano: Assoimballaggi FederlegnoArredo, Lampi di Stampa; 2004.

Assoimballaggi di FederlegnoArredo. *Procedura operativa per la gestione della rintracciabilità per le imprese produttrici di imballaggi ortofrutticoli in legno.* Milano: Assoimballaggi; 2006.

Milana MR, Feliciani R, Gesumundo C, Giamberardini S, Padula G, Panico O. *Linea guida sull'idoneità al contatto con alimenti di cassette di legno per ortofrutta*. Roma: Istituto Superiore di Sanità; 2015. (Rapporti ISTISAN 15/38).

Useful sites

European Federation of Wooden Pallets and Packaging Manufacturers:
www.fefpeb.org

FederlegnoArredo:
www.federlegnoarredo.it

Annex B5.1

Technical glossary

Adhesive: A substance to bind two elements of the same or different material by forming an interface surface to favour adhesion. A general term that includes cement, mucilage, resin and others; used as a synonym for "glue". See also "binding mix".

Assembly: General term, normally used to indicate the operation of fitting together several components to make a given semi-processed product or finished packaging; sometimes the term is used for a group of wood materials to be glued together where the adhesive has already been applied and that are ready for pressing (e.g., overlapping rotary cut veneer, a mat of particles, etc.).

Bark: Non-technical term used for all the exterior coverings of wood stems (i.e., external to the last formed outer layer). See "Rhytidome".

Base: All the components that make up the base of the packaging.

Binders: Mainly PVA acetate (polyvinyl acetate in aqueous dispersion) based adhesives are used in the production of wood cutting boards, chopping blocks/boards to guarantee highly stable joints in solid wood.

Binding mix: A mix generally used for gluing plywood, formed of an adhesive (resin), excipients, and additives. A hardening solution and a solvent (usually water) that are mixed together in pre-set proportions. In the case of solid wood fruit and vegetable packaging, assembly involves uniting two types of components: the square blocks (or corner brackets) and semi-processed products (obtained from logs after cut-off sawing, debarking, rotary cutting/cutting to size and printing); the first, after cutting to size, are assembled with the semi-processed products by means of nails, magnetizable metal staples or iron wire for staplers. In the production of wood cutting boards, chopping blocks and boards, it refers to the mechanical operations performed with a press to assemble the strips (or end grains) and obtain the work surface (cutting board or chopping block/board). In the production of fruit and vegetable packaging vinyl glues are normally used.

Block and board (with end-grain construction): Surface used for heavy-duty food processing (e.g. meat cutting) and obtained by assembling the wood "end grain" (to give the block and board more cutting resistance than a normal cutting board obtained by gluing and assembling strips).

Bolt: Log cut to an appropriate length for processing (sawing, rotary cutting, etc.). Also called "core", especially for hardwood.

Bottom: The lower side of a 6-faced polyhedron.

Bucking: Operation that involves reducing a stem into shorter pieces (logs or bolts). As such, this is also a form of cross cutting. This is usually performed using a large circular saw or a chain saw hinged to a fulcrum.

Chipping: A mechanical action by means of which special cutting systems with rotating knives are used to turn industrial wood or other wood (top ends, branch wood, wood waste) into particles of a specific size for use in paper production or in the panel industry.

Component: Single construction element of packaging.

Conditioning phase: Period after drying or before equalization during which the residual tension or the hardened surface crust can be lessened, preferably by using high temperatures and high values of relative humidity.

Conditioning: Adjusting the moisture content of processed wood or another material to its intended conditions of use in special conditioning chambers; also performed to facilitate the penetration of antiseptics. In particular, the treatment applied after seasoning to lower the moisture content gradient

among the pieces or to bring the moisture content to the desired level: this operation is called equalizing.

Corner bracket or connecting angle or square block: Member designed to reinforce the side edges of the packaging, allowing the base and sides to be fitted together in a sufficiently rigid and strong manner.

Cross-cutting: Cutting perpendicular to the grain to create an end grain.

Cutting board (with strip construction): Surface used for light-duty food processing. It is obtained by assembling the strips with the grain perpendicular to the direction of the stress during food processing.

Cutting saw: Machine used to cut semi-processed wood products.

Cutting to size: Operation by means of which a semi-processed product of a standard size is made into shorter and narrower pieces as requested by a processing order. Modern facilities can stack and process several semi-processed products simultaneously (e.g., panels) and use CNC systems to manage and optimize multiple cutting.

Debark: To remove the bark from a stem or from round timber. The operation can be performed in a more or less complete manner.

Debarking machine: Machine used for debarking industrial wood. According to the model and operating method, there are: debarking drums (used for bolts from paper mills, cause an attrition between the pieces inserted in a large rotating metal cylinder that is slightly inclined to facilitate the feeding of the material being processed); chain debarking machines (the bark is eliminated by short chains that extend out by centrifugal force from a rotating container); rotor or ring debarking machines (a number of knives – cutters and tearers – mounted on the edge of a rotating ring remove the bark while the piece, held firm by special feeding rollers, passes through the ring); milling head debarking machines (a rotating head with protrusions on its surface tears the bark away while the piece moves forward rotating on a supporting system).

Debarking: Preparation phase which consists in removing the bark from a wood stem.

Defiberising: Mechanical, chemical or thermo-mechanical action by means of which, particles, sawdust, or various kinds of wood waste can be made into bundles of fibres.

Desiccation: Process that reduces the moisture content of the wood in order to improve its performance. This can be carried out by means of exposure to the outdoor air under cover (referred to as "natural seasoning") or artificially by using a kiln inside which a heated atmosphere can be produced, and the humidity, ventilation and possibly air pressure can be modified.

Drying: Operation that is performed by passing the cutting boards and chopping blocks in a special chamber to remove any excess oil (after oiling).

Dry-process manufacture fibreboard (MDF): Wood fibre panel (EN 316) produced from lignocellulosic fibres using dry-process manufacture, that is with a moisture content of less than 20% during preparation and made with the use of heat and pressure. A thermo-hardening adhesive (phenolic, aminoplastic, ureic, melaminic or isocyanic) may be added.

Feet: Elements made of solid wood (polyhedron shape), with a support function, to be assembled together with the block or board.

Fibreboard: Two kinds of fibreboard are often used in the fruit and vegetable packaging industry: dry-process manufacture fibreboard (MDF) and Masonite (wet-process manufacture).

Glue line: Trace of the gluing surface that can be seen along the outer edges of a semi-processed product or panel made of stratified wood strips or plies (e.g., a laminated plywood, plywood, LVL).

Glue: Originally a jelly-like protein substance deriving from animal horn, hide, bones or cartilage and specially processed to obtain its adhesive properties. Although the term is commonly used as a synonym for "adhesive", there is still a tendency to use it specifically for adhesives of natural origin.

Gluing: A bond achieved using an adhesive. The latter is usually applied on semi-processed wood products under the form of a binding mix. Most gluing operations in wood-based panel production require that adhesive polymerization is performed at certain pressure (constantly applied to keep the parts to be assembled in close contact) and temperature conditions.

Grinding: Procedure carried out with a machine to bring any component or surface to an optimal state for a project.

Head: The components that form each of the two shorter sides of the packaging.

Height: Longest measurement perpendicular to the base, expressed in mm.

Joining elements for wood components of fruit & vegetable packaging: A metal material, usually in the form of a wire, used during assembly to join the various components of a fruit & vegetable box.

Jointing: In plywood, an operation by means of which single plies of sliced veneer or strips of rotary cut veneer are temporarily jointed together to form a surface of the same size as the finished panel in order to facilitate its composition. The most commonly used jointing systems involve the longitudinal or transversal (continuous) pairing of edges to be glued together, followed by cutting the resulting ply to size, and include the following operations: gluing with a nylon thread impregnated in a hot-melt adhesive that is reactivated by special electrical elements and applied in a zig-zag pattern, on a single surface, across the edges of two adjacent plies; adjacent edges are glued together after shaping, coated by a hot-melt adhesive and then passed in a system that places the plies closely together and reactivates the adhesive through high temperatures; a localized system of applying appropriately-spaced "spots of glue" across the surface of two adjacent plies along the jointing line.

Length: Longest measurement of the base, expressed in mm.

Masonite: A trademark used for a high density (>900 kg/m^3) fibreboard that has been obtained using wet-process manufacture. In most cases production does not include the use of glues. If glues are added to obtain a better consistency, small quantities of ureic glues are used.

Moulding: Operation aimed at processing the strips so that they can be glued together and a work surface produced.

Natural seasoning: See **"Drying"**

Oiling: Operation performed to finish working surfaces: varnishes and oils are commonly used. In the production of professional cutting boards, the use of mineral oils from paraffin distillates has recently become the standard.

Packaging size: The size of a 6-faced polyhedron, expressed in mm.

Planning: Operation which consists in obtaining a flat surface (thin planning) and possibly in bringing sawn timber to the desired thickness (thick planning).

Ply: In plywood, the term is used for a single or several wood veneers placed side by side (either glued or not) along their length or width. U.S. regulations on traditional plywood also use the terms: "Cores (or Crossband)" for the inner plies whose grain runs perpendicular to the outer plies, the function of which is to minimize shrinkage and warping especially in plywood with 5 or more plies; "Centers" for the inner plies whose grain runs parallel to the face and back of the panel; "Sub-face" for the inner ply directly below the panel face; "Sub-back", as above, for the inner ply adjacent to the panel back. In some compositions the plies can overlap with the parallel grain. Last, the term "inner plies" refers to all the plies in plywood, excluding the face and back.

Plywood panel: Wood-based panel made of a number of layers (usually an odd number of layers even if fruit and vegetable packaging practically always have two layers) that are glued together (gluing is performed by using adhesive or vinyl glues) and laid one over the other and where the grain direction of two adjacent layers is generally at a right angle. In the outer layers and all the odd-numbered inner layers the grain generally runs parallel to the length of the panel. Stratification with alternating grain directions offers uniform resistance to the main conditions of stress, reduces splitting, minimizes

panel shrinkage and warping. Plywood is generally classified on the basis of exposure to certain weather conditions (determined mainly by the gluing method used) and on face quality (aspect) and panel composition.

Polyhedron: The 6-facepolyhedron that represents the space occupied by the packaging.

Polymerization: A hardening or other variation in the physical properties of an adhesive caused by a chemical reaction that can be vulcanization, condensation or the continuation of polymerization, generally induced by the action of heat and a catalyst, added alone or in combination, with or without pressure. More specifically the term refers to the variation in the state of an adhesive or binding mix which, in the case of certain thermo-hardening adhesives, reticulates and hardens in an irreversible and non-hydrolysable manner.

Pre-assembly: Manual operation performed by an operator that involves uniting (and possibly pre-gluing) the strips (or end grains) that will go to form the work surface of cutting boards (or of chopping blocks or boards).

Pre-pressing: The cold pressing applied to a pack of plies after composition and that is sufficient to keep the panel intact as it is sent to the hot press loading system.

Pressing: A mechanical action by means of which semi-processed wood products, products based on other materials, a mat of particles or fibres can be kept in close contact with each other. When these elements are appropriately treated with adhesive, this action allows for the proper polymerization of the binding mix and gluing. Pressing aimed at gluing the wood can be cold, hot, high frequency and with the discontinued or continued feeding of the material being processed. Pressing is also performed to apply a decorative coating to a supporting semi-processed product.

Printing: The printing of promotional messages (when requested by the customer) and of compulsory information on the packaging weight, etc. as required by the laws in force. The ink is applied to the non-food-contact side of the packaging.

Puttying: Repairing any open flaws with putty.

Refining: The reduction, by attrition, of particles or other fibrous material to a state of bundles of fibers for panel production. Refining can be carried out at atmospheric or under pressurized pressure and uses steam to condition (“cook”) the material to facilitate cell separation.

Resin content: Fraction of the resin (dry substance) found in the anhydrous weight of the solid component contained in a mix or solution. The term is used to indicate the actual quantity of resin found in a liquid adhesive.

Rotary cut veneer: Wood ply obtained by rotary cutting.

Rotary cutting: Industrial transformation by means of which an assortment of wood having the appropriate features can be turned into veneer (called “plies”). This involves fixing a debarked bolt, that has possibly been steamed and is centred, to a spindle shaft that makes it rotate around its own axis while the bolt enters into contact with a cutting system made of a knife and pressure bar which are at least the same length as the piece being processed. Cutting generally begins from the side of the bolt, at angles to its spindle centring axis. After an initial “rounding” phase during which the bolt is made perfectly cylindrical (and from which thin strips of plies can be obtained), the combined movements of bolt rotation and the advancement of the cutting system, which at every turn of the bold moves at a pre-set distance towards its geometrical centre, obtain a continuous strip of veneer of the desired thickness (generally between 1 and 5 mm) which continues until the bolt is the size of a cylinder (core) whose diameter is close to that of the spindles. In plywood production, this strip is “clipped” i.e. cut parallel to the fiber, to obtain plies of the size of finished panels (which however include the excess size that is necessary to allow for shrinkage after drying and facilitate composition). The plies produced after clipping are stacked separately on the basis of size, quality and moisture content. Rotary cutting is usually performed on bolts with a high moisture content (freshly cut wood) the transformation of which requires less energy and produces veneer of a better quality and with a

smooth surface. Rotary cutting however is not only used in plywood production but is also carried out to produce other semi-processed products which are mainly used in the packaging sector.

Round timber: Tree that has been felled and delimbed. It can be bucked or not.

Sandpapering: A finishing operation that is performed by machine or by hand, to smooth the surface of parts of wood or panels, by using an abrasive sheet, disc or belt (disc, belt or drum sandpapering machine). In the case of wood-based panels, this is performed at the final stage of production, and generally when the appearance of the panel face is particularly important.

Sawn timber: Product obtained from logs or larger pieces of solid wood by sawing or removing the shavings in a longitudinal direction, followed by cross sawing and/or further processing in order to obtain the required level of precision.

Shaping: In general, any processing with machinery using rotating blades, on the edge or on the extreme portion of a piece.

Side: All the members that make up the longer sides of the packaging.

Side: One of the side faces of a polyhedron.

Solid wood: Material of natural origin obtained by rotary cutting, sawing or splitting a portion of a log and where the typical structure and macroscopic characteristics of the wood species (softwood or hardwood) from which it has been obtained can be recognized.

Square block: A solid, wood semi-processed product having 6 plane faces obtained from the cutting to size of sawn timber.

Squaring: An operation which, by means of cuts performed by a pair of circular saws working in a perpendicular direction, straightens the edges of wood panels after pressing (making the sides parallel) and produces their final size. The term therefore also refers to the edges of a panel or semi-processed product having parallel opposite sides and perpendicular adjacent edges (right angles). In the Regulations on plywood, it is calculated on a 1-meter edge length.

Steaming: Treatment (commonly but wrongly referred to as "Evaporation") sometimes performed on industrial wood or semi-processed articles for one or more of the following main reasons: to make the next stage of processing easier (e.g., rotary cutting); wash the cells from the agents of biodegradation; modify (darken) the natural wood colour; harmonize or reduce any differences in colour between the portion of sapwood and the heartwood; reduce or harmonize any moisture gradients between the inside and surface of the wood assortment. Steaming involves the use of special cells or tanks inside which, after inserting the pieces to be treated, hot water or saturated steam is placed until the planned objectives are reached. The duration of the treatment depends on various parameters, such as, wood species, piece size, and temperature of the heating element.

Strips: Thin wooden strip deriving from the removal of defective parts during rotary cutting or in other operations, which is recovered by jointing.

Thickness sandpapering: Operation that generally precedes the sandpapering of a wood-based panel and that involves levelling its thickness by passing it through two sandpaper-lined cylinders.

Trimming: Removal of two side strips (called "chamfer" or "wane") from the untreated boards obtained after sawing in order to produce straight edges and ensure that these are perpendicular to the board face. If the board has a uniform width, reference is made to "trimming parallel edges" and to "non parallel edges" if the edges are left tapered. Also performed on wood panels to bring them to the desired size after pressing.

Width: Shortest measurement of the base, expressed in mm.

Wood fruit & vegetable packaging: Rigid wood, disposable, recyclable packaging, of a polyhedron shape, for the road, rail and sea transport of fruit and vegetable products as well as their warehousing, which can be long-term. Commonly called "fruit or vegetable boxes". Generally made of a wood-based panel (see EN 316) having a nominal thickness of at least 1.5 mm, and produced with lignocellulosic

fibres by applying heat and/or pressure. Binding is achieved by means of fibre felting which exploits the adhesive properties or by adding a thermo-hardening synthetic adhesive (phenolic, aminoplastic, ureic, melaminic or isocyanic). Other additives can be used in the production of wood fibre panels.

Annex B5.2

Frequently asked questions

Q1 *Is the application of the Regulation (EC) 2023/2006 to be requested for semi-processed or finished products from non-EU countries?*

Yes. Non-EU trade only takes place by having goods circulating under EU laws, so a non-EU producer should comply with Regulation (EC) 2023/2006 as amended.

Q2 *Is GMP required in the production of fibreboard using dry-process manufacture (e.g., for MDF)?*

If production takes place using only heat and/or pressure, there is no GMP obligation. Otherwise, if glues or other chemical products are used, the answer is yes.

Q3 *Is GMP required in the production of fibreboard using wet-process manufacture (e.g., for Masonite)?*

If the production using wet-process manufacture does not involve the use of glues (for Masonite this is practically always the case) there is no GMP obligation, otherwise the answer is yes.

Q4 *Are those engaged in the trade of MDF or Masonite required to comply with GMP?*

Yes, in terms of traceability obligations (under Regulation (EC) 1935/2004/ as amended, of which Regulation (EC) 2023/2006 as amended is the "offspring" and under Italian Legislative Decree No.108/1992) and in terms of the attention to be focused on warehouse management. Those engaged in the trade are responsible for their area of competence.

Q5 *Are assemblers of fibreboard to produce fruit and vegetable boxes required to comply with GMP?*

Yes. Assemblers of fibreboard, if intended specifically for fruit and vegetables, are required to comply with GMP.

Q6 *What is "starting material"?*

Starting material is round timber, sawn timber and semi-processed products that have undergone a reduction in volume but that have not been chemically treated (e.g., with glue).

Q7 *Does this guideline concern "fish boxes"?*

Yes, fish boxes can be used, as clarified in the Ministry of Health note "Use of wood for packaging fish products" – Ministry of Health DGSAN 0013565-P-06/04/2016.
https://www.federlegnoarredo.it/it/associazioni/assoimballaggi/imballaggi-ortofrutticoli/conformita-contatto-con-gli-alimenti

Q8 *Is GMP required for producers of plywood panels?*

Yes. The layers of the panel are made solid by means of gluing, therefore by means of a chemical product: this production therefore falls under the GMP obligation of the Regulation (EC) 2023/2006 as amended.

Q9 *If a company produces bases and/or corner brackets intended for assembly to produce fruit and vegetable boxes and sells these to another company that assembles them, is it required to comply with GMP?*

The GMP obligation for wood starts when at least one of the following cases occurs first:

- the wood undergoes a chemical treatment or more simply a chemical product is used (e.g., printing ink),
- there is an assembly process (NB: the GMP obligation applies to companies involved in assembly only),
- there is a stage when the wood enters into "contact" with other materials that will become part of the finished product (e.g., nailing of the bases).

Q10 *Do the GMP obligations apply to companies which – in the production of fruit and vegetable boxes – are only involved in assembly?*

Yes, they do.

Q11 *Where does GMP start in the production of wood cutting boards (or chopping blocks/boards)?*

GMP becomes compulsory starting with pre-assembly, if gluing is already required, otherwise immediately after pressing, when gluing takes place.

Q12 *If a company produces semi-processed products intended for the production of wood cutting boards and/or chopping blocks, is it required to comply with GMP?*

If the company simply produces blocks, it is not required to comply with GMP, since the processing of raw materials (virgin or solid wood and/or sawn timber) only involves reducing the volume of solid wood; instead, if the company produces semi-processed products, made of "untreated processing surfaces" obtained by gluing the parts that will go to make the future cutting board (or the future chopping block), it is required to comply with GMP.

Q13 *Are those engaged in the trade of "untreated processing surfaces "for the production of wood cutting boards, chopping blocks and boards required to comply with GMP?*

Yes, in terms of traceability obligations (under Italian Legislative Decree No. 108/1992) and in terms of the attention to be focused on warehouse management. Those engaged in the trade are responsible for their area of competence.

Q14 *If the company has not prepared a manual, but simply registers its own management system using special documentation, is this sufficient to demonstrate conformity with the Regulation (EC) 2023/2006?*

Yes. The Regulation (EC) 2023/2006 as amended does not refer to any obligation to prepare a manual but to "Documentation" (Article 7 refers to "appropriate documentation in paper or electronic format").

Q15 *For companies producing fruit and vegetable wood packaging and wood articles, how is the risk of finished products deviating from established conformity requirements kept under control?*

Companies involved in the manufacture of fruit and vegetable wood packaging and wood articles should keep the production process under control, also by adopting preventive measures such as a risk analysis method (e.g., HACCP, risk analysis, etc.).

Q16 *In the production of wood articles, how should hygiene-related issues be addressed?*

Although Regulation (EC) 2023/2006 as amended does not call for the adoption of a hygiene management and control system, special attention should be given to control possible contamination, by laying out procedures to assess and manage this risk (e.g., regular cleaning of machinery and equipment, hygiene in the workplace, prevention against insects and rodents, etc.).

Q17 *Do the obligations of the Regulation (EC) 2023/2006 remain the same for small businesses?*

The obligations set by the Regulation (EC) 2023/2006 as amended do not consider the size of the business but the premise (paragraph 6) specifies that "the rules on GMP should be applied proportionately to avoid undue burdens for small businesses". Furthermore, Article 5 ("Quality Assurance System") states that the "system should [...] be applied taking into account the size of the business run by the operator, so as not to be an excessive burden on the business ".

Q18 *Is there any specific European and/or Italian legislation for wood intended to come into contact with food?*

Up to now wood has not been the subject of specific regulations, either at Italian or EU level. However, there are general rules applicable to all materials intended to come in contact with food and which therefore also apply to wood materials and articles. The general rules are:

- Italian DPR 777/1982 and Legislative Decree 108/1992, (in effect for the statement of conformity and applicable penalties);
- Italian Legislative Decree No. 29 of 10th February 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 objects intended to come into contact with food;
- Regulation (EC) 1935/2004 as amended on materials and articles intended to come into contact with food;
- Regulation (EC) 2023/2004 as amended on Good Manufacturing Practice (GMP);
- Regulation (UE) 2017/625 of the European Parliament and of the Council of 15th March 2017 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Q19 *Are there any specific requirements for special sectors?*

There is a specific regulation – Law No. 128/1991 Art. 1(1)b – under which used wood packaging can be used in the wholesale of fruit and vegetable products, of a quality other than "extra" and "first" only if intact, clean and dry.

Q20 *Are those engaged in the trade of MDF or Masonite required to comply with GMP?*

Yes, in terms of traceability obligations – under Regulation (EC) 1935/2004 as amended, of which Regulation (EC) 2023/2006 as amended is the "offspring" and under Italian Legislative Decree No. 108/1992 – and in terms of the attention to be focused on warehouse management. Those engaged in the trade are responsible for their area of competence.

B6. PLASTIC PACKAGING

B6.1. Characterisation of the sector

B6.1.1. 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 complying 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) are excluded as well from the scope of this guideline.

B6.1.2. Applicable legislation

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.[13]
- Regulation (UE) 10/2011 on plastic materials and articles intended to come into contact with food as amended.
- Regulation (UE) 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.
- Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs.
- Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs.

[13] It replaced the Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Italian legislation

- Decree of the Italian 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.
- Italian Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- Italian 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 objects intended to come into contact with food.
- Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, intended to come into contact with food or substances for personal use as amended.

B6.1.3. Phases of the production process

In the following page Table B6.1 is presented; the table schematically summarizes the production flows related to the production processes starting from raw materials.

Process flows are described into the vertical columns (e.g., extrusion, injection moulding) and show synoptically the various manufacturing steps (e.g., additivation, extrusion, etc.), the raw materials used (e.g. polymers) and the related starting physical shape (e.g., pellet, powder).

For each process a number of examples of typical products obtained have been reported (e.g., bottles, trays, yoghurt cups).

Technical terminology is explained in the glossary (Annex B6.1)

The main conversion technologies for thermoplastic polymers are reported in Annex B6.2

B6.1.3.1. Brief description of the process phases

Plastics packaging, both rigid and flexible, intended to come into contact with foodstuffs and beverages are almost totally produced with thermoplastic resins. Polymers which melt by heating and change from solid to a fluid status are defined as “thermoplastics”**.**

In the fluid status such polymers can be shaped in packaging having several possible forms (thin films, sheets, large and small liquid containers, boxes, etc.) depending on the conversion process applied.

After the conversion into a specific shape the cooling makes the polymer solid again obtaining a semifinished item (films and sheets) or a finished end-product ready for use.

All the primary conversion technologies start from plastic pellets and differ by the semifinished/finished good to be produced.

More detailed explanation on the various conversion technologies is reported in Annex B6.2.

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

B6.2. Fulfilments deriving from the application of the Regulation (EC) 2023/2006

In this part are described the activities and the implementation enacted by the plastic packaging production chain to conform to the Regulation (EC) 2023/2006 as amended. Since this Regulation was laid down when the quality assurance systems had already become a daily work tool in most of the manufacturing businesses, it is likely that these businesses already produce in conformity with technical specifications laid down by themselves.

All the same, should it be necessary, the Quality Assurance System and the Quality Control System should be extended to ensure:

> "[...] that the materials and articles are constantly manufactured and controlled, to ensure their conformity to 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" (art. 3 paragraph a Regulation (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006 as amended. Every paragraph is hence the response of the manufacturers of the plastic packaging to the requirements of the article in question. To facilitate reading, the paragraphs keep the same title as the article considered, while the subparagraphs indicate specific subjects.

B6.2.1. Quality Assurance Systems (Regulation (EC) 2023/2006, art. 5) and Size of the business

Quality Assurance Systems

The plastic packaging producer should establish and maintain a Quality Assurance System capable of ensuring the achievement of the objectives laid down by the Regulation and described in the general guideline.

The Quality Assurance System should be documented so as to enable control by the competent authorities.

The Quality Assurance System should establish rules and procedures that regulate the company activity, at least concerning the following points:

- conformity to the requirements of the legislation in force;
- human resources and training:
- raw materials and suppliers including suppliers of goods and services and third parties;
- production;
- quality control;
- storage (raw materials and finished products), reception, handling and shipment;
- traceability
- claim management
- preventive and corrective actions.

The system must ensure adequate monitoring and implementation of the future legislative and normative changes applicable to the specific chain.

As regards the suppliers of raw materials and/or the third parties (tollers), it is advisable to implement an adequate qualification plan that includes also verifications of their Quality

Assurance System. This to ascertain that their Quality Assurance System, where applicable, will conform to the requirements of the Regulation (EC) 2023/2006 as amended.
It is to be stressed that the starting substances for the production of polymers (e.g., monomers, catalysts, additives) are excluded from the field of application of the GMP Regulation. Differently, plastics in form of pellets and semifinished products are starting materials for which the application of the GMP Regulation is required.

Size of the business

Independently from the business size, it should at any rate be guaranteed that the Quality Assurance System, as demanded and finalised by the Regulation (EC) 2023/2006 as amended, is always applied.
The system should be established, implemented and run taking into account the actual size and complexity of the company as well as the technical and human resources available.
On its own premises the business has to at any rate be capable of guaranteeing the application and running of the Quality Assurance and Quality Control System in order to obtain finished materials and products in compliance with the legislation in force on FCMs.

B6.2.1.1. Human resources and training

The *Business operator,* in compliance with the objectives of the Regulation (EC) 1935/2004 as amended and the Regulation (EC) 2023/2006 as amended is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 as amended is applied at all levels of their organization.

The operative aspects relating to the application of the provisions laid down in the Regulation (EC) 2023/2006 as amended can be entrusted by the Business operator to competent and adequately trained people that have to at any rate have at their disposition adequate means to ensure that the requisites of the Regulation (EC) 2023/2006 as amended are respected.

The *company organization* has to at any rate enable the location of the functions to enable inspection by the Competent Authorities.

All *company personnel* potentially involved has to be informed on the principles of GMP, on the obligations that derive from the Regulation (EC) 2023/2006 as amended, on its objectives and on the policy for applying the Regulation.

The *Business* should operate and implement adequate training plans of all staff regarding the tasks that might affect the compliance to the GMP Regulation.

The *personnel* assigned to GMP control activities should be qualified on the basis of the training and the experience acquired.

An appropriate registration of the training process of all personnel must be kept.

B6.2.1.2. Production

The company production phase extends from design and planning to storage of the finished product.

The production process includes all the company phases that combine to guarantee that the end product complies with the legislative, technical and performance requisites laid down at the planning phase to guarantee the suitability for intended use.

Hence the Quality Assurance System should comprise procedures that regulate all the phases listed hereafter:

- Design and development of the product;
- Selection of starting material and suppliers;

- Acceptance of raw material and storage;
- Quality control of raw material;
- Production processes and traceability of the raw materials used;
- Control of process parameters;
- Quality control during production;
- Quality control of the finished product and storage.

Selection of the starting materials of the suppliers and/or services and/or third parties

All the starting materials should be procured from approved and/or qualified suppliers. By qualification is meant a pre-established, organized and documented process that can also include supply contracts and the implementation by the supplier company of a Quality Assurance System conceived so as to be able to guarantee the constant fulfilment of the pre-defined requirements. The plastic packaging producer should ascertain that, where applicable, the following requirements are met:

- traceability according to the Framework Regulation (EC) 1935/2004 as amended;
- declaration of conformity in accordance with the provisions of Regulation (EU) 10/2011 as amended;
- conformity to the Regulation (EC) 2023/2006 as amended.

Should the suppliers not yet been submitted to the approval or qualification process, the starting materials have to be at any rate characterized; nevertheless, a supply contract must be settled. The customer has to be sure that the supplier is always able to guarantee the maintenance of the expected quality level of the production and the conformity to the supply specifications.

Conformity of the production system

The production process has to be kept under control with a Quality Assurance System that has to be conceived so as to be able to guarantee and document that the packaging material produced comply with the applicable legislative and technical provisions.

Documentation of procedure/instructions

Every production phase that may influence the final compliance of the product to the relevant food contact legislation has to be regulated through adequate documentation. Examples of documentation can be: manuals, procedures, working instructions, technical rules and registrations. The documentation required to perform the activity must be available to the appointed personnel, must be kept updated and the distribution of the same must be controlled, so that non updated information is rapidly withdrawn.

B6.2.2. Quality Control System (Regulation (EC) 2023/2006, art. 6)

The Regulation (EC) 2023/2006 as amended laid down that an effective Quality Control System is implemented and maintained, capable of ensuring the compliance with the Regulation, as described in the general guideline in this document.

The system should include procedures that envisage all the necessary controls, the relevant registrations and the actions to be carried out in the event of lack of conformity.

All the documentation relevant for implementation has to be available for the Competent Authorities on demand in accordance with the Regulation (EC) 2023/2006 as amended and the Framework Regulation (EC) 1935/2004 as amended.

The rules and the procedures have to cover the entire production process, as described in paragraph B6.2.1.2, also including a part that contemplates the handling of any non-conformities and corrective actions.

B6.2.2.1. Management of raw materials warehouses

The starting materials from qualified suppliers or approved supplies must be clearly separated from other starting materials that have not been homologated (or approved) or that are from suppliers who are in the process to be qualified or who have not been qualified yet.

For the latter materials a procedure must be established that authorizes their use in production only after the responsible function has confirmed the suitability of the material for use in production.

At the arrival of the supply, any starting material non-compliant with the specification, and then subject to a claim, has to be segregated in a predefined area and clearly identified pending suitable verification.

The segregation of non-compliant material can also be carried out through system procedures other than that of physical separation in an especially defined area (IT blocking).

To demonstrate the correct management of the above materials, the businesses should implement a procedure to manage the materials after the verifications.

The conditions of storage must be such as to guarantee that there is no risk of contamination or deterioration of the material.

B6.2.2.2 Production controls

The traceability of the products through suitable registration of the lots of starting materials used, of the operating conditions of the machinery, recorded during production and the quality controls performed must be guaranteed.

The storage of the finished product and the shipment to the customer should only be enacted against procedures that enable the unequivocal documentation that the material has been controlled in all the established phases and that the final controls, whether planned, have ascertained the conformity to all the requirements identified in the production phase.

This conformity should be ascertained through the comparison between the control data collected and the values and/or ranges listed in the product specifications or in the applicable legislation.

B6.2.2.3. Quality Control of finished products

The Quality Control System has to include suitable procedures to controlling the finished products, taking into account the position in the supply chain. In verifying the conformity of the finished product, Quality Control has to use the information available on starting materials and on the process applied to highlight any limitations and restrictions of use.

Particular attention should be paid to the test conditions used for carrying out the controls, which have to be suited to the verifications of the intended final use of the material.

The analyses should always be carried out using validated methods of analysis. If these methods are not available, an analytical method with performance characteristics adequate to the verification of the specific parameter may be used pending the availability of a validated method.

The equipment for tests and analysis must be properly calibrated and the calibration operations must be adequately recorded.

B6.2.2.4. Management of finished products warehouses

In the warehouse, depending on the classification given by the Quality Control, the approved finished products must be clearly separated from those that still have to be controlled or identified as not compliant.

For any products that are declared unsuitable, a procedure should be in place that prevents their commercialization as FCMs. The unsuitable products, clearly identified, must be segregated in a predefined area of the storage.

Any finished products returned by customers due to non-conformity, have to be segregated in a predefined area and clearly identified pending the definition of the claim.

It is advised that a procedure for managing non-compliant materials is set up; these products have not necessarily to be disposed because of the possibility of their recover /recycling in less critical sectors.

B6.2.2.5. Distribution, shipment and delivery

The plastic packaging producer, if responsible for the transport and the delivery of the material to its destination, has to also guarantee that this phase is regulated by instructions and procedures that guarantee the quality of the material preserving it from any damage and contamination risk that might compromise its use or suitability.

If the means of transport are property of the packaging producer, it must be ensured, also by periodic checks, that these are suited for transporting goods and that maintain intact the requisites of safety and hygiene required to guarantee the integrity of the product.

If the delivery is via external shipping companies, a procedure should be established that qualifies the shipping company and a technical contract should be defined that sets the minimum requirements to be fulfilled to remove possible risks (i.e., damage, contamination, etc.).

If the transport is under the responsibility of the customer, it will be a responsibility of the customer to guarantee the necessary requirements to maintain integrity of the products.

B6.2.2.6. Conformity of the application of the GMP and claims management, corrective and preventive actions

The Quality Control System has to enact suitable procedures so as to periodically monitor the correct implementation and total respect of the GMP.

The Quality Control System has also to enact procedures for documenting the identification of lack of conformity, eventual corrective measures and monitoring of the implementation of the said measures, with particular attention to the time frame envisaged.

The Quality Assurance System of the Business must be therefore structured to include periodical control and verification plans on the fulfilments of the preestablished parameters and specifications, relevant for the conformity to the legislation on materials in contact with foodstuffs; procedures to manage non-compliance and corrective actions should be implemented.

B6.2.3. Documentation (Regulation (EC) 2023/2006, art. 7)

All the documents concerning the Quality Assurance System (procedures, specifications, formulations, etc.) and all the activity of the Quality Control System (instructions, registrations

of control data, machine setup data, tolerances and measurements, etc.) have to be organized so as to constitute a paper or electronic archive, immediately accessible and easily consultable on request by the Competent Authorities.

The documents guaranteeing the traceability will also constitute an integral part of the same, as under art. 17 of the Regulation (EC) 1935/2004 as amended, the copies of the declarations of compliance issued by the customers in observance of art. 16 of the Regulation (EC) 1935/2004 as amended and the applicable national regulations, and the supporting documentation. This documentation will also include any conditions for tests, calculations and analyses, carried out by internal and external laboratories, that serve to demonstrate conformity.

In the event of substantial changes in production liable to change the essential requirements regarding compliance, or when the legislative benchmarks are modified and/or updated, it should be verified whether the documentation relating to the Regulation (EC) 2023/2006 as amended should be updated.

Annex B6.1

Processing technologies for thermoplastic polymers

Acronyms

ABS	Acrylonitrile Butadiene Styrene
EPS	Expanded Polystyrene
HDPE	High Density Polyethylene
HIPS	High Impact Polystyrene
LDPE	Low Density Polyethylene
LLDPE	Linear Low Density Polyethilene
PA	Polyamide
PE	Polyethylene
PET	Polyethyleneterephthalate
PP	Polypropylene
PS	Polystyrene
PVC	Polyvinylchloride

Main features of thermoplastic polymers

Thermoplastic polymers are divided in two groups, according to polymerization type:

– *Polyaddition polymers*
Monomers present a double link in the molecule, which is set to be opened in particular conditions (temperature and pressure). Under the presence of specific catalysts, they establish a link to form the macromolecule, which by itself can have a pronged structure (e.g., LDPE) or a linear one (e.g., HDPE, PP isotactical). Other polyadditioned polymers commonly adopted in food packaging are: PVC, PS, HIPS, and LLDPE.
These polymers don't need to be dried before being processed.

– *Polycondensation polymers*
Polymerization develops by chemical reaction, which eliminates water as a by-product.
Two types of reaction occur in polymers used in the packaging industry:
- Reaction between an acid group (-COOH) and an alcoholic one (-OH) with production of polyesters. (PET)
- Reaction between an acid group (-COOH) and an amino group (-NH2) with production of polyamides (PA.6 - PA.66).

In both cases the presence of residual water in polymer pellets triggers depolymerisation reactions during polymer melting.
Therefore, the polymer needs to be dried before processing.
The dryer is usually set under the hopper of the processing plant.
As an example, the "bottle grade" PET pellet contains about 0.2% of water (that is 2000 ppm) and an appropriate drying must guarantee water content below 50 ppm before processing.

Preliminary operations with additives

Before processing pellets into semifinished or finished products, there are cases in which it is necessary to operate preliminary operations with additives, which enhance polymer processing.

Additives are chosen according to the performance required by the semifinished or finished product. For example, for processing PVC, a polymer which shows a low heat resistance, indispensable additives

are thermal stabilizers and lubricants. PVC in powder, with the addition of these technical aids and ready to be processed, is called "dry-blend".

The following additive groups are the most commonly adopted:

- *Masterbatch - concentrate products*
  The word "masterbatch" identifies a polymer with a high concentration of a product to be mixed with the polymer base, in order to be dispersed properly and safely – considering homogeneity and content.
  Masters are often used as colour concentrates and are added in quantities related to the targeted colour tone and shade.
  Sometimes they are mixed with small amounts of chemical compounds with special functions such as stabilizers, antislip, antistatic, anti-UV, anti-moisture agents, flame retardants, blowing agents etc.
- *Mineral charges, reinforcements (fibres)*
  Beside reducing the polymer content and reducing costs, additives with mineral charges provide better rigidity performance and heat resistance, together with dimensional stability and lower thermal swell. The main mineral charges used in this kind of process are: calcium carbonate ($CaCO_3$), silicon dioxide (SiO_2), quartz flour, talc, mica, wollastonite, kaolin, calcium sulphate ($CaSO_4$), barium sulphate ($BaSO_4$), alumina (Al_2O_3). As alternative to these charges also fibres can be used, the most common being glass fibres, of length ranging from few microns to some mm, with filament thickness from 5 to 25 microns. Added fibres improve rigidity, mechanical resistance and resilience of finished products.
- *Blowing agents*
  Mixing with thermo-sensible chemical compounds induces the formation of an expanded structure in the molten polymer, which persists in the cooling phase. Semifinished and finished products present particular features, due to the low density obtained, which varies from 20 to 650 kg/m^3, depending on technology. The main processes under consideration are:
  - Mixing with solid compounds, which turn into gases at the processing temperatures. It is adopted both in injection moulding and sheet extrusion and enables the production of parts with minimal density around 400 kg/m^3.
  - Mixing with low boiling solvents. To obtain semifinished and finished products a specific technology is used (steam moulding of expanded polystyrene), as described later. The polymer used is just polystyrene, with heptane as blowing agent. This process permits the production of very light items (15-50 kg/m^3) with high insulating properties. The best results are attained with a density range from 25 to 35 kg/m^3.
  - Pentane injection (ongoing test are trying to substitute it with CO_2) in the head of an extrusion line for crystal polystyrene blown film. This helps in obtaining an expanded sheet, with a few mm thickness and 50-100-kg/m^3 density, very well rated in the production of thermoformed trays for retail packaging of meat, fruits and vegetables.

Processing operations

The processing phases which occur after preliminary operations of course depend on the type of polymer and the product to be obtained. They can be: extrusion, extrusion-blow moulding, injection-stretch-blow moulding, injection moulding, calendering, expanded polystyrene moulding, rotational moulding, thermoforming.

Extrusion

Extrusion is the basic method for continuous processing of plastics. It is the primary operation of several processing technologies for applications such as sheets, profiles, pipes, films, wires & cables, sheathing,

tapes, filaments and so on. Most of these processes can be performed just modifying or changing the extrusion head.

A single-screw extruder (or a co-rotating or counter-rotating twin-screw extruder) is composed of two main sections: the barrel-screw unit and the extrusion head. In the first section the polymer is melted and fed along the rotating screw toward the extrusion head. As the plastic granules move along the screw they melt and are forced through a die which is located at the barrel end.

Usually, an extrusion line presents the following structure:

- feeding system (hopper);
- extruder (cylinder + screw);
- head;
- cooling circuit;
- calibration system;
- collection system.

The feeding system is made up by one or more hoppers (dosing units) through which the plastic pellets, additives and colorants are introduced in the extruder barrel.

The heart of the extrusion process is the screw rotating inside the heated cylinder. Their combined action leads to the melting and mixing of the masterbatch, pushing the melt towards the head. The screw has a starting feeding section, a central body with a progressively larger diameter, and a final part with the largest diameter in order to fulfil the compounding and reach proper pressure levels.

In the extruder, the heat needed to melt the pellets originates from different sources, such as the pre-heating treatment during feeding, the electric band heaters of head and cylinder and the heat produced inside the cylinder itself as the engine moves the screw opposing to melt resistance.

The head is the part in which the melt takes shape and dimensions. The screw head matrix shape is set according to the targeted final product. As the melt is pushed off the extruder, it must be chilled to take the definitive shape (cooling and calibration system). These operations can be executed in various ways, depending on the type of product.

Once finalized, the continuous product must be cut and collected. This operation also varies from each product typology to another. Sheets and pipes are cut lengthwise and then stacked in piles. Cast and blown films are wound in reels on cardboard cores.

As already introduced, there exist two main typologies for extruders:

- *single-screw*: it is preferred for film, profile and sheet production (mainly in polyethylene).
- *twin-screw*: it can operate with the two screws rotating in the same or alternate direction and it is mainly used for compounding difficult materials.

Extrusion can be performed through several technologies:

- *Flat-die extrusion*
  This technology is particularly efficient for sheets and films. The head is composed of two metal "lips", varying their length according to extruder production output and required length of sheet or film. The melt is fed to the head lips through a distribution channel which assures a constant feeding speed. Thick sheets are extruded horizontally and then cooled in a vacuum calibrator. Flat sheets with thickness lower than 0.5 mm are also extruded horizontally, but then cooled and dimensionally stabilized with a calender. Instead, thin films are extruded transversally downward and then collected on the cooling cylinder (chill-roll).

- *Flat-die extrusion with biaxial orientation*
  Extruded films can be stretched mono-axially or bi-axially, in some cases with particularly high degree of stretching. The films, by a 2-step process, is beforehand lengthwise stretched between two or more couples of rolling cylinders with different peripheral speed. Cross stretching is then applied: lateral film trims are caught by jaws and stretched moving outside. The stretch temperature of the film – which is in amorphous state – has to be lower than the melting point, and above the glass transition temperature (Tg). In the case of simultaneous biaxial stretching, the jaws are guided outside as the speed in the extrusion direction increases. After stretching, biaxial-oriented films are conditioned through a passage in the oven, at a certain temperature depending on the type of polymer, in order to eliminate the internal stresses due to bi-orientation.

Polymers used in this film production are crystallised, thus presenting a linear molecular structure with no branches. The main examples are PP, PET, and PA.6. In food and beverage packaging they are commonly used in multilayer flexible solutions.

- *Flat-die extrusion for coating*
  The film is extruded with the chinked head vertically set. The film lays on a flexible substrate (commonly paper, paperboard, or alusheet) which is unwound from a reel at the same film extrusion speed. As the parts interact, the film is cooled off and coats it, thus creating a continuous surface. This technology is suitable for lamination substrates, so the film acts in this case as an adhesive.

- *Coextrusion and lamination*
  In food and beverage packaging, there are binding requirements on high water and gas non-permeability (to avoid weight loss). Outstanding barrier properties are crucial to the realisation of packaging which has to guarantee protective atmosphere. To satisfy these demands it is necessary to produce multilayer films and sheets to combine physical characteristics of different materials, so obtaining a multilayer which satisfies top level safety requirements. Coextrusion consists in having more than one extruder to feed one single head. There exist plants with up to 7 extruders jointly operating. Film coextrusion can be carried out through flat head or blown film technologies.
  Coextrusion is suitable to produce multilayer items. It is not possible to coextrude bi-oriented cast films. The production of multilayer items composed by polymers and other materials requires the lamination technology. In this case, film reels are unwound and laminated in several layers by adhesives. By this technology it is possible to print a layer with writings and images and laminate it with the others, thus incorporating the printed surface within the multilayer item.
  Today coextruded multilayer items are used to produce containers (bottom) and laminated multilayer items for the thermo-sealed closing film (top).
  In order to increase gas barrier performance bi-oriented films are coated with a thin aluminium layer, sublimated on the film by vacuum coating.

- *Blown film extrusion*
  Blown film production is a processing technology which consists in extruding the polymer melt through a round crown head. The extruder is horizontally set, while the head conveys the produced tubular upwards. The melt polymer tubular is then caught by two rollers placed few metres above the extrusion head, while a continuous air jet flows in the tubular itself to form the bubble that characterizes the whole process. The so obtained bubble develops upwards and it is dragged by pincer rollers in a way to get the desired depth and to permit the cooling off. Afterwards, the film can be cut according to design and size of the required items, mostly bags and other types of film. As the bubble can be cut down in two halves, it is possible to realize films with relevant width (e.g., agricultural film for green houses)
  The head is what gives a tubular shape to the melt, as a starting point to obtain the bubble. The air required to inflate the bubble comes straight from the body of the die itself. The so called “bubble-guides” which embraces the films helps in stabilizing the bubble formation.
  Considering all polymer families, blown film extrusion is applied to PE, PP, PVC, PA, even if PE is preferred in 99% of the cases.
  A blown film extrusion line is essentially made up by the following units:
  - extruder;
  - head;
  - take-off unit;
  - cooling circuit;
  - winding system.

Extrusion-blow moulding of hollow bodies

This process can be divided in two phases: the extrusion of a tubular piece (parison) and its shaping (blow moulding).

By extrusion-blow moulding an up-down tube is obtained which is going to be cut at regular intervals, and finally cut at the bottom of its head in pieces called parison. In the meanwhile, two side mould halves are pushed forward to seal up the tube in its inferior side; the parison is then inflated by air pressure to take up the design of the mould. As the mould is cold the polymer solidifies, retaining its shape. After solidification the two mould halves are opened and the finished part is extracted.

Extrusion-blow moulding is often used with intermittent extrusion by accumulation head, where the molten polymer is collected and kept hot in the quantities needed for the production of the part, to be able to process materials with low melt strength and to prepare larger parisons. This is because materials with low melt strength involve a risk that the parison is deformed due to gravity, under its own weight, thereby producing a parison of uncontrolled size.

Injection-stretch-blow moulding of hollow bodies

Injection stretch blow moulding is used for the production of high-quality containers. Molten polymer flows into the injection cavity via the hot runner block, to produce the desired shape of the pre-form with a mandrel (the core pin) producing the inner diameter and the injection cavity the outer. After a set time the injection moulds and core pins part and the pre-form held in a neck carrier is rotated 90º. Once conditioned to the correct temperature the pre-form is ready for stretching and blowing to the finished shape. Once the pre-form is within the blow-mould area the moulds close, a stretch rod is introduced to stretch the pre-form longitudinally and using two levels of air pressure, the pre-form is blown circumferentially. After a set time for cooling, the moulds open and the pre-form is removed via drop chutes or robotics. In practice the four stages are carried out concurrently using a revolving carousel of moulds.

According to the two variants of the process, the blow phase is performed after the injection, in the same machine or in a separate blowing station.

Separate production of pre-forms and blown bottles makes both processes independent of each other. Therefore, they can also be used separately in order to optimize the production process. After being moulded, the pre-forms can be sold separately as they are not yet conditioned by the design.

This means that a single pre-form can be produced bottles with similar geometries on different blow-up machines.

Injection moulding

Injection moulding along with extrusion ranks as one of the prime processes for producing plastics articles.

Material is introduced into the injection moulding machine via a hopper. The injection moulding machine consists of a heated barrel equipped with a reciprocating screw (driven by a hydraulic or electric motor), which feeds the molten polymer into a temperature controlled split mould via a channel system of gates and runners.

Before submitting the plastic material to this type of process, depending on the specific needs of material and end use of the article, you may need to condition the material. Examples of such treatment are: the action of drying, if the polymer is particularly hygroscopic (inclined to absorb moisture), the addition of master batches (dye) to get coloured parts or the addition of minerals to improve certain physical/chemical properties.

The screw melts (plasticises) the polymer, and also acts as a ram during the injection phase. The screw action also provides additional heating by virtue of the shearing action on the polymer. The polymer is injected into a mould tool that defines the shape of the moulded part.

The pressure of injection is high, dependant on the material being processed; it can be up to one thousand atmospheres. Tools tend to be manufactured from steels, (which can be hardened and plated), and Aluminium alloys for increased cutting and hand polishing speeds. The costs associated with tool manufacture means that injection moulding tends to lend itself to high volume manufacture.

The mould can be used to manufacture one consistent part in a repeating process or incorporate multi cavities (a multi-impression mould), that is many components can be manufactured on the same mould repeatedly with a single injection.

Variants of the injection moulding process include multi-shot (or 2K moulding) (where different materials are injected into the same mould), insert moulding (where metal components are incorporated), structural foam moulding (where the material is foamed to reduce density) and assisted moulding (where gas or water are incorporated to reduce wall thickness).

During the whole period of molten material injection into the mould, the latter is kept locked by the clamping unit to which it is attached. This unit has the task to counteract the force generated by the injected material pressure, which tends to open the two moulds as a side effect. In traditional construction systems, the clamping unit consists of a fixed platform which ensures a half mould, a mobile platform to which you attach the other half mould (to allow the closing, opening and extraction operations), a support system and guide for the moving platen (4 columns, generally with cylindrical section) and a mechanism for closing the mould (usually a knee operated by hydraulic cylinders, actuators and linear electrical motors).

The sequence of operations described above is performed on a single automatic machine, with hydraulic and/or electrical drives and (injection moulding). The characteristic time for the execution of a cycle obviously varies from case to case, but it hardly takes more than a few minutes. The productivity of the process is very high when you consider that a mould may contain a large number of prints of the same product.

There exists different kind of injection moulding machines: hydraulic, hybrid and all-electric.

Developments over the past years in injection moulding have resulted in advances in the way in which injection moulded components are manufactured. Enhanced quality, reduced cycle times and component weight reductions can be achieved by the process.

The innovation process has provided the market with electric machines for the different movement groups of sliding, mould opening/closing, etc., instead of the traditional pneumatic (hydraulic) movements.

Calendering

The production of leaves and sheets with a thickness greater than 200 microns is made using calenders which cool the leaves after flat head extrusion and determine planarity and thickness consistency.

The calenders are made up of three or more cylinders, working at different temperatures and pressures to achieve the characteristics of the leaf according to required performance.

This technology is particularly suitable to produce PVC sheet, since this polymer -having a low thermal resistance - must always be added with stabilizers, lubricants and other compounds.

The intimate addition of several compounds with PVC is made in a blender at low temperature that is practically an extruder without the head. As a consequence, rather than melting the polymer, it intimately blends PVC with the additives. The mixture is then placed in a mixer with heated rollers that cause the melting of the polymer. Once completely melted, the polymer is placed in a calender with multiple cylinders that turn it into leaf.

Moulding expanded polystyrene

Unlike other thermoplastic processes, the production of EPS products requires that the raw materials be pre-conditioned prior to their final “tooled” moulding process. The raw material (also known as “expandable polystyrene” or “bead”) has a spherical shape and is similar to sugar in appearance).

EPS production requires that during polymerization polystyrene is added with a low-boiling expander (typically pentane, a hydrocarbon that, at atmospheric pressure, boils at room temperature).

The added polymer is in the form of granules, having a glassy appearance with a particle size from 0.3 to 2.8 mm, depending on the applications to be produced.

The conversion process is carried out in three stages:

- *Pre-expansion*
  The tiny spherical polystyrene beads are expanded to about 40 times their original size using a small quantity of pentane (typically 5% by weight) as a blowing agent. This process involves the heating of beads, using a flow of steam, which causes the blowing agent to boil and thus a honeycomb of closed cells is formed. The mould is filled with pre-expanded beads and closed. Saturated steam is

injected into the mould at 110-120°C. The beads soften and further expand, welding together without losing the closed cell structure

- *Maturing*
  As the material cools the pentane liquefies and a partial vacuum is formed inside the bead. The beads are returned to a holding tank for approximately twelve hours to allow the pressure differential to equalize, giving a stabilised granule.
- *Injection*
  In this final stage the pre-expanded stabilized beads are reheated with steam in a mould. The final expansion takes place and the beads coalesce to give a shaped moulding. The simplest mould is a parallelepiped with the vapor inlets distributed evenly on all sides.

The mould is filled with pre-expanded beads and closed. Saturated steam is injected into the mould at 110-120°C. The beads soften and expand further, welding together without losing the closed cell structure.

A cooling of the mould is then required, which is the last step before getting sintered blocks of beads.

With the same technology it is possible to produce items which are widely used in insulating packaging for food. For example, boxes for transporting fresh fish, insulated containers for ice cream and ready meals, and insulating glasses for hot drinks or similar applications.

Rotational moulding

Rotational moulding (often referred to as rotomoulding) is a process used for producing hollow plastic products with no welds.

Rotational moulding differs from other processing methods in that the heating, melting, shaping, and cooling stages all occur after the polymer is places in the mould; therefore, no external pressure is applied during forming. The process is implemented by means of a hollow mould whose inner surface has the shape of the outer surface of the finished item to be obtained.

The rotational moulding process is essentially split into five operations.

- A pre-determined amount of polymer powder is placed in the mould. With the powder loaded, the mould is closed, locked and loaded into the oven. The powder can be pre-compounded to the desired colour).
- Starting rotation around two perpendicular axes.
- Once inside the oven, the mould is rotated around two axes, tumbling the powder – the process is not a centrifugal one. The speed of rotation is relatively slow, less than 20 rev/min. The ovens are heated by convection, conduction and, in some cases, radiation. As the mould becomes hotter the powder begins to melt and stick to the inner walls of the mould. As the powder melts, it gradually builds up an even coating over the entire surface. The mould is heated to a temperature above the melting point of the polymer.
- Cooling is applied from outside the rotating mould, providing the solidification of the material till the moment in which the withdrawal, due to the cooling, causes detachment of the piece from the wall of the mould.
- When the polymer has cooled sufficiently to retain its shape and be easily handled, the mould is opened and the product removed. At this point powder can once again be placed in the mould and the cycle repeated.

This technology has roughly a 10 minutes production cycle; it is mainly used to obtain oversized or designedly complex items, to be produced in little series.

In the meat transformation sector (slaughtering and cold cuts production) small trays obtained through this process are largely adopted, as their physical properties simplify safe cleansing and sanitation operations. Polyethylene is widely adopted in this field, while HDPE is preferred when rigidity and resistance are critical.

Thermoforming

In this process, the plastic material may be a foil or a sheet produced by extrusion.

The opportunity to use this technique of transformation is determined by the amount or thickness of the walls of the parts to be produced. Thermoforming is more convenient than injection moulding to obtain large objects such as tanks and light fittings in small numbers, or to produce large numbers of containers with very thin walls (glasses, plates, food trays, etc.). A limitation of this technology is the low rate of production compared to the injection system, but the advantage is the low cost of the moulds.

Thermoforming can be accomplished by vacuum forming or combining stretch and vacuum process by using counter-moulds. In the process of vacuum forming the preheated sheet of plastic material (generally placed in a tunnel heated by hot air or infrared) lies on the mould due to suction, copying the entire sinuosity of the mould itself (undercuts, trapping of metal or high resistance plastic accessories). In the vacuum-stretch process, the heated plastic sheet is pre-stretched pneumatically by the positive mould and then sucked to the wall with suction.

The process is invariably automated and faster cycle times are achieved than in the Vacuum Forming process. Only thermoplastics sheet can be processed by this method.

The cycle time varies from few seconds to several minutes: since the positioning of the plate on the machine to the removal of the thermoformed part by simple air or water spray cooled. The most crucial variables to the forming time are the type of plastic used the thickness of the sheet or leaf and, obviously, the mould complexity. For example, few seconds are needed for a thermoform tray for food, using a combination of PS-PE with a thickness of 400 microns, about while it takes a minute to thermoform a blister with a hook closure, using PVC with a thickness of 600 microns, and up to several minutes to print shaped trays, using ABS with a thickness of 3 mm.

Annex B6.2

Technical glossary

Co-extrusion: Production process for multilayer films and sheets starting from different polymer matrices.

Custom processing: Processing made by a company producing MCA on behalf of a purchaser that keeps the final responsibility (sometimes called "third party" or "toller").

Extrusion: Processing of a thermoplastic polymer for the production of films and sheets.

Extrusion-blow moulding: Production process for items through extrusion of a parison and subsequent welding and blowing in a female mould.

Foaming-sintering: Production process for items or slabstocks of expandable polystyrene (EPS) by means of steam heating into a suitable mould and in the presence of a blowing agent that – heated – foams plastic chips by heating and welding them with a process called sintering.

Injection moulding: Production process for items by means of polymer melting and injection at high pressure in a male-female mould.

Injection-blow moulding: Production process for items through the production of a preform by injection moulding and subsequent blowing in a female mould.

Rotational moulding: Production process for hollow bodies with powder polymers or liquid plastisol fed in a mould that rotates in two orthogonal directions with external heating.

Spread coating: Coating process of flexible supports with fluid suspensions applied by spreading and solidified in a tunnel-type oven. Extrusion coating of melted polymers extruded from slit die-head on different flexible supports such as film, aluminium foil, paper.

Thermoforming: Production process for items by means of sheet forms with heating and vacuum forming in a male-female mould.

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

B7.1. Characterisation of the sector

B7.1.1. Field of application for 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).

Thin foils and laminates for aluminium bowls are treated in a specific guideline.

B7.1.2. Applicable legislation

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.[14]
- Regulation (EC) 1895/2005 on the restriction of the use of certain epoxy derivates in materials and articles intended to come into contact with food. (Application areas: Paints for boxes and lids, Seals for capsules.)
- Regulation (UE) 10/2011 on plastic materials and articles intended to come into contact with food[15] as amended. (Application field: Seals for capsules and crown caps.)

[14] It replaced the Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

[15] Directives are regularly transposed as amendments to Ministerial Decree of 21st March 1973.

Italian legislation

- Decree of the Italian 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.
- Italian Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- Italian 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 objects intended to come into contact with food.
- Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, intended to come into contact with food or substances for personal use as amended. (Application areas: Paints for boxes and lids, seals for capsules, additives for paints and plastics.)
- Ministerial Decree No. 405/1984 updated by Decree of 13rd July 1995 on the determining the composition of tinplate welded with tin-lead alloy and other methods; migration limits for Sn, Fe and Pb; sampling methods and processes for global organic migration test; some technical requirement. (Field of Application: tinplate).
- Ministerial Decree No. 243/1988 on the determining the composition of tin-free steel; migration limits for Cr and Fe; sampling methods; processes for global organic migration test. (Field of Application: tin-free steel).

B7.1.3. Phases of the production process: flowcharts and descriptions

The next pages treat in schematic way the production flow for metal materials and articles, coated and not-coated, in the field of application of this guideline.

Technical terms are described in the glossary.

Typical examples of products can be found in the dedicated paragraphs.

For each flowchart, those phases of the manufacturing process usually considered as critical in relation to the application field of the Regulation (EC) 2023/2006 as amended are pointed out.

Beside each critical phase, a dashed box describes the specific aspects to guarantee conformity to the applicable laws.

B7.1.3.1. Production flowchart: 3-piece cans and aerosol cans with electro welded body

Figure B7.1 illustrates the flowchart for the production of three pieces cans and aerosol cans with electro welded body (the dashed part is compliant with the GMP Regulation (EC) 2023/2006 as amended).

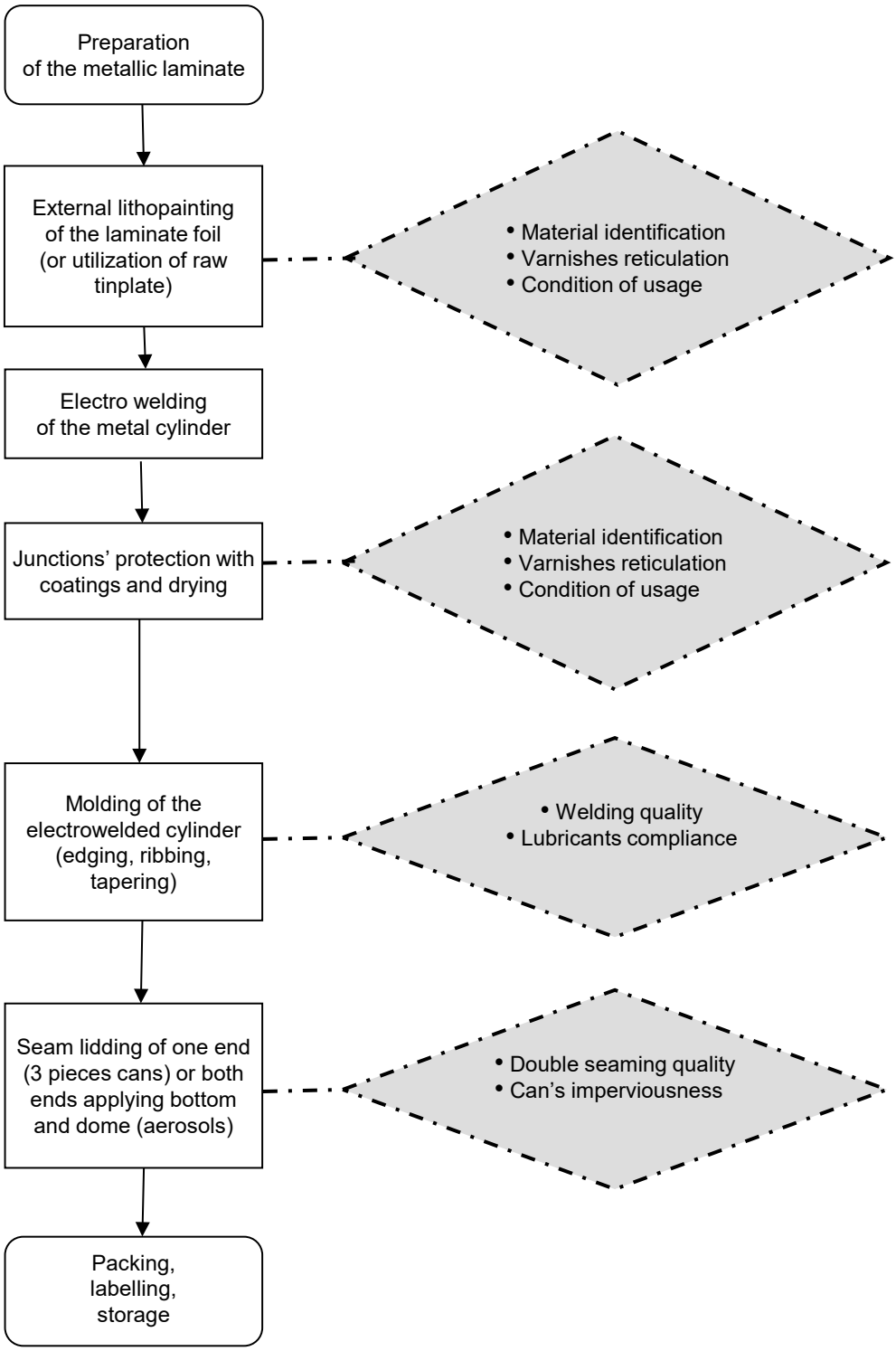


Figure B7.1. Production flowchart for 3-piece cans and aerosol cans with electrowelded body

B7.1.3.2. Brief description of process phase

Preparation of the laminate

In the case of transformation implants including one or more cutting lines, the preparation starts from metallic laminates' coils with defined characteristics and thickness to obtain, by cutting operations, plane foils of required dimensions to be piled up.
The preparation includes also the inspection of the material and the correct positioning according to the next manufacturing operations.
Otherwise, the material is received already piled and the preparation consists in pulling out the foils from the protection package, inspecting the material and then positioning in the correct verse according to the next manufacturing operations.

Lithopainting of the laminate foil

This operation consists in the internal application of protective varnishes and the only external application of inks on the metallic plane laminate, followed by reticulation through conventional thermic processes of UV or mixed.
The painting operation can be conducted by coil coating application: the metallic laminate coil is rolled out passing through a painting machine, dried and the rolled up.

Electro-welding of the metal cylinder

Starting from plane foils properly set up (they can be both painted and raw), forms corresponding to height and circumference of the can you are going to produce are cut.
The plane ties obtained are calendered and then the longitudinal edges are overlapped and electro-welded so that they result welded by melting.

Junctions' protection with coatings and drying

The protection of the welding longitudinal line (both internal and external) is made by applying liquid varnishes called "side stripe" through spraying or rolling technology.
In the first case, the varnish is applied through a pumping system generally without the use of air, while in the second case the varnish is applied transferring it from a shaped steel roll.
Also powder coatings are used for the internal protection, applied by means of an electrostatic gun that electro-statically charges the powder putting down it on the welding line.
After the application phase succeeds, for every applied category of product, the thermic drying phase obtained by passing through furnaces reaching temperatures around 300°C for relatively short times (usually less than a minute).

Moulding of the electro-welded cylinder (edging, ribbing, tapering)

It is a succession of mechanical operations processed on the electro-welded cylinder in order to obtain the desired shape.
Usually, the operations are:

- flaring of the two ends of the cylinder (edging) in order to create a flange so that the next seam lidding operations are possible;
- forming of circumferential ribbing on the body in order to increase the mechanical resistance to radial load.

The edging phase can be preceded by shrinkage operations called "necking" of one end. It makes the cans able to be stacked up.

Seam lidding of one end (3-piece cans) or both ends applying bottom and dome (aerosols)

Mechanical overlapping of the can's components (body, bottom and lid) to obtain a hermetic coupling.
The seam lidding of the two ends is conducted by the can-maker (bottom) and by the food producer (lid), but they are based on the same principles: the body's flange and the curled end of the bottom are mechanically bonded by rolls.

Packing, labelling, storage

Disposition of the cans on ordered plans inside carton-boxes (or other kinds) so that they are disposed in deliverable units called pallet, clearly identifiable by labels and codes placed on each side of the platform.
Usually, pallets are wooden or plastic platforms, allowing handling, charge and discharge operations using forklifts.
These platforms in the warehouse are usually piled forming stowed columns.

Figure B7.2 shows examples of typical products.

Figure B7.2. Example of 3-piece cans

B7.1.3.3. Production flowchart: open top, easy open and peelable lids

Figure B7.3 illustrates the flowchart to produce open top, easy open and peelable lids (the dashed part is compliant with the GMP Regulation (EC) 2023/2006 as amended).

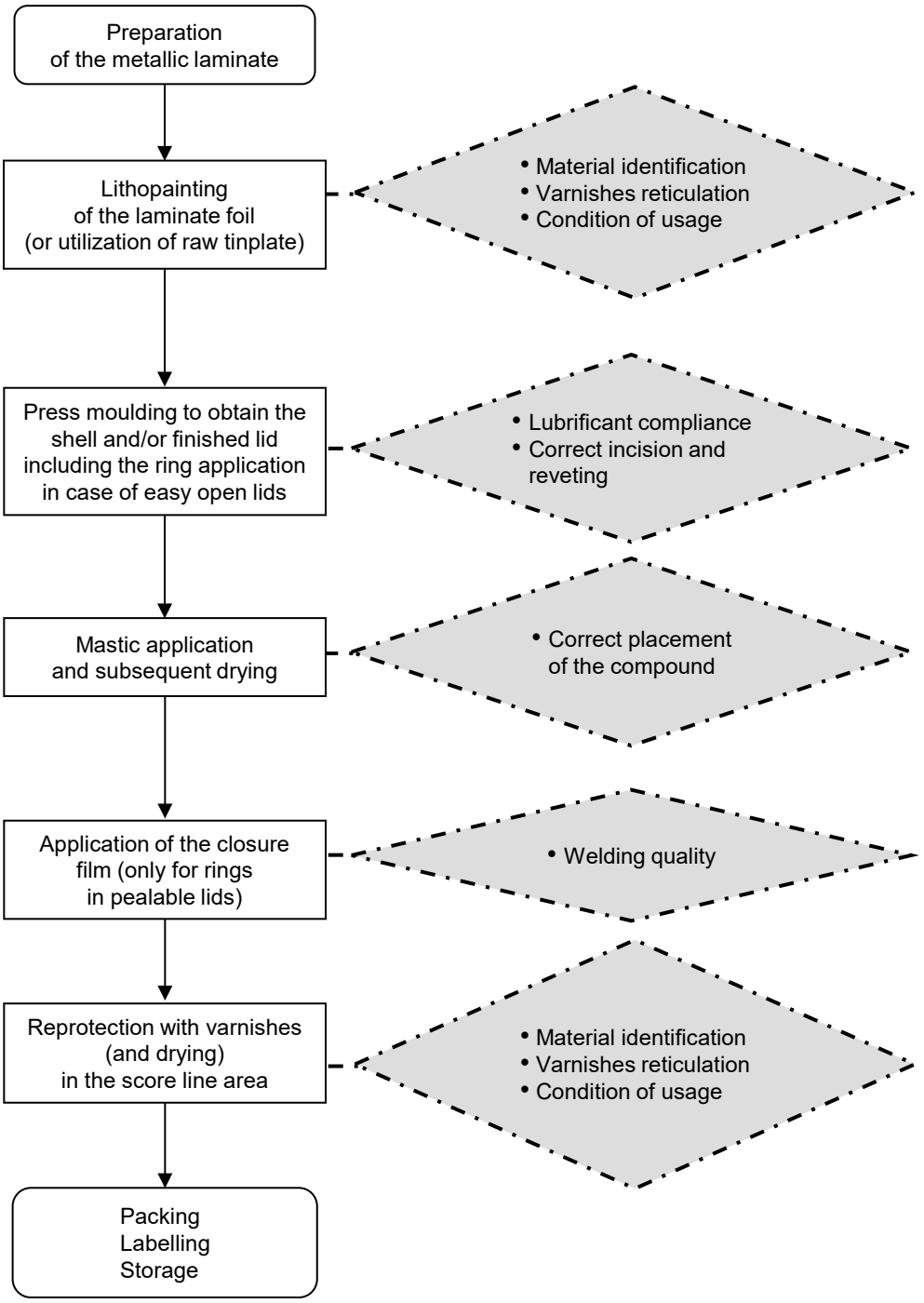


Figure B7.3. Product flowchart for open top, easy open and peelable lids

B7.1.3.4. Brief description of process phases

Preparation of the laminate

In case of transformation implants including one or more cutting lines, the preparation starts from metallic laminates' coils with defined characteristics and thickness to obtain, by cutting operations, plane foils of required dimensions to be piled up.
The preparation also includes the inspection of the material and the correct positioning according to the next manufacturing operations.
Otherwise, the material is received already piled and the preparation consists in pulling out the foils from the protection package, inspecting the material and then positioning in the correct verse according to the next manufacturing operations.

Lithopainting of the laminate foil

This operation consists in the internal and external application of protection varnishes and inks (only external) on the metallic plane laminate, followed by reticulation through conventional thermic energy or UV or mixed.
The painting operation can be conducted by coil coating application: the metallic laminate coil is rolled out passing through a painting machine, dried and the rolled up.

Press (or print) moulding

The foil has to be previously cut in strips of defined dimensions. After this operation, the lids are created by press moulding: using one (if the cutting and printing operations are conducted at the same time) or two dies, the lids are cut out and shaped.
Then follows the curling operation: the edge of the lids is curled inside.
In the case of easy open lids, the manufacturing operations of the lid include other steps such as the "conversion" (press moulding to obtain from the shell the finished lid including the ring application).
In case of peelable lids, the moulding operations also include the cutting of the central disk, the curling of the edge and the application of a film.

Sealing compound application

With this operation, a natural or synthetic rubber gasket is applied on the curling in order to improve the hermetical seaming conditions.
After the application follows the drying of the sealing compound, usually obtained passing the lid through drying oven. By the way other methods can be used too.

Reprotection with varnishes (only in case of easy open lids)

The protection of the semi-incision (on the external side of the lid but sometimes on the internal one too) is realized thanks to electrophoretic reprotection (immersion in the varnish so that the varnish particles are deposited on the uncovered places) or spraying varnishes (or oil, but this system is almost abandoned).

Membrane application (only for peelable lids)

Welding operation through the combined action of temperature and pressure of a thin aluminium membrane (on the order of a few tens of microns) with an inner coating of plastic material film to a raw or painted metal ring.

Film application (only in the case of peelable lids)

A thin (about 10 micron or more) aluminium film (coated with a plastic film) is welded to a metallic ring (varnished or raw) thanks to the combined action of temperature and pressure.

Packing, labelling, storage

Disposition of the cans on ordered plans inside carton-boxes (or other kinds) so that they are disposed in deliverable units called pallet, clearly identifiable by labels and codes placed on each side of the platform.
Usually, pallets are wooden or plastic platforms, allowing handling, charge and discharge operations using forklifts.
These platforms are usually piled forming stowed columns.

Figure B7.4 shows some examples of lids.

pealable lids

open top lids

easy open lids

Figure B7.4. Examples of different typologies of lids

B7.1.3.5. Production flowchart: drawn and redrawn metal cans (2-pieces DRD cans)

Figure B7.5 illustrates the flowchart to produce drawn and redrawn metal cans (2-piece can DRD) (the dashed part is compliant with the GMP Regulation (EC) 2023/2006 as amended).

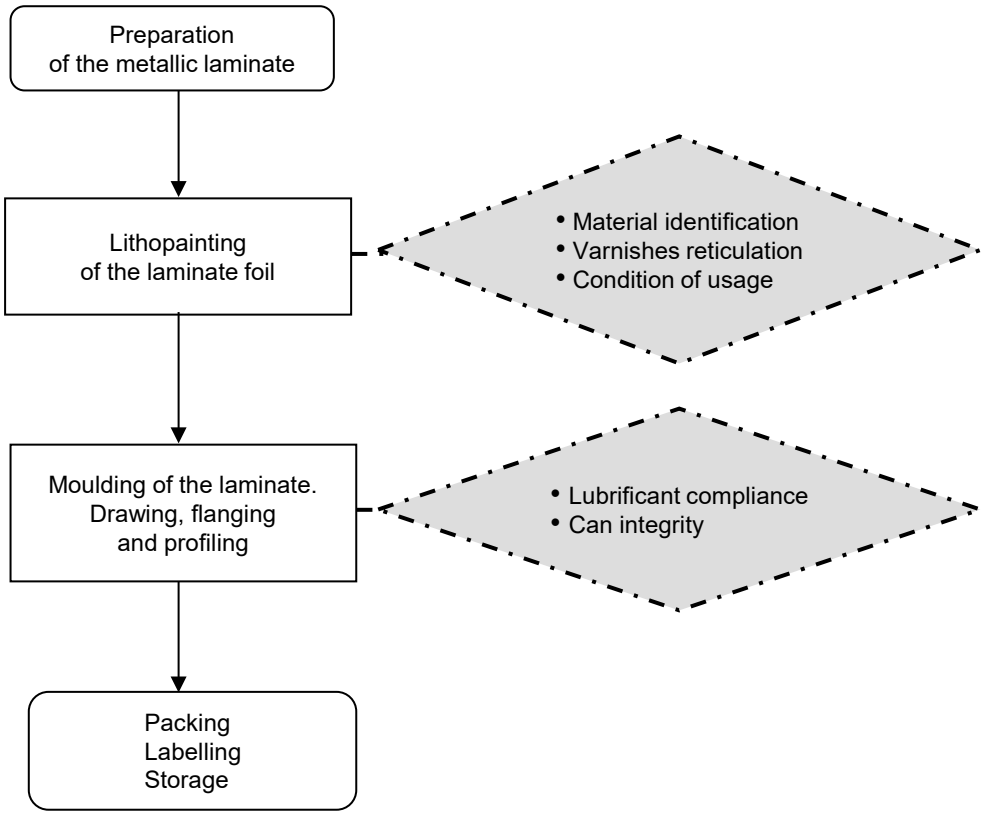


Figure B7.5. Production flowchart for drawn and redrawn metal cans (2-pieces DRD cans)

B7.1.3.6. Brief description of process phases

Preparation of the laminate

In case of transformation implants including one or more cutting lines, the preparation starts from metallic laminates' coils with defined characteristics and thickness to obtain, by cutting operations, plane foils of required dimensions to be piled up.

The preparation also includes the inspection of the material and the correct positioning according to the next manufacturing operations.

Otherwise, the material is received already piled and the preparation consists in pulling out the foils from the protection package, inspecting the material and then positioning in the correct verse according to the next manufacturing operations.

Lithopainting of the laminate foil

This operation consists in the internal and external application of protection varnishes and inks (only external) on the metallic plane laminate, followed by reticulation through conventional thermic energy or UV or mixed.
The painting operation can be conducted by coil coating application: the metallic laminate coil is rolled out passing through a painting machine, dried and the rolled up.

Moulding of the laminate. Drawing, flanging and profiling

A disk has to be cut out starting from the laminate. Then a first drawing operation takes place creating a cup, followed by a second drawing operation with a press called redraw that realizes the complete drawing of the can body.
The can bottom is then profiled, the flange is trimmed and the end of the can is flared. The process can be conducted in a single drawing phase, usually in case of short cylindrical cans.

Packing, labelling, storage

Disposition of the cans on ordered plans inside carton-boxes (or other kinds) so that they are disposed in deliverable units called pallet, clearly identifiable by labels and codes placed on each side of the platform.
Usually, pallets are wooden or plastic platforms, allowing handling, charge and discharge operations using forklifts.
These platforms are usually piled forming stowed columns.

Figure B7.6 shows some examples of typical products.

Figure B7.6. Examples of 2 piece can DRD

B7.1.3.7. Production flowchart: drawn and wall-ironed cans (2-pieces DWI cans)

Figure B7.7 illustrates the flowchart to produce Drawn and wall-ironed (2-piece DWI boxes) (the dashed part is compliant with the GMP Regulation (EC) 2023/2006 as amended).

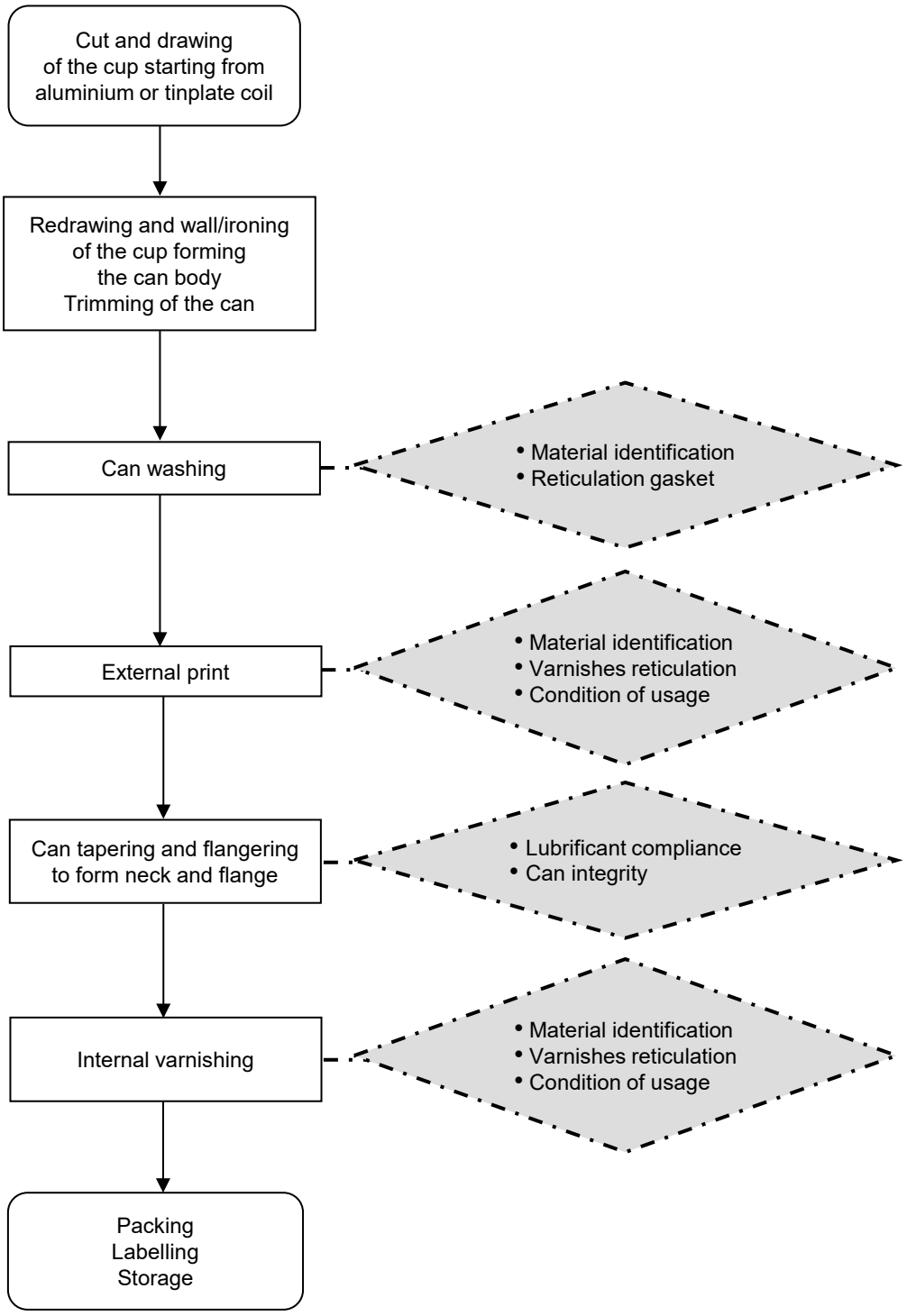


Figura B7.7. Production flowchart for drawn and wall-ironed cans (2-pieces DWI cans)

B7.1.3.8. Brief description of process phases

Cut and drawing of the cup starting from aluminium or tinplate coil

Starting from an aluminium or tinplate coil, a press (with dies) is used to form a quite thick (0.25-0.35 mm) cup called initial cup. This initial cup will be then subjected to drawing operations.

Redrawing and wall-ironing of the cup

The cup walls are ironed (operation called wall-ironing) forcing the redrawn body with ironing rings so that the walls are very thinned and the can body has a high drawn ratio.
These operations are conducted on non-varnished laminates with high usage of direct lubes.

Can washing

Washing phase, removal of lubes residues.

External print

The external decoration is created applying the inks with dry offset printing devices.

Tapering and flangering

The edge of the cylinder's open end is tapered and then trimmed in order to create the flange necessary for the seam lidding.

Internal varnishing

An internal protective spray varnish is applied and then thermically reticulated passing the can into an oven.

Packing, labelling, storage

Disposition of the cans on ordered plans inside carton-boxes (or other kinds) so that they are disposed in deliverable units called pallet, clearly identifiable by labels and codes placed on each side of the platform.
Usually, pallets are wooden or plastic platforms, allowing handling, charge and discharge operations using forklifts.
These platforms are usually piled forming stowed columns.

B7.1.3.9. Production flowchart: closures (capsules with fins, PT capsules, crown caps)

Figure B7.8 illustrates the flowchart to produce closures (capsules with fins, PT capsules, crown caps) (the dashed part is compliant with the GMP Regulation (EC) 2023/2006 as amended).

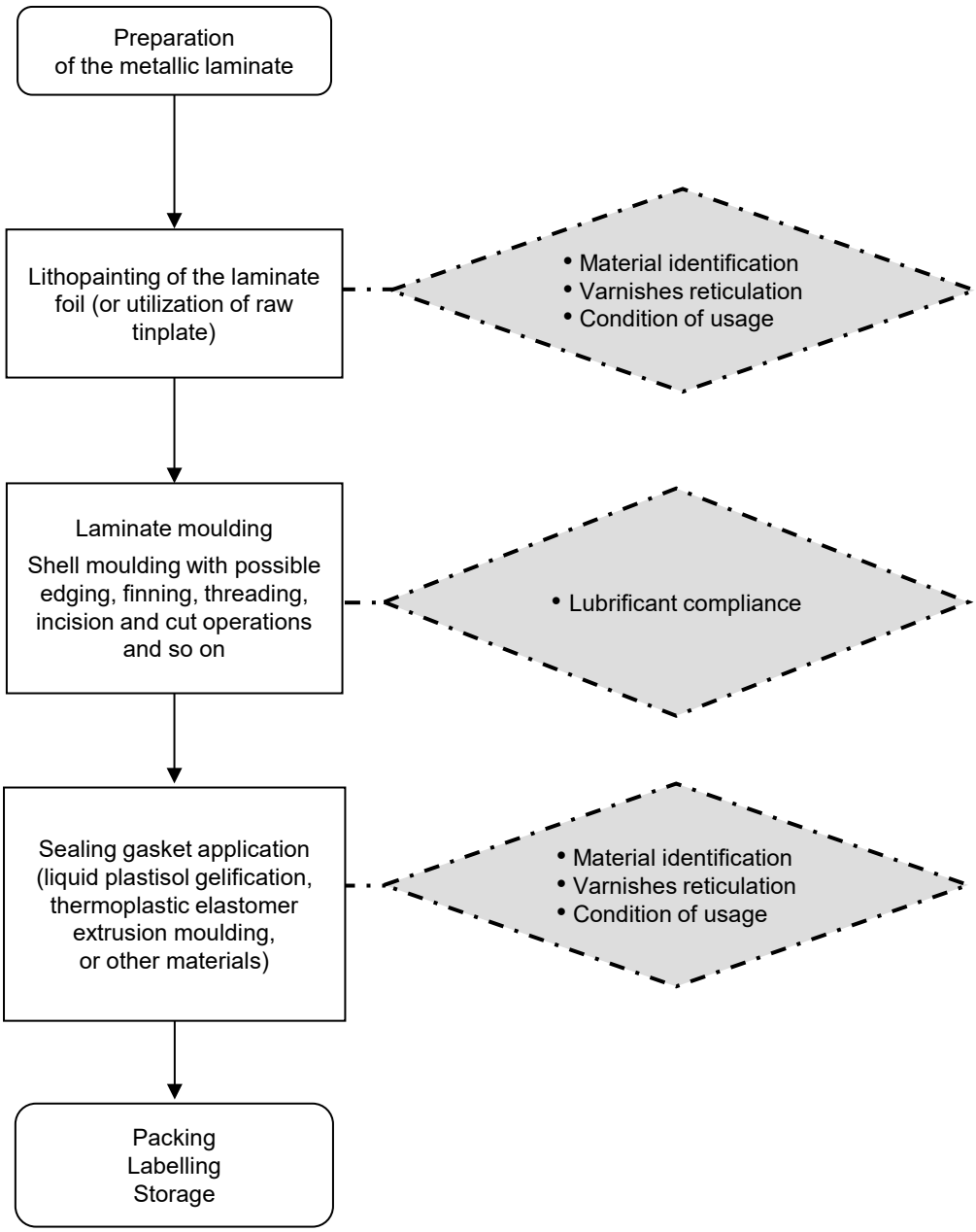


Figure B7.8. Production flowchart for closures (capsules with fins, PT capsules, crown caps)

B7.1.3.10. Brief description of process phases

Preparation of the laminate

In case of transformation implants including one or more cutting lines, the preparation starts from metallic laminates' coils with defined characteristics and thickness to obtain, by cutting operations, plane foils of required dimensions to be piled up.

The preparation also includes the inspection of the material and the correct positioning according to the next manufacturing operations.

Otherwise, the material is received already piled and the preparation consists in pulling out the foils from the protection package, inspecting the material and then positioning in the correct verse according to the next manufacturing operations.

Lithopainting of the laminate foil

This operation consists in the internal and external application of protection varnishes and inks (only internal) on the metallic plane laminate, followed by reticulation through conventional thermic energy or UV or mixed.

The painting operation can be conducted by coil coating application: the metallic laminate coil is rolled out passing through a painting machine, dried and the rolled up.

Moulding of the laminate

The moulding process consists of trimming the foil, cutting by press, drawing it in order to obtain the desired final shape (finishing operations may consists of fins' moulding in case of capsule production).

Gasket application

Application of the plastic sealing liner (liquid plastisol for injection and heat gelification by oven curing or thermoplastic elastomer to be applied by extrusion moulding).

Packing, labelling, storage

Disposition of the cans on ordered plans inside carton-boxes (or other kinds) so that they are disposed in deliverable units called pallet, clearly identifiable by labels and codes placed on each side of the platform.

Pallets are usually wooden or plastic platforms, allowing handling, charge and discharge operations using forklifts.

These platforms are usually piled forming stowed columns.

B7.1.3.11. Production flowchart: flexible tubes, not deformable

Figure B7.9 illustrates the flowchart to produce flexible tubes, not deformable (the dashed part is compliant with the GMP Regulation (EC) 2023/2006 as amended).

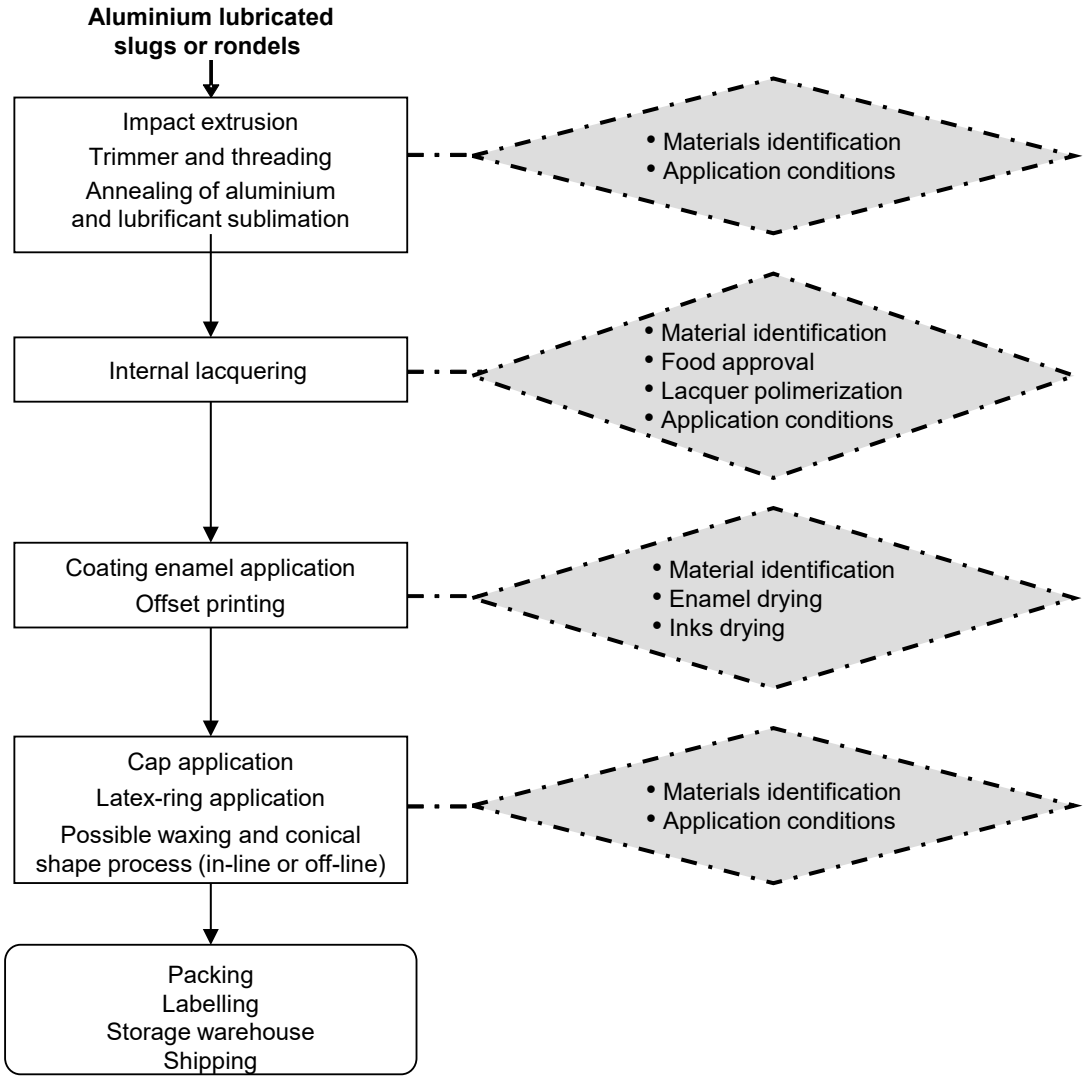


Figure B7.9. Production flowchart for flexible tubes, not deformable

B7.1.3.12. Brief description of process phases

Blank lubricant

The aluminium slugs or rondels are lubricated by the tumbling process to facilitate the phase of impact extrusion. The lubricant in most cases is solid and is removed by sublimation in the annealing oven.

Impact extrusion

The slug or rondel positioned in the die is hit by a mandrel and the aluminium compressed between the mandrel and the matrix takes the shoulder shape and come back along the surface of the mandrel taking the cylindrical shape.

Dimensional finish

By turning operation, the aluminium scraps are eliminated to reach the nominal length and the thread is created on the nozzle.

Annealing

The hardened tube coming from the extrusion phase resumes its typical characteristics of deformation by passing in the oven at about 450°C. In this phase the lubricant is eliminated by sublimation.

Internal lacquering

At the exit of the annealing oven the tube is internally coated by spraying with 2 or 3 passes. This is necessary to ensure the protection of aluminium to the chemical product contained therein. During the passage through the curing oven, generally at 280-300°C, the internal coating cures and becomes solid and homogeneous. The complete protection of the aluminium must be guaranteed by the thickness, degree of polymerization, flexibility and uniformity of the internal film.

Printing

The first phase of the printing process is the application of the enamel which consists to apply a coating on the external surface of the tube with a roller. The enamel can be transparent, white or coloured, glossy or matt. The next step in the drying oven at a temperature between 120 and 140°C allows the not completely drying of the enamel to improve the adhesion of printing inks.

The printing technology is the indirect offset wet on wet. The ink, through a series of rubber and metal rollers, is uniformly distributed and transferred to the photopolymer plate. Then the colour is transferred, one by one, without drying, on a blanket. The complete image is transferred from the blanket to the tube. The enamel and inks are completely dry after passing in the curing oven at a temperature of 170°C.

Finishing

This phase consists into 3 operations:

- Cap application, usually in plastic material;
- Latex-ring application near the open end of the tube;
- Boxing and positioning of the tubes in the boxes suitable for transport and shipping.

For specific requirements it may be necessary to apply a layer of natural wax on the inside (treatment suitable for very aggressive products) or the operation of conical shaping to reduce the transport volume (e.g., sea or air transport).

B7.1.3.13. Production flowchart: Semi-rigid containers lacquered or coupled with polymer films

Figure B7.10 illustrates the flowchart to produce semi-rigid containers lacquered or coupled with polymer films (the part in grey is compliant with the GMP Regulation (EC) 2023/2006 as amended).

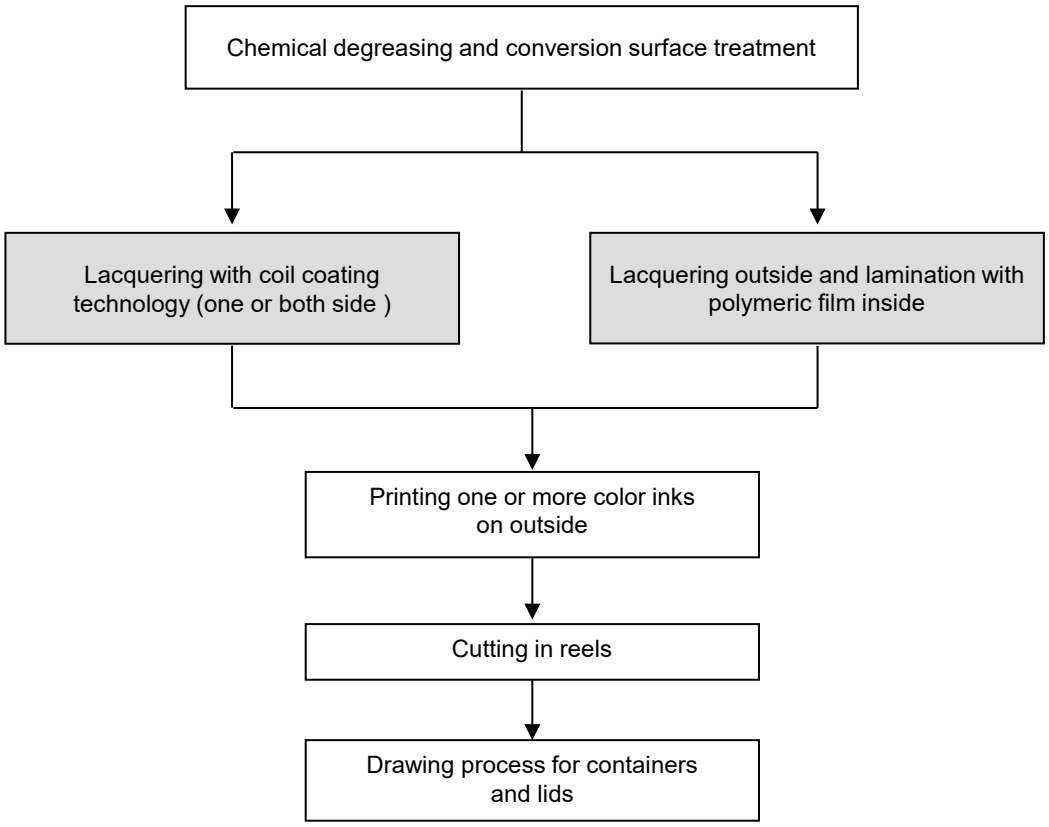


Figure B7.10. Production flowchart for semi-rigid containers lacquered or coupled with polymer films

B7.1.3.14. Synthetic description of the process phases

Coil coating technology

The aluminium coil, after being chemically degreased and submitted to surface conversion treatment (e.g., phosphocromatation, fluotitanation, fluo zirconate treatment), is lacquered with *coil coating* technology.

Such technology allows to lacquer one or both the sides of the laminate coming from a master coil in one single step: the liquid lacquer is applied on the surface/surfaces by cylinders that spread a uniform film that is, immediately after, submitted to a thermal cure in appropriate air flotation ovens (where the laminate is supported by the hot air used also to polymerise/dry the film).

Normally the drying tunnels are dozen meters long and distinguished in areas with different temperature profiles.

In the first areas of the oven the solvents of the lacquers evaporate, in the following zones the metal reaches the necessary temperature for the complete cross-linking of the polymer in it contained.

Within these features it is possible to reach metal temperatures up to 270-280°C: this allows, with lacquering products appropriately set, to dry the lacquer in few dickers of seconds. The foil is subsequently cooled and rewound in coils.

With this technology it is possible to lacquer coils with a maximum speed of approximately 200 m/minute.

Coupling with polymer films

It is possible to couple aluminium laminates with polymer films.
The technologies used up to date to produce semi-rigid food containers are essentially:

- *Dry coupling with solvent*
  Within this technology an adhesive, conveyed in solvent, is used. The adhesive is applied on the metal surface that, after spreading, goes into a warm air oven in which solvents contained in the adhesive evaporate. Then the metal is coupled with a plastic film (which can be of different chemical natures as for example BOPP, PP cast, LDPE, MDPE, PET, PA, etc.). Often, in order to obtain the complete adhesives cross-linking, it is necessary to put the coils, after coupling at appropriate temperature and moisture (humidity), in a climatic chamber for several hours.
- *Dry coupling without solvent*
  Within this technology the adhesive (without solvent content) is spread on the metal laminate and then the polymer film is coupled. The plant (system) used for this coupling does not have an oven (evaporation tunnel). The adhesives used can be with one or more components (elements).
- *Extrusion and coextrusion*
  This technology is totally different from the previous ones. No polymer films are used, but rather polymer granules are used. They are melted in order to be subsequently spread in a dense film with width and thickness intended, which is applied on the laminate. The metal, with still hot polymer, undergoes to press cylinders that spread it on the laminate (so that distribution is uniformed, especially concerning the thickness of the film applied) and grant a good adhesion of the polymer to the support.
  It is possible to extrude, by melting resin granules of different chemical nature, several film in order to apply on the laminate a polymer "stratigraphy" which arise from several polymers even if apparently it seems to be composed by a single layer. This technology is called coextrusion and has the advantage to combine polymers with different features in order to obtain a much more performant film, which exploits synergically the multiple features of a single polymer.

Figures B7.11a to B7.11e show some examples of semirigid containers of coated aluminium with different types of closures.

Figure B7.11.a. Typical tray used by air line companies with wrapped lid

Figure B7.11.b. Typical dessert cup (smooth wall container) with heat sealing lacquers applied inside of container and lid (used also for marmalade, chocolate, honey, milk, etc.)

Figure 7.11.c. Smooth wall containers lacquered with the layer appropriate for traditional oven cooking (with heat sealing multi-layer lid film) used for frozen and non-frozen product

Figure B7.11.d. Typical PET-food container lacquered outside; laminated with CPP inside with thermo-sealable lid (inside CPP coextruded and outside lacquered and, possibly, printed)

Figure B7.11.e. Typical tray used for collective catering lacquered inside white and outside decorative colours, used for acid and/or salt foods or for preservation for more than 24 hours in not refrigeration conditions

B7.2. Fulfilments deriving from the application of the Regulation (EC) 2023/2006

In this part are described the activities and the implementation enacted by the metal packaging (coated and not-coated) chain to conform to the Regulation (EC) 2023/2006 as amended. Since this Regulation was laid down when the quality assurance systems had already become a daily work tool in most of the manufacturing businesses, it is likely that these businesses already produce in conformity with technical specifications laid down by themselves.

All the same, should it be necessary, the Quality Assurance System and the Quality Control System should be extended to ensure:

> "[...] that the materials and articles are constantly manufactured and controlled, to ensure their conformity to 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" (art. 3 paragraph a Regulation (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006 as amended. Every paragraph is hence the response of the manufacturers of the metal packaging (coated and not-coated) to the requirements of the article in question. To facilitate reading, the paragraphs keep the same title as the article considered, while the subparagraphs indicate specific subjects.

B7.2.1. Quality Assurance Systems (Regulation (EC) 2023/2006, art. 5) and Size of the business

Quality Assurance Systems

The metal packaging producer (called, from now on, simply "producer"), intended as the one who produces one or more parts of the can components (bottom, body, caps, easy open closure and so on) starting from half-processed metallic laminates (coated and/or rough), should establish and maintain a Quality Assurance System capable of ensuring the achievement of the objectives laid down by the Regulation and described in the general guideline. The Quality Assurance System should be documented so as to enable control by the competent authorities.

The Quality Assurance System should establish rules and procedures that regulate the company activity, at least concerning the following points:
- conformity to the requisites of the legislation in force;
- human resources and training:
- raw materials and suppliers including suppliers of goods and services and third parties working under contract;
- production (conformity of the process, planning, documentation);
- quality control;
- storage, handling and shipment;
- complaints and corrective and preventive action.

The system must ensure that the future legislative changes are adopted in all the phases of the company process also including the specifications and any contracts with qualified suppliers.
It is recommended to implement a procedure which enables the company to adopt the changes deriving from updates of the applicable legislation on FCMs.

Size of the business

Independently from the business size, it should at any rate be guaranteed that the Quality Assurance System, as demanded and finalised by the Regulation (EC) 2023/2006 as amended, is always applied.
The system should be established, implemented and run taking into account the actual size and complexity of the company as well as the technical and human resources available.
On its own premises the business has to at any rate be capable of guaranteeing the application and running of the Quality Assurance and Quality Control System in order to obtain finished materials and products in compliance with the legislation in force on FCMs.

B7.2.1.1. Human resources and training

The *Business operator,* in compliance with the objectives of the Regulation (EC) 1935/2004 as amended and the Regulation (EC) 2023/2006 as amended is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 as amended is applied at all levels of their organization.

The operative aspects relating to the application of the provisions laid down in the Regulation (EC) 2023/2006 as amended can be entrusted by the Business operator to competent and adequately trained people that have to at any rate have at their disposition adequate means to ensure that the requisites of the Regulation (EC) 2023/2006 as amended are respected.

The *company organization* has to at any rate enable the location of the functions to enable inspection by the Competent Authorities.

All *company personnel* potentially involved have to be informed on the principles of GMP, on the obligations that derive from the Regulation (EC) 2023/2006 as amended, on its objectives and on the policy for applying the Regulation.

The *Business operator* should operate and implement procedures for identifying personnel training requirements and has to see to the training of all staff regarding the tasks that might affect the compliance to the said Regulation.

The *personnel* assigned to GMP control activities should be qualified on the basis of the training and the experience acquired.

An appropriate registration of the training process of all personnel must be kept.

B7.2.1.2. Selection of starting materials and suppliers

In this guideline "starting materials" is intended for both the metallic part and the internal coating in direct contact with food products.

The producer is called upon to use only approved starting material for which he has all the necessary data guaranteeing the conformity of the packaging produced to the legal requisites, including the restrictions due to conditions of use, this by way of information from the supplier and/or through controls and checks.

The producer should have available the following documents:

- declaration of compliance of the starting materials, according to what has been established by the applicable European and/or Italian legislation;
- necessary information to ensure that the supplied products conform to the requirements applicable to FCMs (for example, in the case of coatings, the producer must have supplier's information on terms of application of the coating, as indicated in the technical report).

Any supply of starting material has to be kept under adequate control.

It is good practise that the starting materials/raw materials are procured from qualified suppliers. By qualification is meant a pre-established, organized and documented process that can also include supply contracts.

It is advised to verify, also through periodical visits of inspection (audits), the Quality Assurance System of the supplier of starting materials or third parties to ascertain whether it is compliant with the requisites as laid down by the Regulation (EC) 2023/2006 as amended, where applicable.

In case the supplier is not under a GMP regime, the producer must ensure that raw materials or semi-finished products to be used will be appropriate to produce materials and articles suitable to contact with food; this verification, which is at producer's costs, could be carried out by means of checking of the compositional certification given by the suppliers, and by carrying out appropriate technical and analytical evaluations.

B7.2.1.3. Production

The company production phase extends from design and planning to storage of the finished product.

The producer should implement procedures and/or instructions that regulate at least the phases listed hereafter:

- Product planning;
- Arrival of raw materials
- Painting and printing of the metal laminate;
- Moulding of can and components;
- Reprotection with coatings applied to finished cans and components;
- Application of sealing mastic and/or sealing gaskets.

During all the phases, the complete traceability of used materials has to be ensured.

All the phases should be carried out following precise instructions indicating the required technical specifications of materials to be used, the operations order and the manufacturing and process conditions needed (for example the specific burning temperature, timing and weight to be applied in case of varnishes, mechanical characteristics in case of laminates).

Specific and characteristics of the finished product should be clearly defined.

Design of new products and conformity assessment for food contact

The most important concept implied by the GMP is that of a product designed to be compliant to the legislative requisites on materials and articles intended for food contact (FCMs).
Distinctions can be made between the design of a product and the adaptation of a product to the requirements of a customer, who may have a product developed for a specific use subsequently suited to the precise and different demands of a customer.
If a producer develops a product compliant to a project for conformity of use, then packaging material produced must:

- comply with the performances for the final use it is intended for;
- comply with the requisites of the legislation in force for materials intended for food contact.

To this purpose the product has to be produced with raw materials that, subject to controls, guarantee, in all the process phases, the compliance to use the same are intended for and the legislative requisites covering food contact. To enable the development of a project of a packaging compliant to customer requisites the following information has to be known and available:

- nature of the food product to be packed;
- surface/volume ratio;
- shelf life of the product to be packed;
- filling, closure and preservation techniques of the final pack;
- thermal preservation processes that the pack along with its contents will be subjected to;
- storage conditions.

In absence of this information, the packaging producer will refer to existing documents or know-how, such as the "Raccomandazioni ANFIMA" (ANFIMA Recommendations, a general technical document).
When an already existing packaging material is adapted to the requisites of a new product launch (new customer for an already known type of product) or to the requisites of a different use (same customer for a modified product), the initial project has to be recontroled and verified to make sure it complies to the new use.
To ensure that the project of conformity of a packaging item remains valid for the new use, the necessary information should be given by the food producer at least including the data described above (nature of the food product, shelf life, filling and preservation techniques, storage conditions). In absence of this information, the reference will be the existing know-how, as above.
All the modifications on the original project have to be verified to control any undesired effects on the conformity of the product.
The requisites of the new packaging must be suitably documented.
Lastly, the producers have to indicate to the customer any possible change that might in some way undermine the material's correspondence to the requisites demanded.
In developing a packaging, a particular attention has to be paid to the adopted test conditions that must fit as much as possible to the conditions of use of the final material, relatively to the position of the product in the manufacturing chain.
The analytical tests should always be conducted following validated methods. If these methods do not exist, an analytical method characterized by adequate performances at the established limits should be used, waiting for the development of a validated method.

Conformity of the production system

The production process has to be kept under adequate control with a Quality Assurance System that has to be conceived so as to be able to guarantee and document that the product responds

to the relevant technical specifications and that these specifications comply with the product design.

The Quality Assurance System has to be finalised so as to proffer sufficient attention to the most critical points of the production system that might endanger the attainment of both legislative, technical and qualitative conformity of the end product.

Documentation of procedures/instructions

Every production phase has to be regulated through adequate documentation. Examples of documentation can be: manuals, procedures, working instructions, technical rules and registrations. The documentation required to perform the activity must be at the disposition of the appointed personnel, must be kept updated and the distribution of the same must be controlled, so that non updated information is speedily withdrawn.

B7.2.2. Quality Control System (Regulation (EC) 2023/2006, art. 6)

The metal packaging producer (producer) should establish and maintain an effective Quality Control System capable of ensuring the respect of the conformity to the Regulation as laid down in the general guideline.

The system should include procedures that envisage all the necessary controls, the relative registrations and actions to be carried out in the event of lack of conformity.

All the documentation has to be available for the competent authorities that demand to see it in accordance with the Regulation (EC) 2023/2006 as amended and the Framework Regulation (EC) 1935/2004 as amended.

The rules and the procedures have to cover the entire production process, as described in paragraph B7.2.1.3, also including a part that deals with the management of any non-conformities and corrective actions.

The Quality Control System has to be applied to every phase of the production process and it does not include specific controls on the finished product to authorize its release.

In absence of non-conformities noticed in each phase, the finished product is considered compliant with the legislative requirements and so directed to the labelling phase, attesting the final conformity.

B7.2.2.1. Management of raw materials warehouses

The approved starting materials from qualified suppliers must be clearly separated from other starting materials that have not been homologated or that are from suppliers who are undergoing qualification or who have not been qualified.

For the latter materials a procedure must be established that authorizes their use in production only after the function laid down under the Quality Control System has confirmed the suitability of the material for use in production.

Any raw materials that are the subject of disputes have to be segregated in a predefined area and clearly identified pending the problem is solved. The segregation of non-compliant material can also be performed through restrictions other than physical segregation in a specially assigned area (IT block).

Only the function laid down under the Quality Control is enabled to authorize any use of these materials.

The conditions of the environment, of the storage and handling of the storage areas must be such as to guarantee that there is no risk of deterioration of the material.

Special attention should be given to the storage, warehousing and handling of raw materials to avoid any damage that can make the materials unusable.

B7.2.2.2. Production controls

The Quality Control System has to be regulated by suitable procedures that guarantee that during the production process all the necessary controls are carried out to guarantee that the product conforms to the legal, technical and quality specifications defined during the design phase.

The traceability of the products through suitable registration of the raw material lots used, by the machine conditions set and registered during production and the quality controls also carried out on intermediate products and semi processed articles must be guaranteed.

The storage of the finished product and the shipment to the customer should only be enacted against procedures that enable the unequivocal documentation that the material has been controlled in all the established phases.

This conformity should be ascertained via the comparison between the control data collected and the values and/or tolerances entered in the product technical specifications or the specific legislation.

As an example, some characteristic parameters that can be kept under control are listed:

1. airtightness parameters of the package:
   - seaming dimensions
   - welding characteristics
2. application parameters of the roll paintings:
   - dried up weight
   - control of the reticulation conditions
   - distribution on the support
3. application parameters of the re-protective paintings:
   - control of the placing
   - control of the reticulation conditions
   - stoicometric ratios (for bi-component adhesives and/or inks);
   - global and/or specific migrations (when called for);
   - solvent residue (when called for);
4. control of the materials specifications (conformity to the work order)
5. absence of set-off.

In order to complete the production controls, it is advisable to set up a plan of analytic tests to ensure the respect of global and specific migration limits applicable to FCMs and articles.

In this case it is suitable a specific operative procedure to be defined in the Business to establish and regulate both frequency and methods of controls.

Special attention must be paid to the control of possible contamination. A procedure should be in place to assess this risk and actions established to prevent this should be documented (e.g., regular cleaning of machinery and equipment, hygiene in the workplace, prevention against insects and rodents, etc.).

B7.2.2.3. Quality Control of finished products

The Quality Control System has to dispose of suitable procedures to verify the conformity of the finished product. In verifying the conformity of the finished product, Quality Control has to

use the information available on raw materials and on the process applied to highlight any limitations and restrictions of use for food contact.

B7.2.2.4. Management of finished products warehouses

The compliant finished products should be clearly separated from those non-compliant.

For non-compliant products, a procedure should be available that prevents their expedition (or their internal use) pending the definition of the problem. Any derogations are only to be authorized by the function established in the Quality Control System.

The non-compliant products, clearly identified, should be kept separated in a predefined area in order to impede their use, even accidental.

Any finished products returned by customers due to non-conformity, should be kept in a predefined area and clearly identified, pending the definition of their final destination/use (sorting, scrapping, downgrading, etc.). Only the function laid down under the Quality Control System is allowed to authorize any use of these materials.

In any case, unsuited products can be blocked through other system device (for example via IT system) different from the physical segregation: it is fundamental that the unsuited products are in any way not available for both the internal utilization and the expedition.

It is advised that a procedure for managing non-compliant materials is set up also providing for their disposal or the destruction of the same.

The environmental conditions of storage of the said areas have to be such as to guarantee that there is no risk of deterioration of the materials.

B7.2.2.5. Distribution, shipment and delivery

The producer, if responsible for the transport and the delivery of the material to its destination, has to also guarantee that this phase is regulated by instructions and procedures that guarantee the quality of the material, preserving it from any damage and contamination risk that might compromise its use or suitability.

If the means of transport are the property of the packaging producer, it must be ensured, also by periodic checks, that these are suited for transporting goods and that maintain the requisites of safety and hygiene required to guarantee the integrity of the product.

If the delivery is via external couriers, a procedure should be established that qualifies the courier and a technical contract should be defined that sets the minimum requisites to be respected to eliminate possible risks (i.e., damage, contamination, etc.).

B7.2.2.6. Conformity of the application of the GMP and claims management, corrective and preventive actions

The Quality Control System has to enact suitable procedures so as to monitor the correct implementation and total respect of the GMP.

The Quality Control System has to enact procedures for documenting the identification of lack of conformity, the enacting of any corrective measures and the monitoring of the implementation of the said measures, with particular attention to the time frame envisaged to implement the measures.

The Quality Assurance System of the Business should therefore be implemented to include periodical verification and control plans on conformity to pre-established parameters and specifications, relevant to compliance with legislation on FCMs; procedures for managing non conformities as well as corrective and preventive actions deriving from eventual claims should be implemented.

Indications about the main critical phases generally identified in the metal packaging manufacturing chain are pointed out in the previous specific paragraphs on flowcharts.

B7.2.3. Documentation (Regulation (EC) 2023/2006, art. 7)

All the documents concerning the Quality Assurance System (procedures, specifications, formulations, etc.) and all the activity of the Quality Control System (instructions, registrations of control data, machine setup data, tolerances and measurements etc.) have to be organized so as to constitute a paper or electronic archive, immediately accessible and easily consultable on request by the Competent Authorities.

The documents guaranteeing the traceability will also constitute an integral part of the same, as under art. 17 of the Regulation (EC) 1935/2004 as amended, the copies of the declarations of compliance issued to the customers in observance of the applicable European and national regulations and the applicable national provisions, and the supporting documentation. This documentation will also include any conditions for tests, calculations and analyses, carried out by internal and external laboratories, that serve to demonstrate conformity.

In the event of substantial changes in production liable to change the essential requirements regarding compliance, or when the legislative benchmarks are modified and/or updated, it should be verified whether the documentation relating to the Regulation (EC) 2023/2006 as amended should be updated.

Annex B7.1

Technical glossary

2-piece can: A can where body and base are integral and separate top end is seamed on after filling.

3-piece can: A can comprising a double open-ended body cylinder with separate ends on at both ends.

Aerosol can: A can to contain pressurised, sprayable products with special top end components and valve. Body construction may be 2-piece or 3-piece.

Black plate: Packaging steel with only a thin coating of oil for anti-corrosion protection. Generally used in the manufacture of drums.

Coil: A rolled flat strip product which is wound into regularly superimposed laps so as to form a coiI with almost flat sides.

Conical shaping: Transformation of the cylindrical shape of tube by compressed air to make it slightly conical.

Coolant: Water with additives which acts both as a lubricant during the body making part of the DWI process and a means of cooling the wall ironing process.

Crown closure: Closing means for glass bottle or necked-in can from light gauge tinplate, TFS or aluminium with dentate (castellated) skirt.

Cupper: The first drawing stage of 2-piece can body making process.

Deep drawing: Process consisting in forming flat metal into a hollow shape by means of a punch and a die.

Differentially coated electrolytic tinplate: electrolytic tinplate, one surface of which carries a heavier tin coating than the other. In some cases, one surface may have no tin coating.

Dimensional finishes: Obtain the final dimensions of the tube by turning.

DRD process: Draw/ReDraw process whereby a two piece can body/base is formed via successive drawing operations.

Drum: A medium or heavy gauge metal package, of 3-piece construction and with special closing features, with a capacity between 20 and 240 litres.

DWI process: Metal forming process (Drawing and Wall Ironing) by which an initially formed shallow cup is increased in height by progressive reduction of the cup diameter and thinning of the wall to produce a 2-piece can.

Easy-open end: Seamed-on rigid end which can be opened without using a tool by means of a ring-pull feature.

Electrolytic Chromium/Chromium oxide coated Steel (ECCS): Cold rolled low carbon mild steel sheet or coil electrolytically treated to produce on both surfaces a duplex film of metallic chromium adjacent to the steel substrate with a top layer of hydrated chromium oxides or hydroxides.

Electrolytic TinPlate (ETP): Cold rolled low carbon mild steel sheet or coil coated on both surfaces with tin that is applied in continuous electrolytic operation.

Enamel application: Application of a layer of thermosetting polymeric material on the outer surface of tube by a rubber roller in order to promote the adhesion of the inks in the printing process.

Enamel drying: not completely drying in the hot-air oven of the enamel to improve the inks incorporation in the enamel.

End: Collective term for devices serving to close, protect and secure the top and/or bottom ends of metal packaging.

Flanging: Flaring out of a can's open end(s) to receive an end for seaming.

Foil: Flexible material with an internal aluminium layer lacquered and/or coextruded with PP polymer.

Impact extrusion: Cold plastic deformation of aluminium blanks through impact to obtain the cylindrical shape. The aluminium compressed between the die and the tip comes back along the tip taking the cylindrical shape and the nozzle shape also.

Ink: Material containing resins, pigment and additives that mixed allow to obtain a viscous fluid suitable to be applied on metal sheets by an offset printing process.

Lacquer: Coating products of variable viscosity grade suitable to be applied over a metal support.

Lacquering process: Lacquer application process generally performed by the application of thermoset coatings to a metal coil or to a flat sheet or to a final product. Roll, spray or electrostatic deposition are the main adopted process.

Lining: Application of a (elastomer) sealing compound intended to make an end seam leak proof.

Lubricant by tumbling: lubricant of aluminium slugs and rondels by lubricants usually solid (Zinc Stearate or Zinc Arachinate) to facilitate the impact extrusion. The lubricant is eliminated in the annealing oven by sublimation.

Neck: end side of the tube where the product is discharged during the use.

Necking: Forming inwards of the upper end of a can body to allow the application of a smaller diameter end.

Offset printing process: Ink application process over a metal sheet based on the process of transferring the ink from a printing plate to the metal support by the action of a rubber cylinder.

Pail: A medium gauge, generally tapered and nestable metal container, with a fully removable top end, of a capacity in the range 5-40 litres.

Peelable end: End with a flexible foil heat-sealed on a metal ring which can be opened without using a tool by means of foil tab feature.

Plastisol: A gasket compound for a metal closure which is based on plasticised polyvinyl chloride.

Polymer coated metal: Metal substrate coated with a thermoplastic layer by lamination or extrusion.

Post repair: Score easy-open protection by lacquer application and curing at the end of the lid manufacturing process. Sometimes the protection consists just of oil spray over the score.

PT Closure: Metal closure for glass jar of a type which is pressed on after the initial filling of product by twisted off by the consumer.

ROPP closure: "Roll-on pilfer-proof" closure for bottles, normally drawn from pre-coated aluminium.

Sealing liner: Plastic sealing gasket applied on the internal side of a metal closure for produce the hermetic sealing between the glass bottleneck and the closure

Score: Thinning of the metal of an easy opening end such that it tears readily when the tear tab/ring is pulled

Seaming: The process of applying an end to a can body specially interlocking the end with the flange of the can.

Side seam: Welded or interlocked joint when a rectangular body blank for a 3-piece can is formed into a body cylinder.

Side stripe: Protection of side-seam area with an organic coating.

Stoving: Support for lacquered/printed metal sheet during its passage through a drying/curing oven.

Tab/Ring-pull: Feature of an easy opening end which provides the grip for a manual opening.

Thermoplastic coating: A coating product in solvent, or as a powdered solid, which when applied/dried under the action heat does not undergo nay further chemical reaction.

Thermoset coating: A coating product in solvent, or as powdered solid which, when applied to a metal substrate and heated, develops its mechanical and chemical resistance properties through further chemical reaction (cross-linking).

ThermoPlasticElastomer (TPE): Plastic blend for sealing gaskets, to be applied by extrusion moulding on the internal side of the metal closure.

Traceability: The ability to trace and follow a material or article through all stages of manufacturing processing and distribution.

Waxing: Hot application by spraying of natural wax to avoid the interaction between the aluminium and the alkaline substances.

Annex B7.2

Frequently asked questions

Q1 *Does Regulation (EU) 10/2011 of the Commission of January 14, 2011, regarding plastic materials and articles intended to come into contact with food, and its subsequent updates, apply to metal coatings?*

No, they apply to plastic materials only, not to metal coating.

Q2 *Is there a specific European legislation for metal coatings?*

No, in addition to the general provisions of Regulation (EC) 1935/2004 as amended, the only specific legislative reference applicable at the European level is Regulation (EC) 1895/2005, which defines the migration limit of certain epoxy derivatives in plastic materials or those protected by a surface coating. However, there is voluntary technical documentation from the European association of paint manufacturers that defines sector-specific Good Manufacturing Practice (GMP) (CEPE guidelines).
Commission Regulation (EU) 2018/213 of February 12, 2018, regarding the use of bisphenol A in paints and coatings intended to come into contact with food.

Q3 *Is there a specific European legislation for tinplate in direct contact with food?*

No, but some technical standards are available such as:

- EN 610:1995 Tin and tin alloys-Ingot tin;
- EN 10202:2022 Cold reduced tin mill products. Electrolytic tinplate and electrolytic chromium/chromium oxide coated steel;
- EN 10333:2005 Steel for packaging - Flat steel products intended for use in contact with foodstuffs, products and beverages for human and animal consumption - Tin coated steel (Tinplate).

It is also available a voluntary GMP (APEAL guidelines) from the European tinplate producers.

Q4 *Is there a specific European legislation regulating the use of chrome plating on food cans?*

No, there are only general requirements.
There is the voluntary technical standard UNI EN 10335:2005 Steel for packaging - Flat steel products intended for use in contact with food, products, and beverages for human and animal consumption - Electrolytically coated chromium and chromium oxide unalloyed steels.
It is also available a voluntary GMP (APEAL guidelines) from the European tinplate producers.

Q5 *Is there a specific European or Italian legislation for lacquered aluminium in contact with food and beverage?*

For the raw material itself, there is the voluntary technical standard EN 14287:2004 Aluminium and aluminium alloys - Specific requirements on the chemical composition of products intended to be used for the manufacture of packaging and packaging components.
The paint film falls within the national scope of the Ministerial Decree of March 21, 1973.

Q6 *Do reference documents exist to properly define the appropriate specifications for metal containers?*

Yes, for instance, the “Raccomandazioni ANFIMA” in Parma, written in cooperation with “Stazione Sperimentale per le Industrie delle Conserve Alimentari” defines the overall specification of metal cans related to the food product.
This is a voluntary reference document. The document is in constant evolution and updating, and the most recent version can be requested from ANFIMA.

Q7 *How do you choose a coating?*

The choice of the proper coating and the number of coating layers has to be performed on the basis of the following parameters: 1) pH of the food;2) saline content in aqueous solutions;3) cooking/heating temperatures of the food; 4) filling systems ;5) food storage conditions (frozen, refrigerated, room temperature, etc.); 6) type of oven (conventional or microwave); 7) closure system for trays; 8) shelf life. Based on such information, the most proper coating is selected, suitable for the food to be preserved and the cooking conditions that will be used.

Q8 *Are there reference documents for the radiometric control of metallic products from non-EU countries?*

Legislative Decree no. 100 of June 1, 2011 (updating Legislative Decree no. 23 of February 20, 2009, implementing Directive 2006/117/Euratom), imposes on the importer (not on the user if different from the importer) the radiometric surveillance of metallic products originating from non-EU countries and cleared through an Italian port to verify the absence of radiological contamination and radiation levels above the natural background level.

Q9 *Are there reference technical documents for the supply of raw materials from abroad?*

In addition to the previously mentioned international voluntary technical standards, there are other standards different from ISO EN, such as ASTM A623-9 “Standard Specification for Tin Mill Products General Requirements” or JIS G 3303 “Tinplate and Blackplate” and generally, all those commonly used as references in commercial exchanges.

There are also the EuPIA Guidelines “Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles, November 2011 - corrigendum July 2012,” and “Guideline on Printing Inks applied to Food Contact Materials, April 2020.”

Q10 *For the calculation of migration (both global and/or specific), is it possible to use mathematical calculations and/or screening tests?*

Where not covered by a regulatory reference (as in the case of metallic packaging – lids and similar coated closures as per Article 1, paragraph 1, letter d) - mentioned by Regulation (EU) 10/2011 and subsequent amendments), for other metallic packaging, it is possible to calculate migration by applying mathematical criteria that ensure the use of the worst-case scenario as the prevailing reference over less extreme scenarios.

B8. CORK: CORK STOPPERS

B8.1. Characterisation of the sector

B8.1.1. Field of application of the guideline

This guideline is applicable to companies that produce cork stoppers or parts of cork of cork stoppers or any other material or article for cork stoppers in which the main component is cork manufactured that, as a finished product, are intended to come into contact with food. Corks stoppers or the cork part of stoppers, in which the cork manufactured article is at least 51%, fall within the scope of this guideline[16]. Exclusion from the application of this guideline does not automatically imply exclusion from the Regulation (EC) 2023/2006 as amended. The cork or part of cork stoppers should be formed from one piece only, or from two or more pieces of cork, or cork granules bound together by glue, adhesives or other means. For cork, used to produce articles intended for contact with food, the starting material under GMP Regulations should be cork produced by 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 field of application of the GMP Regulations and therefore from this guideline.

B8.1.2. Applicable legislation

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.[17]

Italian legislation

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

[16] The definition coincides with the definition in the "Appendix to the Resolution ResAP(2004)2 on cork stoppers and other materials and articles made of cork intended to come into contact with food"

[17] It replaced the Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

– Italian 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 objects intended to come into contact with food.
– Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, intended to come into contact with food or substances for personal use as amended.

B8.1.3. Phases of the production process: flowchart and description

B8.1.3.1. Production flowchart

Figure B8.1 illustrates the flowchart to produce cork stoppers (the part in grey is compliant with the GMP Regulation (EC) 2023/2006 as amended).

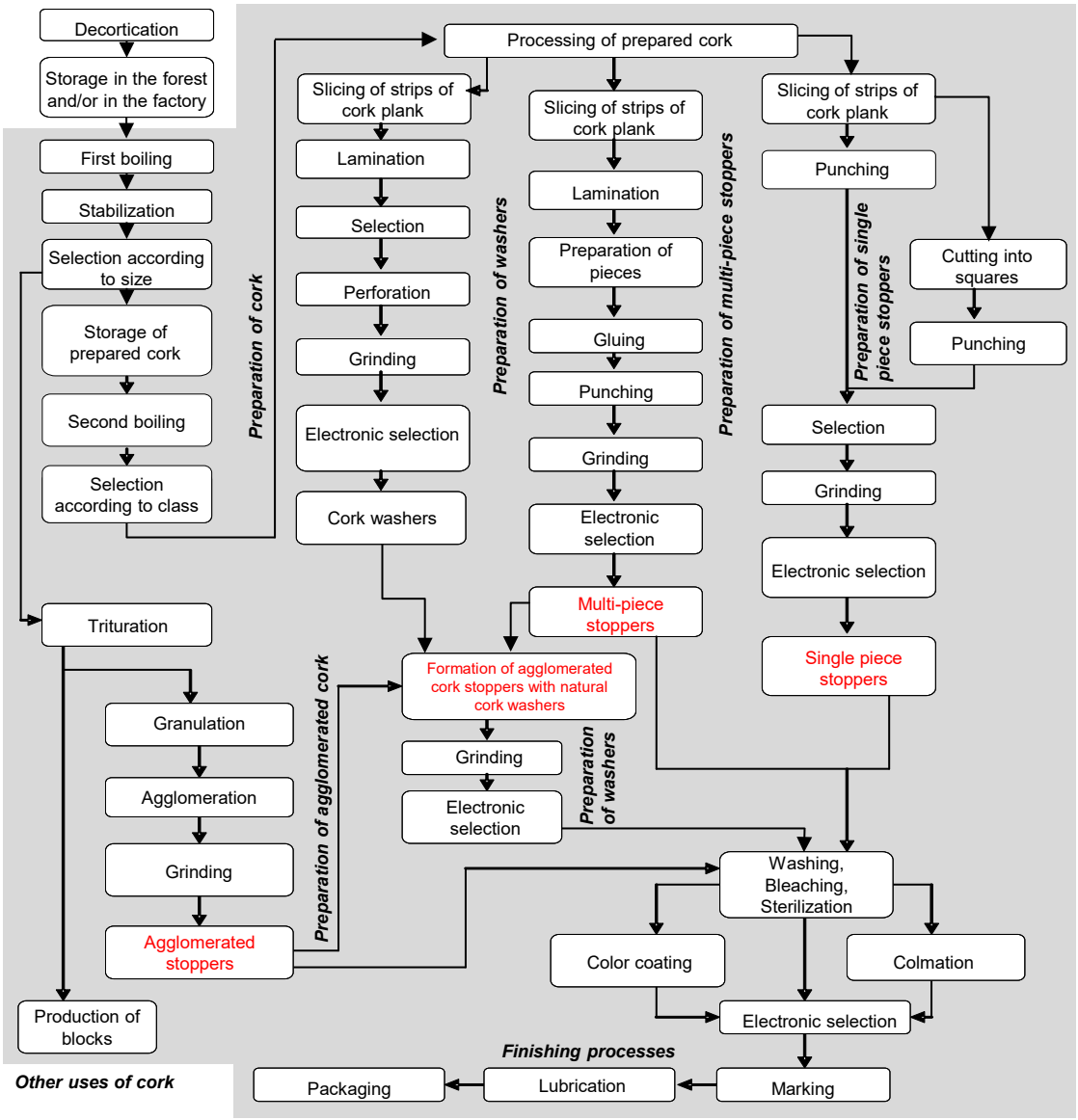


Figure B8.1. Production flowchart for cork stoppers

B8.1.3.2. Brief description of process phases

The manufacture of cork stoppers begins by harvesting cork in the forest using *decortication* methods (or rather, "the extraction of male cork"). Traditionally this is carried out using the blunt curved edge of a hatchet blade, and is divided into four phases:

- a horizontal incision of the cork at the top of the surface to be decorticated;
- a vertical incision on the tree along the full length to be removed;
- introduction of the hatchet blade and then the handle, between the cork and the "mother" to aid separation;
- detachment from the trunk to separate the lower part of the tree.

Following *decortication*, cork planks are stacked with the belly facing the ground and are left outdoors for a period ranging from one to two years (during storage, raw cork bark refines through oxidation and loses, as a result of run-off, tannins and minerals).

To obtain cork, planks are immersed in clean boiling water and kept immersed for 30 to 60 minutes according to the type of cork (*first boiling*). This operation is designed to:

- clean the cork, extracting any pests that it may contain;
- eliminate a portion of the water-soluble substances that it contains, mainly minerals and tannins;
- obtain, with a 20% increase in volume, a sufficient thickness from which stoppers can be obtained;
- increase softness.

A *stabilization* phase follows the first boiling, consisting of a series of phenomena occurring after boiling, which allow cork to acquire the optimum conditions for processing. An operation called trimming, with which the edges of the cork planks are made even by cutting away the edges of the plank with a knife, is performed on the planks to aid selection of the boiled cork (*selection according to size*) prior to storage. This procedure enables for the planks to be visually inspected to determine the exact thickness and quality of each plank and thus to determine their destination. The planks are divided into different classes and qualities according to their porosity and aesthetics. Planks bearing any kind of defect are removed at this stage.

Any cork with suitable chemical and physical characteristics to be used for wine making undergoes *trituration* (manufacture of agglomerated cork stoppers). In general, processing off-cuts provide sufficient materials for production requirements and therefore planks are not employed for trituration.

Cork that is unsuitable for use in wine making (virgin cork, burnt cork, cork bark with yellow stain, etc.), or low-quality cork that does not provide sufficient yield for wine-related use, is employed for other uses.

Cork is generally *produced in blocks,* however, not to produce stoppers (*other uses of cork*).

Prepared and stored cork is boiled a second time (*second boiling*) for a shorter length of time, in order to make it more suitable for processing to obtain bottle closures. Following boiling, the cork undergoes a further *selection according to class*, after which the manufacture of *cork* stoppers (*processing of prepared cork*) begins on the prepared cork. This is followed by a phase of *cutting into strips of cork plank,* during which the planks are cut perpendicular to the plant's axis: in other words, the planks are cut into strips of a breadth corresponding to the height of the future stoppers. This cut is made using special machines with circular self-sharpening knives.

The production process can lead to the manufacture of:

- single piece stoppers;
- multi-piece stoppers;
- cork washers;
- agglomerated cork stoppers with natural cork washers.

Preparation of single piece stoppers

The strips of cork are processed manually and automatically with punching machines. The stoppers are therefore punched vertically on the cork planks, perpendicular to the lenticels and parallel to the plant's axis (*punching*).

Prior to punching, the strips may also be *cut into squares* by cutting pieces in the shape of rectangular parallelepiped without a crust or belly.

In any case, the stoppers undergo an initial rough selection following punching, after which they are buffed to obtain a regular shape and a smooth surface (this phase is referred to as *grinding,* involving mechanical abrasion of the stoppers). At this point, the stoppers are selected by *electronic selection* that divides and stores them in classes of different qualities.

Preparation of multi-piece stoppers

The multi-piece stopper consists of pieces of glued natural cork. The stopper is derived from the *cutting strips of cork plank* and *lamination* stages: the pieces are prepared and then glued (usually using polyurethane glue). This is then followed by stages of *punching*, *grinding* and *electronic selection*, as for single piece stoppers. Stoppers made with multiple pieces of natural cork are generally created from two pieces, assembled using glue along the length of the stopper. This type of design provides for use of good quality thin planks of cork, which are glued observing the direction of the years of growth of the cork. The stoppers are then trimmed from the thickness of the plank which has been created.

Washers

The washers are cylindrical pieces of natural cork, of variable thickness and diameter, made by cutting perpendicularly along the growth lines of the plank. The cork is first *Cut into strips of cork plank*, after which it is *laminated* and *scraped*, so as to obtain strips of a thickness corresponding to the washer: at this stage the cork is *perforated* using a punch, in order to obtain a cylindrical washer without deformations within the prescribed dimensional limits. The faces of the washers obtained are polished (ground) to rectify any imperfections, after which a selection is made and they are divided into a number of classes (electronic selection).

Agglomerated cork stoppers with natural cork washers

These are agglomerated cork stoppers with one or two natural cork washers at both ends. Such stoppers are manufactured by assembling washers to an agglomerated body and/or by assembling a series of washers (*forming agglomerated cork stoppers with natural cork washers*). The stoppers are then ground and selected electronically.

The operations that follow the manufacture of cork stoppers are identical, irrespective of the type of stopper.

First, stoppers undergo a process of "sanitization" which consists of washing, bleaching and sterilizing. Different substances may be employed for washing (washing with water, with peroxides, with sulfamic acid or with metabisulfite). Usually, the stoppers undergo several successive immersions to clean, sterilize and provide them with a uniform appearance: they are initially immersed and agitated in a solution containing calcium chloride, or bleach, and then rinsed with clean water. Following this, they are immersed in a solution of oxalic acid diluted in water. This is designed to neutralize the calcium chloride, causing the calcium oxalate to react and combine with any residue iron deposited on the stopper during trimming (preventing it from blackening because of the iron tannates). After further rinsing with clean

water, the stoppers may be coloured (*colour coating*) employing a solvent or aqueous based coating. The use of dyes is decreasing, although numerous users still request pinkish stoppers The stoppers are then centrifuged and dried in a tunnel of hot air. During this stage, they can be processed to form stoppers without pores called "colmated" closures, a process that improves the appearance of ugly stoppers and stoppers with too many lenticels. This method allows for highly perforated stoppers that nevertheless have good mechanical quality, to be sold. *Colmation* consists in filling the superficial cavities of the cork, in order to confer a smooth and uniform appearance to the stoppers. This is done by placing the stoppers in a rotating drum made of a perforated sheet, with cork dust and glue. After a certain length of time, the lenticels of the closures clog up and their lateral surface appears uniform.
An electronic selection divides the closures into classes for finishing operations, which consist in *marking* or *lubrication.*
Marking or *stopper printing* on the body of the closure is made either in ink or by brand printing with a hot stamp. Marking at the ends of the stoppers is always made with brand printing with a hot stamp. The stoppers are rolled along a heated or inked sheet that is embossed with the text or logo to be printed.
As cork has a very high friction coefficient that prevents the use of raw stoppers for closure, a surface treatment to lubricate the cork is performed. The lubricant (paraffin or silicone) is applied to help compress the stopper between the jaws of the machine and to aid its introduction into the bottle.
Stoppers are supplied to the user with two types of *packaging:* in bales or in cardboard boxes. Bales, made of woven jute or polypropylene, can be lined with paper or polyethylene bag. Despite having the advantage of being economical, this kind of packaging is not watertight and therefore exposes the stoppers to the effects of external agents, odours, dust, microorganisms, which may contaminate the closures.
Jute, of vegetable origin, can contaminate the closures with flavours or microorganisms and is generally replaced with polypropylene.

Packaging in bales does not prevent exposure of stoppers to hygrometric and temperature variations (which should be avoided during storage). For this reason, stoppers are mainly packaged in polythene bags inside cardboard boxes (which are also easier to handle and stack than the bales). This type of packaging protects the closures from external contamination. As this prevents humidity-induced changes, the hygrometry of the stoppers can be adjusted immediately before sealing the polyethylene bags, usually by adding an antiseptic such as sulphur dioxide. Hermetic bags or bag that can be perforated to prevent condensation and the proliferation of microorganisms may be used as an alternative.

B8.2. Fulfilments deriving from the application of the Regulation (EC) 2023/2006

In this part are described the activities and the implementation enacted by the cork stopper industry to conform to the Regulation (EC) 2023/2006 as amended. Since this Regulation was laid down when the quality assurance systems had already become a daily work tool in most of the manufacturing businesses[18], it is likely that these businesses already produce in conformity with technical specifications laid down by themselves.

[18] For cork stopper manufacturers, there is *Systecode EC. Liège* (International Code of Practice for the Production of Cork Stoppers).

All the same, should it be necessary, the Quality Assurance System and the Quality Control System should be extended to ensure:

> "[...] that the materials and articles are constantly manufactured and controlled, to ensure their conformity to 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" (art. 3 paragraph a Regulation (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006 as amended. Every paragraph is hence the response of the manufacturers of the cork stoppers to the requirements of the article in question. To facilitate reading, the paragraphs keep the same title as the article considered, while the subparagraphs indicate specific subject.

B8.2.1. Quality Assurance Systems (Regulation (EC) 2023/2006, art. 5) and Size of the business

Quality Assurance Systems

The manufacturer of cork stoppers (hereinafter called "the producer") should establish and maintain a Quality Assurance System capable of ensuring the achievement of the objectives laid down by the Regulation and described in the general guideline. The Quality Assurance System should be documented so as to enable control by the competent authorities.

The Quality Assurance System should establish rules and procedures that regulate the company activity, at least concerning the following points:

- conformity to the requisites of the legislation in force;
- human resources and training:
- raw materials and suppliers including suppliers of goods and services and third parties working under contract;
- production;
- quality control;
- storage, handling and shipment;
- complaints and corrective and preventive action.

The system must ensure that the future legislative changes are adopted in all the phases of the company process also including the specifications and any contracts with qualified suppliers. It is recommended to implement a procedure which enables the company to adopt the changes deriving from updates of the applicable legislation on FCMs.

Size of the business

Independently from the business size, it should at any rate be guaranteed that the Quality Assurance System, as demanded and finalised by the Regulation (EC) 2023/2006 as amended, is always applied.

The system should be established, implemented and run taking into account the actual size and complexity of the company as well as the technical and human resources available.

On its own premises the business has to at any rate be capable of guaranteeing the application and running of the Quality Assurance and Quality Control System in order to obtain finished materials and products in compliance with the legislation in force on FCMs.

B8.2.1.1. Human resources and training

The *Business operator,* in compliance with the objectives of the Regulation (EC) 1935/2004 as amended and the Regulation (EC) 2023/2006 as amended is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 as amended is applied at all levels of their organization.

The operative aspects relating to the application of the provisions laid down in the Regulation (EC) 2023/2006 as amended can be entrusted by the Business operator to competent and adequately trained people that have to at any rate have at their disposition adequate means to ensure that the requisites of the Regulation (EC) 2023/2006 as amended are respected.

The *company organization* has to at any rate enable the location of the functions to enable inspection by the Competent Authorities.

All *company personnel* potentially involved, including the highest management levels, has to be informed on the principles of GMP, on the obligations that derive from the Regulation (EC) 2023/2006, on its objectives and on the policy for applying the Regulation.

The *Business* should operate and implement procedures for identifying personnel training requirements and has to see to the training of all staff regarding the tasks that might affect the compliance to the said Regulation.

The *personnel* assigned to GMP control activities should be qualified on the basis of the training and the experience acquired.

An appropriate registration of the training process of all personnel must be kept.

B8.2.1.2. Production

The company production phase extends from design and planning to storage of the finished product.

The production process includes all the company phases that combine to guarantee that the end product complies with the legislative, technical and performance requisites laid down at the planning phase to guarantee the suitability for intended use.

Hence the Quality Assurance System should comprise procedures that regulate all the phases listed hereafter:

- Design of compliant products;
- Selection of source materials and suppliers;
- Arrival of raw materials and storage;
- Control of raw materials;
- Production processes and traceability of raw materials used;
- Monitoring process parameters;
- Inspection during production;
- Control of the final product and warehouse storage.

During all the phases listed above an evaluation of the risks of contamination should be made identifying the potential sources and the actions to prevent the same.

Product design and development

The most important concept implied by the GMP is that of a product designed to be compliant to the legislative requisites on materials and articles intended for food contact (FCMs).

Distinctions can be made between the design of a product and the adaptation of a product to the requirements of a customer, who may have a product developed for a specific use subsequently suited to the precise and different demands of a customer.

If a producer develops a product compliant to a project for conformity of use, then packaging material produced must:

- comply with the performances for the final use it is intended for;
- comply with the requisites of the legislation in force for materials intended for food contact.

To this purpose the product has to be produced with raw materials that, subject to controls, guarantee, in all the process phases, the compliance to use the same are intended for and the legislative requisites covering food contact.

Selection of starting materials, suppliers and/or services and/or third parties

The producer is called upon to use only approved starting material for which he has all the necessary data guaranteeing the conformity of the packaging produced to the legal requisites, including the restrictions due to conditions of use, this by way of information from the supplier and/or through controls and checks made during the design phase.

Observance of the following requisites should also be ensured:

- declaration of compliance according to what has been established by the applicable European and/or Italian legislation;
- traceability according to the Framework Regulation (EC) 1935/2004 as amended (where applicable);
- conformity to the Regulation (EC) 2023/2006 as amended (where applicable).

Any supply of starting material has to be kept under adequate control.

It is good practise that the starting materials are procured from qualified suppliers. By qualification is meant a pre-established, organized and documented process that can also include supply contracts.

It is advised to verify, also through periodical visits of inspection (audits), the Quality Assurance System of the supplier of starting materials or third parties to ascertain whether it is compliant with the requisites as laid down by the Regulation (EC) 2023/2006 as amended, where applicable.

In the event that the supplier does not operate under Good Manufacturing Practice (GMP) regulations, the manufacturer is required to ensure that the raw materials and/or semi-finished products they use are suitable for producing materials and objects intended for contact with food. This verification, which must be carried out by the manufacturer, can be conducted either through the examination of composition certifications provided by suppliers or through the performance of appropriate technical-analytical determinations.

Process compliance

The production process has to be kept under adequate control with a Quality Assurance System that has to be conceived so as to be able to guarantee and document that the product responds to the relevant technical specifications and that these specifications comply with the product design.

The Quality Assurance System has to be finalized so as to proffer sufficient attention to the most critical points of the production system that might endanger the attainment of both legislative, technical and qualitative conformity of the end product.

Documentation of procedures/instructions

Each stage of production should be regulated by appropriate documentation. Examples of documentation may include: manuals, procedures, operating instructions, technical standards and records.

The documentation required to perform the activity should be made available to the staff concerned, be updated, as well as having its distribution monitored in order that any outdated information is promptly withdrawn.

B8.2.2. Quality Control System (Regulation (EC) 2023/2006, art. 6)

The producer should establish and maintain an effective Quality Control System capable of ensuring the respect of the conformity to the Regulation as laid down in the general guideline.

The system should include procedures that envisage all the necessary controls, the relative registrations and actions to be carried out in the event of lack of conformity.

All the documentation has to be available for the Competent Authorities that demand to see it in accordance with the Regulation (EC) 2023/2006 as amended.

The rules and the procedures have to cover the entire production process, as described in paragraph B8 2.1.2., also including a part that deals with the handling of any non-conformities and corrective actions.

B8.2.2.1. Management of raw materials warehouses

Unless otherwise specified, the materials should be used based on the principle “first in first out” (rotation of materials rule for which older materials are to be used first).

The approved starting materials from qualified suppliers must be clearly separated from other starting materials that have not been homologated or that are from suppliers who are undergoing qualification or who have not been qualified.

For the latter materials a procedure must be established that authorizes their use in production only after the function laid down under the Quality Control System has confirmed the suitability of the material for use in production.

Any raw materials that are the subject of disputes has to be segregated in a predefined area and clearly identified pending the problem is solved. The segregation of non-compliant material can also be performed through restrictions other than physical segregation in a specially assigned area (IT block).

Only the function laid down under the Quality Control is enabled to authorize any use of these materials.

The conditions of the environment, of the storage and handling of the storage areas must be such as to guarantee that there is no risk of deterioration of the material.

Special attention should be given to the storage, warehousing and handling of raw materials to avoid any damage that can make the materials unusable.

B8.2.2.2. Production controls

The Quality Control System has to be regulated by suitable procedures that guarantee that during the production process all the necessary controls are carried out to guarantee that the product conforms to the legal, technical and quality specifications defined during the design phase.

The traceability of the products through suitable registration of the raw material lots used, by the machine conditions set and registered during production and the quality controls also carried out on intermediate products and semi processed articles must be guaranteed.

The storage of the finished product and the shipment to the customer should only be enacted against procedures that enable the unequivocal documentation that the material has been

controlled in all the established phases and that the final controls have ascertained the conformity of the same to all the requisites laid down in the design phase.

This conformity should be ascertained via the comparison between the control data collected and the values and/or tolerances entered in the product technical specifications or the specific legislation.

Characteristic parameters such as size, mass, apparent density, moisture content, etc., can be controlled by referring to the main part of the ISO/DIS 9727 norms, rules on migration and sensory analysis.

B8.2.2.3. Quality Control of the finished products

The Quality Control System has to dispose of suitable procedures for controlling the finished product. In verifying the conformity of the finished product, Quality Control has to use the information available on raw materials and on the process applied to highlight any limitations and restrictions of use for food contact.

Particular attention should also be paid to the test conditions used for carrying out the controls, which have to be suited to the verifications of the intended final use of the material taking into account the position in the supply chain.

The analyses must always be carried out using validated methods of analysis. If these methods do not exist, an analytical method with performance characteristics adapted to the specified limits may be used pending the drawing up of a validated method.

B8.2.2.4. Management of finished products warehouses

The Quality Assurance System should establish a procedure to authorize the storage of finished products. The authorization for storage of the products and for their delivery to customers should be given by the function laid down under the Quality Control System, after performing all the controls provided for by the relevant procedures to ascertain the suitability of finished products for their intended use.

The approved finished products should be clearly separated, or in any case clearly labelled from those that still have to be controlled or subject to further controls as to their suitability.

For any products that are declared as unsuited, a procedure should be available to prevents their storage pending the definition of the problem.

The unsuited products, clearly identified, should be kept separated in a predefined area. Any derogations are only to be authorized by the Quality Control System

Any finished products returned by customers due to non-conformity, should be kept in a predefined area and clearly identified, pending the definition of the contestation. Only the function laid down under the Quality Control System is allowed to authorize any use of these materials.

It is advised that a procedure for managing non-compliant materials is set up also providing for their disposal or the destruction of the same.

The environmental conditions of storage and of the warehouses should be such as to guarantee that there is no risk of deterioration and/or contamination of the materials.

Special attention should be paid during handling operations of the raw materials in order to avoid damaging that may make the material useless.

B8.2.2.5. Distribution, shipment and delivery

The producer, if responsible for the transport and the delivery of the material to its destination, has to also guarantee that this phase is regulated by instructions and procedures that guarantee the

quality of the material preserving it from any damage and contamination risk that might compromise its use or suitability.

If the means of transport are the property of the packaging producer, it must be ensured, also by periodic checks, that these are suited for transporting goods and that maintain the requisites of safety and hygiene required to guarantee the integrity of the product.

If the delivery is via external couriers, a procedure should be established that qualifies the courier and a technical contract should be defined that sets the minimum requisites to be respected to eliminate possible risks (i.e., damage, contamination, etc.).

B8.2.2.6. Conformity of the application of the GMP and claims management, corrective and preventive actions

The Quality Control System has to enact suitable procedures so as to monitor the correct implementation and total respect of the GMP.

The Quality Control System has to enact procedures for documenting the identification of lack of conformity, the enacting of any corrective measures and the monitoring of the implementation of the said measures, with particular attention to the time frame envisaged to implement the measures.

The Quality Assurance System of the Business should therefore be implemented to include periodical verification and control plans on conformity to pre-established parameters and specifications, relevant to compliance with legislation on FCMs; procedures for managing nonconformities and corrective measures should be implemented.

B8.2.3. Documentation (Regulation (EC) 2023/2006, art. 7)

All the documents concerning the Quality Assurance System (procedures, specifications, formulations, etc.) and all the activity of the Quality Control System (instructions, registrations of control data, machine setup data, tolerances and measurements, etc.) have to be organized so as to constitute a paper or electronic archive, immediately accessible and easily consultable on request by the Competent Authorities.

The documents guaranteeing the traceability will also constitute an integral part of the same, as under art. 17 of the Regulation (EC) 1935/2004 as amended, the copies of the declarations of compliance issued to the customers in observance of the applicable European and national regulations and the applicable national provisions, and the supporting documentation. This documentation will also include any conditions for tests, calculations and analyses, carried out by internal and external laboratories, that serve to demonstrate conformity.

In the event of substantial changes in production liable to change the essential requirements regarding compliance, or when the legislative benchmarks are modified and/or updated, it should be verified whether the documentation relating to the Regulation (EC) 2023/2006 as amended should be updated.

B8.2.4. Useful bibliographic references

ISO/DIS 9727 – 1: *Cylindrical cork stoppers – Physical tests – Part 1: Determination of dimensions.* Geneva: International Organization for Standardization; 2007.

ISO/DIS 9727 – 2: *Cylindrical cork stoppers – Physical tests – Part 2. Determination of mass and apparent density.* Geneva: International Organization for Standardization.; 2007.

ISO/DIS 9727 – 3: *Cylindrical cork stoppers – Physical tests – Part 3: Determination of moisture content.* Geneva: International Organization for Standardization; 2007.

ISO/DIS 9727 – 4: *Cylindrical cork stoppers – Physical tests – Part 4: Determination of dimensional recovery after compression*. Geneva: International Organization for Standardization; 2007.

ISO/DIS 9727 – 5: *Cylindrical cork stoppers – Physical tests – Part 5: Determination of extraction strength*. Geneva: International Organization for Standardization; 2007.

ISO/DIS 9727 – 6: *Cylindrical cork stoppers – Physical tests – Part 6: Determination of liquid tightness.* Geneva: International Organization for Standardization.; 2007.

ISO/DIS 9727 – 7: *Cylindrical cork stoppers – Physical tests – Part 7: Determination of powder.* Geneva: International Organization for Standardization; 2007.

ISO 10106:2003: *Cork stoppers – Determination of global migration*. Geneva: International Organization for Standardization; 2003.

ISO 10718:2002: *Cork stoppers – Enumeration of colony forming units of yeasts, moulds and bacteria capable of growth in an alcoholic medium*. Geneva: International Organization for Standardization; 2002.

ISO/DIS 20752: *Cork stoppers – Determination of releasable 2, 4, 6, - trichloroanisol (TCA).* Geneva: International Organization for Standardization; 2007.

ISO 21128:2006: *Cork stoppers – Determination of oxidizing residues – lodometric titration method.* Geneva: International Organization for Standardization; 2006.

ISO 22308:2005: *Cork stoppers – Sensory analysis*. Geneva: International Organization for Standardization; 2005.

Technical articles for further reading

Assoimballaggi FederlegnoArredo. *Linee guida per la realizzazione di un manuale aziendale di autocontrollo/HACCP per il comparto sughero* Milano: Assoimballaggi FederlegnoArredo, Lampi di Stampa; 2006.

Assoimballaggi FederlegnoArredo. *Linee guida per la rintracciabilità dei tappi di sughero*. Milano: Assoimballaggi FederlegnoArredo, Lampi di Stampa; 2004

Confédération Européenne du Liège - Europen Cork Confederation. *CIPB - Codice Internazionale delle pratiche per la produzione di tappi in sughero (ai sensi del Regolamento (CE) n. 2023/2006 della Commissione del 22 dicembre 2006 sulle buone pratiche di fabbricazione dei materiali e degli oggetti destinati a venire a contatto con prodotti alimenti) – Versione 7.00*. Milano: Assolegno; 2018.

Riboulet JM, Alegoet C. *Aspetti tecnici della tappatura dei vini*. Chaintré: Burogne Publications sarl; 1997.

Stazione Sperimentale del Sughero. *Disciplinare sulla produzione e utilizzo del tappo di sughero in enologia*. Tempio Pausania (Sassari): Stazione Sperimentale del Sughero; 1996.

Annex B8.1

Technical glossary

Agglomerated cork: A product obtained by agglutination or agglomeration of granules, powder or pieces of cork.

Agglomerated stopper by extrusion: Cork stopper obtained by agglutination of cork granules with binders from a process of extrusion, made from granules of cork with a granulometric size between 0.25 and 0.8 mm.

Agglomerated stopper made by moulding: Cork stopper obtained by agglutination of cork granules with binders from a process of moulding, made up of at least 51% of cork granules (by weight) with a granulometric size between 0.25 and 0.8 mm.

Agglomerated stopper with natural cork washers for still wines and sparkling wines: Stopper created from a body made of agglomerated cork, with one or more natural cork washers glued on one or both ends.

Agglomerated stopper with washers of natural cork for semi-sparkling wines, sparkling wines, gaseous beverages, beer and cider: Agglomerated stopper made up of one or more washers of natural cork at each end.

Agglomerated stopper: The considerable volume of off-cuts resulting from the trimming of stoppers is employed to create agglomerate cork stoppers. Quality off-cuts, and above all off-cuts from trimming and washer cutting, are employed for creating granules used for the manufacture of agglomerated closures or of agglomerated rods for sparkling wine stoppers. The granules obtained from *trituration* are chosen using a system of ventilated sieves and screens according to two criteria: size and density. The fine, medium and large granules are used for manufacturing stoppers according to their proportions and the type of product to be produced. Agglomerated corks are made using a glue (usually polyurethane) that binds the grains. Two procedures are used to produce agglomerated corks for still wines: the creation of rods or punching blocks of agglomerated cork. In the first procedure, the granulated-glue mixture, is placed in a hopper containing a pipe system in its base, in which the mixture itself is compressed with pistons. The continuous extrusion bar is heated to a temperature of 95-105°C at the outlet of the pipes to ensure polymerization of the adhesive. Subsequently, the bar itself will be cut into smaller bars and ground to the diameter of the future stopper. The ground bars will then be cut into cylinders having the length of the stoppers. The sides and ends of the closure obtained are then polished. The process of punching is identical to that used for the manufacture of natural corks, in fact, agglomeration is carried out in blocks that will be processed identically to the cork planks. To obtain these blocks, the granulated-glue mixture is introduced into a parallelepiped mould, covered with a lid and heated under a vertical press. The blocks are then cut into strips of cork plank from which closures are punched.

Agglomerated stoppers with natural cork washers: Agglomerated stoppers made up of one or two washers of natural cork at both ends.

Agglomeration: Union of cork granules, with or without added adhesives.

Bartop cork stopper: Natural cork stopper, colmated cork stopper, composite or agglomerated cork stopper having a cylindrical or tapered body with a diameter that is smaller than that of the top (if the head is made of a material different to that of the body, the type of material used should be specified, e.g., stoppers with a wooden head, or with a plastic head).

Belly removal: Elimination of the belly from planks or strips of cork planks.

Belly: The internal part of cork bark corresponding to the last annual growth, reproducing the irregularities of the phloem.

Block: Large piece of cork, in the shape of rectangular parallelepiped, made up of several glued components.

Body: Cylinder of natural cork, of one or more pieces, or made of agglomerated cork, on which one or two washers, on either one or both ends, are glued.

Boiling: Immersion of the planks of cork in boiling water for a specified length of time.

Colmating, plugging: Applying a mixture of cork dust and glue to the surface of the stoppers.

Colour coating: Application of a coloured film on the surface of the stoppers.

Colouring: Application of a dyestuff on the surface of the stoppers.

Cork bark pieces: Pieces of virgin cork or female cork with a surface smaller than 400 cm $^{2.}$

Cork off-cuts Cork residue deriving from preparation or processing.

Cork: Secondary tegument tissue, produced by cork cambium, consisting of an area formed during the spring and summer, usually large and light in colour, and a thin, darker area produced in the autumn at the end of the vegetation period. The number of rings identified corresponds to the number of years.

Crust or back: Outside of female cork made up of dead tissue of the phloem that dries upon contact with air.

Cutting into squares: Cutting strips of cork plank into pieces shaped as rectangular parallelepiped without a crust or belly.

Decortication, extraction: An operation that consists in stripping cork from a *Quercus suber* L.

Disc: Piece of cylindrical or truncated cone shaped cork, intended for closing containers.

Drying: A process which involves modifying the moisture values of the stoppers to those suitable for carrying out subsequent processing.

Dust removal: An operation intended to remove dust from stoppers.

Electronic selection (of stoppers): A process carried out by a machine according to the principle of optical reading: choice is based on reading, with a camera, of areas of different colours on the surface of the stopper according to several levels. The machine thus determines the overall surface of the lenticels taking into account any major defects, even if this is less than the total acceptable area.

First harvest: An operation that consists in stripping virgin cork from a *Quercus suber* L.

Gentile cork, female cork or reproduction cork: Cork formed following the *first harvest.*

Gluing: Bonding phase (usually employing polyurethane glue) of pieces of prepared cork to create multi-piece stoppers.

Granulation: Trituration or comminution of cork to obtain granules.

Grinding: Mechanical abrasion of the lateral surface of the stoppers.

It is the product of subsequent extractions.

Lamination Cutting planks of cork with circular knives parallel to the years of growth in order to obtain sheets of so-called foils, which are then punched to obtain washers or discs.

Lubrication: Application of lubricating products on the surface of the stoppers.

Marking: A process in which text and/or trademarks are impressed on the surfaces of the stoppers.

Marking: See “Stamping”

Multi-piece stopper: Stopper made of pieces of glued natural cork.

Natural cork: Common name of raw cork bark, prepared or processed cork (definition used especially as the opposite to agglomerated cork).

New generation agglomerated stopper: Cork stopper obtained by agglutination of cork granules with binders from a process of moulding, made up of at least 51% of cork granules (by weight), with a granulometric size between 0.25 and 0.8 mm. This stopper is prepared using a procedure which is intended to reduce the organoleptic neutrality and which may contain expanded synthetic materials.

Perforation: A process performed with a punch along the strips of cork to obtain cylindrical washers free from deformations within the prescribed dimensional limits.

Polishing: Mechanical abrasion of the edges of one or both ends of the stoppers.

Prepared cork plank: Prepared cork, free from *cork bark pieces,* suitable for further processing for cutting.

Prepared cork: Gentile cork that has been boiled and flattened, as well as possibly having been selected, trimmed and scraped.

Processing of prepared cork: Working process that initiates the manufacture of different types of stoppers from planks of prepared cork.

Punch: Machine used to pierce strips of cork and that uses of punches whose diameter matches that of the washers to be manufactured.

Punching: Production of cylindrical stoppers by cutting bands, perpendicular to the lenticular canals and parallel to the plant's axis, using a punch.

Raw cork bark plank: A portion of virgin or female cork obtained by *decortication* that maintains the shape of the tree trunk or branches.

Raw cork bark: Cork which has not undergone any treatment following extraction.

Rod: Agglomerated cylinder made from granules of prepared cork.

Sanitization: Chemical or physical treatment aimed at reducing the microbial count of stoppers.

Scraping: Elimination of the crust from planks or strips of cork planks.

Seasoning: A set of physical-chemical phenomena that occur in raw cork bark during storage.

Selection (stoppers): A process aimed at creating homogeneous classes of closures according to visual characteristics. This process can be carried out *manually* by an operator who carefully observes stoppers that run along a belt or on rollers that rotate them so as to be able to view them completely. The final grading of the best quality closures is achieved by manual selection and complete observation of each individual stopper belonging to the batch. This process tends to follow a trend of *mechanization.* The machines employed operate according to the following two principles: *Injection of compressed air* (compressed air machines measure the amount of air that penetrates each stopper, determining its porosity) or *optical reading* "electronic selection").

Selection by calibre (of boiled cork): Selection of cork according to visual inspection and caliber (which generally occurs subsequent to the first boiling).

Selection by class: Grading of planks of prepared cork into homogeneous classes (after storage and boiling).

Sheet: Very thin sheet of cork used mainly for decoration.

Single piece stopper: Single piece stoppers in natural cork are made from one single piece of cork extracted directly from planks of natural cork, purposely selected and processed to provide the typical cylindrical shape. These stoppers are mainly used for bottling quality still wines intended for medium to long ageing, in order that the wine is refined in a bottle.

Slicing of strips of cork plank: Cutting planks of prepared cork perpendicularly to the plant's axis.

Smoothing: Mechanical abrasion of the edges of one or both ends of the stoppers.

Square: Rectangular parallelepiped of prepared cork, without crust or belly, obtained from the strips of cork planks and employed for the manufacture of single piece stoppers.

Stabilization: A series of phenomena following boiling, which allow the cork to acquire optimum conditions for processing.

Stack: Set of cork prepared and discarded planks according to classes of appearance and thickness.

Stopper: Product made from natural cork and/or agglomerated cork, made up of one or more parts and designed to close bottles or other containers, while preserving their content.

Storage of prepared cork: Storage cork after it has been subjected to boiling, has been stabilized and has been selected according to size.

Storage of raw cork bark in the forest and/or in deposits: Storage of raw cork bark in outdoor stacks for the period between the decortication and the first boiling.

Strip: Rectangular parallelepiped of cork, with or without crust and belly, of dimensions suitable to produce one-piece stoppers with a nominal diameter of 24 mm. Obtained from planks of cork prepared for cutting perpendicularly to the plant's axis.

Strip: Rectangular parallelepiped of cork, with or without crust and belly, obtained from planks of prepared cork for cutting parallel to the axis of the plant and parallel to lenticular canals.

Trimming: A process that consists in smoothing out the edges of prepared cork planks.

Trituration: Process of milling off-cuts for the manufacture of agglomerated stoppers. Trituration is carried out using mills, rotary mills, or knives that provide granules which are different in appearance and properties. This is generally cork that is not fit for oenological use, which is ground for other uses (such as insulation for buildings).

Virgin or male cork: The cork which originally covers the tree trunk and branches and that constitutes the product resulting from the first extraction.

Washer: Cylindrical piece of cork, obtained by cutting strips, whose bases are perpendicular to the lenticular canals.

Washing: Treating stoppers with an aqueous solution designed to wash, remove dust, and sometimes bleach and disinfect closures.

Annex B8.2

Frequently asked questions

Q1 *Is the application of the Regulation (EC) 2023/2006 to be required to produce semi-finished or finished products from countries outside the EU?*

Yes, trade outside of the EU only takes place by circulating goods, that are in compliance with the EU laws. Therefore, a producer outside the of the EU should follow the Regulation (EC) 2023/2006 as amended.

Q2 *At what stage of the flowchart of the production of cork stoppers can we speak of "starting materials"?*

Starting material is intended as cork that has been obtained by decortication, which has been stored in the forest or in the factory but has not yet been subjected to boiling. There is no obligation to follow GMP regulations at this stage.

Q3 *What is the C.E. Liege code?*

The C.E. Liège code is a valid example of good practice code, useful to all areas of the cork industry, which can be considered a valuable aid for Quality Assurance in relation to Regulation (EC) 2023/2006 as amended. There is potential for cork manufacturing companies to obtain official recognition when operating in compliance with the requirements of the 'International Code for the production of cork stoppers. This accreditation program is called 'Systecode'. Effective enforcement of the requirements is verified by an independent third-party verification entity of international certification (who decides in relation to application of the Code) and by an expert of the national cork sector (who provides technical/specialist support).

Q4 *What is the document entitiled "Disciplinare sulla produzione e utilizzo dei tappi in sughero in enologia"?*

It is a technical document, currently under review, providing information on product requirements, methods of control and criteria for acceptance/rejection of production batches.

Q5 *If the company has not drafted a manual, limiting itself to register its management system with appropriate documentation, could this be sufficient to demonstrate compliance with Regulation (EC) 2023/2006?*

Yes, the Regulation (EC) 2023/2006 as amended does not refer to drawing up a manual, but "Documentation" (art. 7 refers to "adequate documentation in paper or electronic format").

Q6 *If the company is small, do the obligations under Regulation (EC) 2023/2006 remain the same?*

The obligations imposed by Regulation (EC) 2023/2006 as amended are irrespective of the size of the company, however, the foreword (paragraph 6) states that "the rules on GMP should be applied proportionately to avoid undue burdens for small businesses." Furthermore, Article 5 (quality assurance systems prescribes that the" system should [...] be applied taking into account the size of the company, so as not to constitute an unreasonable burden on the company."

Q7 *Is there any European and/or Italian legislation specific to cork intended for contact with food?*

Until now cork has not been the subject of specific legislative measures, either at Italian or Community level. Nevertheless, there are general rules common to all materials intended for contact with food, which therefore also apply to cork stoppers. The general rules are:

- Decree of the Italian President of the Republic 777/1982 and Legislative Decree 108/1992 (in force regarding declarations of conformity and applicable sanctions);

- Italian Legislative Decree No. 29 of 10th February 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 objects intended to come into contact with food;
- Framework Regulation (EC) 1935/2004 as amended on materials and articles in contact with food;
- Regulation (EC) 2023/2006 as amended on good manufacturing practice (GMP);
- Regulation (UE) 2017/625 of the European Parliament and of the Council of 15th March 2017 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.[19]

[19] It replaced the Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

B9. GLASS

B9.1. Characterisation of the sector

B9.1.1. Field of application of the guideline

This guideline is applicable to the sector of glass for food contact containers.

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, 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. Applicable legislation

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.[20]

Italian legislation

- Decree of the Italian 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.
- Italian Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- Italian 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 objects intended to come into contact with food.
- Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, intended to come into contact with food or substances for personal use as amended.

[20] It replaced the Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

B9.1.3. Phases of the production process: flowchart and description

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

Glass is an inorganic amorphous material that is, by definition, free of crystalline phases.

Containers and articles for food contact are mainly made of silica-soda-lime glass, although borosilicate and crystal glass are also widely used.

Glass has an amorphous chemical structure similar to a liquid and can be defined as a highly viscous fluid acting as a rigid material at room temperature. In fact, glass is characterized by a viscosity curve depending on temperature so that, as temperature decreases, it shifts from a fluid state suitable for shaping, to a state allowing the article to maintain its own stable form.

In the melting phase, at high temperature, a sequence of chemical reactions takes place disrupting the raw materials' crystalline structures. During the subsequent rapid cooling, the chemical elements recombine into amorphous and isotropic structures (vitrification). Silica dioxide, for example, coming from sand where it is present in its crystalline quartz form, becomes the main component of the amorphous network, however other elements (Ca, Mg, Na, etc.) coming from different raw materials (soda, limestone, dolomite, etc.) are also introduced into the silica network for the purpose of tailoring the properties of the obtained glassy materials to the end use (containers and other articles).

In other words, the chemical reactions between raw materials produce a new homogeneous material.

A particular fundamental element of glass is the fact that once composition has been established, this determines both the food contact suitability and the manufacturing parameters. The glass formula in fact determines for example, the melting and forming temperature limit values, the machine speed, the softening and annealing temperatures, and the chemical resistance of the glass to the food it will contain.

In a glass-factory, each step of the process has quality controls carried out to assure the consistency and efficiency of the whole production process.

Possible deviations from the standard production process parameters, due to glass formulation error, cause conditions that typically render impossible the regular production process.
In fact, glass formulation errors so severe as to compromise food contact suitability would render containers manufacturing impossible because the whole production process, from melting to forming, would be disrupted with equal severity.

Therefore, many process controls, required to assure continuity, are to be regarded as controls related to the Regulation (EC) 2023/2006 as amended.

B9.1.3.1. Production flowchart

Figure B9.1 illustrates the flowchart to produce glass (the part in grey is compliant with the GMP Regulation (EC) 2023/2006 as amended).

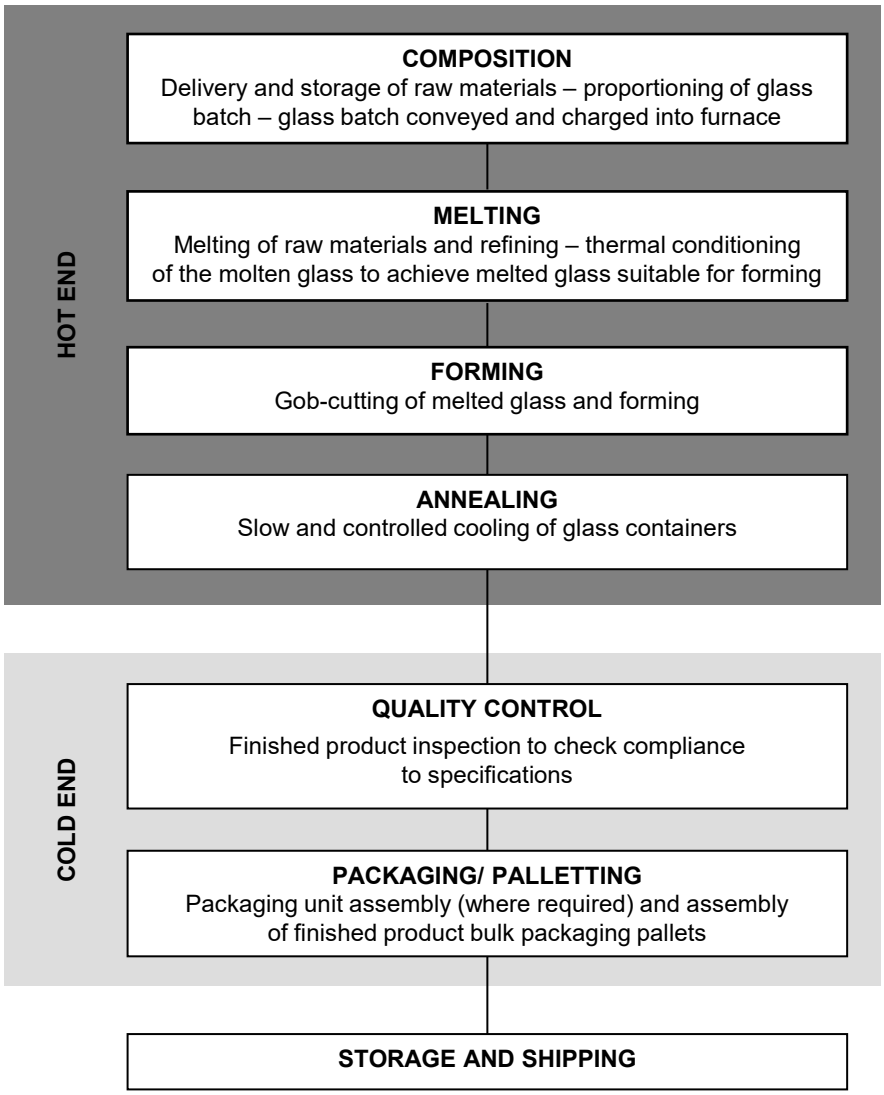


Figure B9.1. Simplified production flowchart for glass containers

B9.1.3.2. Brief description of process phases

The manufacturing process for the industrial production of containers for packaging of foodstuffs can be split into three main areas:

- *Hot-End*
  made up of the sub processes: batch composition, melting, forming and annealing.
- *Cold-End*
  made up of sub processes: finished product control, packaging/pelleting.
- *Storage and shipping*
  made up of storage and shipping areas.

Hot-End

Composition

The preparation of the mixture of raw materials to be fed to the melting furnace is made in "batches", that is discontinuously, producing lots of homogenised raw materials typically weighing from 500 to 2000 kg, one after the other. Batch composition is the first hot-end sub-process and involves receiving and storage of raw materials and the preparation of a homogeneous batch mixture that sent by conveyor belts to a temporary storage/buffer silo or directly to the furnace, into which it is loaded by the furnace chargers.

Another important component of the mixture is recycled glass cullet, which has two main sources: so called "internal" cullet comes from the crushing of containers produced by the plant but rejected by quality controls, while "external" cullet comes from the sorting and treatment (performed by dedicated plants/companies) of post-consumer container glass waste, collected separately from other household solid waste by recycling is extremely beneficial for the melting process, since it reduces both its direct energy consumption and CO2 emissions, while also reducing natural resources extraction and landfill usage, with all associated benefits in terms of circularity, sustainability and environment protection.

Melting

The melting and refining process is composed of a complex sequence of chemical and physical reactions, that take place at high temperatures, in the range of 1450 to 1550°C, depending on the glass chemical formula.

Before the forming process, the molten glass has to be made homogeneous and free of gas bubbles. For this purpose, melting the raw materials is not sufficient and a subsequent refining phase is necessary to remove the gas trapped in the molten glass in order to comply to the agreed product quality specifications.

The melting and refining processes take place in the furnace tank, built with refractory material and thus able to resist to the above-mentioned high temperatures for many years. The glass manufacturing plant operates 24/7 and is controlled by monitors and process control computers which allow the operational parameters to be constantly maintained under control.

At the end of the melting phase, comes the conditioning phase which consists of a controlled and homogenous cooling down of the glass to the gob temperature, that is to a range of between 1000 and 1350°C.

Forming

Glass containers for foods are manufactured by automatic machines which are able to produce a high number of pieces per minute.

It is appropriate to distinguish between the manufacturing process of normal containers (bottles and jars) and the process used in the production of tableware (wine glasses, glasses and dishes)

Container forming process

The containers manufacturing process consists of the following steps:

- cutting of melted glass coming out of the end of the conditiong section (called spout) into gobs of suitable weight, shape and temperature;
- gob delivery to the IS ("Individual Section") forming machine blank mould, by fall guiding system, equipped with troughs;
- parison forming in blank mould;
- parison transfer from the blank mould to the finishing or blow mould;

- blank parison shaping in the blow mould into the definitive container shape;
- container removal from blow mould and its transfer to the annealing lehr by conveyor belts.

The first shaping in the blank mould may be obtained by a pressing process with a metal plunger or by a blowing process with compressed air.
The final shape in the finishing mould, or blow mould, is always obtained by a glass blowing process.
Consequently, the two processes are named, respectively "press and blow" and "blow and blow". The first one is more suitable for wide mouth containers (jars) or small size light weight bottles. The second one is preferred for traditional manufacturing requirements.
Most types of glass containers are submitted to external surface treatments in order to improve their performances in both the handling phase in the glass plant Cold-End, and on customer filling lines.
These treatments are applied in two steps: the first at the exit of the forming machine, when the ware still has a temperature of about 500°C (*hot-end coating*) and, the second, at the exit of the annealing lehr (*cold-end coating*).
The combination of these two treatments is required, because the hot-end treatment represents the ideal substrate for anchoring the subsequent cold-end treatment.
The first treatment can also slightly enhance the mechanical resistance of the container, while the cold one reduces friction, improving the ease with which bottles can travel and be processer by automatic packaging and filling lines and reducing the surface damage bottles withstand when bumping or scratching against each other in the lines, which cause a reduction of mechanical resistance of the containers.

Tableware manufacturing

The following are the main technologies used in manufacturing tableware:

- press-blow;
- blow-blow;
- press;
- centrifuge.

The first two are the same as the above ones mentioned for container's manufacturing. The press process is relatively simple and can be applied in the case of articles having a mouth as large as its base. It consists of pressing glass gobs between a metallic plunger and the mould.
Centrifuge process is, on the other hand, used to produce circular goods such as plates or bowls. Melted glass gobs fall into the mould which is subjected to a fast-spinning movement. The finished glass product is, therefore, manufactured under the effect of centrifugal force.
Manufacturing of some household goods, like steamware, need welding between two parts produced separately (i.e., the "bowl" and the "foot"), by means of a superficial re melting operation. For example, the bowl may be manufactured through the press-blow process, while the foot may be obtained through pressing and the two parts are subsequently welded on a rotary machine, thus also forming the stem by pulling; in other cases, the stem is already part of the bowl.
Drinking vessels, manufactured with the press and blow process, also require cutting the upper part of the bowl, which is typically used for handling the article during shaping. This can be done at high temperature, after forming, in the case of lower quality goods, or, at low temperature, after annealing, in the case of high-end quality drinking vessels. In this latter case, the rim must be finished by grinding and fire polishing the surface of it.

Annealing

Rapid cooling of the container's external surface during the forming process induces tensile stress in the glass mass making the containers mechanically fragile.
In order to remove this tension, the ware is passed through an annealing lehr where it reaches a temperature of around 550°C (the annealing temperature) and then is slowly cooled to avoid creating new uncontrolled tensile stress.
In the case of certain glass articles, especially tableware, the annealing treatment is replaced by tempering, also called thermal strengthening: in this case, after annealing, the articles are quenched, i.e. fast cooled, in and extremely controlled way, in order to create a beneficial residual stress distribution inside their body, which; bestows on the goods special characteristics of mechanical resistance so that, colloquially, these articles are called "unbreakable". However, this process cannot normally be applied in the manufacturing of containers (bottles, jars) and of some household goods (glasses with stems).

Cold-End

Quality control

Soon after annealing, an accurate quality control inspection is carried out manually or automatically to verify the container conformity to agreed specifications. Unsuitable containers are taken off the packing line and subsequently recycled in the production process to be re-melted again. The physical and mechanical checks performed either randomly or continuously, are carried out by means of dedicated instruments, in order to obtain a high-quality product in accordance with consumer demands.

Packaging/palletizing

The packaging unit of finished products is usually the "pallet" which represents the factory's sale unit after labelling and marketing, and is composed of a wood pallet base, a plastic base layer pad, several layers of stacked articles, divided by inter-layer pads, a covering pad, and a thermally shrunk enveloping plastic film, fundamental for protection from the external environment and mechanical stability.
This pack can protect the ware in the warehouse and during transport. Household goods are normally provided in a primary pack (a basket or box of 4 to 6 items) which is placed in a secondary pack consisting of an American box or master.
These last units are positioned on a pallet and, when the stacking is completed, the pallet is wrapped with polyethylene elastic winding film or covered with a polyethylene hood which again is heat shrunk on to and over the entire bulk pallet. The glass companies have adopted the standard procedure to label and identify the single sale unit to the client, in order to fulfil the requirement of traceability required for food containers.

Storage and shipping

Storage and transportation

Once packed and labelled, the product is stored in warehouses arranged by sectors so any type of glass container or tableware requested can be immediately located.

B9.2. Fulfilments deriving from the application of the Regulation (EC) 2023/2006

In this part are described the activities and the implementation enacted by the glass container industry to conform to the Regulation (EC) 2023/2006 as amended. Since this Regulation was laid down when the quality assurance systems had already become a daily production control tool in most of the manufacturing businesses, it is likely that these businesses already produce in conformity with technical specifications laid down by themselves.

All the same, should it be necessary, the Quality Assurance System and the Quality Control System should be extended to ensure:

> "[...] that the materials and articles are constantly manufactured and controlled, to ensure their conformity to 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"; (art. 3 paragraph a Regulation (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006 as amended. Every paragraph is hence the response of the manufacturers of the glass containers to the requirements of the article in question. To facilitate reading, the paragraphs keep the same title as the article considered, while the subparagraphs indicate specific subjects.

B9.2.1. Quality Assurance Systems (Regulation (EC) 2023/2006, art. 5) and Size of the business

Quality Assurance Systems

The manufacturer of glass container (hereinafter called glass plant*)* should establish and maintain a Quality Assurance System capable of ensuring the achievement of the objectives laid down by the Regulation and described in the general guideline in the present document. The Quality Assurance System should be documented so as to enable control by the competent authorities.

The Quality Assurance System should establish rules and procedures that regulate the company activity, at least concerning the following points as regards the technical aspects:

- human resources and training;
- selection of raw materials;
- process control and quality control on the finished product;
- management of product storage;
- implementation of updated legislation.

Size of the business

Independently from the business size, it should at any rate be guaranteed that the Quality Assurance System, as demanded and finalised by the Regulation (EC) 2023/2006 as amended, is always applied.

The system should be established, implemented and run taking into account the actual size and complexity of the company as well as the technical and human resources available.

On its own premises the business has to at any rate be capable of guaranteeing the application and running of the Quality Assurance and Quality Control System in order to obtain finished materials and products in compliance with the legislation in force on FCMs.

B9.2.1.1. Human resources and training

The *Business operator,* in compliance with the objectives of the Regulation (EC) 1935/2004 as amended and the Regulation (EC) 2023/2006 as amended is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 as amended is applied at all levels of their organization.

The operative aspects relating to the application of the provisions laid down in the Regulation (EC) 2023/2006 as amended can be entrusted by the Business operator to competent and adequately trained people that have to at any rate have at their disposition adequate means to ensure that the requisites of the Regulation (EC) 2023/2006 as amended are respected.

The *company organization* has to at any rate enable the location of the functions to enable inspection by the Competent Authorities.

All *company personnel* potentially involved, including the highest management levels, has to be informed on the principles of GMP, on the obligations that derive from the Regulation (EC) 2023/2006 as amended, on its objectives and on the policy for applying the Regulation.

The *Business* should operate and implement procedures for identifying personnel training requirements and has to see to the training of all staff regarding the tasks that might affect the compliance to the said Regulation.

The *personnel* assigned to GMP control activities should be qualified on the basis of the training and the experience acquired.

An appropriate registration of the training process of all personnel must be kept.

B9.2.1.2. Selection of raw materials

The glass plant is required to only use starting materials for which it has, through information provided by the supplier and/or through controls and inspections, all the data necessary to ensure compliance of the finished product to the applicable legislative requirements.

It is good practise that starting materials are sourced from qualified suppliers according to relevant technical specifications. By qualification is meant a pre-established, organized and documented process that can also include supply specifications.

B9.2.2. Process control and Quality Control on the finished product (Regulation (EC) 2023/2006, art. 6)

The phase of production in a glass plant starts from the design, intended as the formulation of the glass batch mixture and the consequent identification of the process parameters related to the production process, and ends with the storage of the finished product.

The production process includes all phases in the business that together guarantee the finished product comply with technical, legislative and performance requirements.

To this end the glass plant carries out various process and quality checks during the different phases of production, some directly binding to guarantee that the glass containers be suitable for food contact (listed in italics in Figure B9.2), while others are necessary to guarantee that the containers respect the quality standards suitable for their intended use.

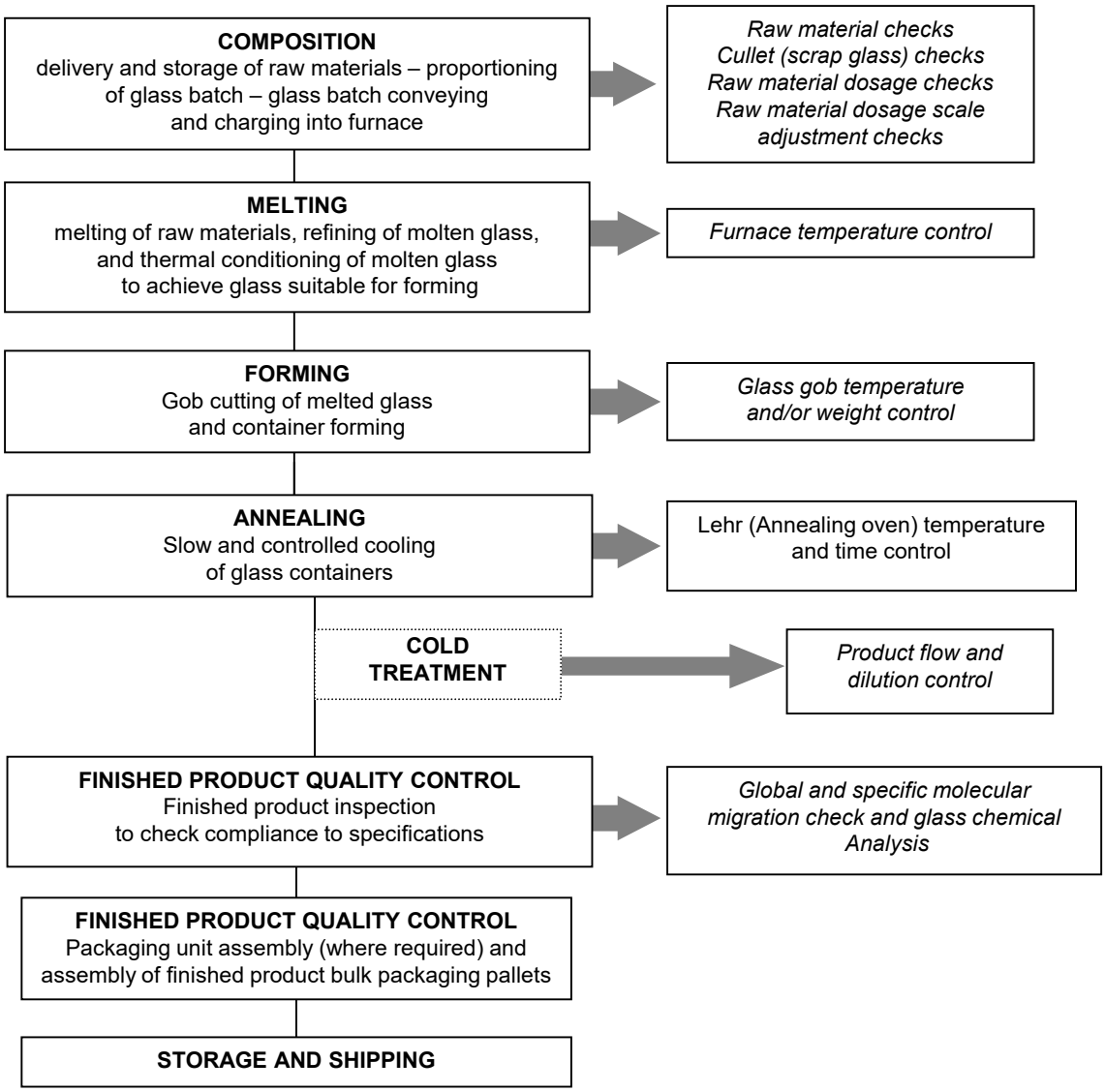


Figure B9.2. Diagram of process and product controls
(controls directly related to compliance with food contact suitability are in italics)

In consideration of the fact that the process is kept constantly under control, the food contact suitability, as well as many others chemical and physical properties, depend therefore exclusively on the chemical composition of the glass, and the controls to guarantee the right formula of the glass ensure the food contact suitability of the glass container.

The above stated controls have to be carried out at the beginning of the process, during the phase described as “Composition”, or before the glass is melted and the container shaped and, subsequently, in order to verify that the glass formula is correct, also on the finished product, during the phase described as “Finished Product Quality Control”.

The controls that a glass plant has to carry out in the “Composition” phase are:

- raw material control;
- cullet (scrap) glass control;
- raw material dosage control;
- setting of the raw material dosage scales.

The phase described as "Melting" occurs in the glass melting furnaces, which are equipped with monitors, supervisory systems and process parameter recording systems.

Furnaces operate continuously, 24hr/day, and a system based on the constant control of the molten glass level feeds the glass mix completely automatically.

To ensure that the melted glass conforms to the required quality standards, the glass plant has to constantly control the fusion process by monitoring the temperature in the furnace.

It is important to stress that, due to the fact that the glass fusion temperature depends on the chemical composition, any anomalies found in this phase of the process can be due to formulation errors, in which case, the glass plant, is expected to immediately carry out tests in the previous "Composition" phase of the process, to ensure there are no errors in the formula.

The "Forming" phase requires the hot shaping of the container.

To ensure the conformity of the glass container, to the quality standards, required for its use, the glass plant has to check the forming process at the following points:

- glass gob forming temperature control;
- glass gob weight control;
- forming machine moulds temperature control.

It is important to underline that the viscosity VS temperature curve of the glass, and therefore the ability to shape it, is related to its chemical composition, consequently, many anomalies found in this part of the process, are due to formulation errors, in which case, the glass plant is expected to immediately carry out tests in the "Composition" phase of the process, to ensure there are no mistakes in the formula.

It is also to be reminded that a severe formulation mistake may jeopardize the food contact suitability of the container and therefore the manufacturing of the product itself, as the whole manufacturing process, from fusion to shaping, will result compromised.

The "Annealing" phase requires the controlled cooling of the glass container just after it has been formed. Although the food contact suitability is not influenced by this process, in order to guarantee adequate mechanical resistance quality standards, the glass plant controls the annealing process through the following tests:

- lehr (annealing oven) temperatures check;
- annealing time control.

The "Finished Product Quality Control" phase in the glass plant, among the different manual and/or automatic controls, must also foresee specific food compatibility tests and the analysis of the glass chemical composition, to confirm the specific process techniques. During this phase, the tests that the glass plant has to carry out are the following:

- global and specific migration (Italian DM 21/3/73 as amended);
- glass chemical analysis of the finished container.

NB: the above-mentioned tests can be carried out by internal as well as external Laboratories.

For the glass containers undergoing a cold external surface coating, the glass plant has to implement procedures and use equipment that guarantee that the product used for the coating does not go into the container. The glass plant has to also have a complete record of the technical specification of the product used for the coating. The glass plant is required to monitor the application phase of the product and in particular:

- product flow;
- product dilution;
- packaging materials.

New packaging materials (wooden pallets, plastic and cardboard interlayers, shrink film, cardboard) undergo an acceptance process that includes verifying their compliance with the contractual requirements. The acceptance process is governed by internal company procedures.

The purpose of the inspection is to ensure that incoming raw materials match the specifications outlined in the purchase order (technical specifications) and that they are unloaded in designated spaces to prevent possible contamination and maintain traceability. Typically, at this stage, documentary and visual checks are performed for all incoming shipments.

Material receipt control for packaging: each company has Operational Instructions (IO) and Recording Forms (MR) for the receipt of packaging materials.

B9.2.2.1. Product storage management

The Quality Assurance System should provide for a procedure to authorize the storage of the final products.

Once all the tests listed in the control procedure to confirm the final conformity of the finished product to its specific use are passed, the function laid down under the Quality Control System will release the authorization to stock the product and/or to ship them to the clients.

For those products that the internal quality control tests might judge not to be up to standards, or for those returned by the clients as defective, a procedure should be provided to help their identification and to impede the shipment.

Any finished products returned by the customers due to non-conformity, have to be stocked in a predefined area of the warehouse and clearly marked.

The environmental and storage conditions of the warehouse should be such as to preserve the conformity of the containers to their use.

Substandard products might be separated from the rest by means other than a physical separation (Digital Block on a software system, IT block).

B9.2.2.2. Adaptation and acknowledge of laws

The Quality Assurance System has to guarantee that future legislative changes will be clearly received in all the company process phases, including also the specifications and contracts with qualified suppliers.

B9.2.3. Documentation (Regulation (EC) 2023/2006, art. 7)

All the documents related to the Quality Assurance System and all the activities of the Quality Control System to fulfil the obligations of the Regulation (EC) 2023/2006 as amended have to be organized so as to constitute a paper or electronic archive, immediately accessible and easily consultable on request by the Competent Authorities.

The documents guaranteeing the traceability will also constitute an integral part of the same, the copies of the declarations of compliance issued by customers and the applicable national and European provisions.

This documentation, serving to demonstrate conformity, will also include:

– specifications, formulations and production process;
– conditions for tests;
– analyses carried out by internal and external laboratories.

In the event of substantial changes in production, liable to change the essential requirement regarding compliance, or when the legislative benchmarks are modified and/or updated, it should

be verified whether or not the documentation relating to the Regulation (EC) 2023/2006 as amended should be or not updated.

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Annex B9.1

Technical glossary

Batch: all raw materials each one correctly proportioned as per the calculated chemical composition to form a mixture to obtain a type of glass with certain specific characteristics.

Blank mould: cavity in which the parison is formed.

Blow mould: cavity in which it is possible to achieve the final shape of the glass container.

Chemical resistance: resistance to chemical interaction between glass surface and substances coming directly into contact with the glass.

Glass structure: random disposition of atoms and molecules typical of the solid state and not crystalline.

Glass: amorphous and homogeneous substances, transparent, at a solid state, not crystalline. In physics it is defined as a liquid with a high viscosity strengthened by cooling, the physical behaviour of which is the same in all the directions of the space (Isotropy).

Mechanical resistance: resistance to any of the possible types of external force, either environmental or human, which can cause breakages in glass.

Palletization: packaging system to allows grouping by stacking of single ware items or unit boxes on a pallet to form a bulk load unit intended to be moved by fork lift trucks or manual pallet transporters.

Parison: preformed blank shape of the body of a hollow glass' s article of which the mouth is though completely formed as when the entire container is finished.

Softening: state connected to a certain glass's temperature (softening point) in which glass is at the limit of undergoing viscous flow deformation under its own weight.

Vitrification: process of transformation of the batch raw materials into homogeneous amorphous glass via melting.

Annex B9.2

Frequently asked questions

Q1 *Do glass plants have a declaration of conformity format, ex article 7, Regulation n. 2023/2006/EC?*

Regulation (EC) 2023/2006 as amended does not foresee a declaration of conformity format. Therefore, companies can organize themselves. Nevertheless, a useful benchmark is the: *Codice di comportamento dell'industria italiana del vetro da imballaggio (Obblighi per materiali e oggetti a contatto con gli alimenti* – Assovetro, 2018), that is, the Italian Glass Packaging Industry Behaviour Code (obligations concerning food contacting materials and articles – Assovetro, 2018) which includes a subject type format which can be provided to customers. It is in any case the responsibility of the company to issue a declaration in accordance with the Italian Ministerial Decree 21st March 1973.

Q2 *Which tests are carried out by glass plants to guarantee the suitability of hollow glass containers and tableware objects for food contact?*

Glass plants have to carry out total migration tests according to the Italian Ministerial Decree 21st March 1973 and the migration tests have to be performed in accordance with the method detailed the same decree. In the case of lead containing glass (e.g. lead crystal glass), also, the Pb specific migration has to be checked in accordance with same decree. In order to evaluate other specific migration parameters, the glass plants may also apply specific migration tests as described in ISO 7086, ISO 6486 or DIN 51031/51032, depending on the intended use, even if they are not compulsory for Italian Regulations. Tests are usually carried out in authorized research laboratories accredited for a specific matrix as per UNI CEI EN ISO/IEC 17025 (for example the Stazione Sperimentale del Vetro, that is the Italian glass research centre).

Q3 *May customers get information on the chemical composition of glass containers for food items?*

Customers and glass plants may enter into a contractual agreement for sharing information related to parameters needed to characterize the product (such as, the minimum and maximum content of main element oxides composing the type of glass).

Q4 *Are the raw materials used in manufacturing glass containers for food contact always the same?*

The main raw materials are used in quantities depending on the type of glass to be manufactured. These main materials are: sand, sodium carbonate, limestone, dolomite, sodium sulphate, internal glass cullet, and external glass cullet coming from separate collection of municipal solid waste for recycling.

Q5 *How much glass cullet can be used in the production process?*

The percentage of glass cullet in glass containers/articles manufacturing is dependent on several factors, such as, the market availability, production demands, glass colour, product quality level, cullet quality level.

Q6 *Are glass containers for food contact recyclable?*

Glass containers/articles are 100% recyclable.

Q7 *Do glass plants have any process flowcharts indicating control test points?*

Each Company has a different scheme according to the specific organizational factory models.

Q8 *How can the traceability of a glass container or article be guaranteed?*

Regulation (EC) 2023/2006 as amended and Regulation (EC) 1935/2004 as amended do not provide for a fixed system. Useful references and label prototypes are provided in the sale unit and may be found in the Italian Glass Packaging Industry Behaviour Code (obligations concerning food contacting materials and articles) (*Codice di comportamento dell'industria italiana del vetro da imballaggio* -

Obblighi per materiali e oggetti a contatto con gli alimenti – Assovetro, 2018). According to this document, if the customer retains the label supplied with the goods, the traceability of the product can be guaranteed.
In particular, the alpha-numeric code (GL 70 colourless - GL71 green - GL72 brown), as specified in European Commission Decision 97/129/EC, is also indicated on the label and/or on the Delivery Note. Assovetro (Italian glass packaging association) has produced the following internal guidance document, useful for better classifying the various code categories.

Classification of packaging for food and cosmetic use in Type III glass (silica soda calcium)

Codification	Colour	Specification for characterization
GL 70 (colourless glass)	White and half-white Uncoloured and partially decorated	Specification for characterization concentration Fe_2O_3 < 0,2%
GL 71 (green glass)	Light green, dark green, and mass-coloured (excluding amber) generally uncoloured and partially decorated	Specification for characterization concentration Fe_2O_3 > 0,3% and < 1,0%
GL 71 (green glass)	Fully decorated/painted	Specification for characterization
GL 72 (brown glass)	Undecorated and partially decorated amber	Specification for characterization concentration Fe_2O_3 > 0,3% and < 1,0% Cr_2O_3 < 0,06%

Q9 *Is there a reference standard for verifying specific migration limits applicable to internally glazed containers or household items glazed in the contact area?*

The ISO 4531:2018 standard defines a reference testing methodology for determining the release of metallic ions from glazed articles intended to come into contact with food, taking into account real-life application conditions (time, temperature, repeated use). The scope of this standard relates to certain types of decorated articles. This testing is not mandatory.

Q10 *Is there a reference method for determining the release of lead and cadmium from articles with silicate glass and glass-ceramic surfaces coated with porcelain enamels intended to come into contact with food?*

The European standard EN 1388-2:1997 defines a reference method for determining the release of lead and cadmium from articles with silicate glass and glass-ceramic surfaces coated with porcelain enamels intended to come into contact with food. Therefore, its scope is related to certain types of decorated articles and is also referenced in the BfR Recommendations on Food Contact Materials. It establishes a test method (4% at 22°C for 24 hours) for determining the release of lead and/or cadmium from the drinking rim that may come into contact with the lips. This testing is not mandatory.

Q11 *What are the reference legislations for verifying limits for specific migration in other European countries?*

- BELGIUM: Royal Decree of May 11, 1992, regulates the release limits of lead and cadmium. Additionally, a limit for total migration is specified.
- FRANCE: For articles made of glass, crystal, ceramics, and enamelled glass-ceramics, it is necessary to check the migration of lead, cadmium, and hexavalent chromium after initial contact with 4% acetic acid at 22°C for 24 hours, and the migration of aluminium, cobalt, and arsenic after the third attack under the same conditions. These migrations have specified limit values. The standard is DGCCRF Fiche MCDA n°2 (V01-01/05/2016) Aptitude au contact alimentaire des matériaux inorganiques (hors métaux et alliages) destinés à entrer en contact avec des denrées alimentaires. verre - cristal - ceramique – vitroceramique objets emailles.

- GERMANY: BfR Recommendations on Food Contact Materials: DIN EN 1388-2 and DIN51031-DIN51032. For packaging in contact with food, it is necessary to check the specific migration of lead and cadmium, including in the mouth contact area, after contact with a 4% acetic acid solution at 22°C for 24 hours. These migrations have specified limit values.
- NETHERLANDS: Regulation of the Minister for Public Health, Welfare and Sport of March 14, 2014, laying down the Commodities Act Regulation on packaging and consumer articles coming into contact with foodstuffs – Commodities Act (Packagings and Consumer Articles) Regulation [Warenwetregeling verpakkingen en gebruiksartikelen] –. For all packaging in contact with food products, it is necessary to check not only the total migration but also the specific migration of antimony, arsenic, barium, boron, cadmium, cerium, chromium, fluorine, cobalt, lithium, lead, manganese, nickel, rubidium, and zirconium after contact with 3% acetic acid at 22°C for 24 hours. These migrations have specified limit values.

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. Applicable legislation

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.[21]
- Regulation (UE) 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food (it applies to paints for boxes and lids, seals for capsules.)

[21] It replaced the Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Italian legislation

- Decree of the Italian 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.
- Italian Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- Italian 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 objects intended to come into contact with food.
- Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, intended to come into contact with food or substances for personal use as amended. (It applies to paints for boxes and lids, seals for capsules, additives for paints, and plastics)[22].

B10.1.3. General description of a metal coating product

Coatings are divided into *varnishes* and *enamels*.

Varnishes are colourless or coloured transparent mixtures (they may sometimes contain matting agents for a non-glossy final appearance).

Enamels are preparations containing pigments; in most cases they are opaque.

A paint product, or coating, is a homogenous or heterogeneous mixture of:

- resins (epoxy, polyester, epoxy ester, acrylic, vinylic, ketonic, etc.);
- cross-linking agents (melamine, urea, benzoguanamine resins, phenolic resins, isocyanates, trimellitic anhydride adducts);
- solvents (aromatics, ethers, glycols, glycol acetates, glycol ethers acetates, ketones, mineral spirits, alcohols, etc.);
- water and aliphatic amines, in the case of water-dilutable products;
- additives (substrate and surface wetting agents, lubricants, etc.);
- catalysts;
- pigments (inorganic, organic and metallic);
- functional fillers (zinc oxide and carbonate, polyvinyl chloride).

Above-mentioned components are mixed in the quantities specified in the recipe in order to obtain the desired and necessary characteristics for the protective function of the metal or the alloys constituting the metal substrate.

The paint products are mainly cured in a thermal oven. There are also UV-curable coatings.

When applied in coils (aluminium for 2-piece cans and *Easy Open End*, EOE) the curing times are very short (30-60 seconds at 250-270°C PMT, Peak Metal Temperature).

When applied in foil they are cured for 9-10 minutes at temperatures varying between 190 and 205°C.

To check the degree of polymerisation during production, it is common practice to test the resistance of the resulting film to a solvent. For this purpose, a cotton ball is wetted with acetone or methyl ethyl ketone and then rubbed onto the film obtained by applying a pressure of 1 kg. The

[22] Useful guidance for regulatory clarifications on coatings was provided by the Ministry of Health in Ministerial Note 15844 dated 12/5/2011 "EU Regulation No. 10/2011 concerning materials and articles made of plastic intended to come into contact with food products".

film must withstand more than a certain number of double blows (1 blow is calculated round trip). The number of double strokes depends on the coating product.

B10.1.4. Requirements of a paint product intended for food contact

General characteristics of a paint product intended for direct contact with food must ensure
- the isolation of the base metal from the food;
- resistance to mechanical processing;
- resistance to chemical agents of the preserving liquid;
- resistance to natural or added food components;
- the necessary inertness to the food.

In addition to the functional characteristics, the basic raw materials must fulfil a fundamental requirement: the monomers necessary for the preparation of the basic polymers (resins) and crosslinkers must be present in the various positive lists contained in the laws regulating the matter at European and national level.

There are also other specific requirements for the product. In fact, the paint product is formulated taking into account the performance to be achieved, for example:
- adhesion to the substrate to be used;
- flexibility (e.g., resistance to deep drawing);
- resistance to heat treatments (sterilisation, pasteurisation);
- compliance with customer requirements (e.g., powder level for crown caps, etc.);
- resistance to food simulants and its preserving liquid (salt solutions, vinegar, sulphides, fats, aromas, etc.);
- resistance to chemicals (solvents, varnishes, paints, etc.).

Once the product has been formulated and the required performance has been verified, laboratory tests are carried out to check global and specific migration, using the food simulants foreseen by the standards in force (e.g. DM 21/3/1973 as amended and amendments, etc.) and the test conditions foreseen for the final products (times, sterilisation temperatures, times and temperatures simulating storage of the filled boxes).

These conditions are set out in the annex that forms an integral part of DM 21/3/1973 as amended and amendments.

For the whole shelf life of the product, it is recommended to carry out at least one overall migration per year (and specific migrations, if applicable) and in every case to analyse at least one batch for every 10 batches produced of each individual product.

B10.1.5. Phases of the production process: flowchart and description

B10.1.5.1. Production flowcharts

The raw materials, foreseen for the formulations, are delivered to the company. For each new arrival of goods:
- a batch number is assigned;
- the specifications on the test bulletin/certificate are checked and the bulletin is archived;
- a sample is taken and stored, appropriately identified.

Incoming raw materials can all be checked, spot-checked or accepted in the quality declaration according to the company's Quality Assurance Manual or management system documents.

The cleanliness of the plant where production will take place is checked and then the product is manufactured according to the formulation and existing manufacturing procedure.

Once the recipe is completed, quality control is performed and, if this is passed successfully, after the filtration the finished product is packed in containers.

Before packaging, the empty containers, which are often disposable, are inspected for cleanliness and then, after the filling, closed at the end of production line. Inspection is important for *pails* (which remain disposable) and steel totes (IBC - which are reused).

During packaging, a counter sample of the batch is also prepared and stored for the time foreseen in the Quality Assurance Manual or management system documents.

The production process differs when producing enamels or paints. Figure B10.1 illustrates the flowchart for varnish production and Figure B10.2 that for enamels (the part in grey is compliant with the GMP Regulation (EC) 2023/2006 as amended).

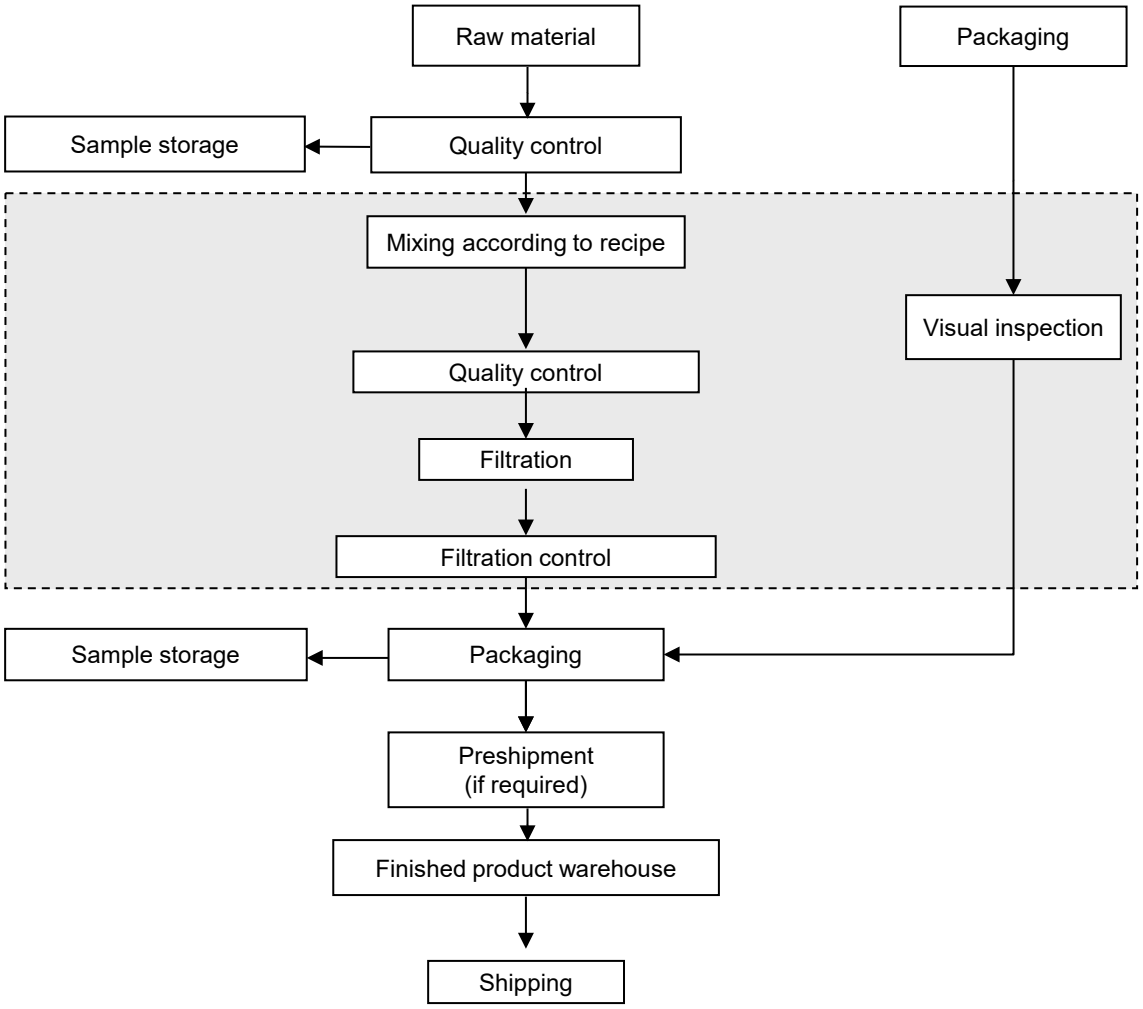

Figure B10.1. VARNISHES: production flowchart for paint products for the protection of metal containers intended to come into contact with foodstuffs

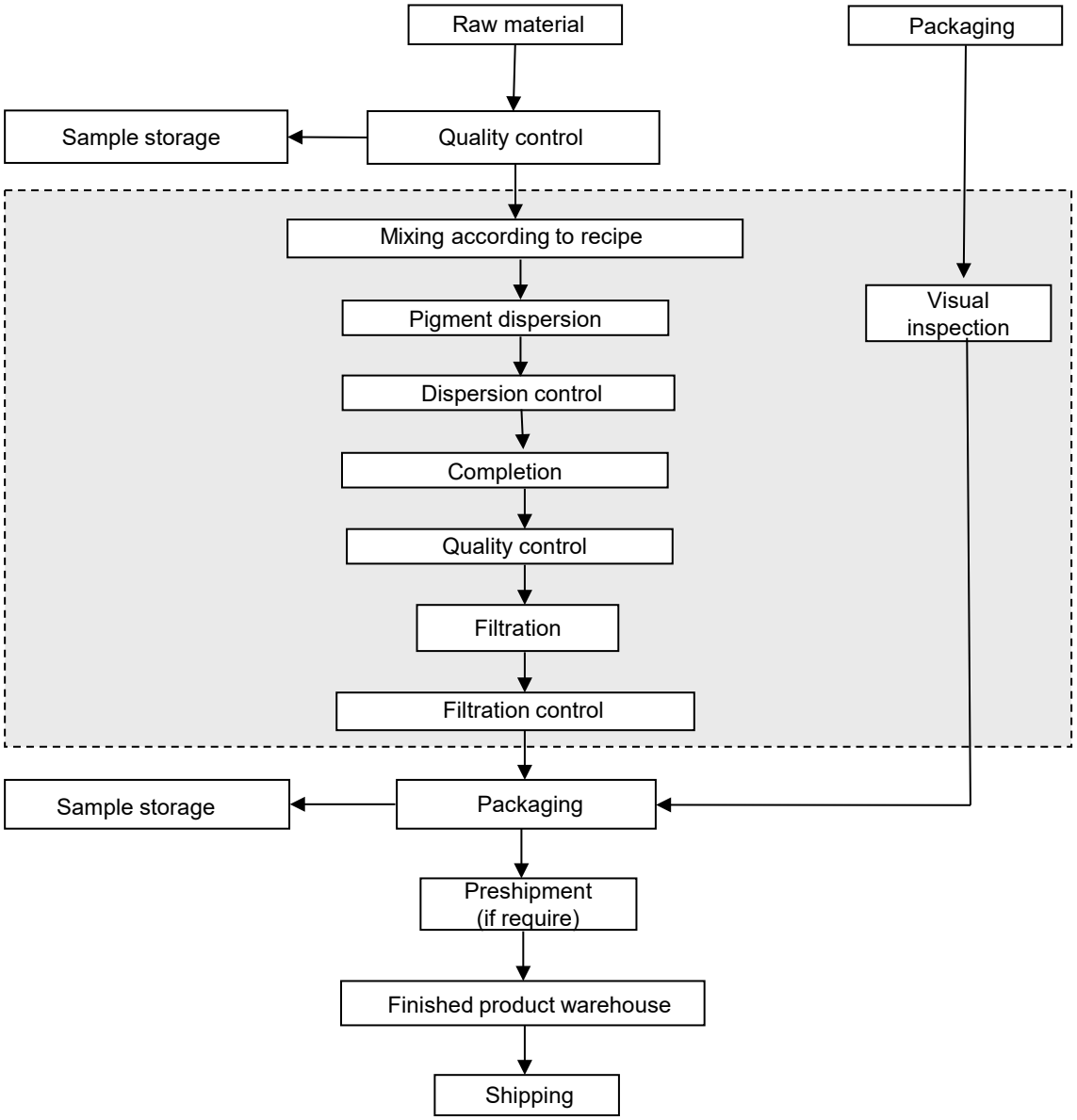

Figure B10.2. ENAMELS: production flowchart for coatings for the protection of metal containers intended to come into contact with foodstuffs

B10.1.5.2. Brief description of process phases

Mixing according to formulation

In a suitable clean (or cleaned by washing) container, the components are added according to a predefined list (recipe) under agitation.

Large quantities are produced in fixed plants; the container is normally equipped with an impeller. Small quantities are produced using mobile containers placed under suitable mixers. The purpose of mixing is to homogenise the components so that at every point the composition is the same.

Pigment dispersion

Pigments (of suitable quality) are delivered as dusts consisting of very small unit particles, averaging under a micron.

The main pigment used is titanium dioxide (for white glazes).

Dispersion phase consists of breaking the agglomerates of particles by applying a force (with a high-speed stirrer or bead mill) that allows the pigment particles to be coated with resin. The operation takes longer or shorter depending on the desired level of fineness, power and type of machines involved.

The fineness of the dispersion is checked with an instrument called "grindometer", which is used to determine the grinding fineness (and also to detect the presence of large particles or agglomerates in a dispersion).

Completion

This operation implies addition of remaining components according to recipe procedure, again under stirring.

Quality control

This consists of checking the characteristics of the coating product, applying it to the correct support (aluminium, tinplate, TFS chrome-plated strip, steel) with a suitable tool. This is normally a stainless-steel bar, coated with a harmonic wire, whose diameter determines the weight of the applied film (*bar coater*). The material is then baked in an oven, according to the specified time and temperature conditions.

The film that is formed is then subjected to the mechanical and chemical-physical tests (pasteurisation or sterilisation) required by the test method.

Filtration and filtration control

Before being packaged, the paint product is filtered according to various techniques (more or less fine nets, filter bags or cartridges). This operation removes possible particles such as coarse pigment particles, possible crusts formed in the mixers, etc.

B10.2. Fulfilments deriving from the application of the Regulation (EC) 2023/2006

This section describes the activities and implementations put in place by manufacturers of paint (coating) products on metals in compliance with the requirements of Regulation (EC) 2023/2006 as amended.

The Quality Assurance System and the Quality Control System shall, if necessary, be modified and finalised in order to ensure:

> "[...] that the materials and articles are constantly manufactured and controlled, to ensure their conformity to 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" (art. 3 paragraph a Regulation (EC) 2023/2006)

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006 as amended. Every paragraph is hence the response of the manufacturers of coating on metals to the requirements of the article in question.

B10.2.1. Quality Assurance Systems (Regulation (EC) 2023/2006, art. 5) and Size of the business

Quality Assurance Systems

The manufacturer of coating products on metals (hereinafter referred to as "the manufacturer") is understood to be the one who, starting from raw materials, must have and maintain a Quality Assurance System capable of ensuring that the objectives foreseen by the Regulation and described in the general guideline are achieved.

The Quality Assurance System must be set up in such a way as to make audits by the competent authorities possible.

The Quality Assurance System must envisage rules and procedures steering the company's activities, concerning at least the following points:

- human resources and training;
- starting materials and suppliers, including suppliers of goods and services and subcontractors;
- production (process conformity, design, documentation);
- quality control;
- warehousing, handling and shipping;
- complaints, corrective and preventive actions.

The system must ensure that any legislative changes are clearly incorporated into the relevant stages of the business process.

It is advisable to have a procedure in place to incorporate changes resulting from updates to current legislation on materials intended to come into contact with food.

Size of the business

Regardless of the size of the company, it must be ensured that the Quality Assurance System, as required and finalised by Regulation (EC) 2023/2006 as amended is always applied.

The system should be established, implemented and run taking into account the actual size and complexity of the company as well as the technical and human resources available.

Within its own structure, the company must in any case be able to guarantee the application and management of the Quality Assurance and Quality Control System that allows obtaining materials or finished products that comply with current legislation on FCMs.

B10.2.1.1. Human resources and training

The *Business operator,* for the goals of Regulations (EC) 1935/2004 as amended and 2023/2006 as amended, is responsible for managing the resources and activities necessary to ensure that Regulation (EC) 2023/2006 as amended is applied at every level of the organisation.

The operational aspects inherent to the application of the provisions of Regulation (EC) 2023/2006 as amended can be entrusted by the Business Operator to competent, adequately trained persons who must have the appropriate means to ensure that the requirements of Regulation (EC) 2023/2006 as amended are met.

The company organisation must make it possible to identify the functions for the purposes of verifications by the Competent Authorities.

All potentially affected company personnel must be informed of the principles of GMP, the obligations arising from Regulation (EC) 2023/2006 as amended, its objectives and the policy for applying the Regulation.

The Business Operator must prepare and enforce procedures in order to identify personnel training needs and must provide training for all personnel involved.

Personnel who must carry out specific GMP control and verification activities shall be qualified on the basis of their specific training and experience.

Appropriate records of the training process of all personnel shall be maintained.

B10.2.1.2. Production

The company's production phase starts from the design of the product and goes all the way till the finished product's storage.

The production process encompasses all the company's activities that contribute to ensuring that the finished product complies with legislative, technical and performance requirements (foreseen from the design phase) to guarantee suitability for its intended use.

Therefore, the Quality Assurance System must have procedures that discipline all the phases listed below:

- Planning of compliant product;
- Selection of starting material and suppliers;
- Arrival of raw material and storage;
- Control of raw material;
- Production processes and traceability of the raw materials used;
- Control of process parameters;
- Control during production;
- Finished product Quality Control and storage.

Product design and development

A distinction can be made between the design of a product from scratch and the adaptation of a product to customer's needs.

Adaptation can be done if you already have a product developed for a specific use that is subsequently adapted to a customer's specific and different requirements.

If the manufacturer develops a totally new product, in accordance with a usage conformity project, the packaging material produced with this paint product must:

- meet the performance requirements for its intended end use;
- meet the requirements of current legislation for food contact materials.

The paint product must be produced with suitable raw materials and production systems that guarantee, at all stages of the process, compliance with the intended use and the legislative requirements for food contact.

Selection of starting materials and suppliers and/or services and/or third parties

The manufacturer must use only approved raw materials.

For such raw materials, he must have – through information from the supplier and/or through analytical checks and verifications made during the planning phase – all qualifying data.

It must also be ensured that the declaration of conformity for end use is available in accordance with the applicable national legislation.

Raw materials must come from qualified suppliers. Qualification means a pre-established, organised and documented process that may also include specifications of involved raw materials.

In addition, the Quality Assurance System of the raw material suppliers or subcontractors must be checked by means of periodic inspections.

If the supplier is not working according to GMP, the manufacturer must ensure that the raw materials and/or semi-finished products he uses are suitable for producing materials and articles approved for food contact.

Process compliance

The production process has to be kept under adequate control. The Quality Assurance System must guarantee that due attention is paid to the most critical points of the production process.

Documentation of procedure/instructions

Each stage of production must be documented. The documentation required to perform the work must be available to the personnel concerned and must be kept up to date.

B10.2.2. Quality Control System (Regulation (EC) 2023/2006, art. 6)

The manufacturer must have in place and maintain a Quality Control System capable of ensuring compliance with the Regulation as described in the general guideline.

The system must include procedures that provide for all necessary controls, related records and actions to be taken in the event of non-compliance.

All the documentation has to be available for the Competent Authorities that demand to see it in accordance with the Regulation (EC) 2023/2006 as amended and Regulation (CE) 1935/2004 as amended.

B10.2.2.1. Management of raw materials warehouses

Starting materials must be clearly identified. All raw materials out of specs must be segregated in a predefined and clearly identified area, pending the resolution of the issue.

The segregation of non-compliant material can also be performed through restrictions other than physical segregation in a specially assigned area (IT block).

Any use of such material will be subject to prior authorisation of the Technical Management or other designated company function.

Special attention should be given to the storage, warehousing and handling of raw materials to avoid any damage that can make the materials unusable.

B10.2.2.2. Production controls

The Quality Control System has to be regulated by suitable procedures that guarantee that during the production process all the necessary controls are carried out.

Product traceability must be granted by mean of suitable records of the batches of raw materials used, of the working conditions recorded during production and of all quality controls performed also on intermediate and/or semi-finished products.

It must be possible to put the finished product into stock only if there is evidence that the quality control has been carried out and finished product passed it.

B10.2.2.3. Quality Control of finished products

The Quality Control System must have appropriate procedures to check the conformity of finished products.

B10.2.2.4. Management of finished products warehouses

Finished products that comply with specs must be clearly separated from non-compliant ones.

For non-compliant products, a procedure must be in place to stop shipment (or internal use) pending determination of the problem.

Non-compliant products, clearly identified, must be stored in a predefined area to prevent their use, even accidental.

Any finished products returned by customers because they are non-compliant must be stored in a predefined area and clearly identified pending definition.

B10.2.2.5. Distribution, shipment and delivery

The manufacturer, if responsible for the transport and the delivery of the material to its destination, has to also guarantee that this phase is regulated by instructions and procedures that guarantee the quality of the material preserving it from any contamination.

B10.2.2.6. Conformity of the application of the GMP and claims management, corrective and preventive actions

The Quality Control System has to enact suitable procedures so as to monitor the correct implementation and total respect of the GMP.

The company's Quality Assurance System must include verification plans and periodic checks on compliance with the pre-established parameters and specifications.

The main critical points in the production process should be identified and monitored.

B10.2.3. Documentation (Regulation (EC) 2023/2006, art. 7)

All the documents concerning the Quality Assurance System (procedures, specifications, formulations, etc.) and all the activity of the Quality Control System (instructions, registrations of control data, machine setup data, tolerances and measurements, etc.) must be readily accessible and easy to consult.

Annex B10.1

Technical glossary

Coating (organic coatings): is the generic name for all coating products, pigmented and non-pigmented.

Baking ovens: these are tunnels of various lengths where paint products are kept at a temperature of between 165°C and 200°C with a dwell time of 9-10 minutes PMT. The temperature is reached by heating air, normally with natural gas, and distributing this air uniformly inside the tunnel.

Organosol: PVC dispersion in a resin system.

Pail: buckets with handle with variable volume from 5 to 30 kg.

PMT: stands for *Peak Metal Temperature*. It represents the temperature at which the metal must be held for the time required for cross-linking. The PMT is very important because the air temperature inside the tunnel is not always the one showed by the external recorder.

MEK Resistance: This is a test done on the paint line used as an evaluation of the cross-linking of the paint film. It is carried out by rubbing a cotton ball soaked in MEK (MethylEthylKetone) or acetone, applying a weight force of one kg and counting the number of strokes (round trip=1) to which the film resists before abrading. The resulting value is not an absolute figure and varies from product to product (even of the same nature). It is actually an index of solvent resistance rather than a cross-linking test, but it has its own validity and is also easy to perform.

Resistance to sterilisation: This test is conducted by treating the painted article in an autoclave with water or steam at a temperature, normally 130°C, for one hour. Tests are also sometimes carried out at lower temperatures for longer times (e.g.: 121°C for 2-3 hours) or with food simulants, such as acetic acid solution, oil, etc.

Enamels: enamels are paint products consisting of resins, cross-linking pigments, additives, lubricants and solvents. The final appearance is highlighted with a colour (white, black, red, aluminium, etc.).

Varnishes: varnishes are coating products with a composition similar to enamels but without pigments. They are generally colourless or transparently coloured (mainly gold). Colour can also develop by baking (see epoxy-phenolic paints).

WBT (Weight Before Tare): Consists of testing a specimen bent at 180°C on a standard shape article and put it on an inclined plane where the bend goes from zero to the diameter of the template. Dropping a weight from a predetermined height allows the bending strength to be verified. This method only gives a relative value, but has the advantage of being quick and giving good indications of the behaviour of the cross-linked film.

Annex B10.2

Frequently asked questions

Q1 *Does Regulation (EU) 10/2011 as amended cover paints applied to metal substrates?*

No, the field of application of the Regulation is exclusively that of plastic materials.

Q2 *Is there any specific EU legislation regulating coatings applied to metal substrates?*

No, in addition to the general provisions of Regulation (EC) 1935/2004 as amended, the only specific legislative reference applicable at European Union level to coatings is Regulation (EC) 1895/2005, which defines the migration limit of certain epoxy derivatives in plastic materials or protected by a surface coating.

Q3 *What is the Code of Practice?*

In absence of a specific piece of legislation regulating organic coatings intended to protect the inner side of metal containers at European level, CEPE (*European Council of the Paint, Printing Ink and Artists' Colours*) started a working group that, beginning its activities in the 1990s, compiled a list of all raw materials used for food-contact coatings. The manufacturers of resins, additives, lubricants, etc. indicated the composition and a complete list was compiled, thus containing all monomers and additives used in at least one European country and suitable for food contact according to FDA 175.300 (*Code of Federal Regulations*, Sec. 175.300 of the Food and Drug Administration).

Q4 *How is the suitability for food contact of a paint product checked?*

It is an industry good practice that all raw materials used are manufactured starting from substances included in the positive lists of Regulation (EU) 10/2011 for the applicable part. Although not binding, the AP Resolution 2004 (1) and CFR Title 21, sect. 175.300 of the *Food and Drug Administration* as well as any other legislation of the EU Member States are also consulted. Subsequently, overall migration tests are carried out in food simulants as well as specific migrations for single substances, if the substances do have a specific migration limit or otherwise a maximum quantity limitation. In the absence of a specific legislation for coatings on metal, the simulants and test conditions currently stipulated in Regulation (EU) 10/2011 are used.

Q5 *How should I choose which coating product to use?*

The choice of the right coating and the number of coating layers should be made according to the following parameters:

- pH of the food;
- salt content of the aqueous solution;
- cooking/heating temperature of the food;
- filling systems;
- food storage (frozen, refrigerator, room temperature, etc.);
- ovens to be used (traditional or microwave);
- tray closure system;
- shelf life of the filled container.
- storage conditions

Based on this set of information, the type of coating suitable for the food to be stored is chosen for the boxes and the cooking system to be used in the case of the trays.

Q6 *What is AVISA?*

AVISA is the acronym for Association, Paints, Inks, Sealants and Adhesives (*Associazione nazionale Vernici, Inchiostri, Sigillanti e Adesivi*). It is one of the sector Associations of Federchimica (https://avisa.federchimica.it/) which protects the interests of its member companies and ensures liaison with the respective branch's European Associations (CEPE, EuPIA, FEICA).

B11. ADHESIVES AND SEALANTS

B11.1. Characterization of the sector

B11.1.1. Field of application of guideline

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

B11.1.2. Applicable legislation

At present time there are only general provisions, as there is neither at European nor at national level, a specific legislation regulating adhesives and sealants used in food packaging domain.

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.[23]
- Regulation (UE) 10/2011 on plastic materials and articles intended to come into contact with food as amended.

Italian legislation

- Decree of the Italian 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.
- Italian Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- Italian 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 objects intended to come into contact with food.
- Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, intended to come into contact with food or substances for personal use as amended.

[23] It replaced the Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

B11.1.3. General description of adhesives and sealants

An *adhesive* is a non-metallic chemical compound able of joining materials by surface fixation (adhesion) and in such a way that the resulting bond possesses adequate internal strength (cohesion). An adhesive is a mixture consisting of following components:

- polymers (polyvinyl acetate-based, acrylic compounds, etc.);
- plasticisers;
- resins (epoxy, polyester, acrylic, vinylic, ketonic, hydrocarbon, natural, etc.);
- cross-linking agents (melamine resins, ureic resins, phenolic resins, isocyanates, diisocyanates, etc.);
- waxes/oils;
- solvents (aromatics, aliphatics, glycol ethers, glycols, acetates, glycol ethers acetates, ketones, etc.);
- additives (wetting agents, lubricants, anti-foaming agents, etc.);
- preservatives;
- catalysts;
- fillers.

The above components are mixed in the quantities provided by the formulation in order to obtain the desired characteristics necessary for the functionality of the adhesive used in the production of packaging of different materials (paper, cardboard, flexible).

A *sealant* is a polymeric chemical compound capable of joining two substrates and filling the gap between them.

B11.1.4. Phases of the production process: flowcharts and descriptions

B11.1.4.1. Production flowchart

Figure B11.1 illustrates the flowchart for the production of adhesives and sealant (the dashed part is compliant with GMP Regulation (EC) 2023/2006 as amended).

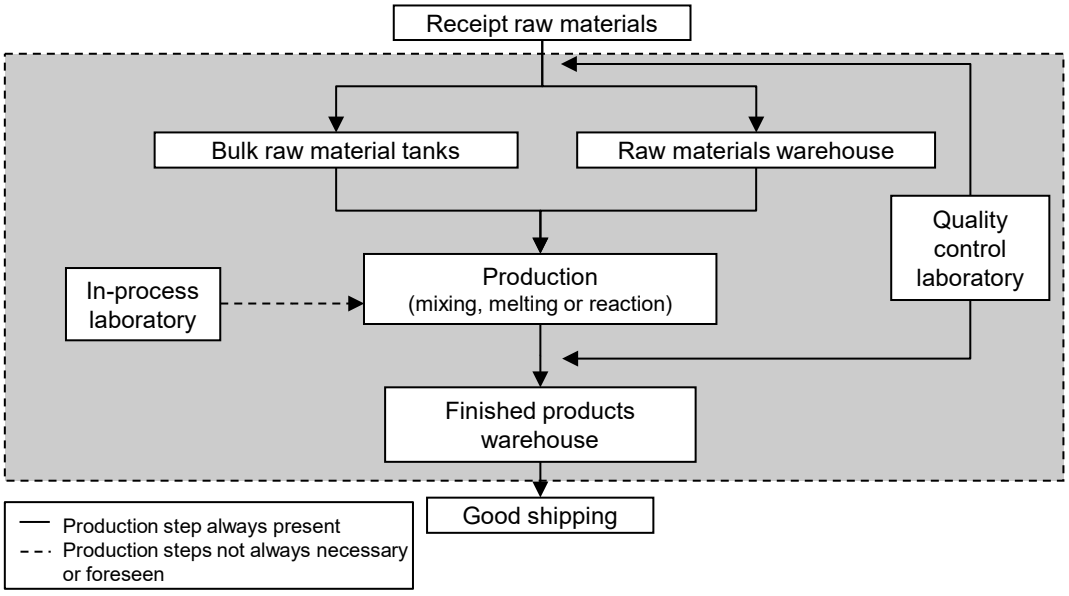

Figure B11.1. Production flowchart for adhesives and sealants

B11.1.4.2. Brief description on phases of the production process

Warehouse for raw materials and bulk raw material tanks

The raw materials used in the production of adhesives and sealants can be classified into two different types:

- basic substances: chemicals as-is or diluted in water
- mixtures and/or polymers: mixtures of different chemical substances, usually in polymer form with the addition of additives (e.g., preservatives, stabilizers, etc.)

Both of these types are considered raw materials and are purchased from suppliers.

The raw materials that arrive at the plant are checked by the Quality Control Laboratory to verify that they comply with the agreed chemical and physical specifications with the supplier and that they do not present any obvious defects.

The received raw materials are stored according to their hazardous nature and are entered into the management operating system where data regarding identification, quantity, and location in the warehouse are recorded.

In the event that a raw material is found to be non-compliant with the specifications, it is blocked in the warehouse by the Quality Control Laboratory until a decision is made regarding its destination (use in derogation or return to the supplier).

Production and packaging

In adhesive manufacturing, it is necessary to distinguish the production processes for the manufacturing of three different types of products commonly used in the production of food packaging:

1. *Water-based adhesives*
   Raw materials, whether synthetic or natural, are loaded into a mixer, blended, and possibly subjected to cooking according to the operating instructions attached to each specific formulation. Finally, the product is packaged in drums, barrels, or buckets or sold in bulk.
2. *Hot-melt adhesives*
   Raw materials, consisting of synthetic and/or natural thermoplastic polymers, are loaded into a melter, melted, and mixed. At the end of the mixing process, granulation may occur to obtain finished product pellets. The product is then packaged in bags, barrels, or trays.
3. *Reactive and non-reactive adhesives, solvent-based and non (solvent-less)*
   Raw materials are either reacted in a reactor or dissolved in an appropriate solvent, following the operating instructions attached to each specific formulation. Finally, the product is packaged in drums, barrels, or sold in bulk.

In-Process Laboratory and Quality Control Laboratory

During the product manufacturing process, product samples are taken to ensure that the material specifications align with the technical specifications of the product. In the event of non-compliance, the product undergoes processing until it meets the specified requirements.

At the conclusion of the production process, the Quality Control Laboratory collects a sample of the finished product to verify its conformity to the specifications outlined in the technical data sheet.

In the case of non-compliance, the Quality Control Laboratory halts the material, awaiting a decision regarding its disposition.

Finished Product Storage

The packaged finished product is stored in a suitable warehouse with controlled conditions to prevent any deterioration of the product.

Non-compliant or customer-returned products are clearly separated and well-identified compared to conforming products. Procedures for the requalification of non-compliant products must be established.

Goods Shipment

The distribution and transportation phase must be governed by procedures that ensure the preservation of the product's integrity and its freedom from potential contaminations.

If the shipment is handled by an external company, a specification must be established to guarantee the minimum requirements to be adhered to in order to maintain the integrity of the product.

B11.2. Fulfilments deriving from the application of the Regulation (EC) 2023/2006

This section describes the activities implemented by companies producing adhesives and sealants for the production of food packaging in order to comply with the requirements of Regulation (EC) 2023/2006 as amended. Since this Regulation was enacted when quality assurance systems had already become an everyday working tool in the majority of manufacturing companies, it is likely that companies are already producing in accordance with technical specifications established by them.

However, if necessary, the Quality Assurance System and the Quality Control System will have to be modified and finalised to ensure:

> "[...] that the materials and articles are constantly manufactured and controlled, to ensure their conformity to 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" (art. 3 paragraph a Regulation (EC) 2023/2006)

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006 as amended. Every paragraph is hence the response of the manufacturers of adhesive and sealants to the requirements of the article in question. To facilitate reading, the paragraphs keep the same title as the article considered, while the subparagraphs indicate specific subjects.

B11.2.1. Quality Assurance Systems (Regulation (EC) 2023/2006, art. 5) and Size of the business

Quality Assurance Systems

Adhesives and sealants manufacturers, if they are intended for use in the production of food packaging, must have in place and maintain a Quality Assurance System able of ensuring that the objectives laid down in the Regulation and described in the General Guideline are achieved.

Quality Assurance System must be documented in such a way that will make possible to conduct audits by competent authorities.
The Quality Assurance System must provide rules and procedures that discipline company's activities, concerning at least the following points:
– compliance with the requirements of current legislation
– human resources and training;
– raw materials and suppliers, including suppliers of goods and services and subcontractors;
– production;
– quality control;
– warehousing, handling and shipping;
– complaints and corrective and preventive actions.

The system must ensure that future legislative changes will be incorporated into all stages of the business process, including specifications and any contracts with qualified suppliers.
It is advisable to have a procedure in place to incorporate changes resulting from updates to current legislation on materials intended to come into contact with food.

Size of the business

Independently from the business size, it should at any rate be guaranteed that the Quality Assurance System, as demanded and finalised by the Regulation (EC) 2023/2006 as amended, is always applied.
The system should be established, implemented and run taking into account the actual size and complexity of the company as well as the technical and human resources available. On its own premises the business has to at any rate be capable of guaranteeing the application and running of the Quality Assurance and Quality Control System in order to obtain finished materials and products in compliance with the legislation in force on FCMs.

B11.2.1.1. Human resources and training

The *Business operator,* in compliance with the objectives of the Regulation (EC) 1935/2004 as amended and the Regulation (EC) 2023/2006 as amended is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 as amended is applied at all levels of their organization.

The operative aspects relating to the application of the provisions laid down in the Regulation (EC) 2023/2006 as amended can be entrusted by the Business operator to competent and adequately trained people that have to at any rate have at their disposition adequate means to ensure that the requisites of the Regulation (EC) 2023/2006 as amended are respected.

The *company organization* has to at any rate enable the location of the functions to enable inspection by the Competent Authorities.

All *company personnel* potentially involved have to be informed on the principles of GMP, on the obligations that derive from the Regulation (EC) 2023/2006 as amended, on its objectives and on the policy for applying the Regulation.

The *Business operator* should operate and implement procedures for identifying personnel training requirements and has to see to the training of all staff regarding the tasks that might affect the compliance to the said Regulation.

The *personnel* assigned to GMP control activities should be qualified on the basis of the training and the experience acquired.

An appropriate registration of the training process of all personnel must be kept.

B11.2.1.2. Production

The company production phase extends from design and planning to storage of the finished product.

The production process encompasses all the company's phases that contribute to ensuring that the finished product complies with the technical, legislative and performance requirements from the design phase to guarantee suitability for its intended use.

Therefore, the Quality Assurance System must have procedures that regulate all the phases listed below:

- Product design and development;
- Selection of starting materials and suppliers;
- Arrival of raw materials and their storage;
- Quality control of raw materials/starting materials;
- Production processes and traceability;
- Process parameter control;
- Quality control during production;
- Quality control of the finished product and storage.

During all the above steps, an assessment of contamination risks must be made, identifying potential sources and actions to prevent them.

Product planning and development

The most important concept implied by the GMP is that of a product designed to be compliant to the legislative requisites on materials and articles intended for food contact (FCMs).

To this end, during the development of an adhesive and sealant, in addition of meeting product's inherent specifications, compliance with the legislative requirements on FCMs must be ensured by identifying the end application as precisely as possible.

Therefore, adhesives and sealants intended for use in contact with foodstuffs must be developed with raw materials that, after testing, grant compliance with the use and legislative requirements for food contact at all stages of the process.

Selection of starting materials and suppliers of goods and/or services and or subcontractors

The manufacturer of adhesives and sealants is obliged to use only approved raw materials, i.e. for which he has, through supplier's information and/or through checks and verifications made during the design phase, all the necessary data to ensure the conformity of the finished product.

It must also be ensured that the following requirements are met:

- adequate information according to the applicable European and/or national legislation;
- traceability according to Framework Regulation (EC) 1935/2004 as amended (where applicable);
- compliance with Regulation (EC) 2023/2006 as amended (where applicable).

Each supply of raw materials must be kept under proper control.

It is branch's good practice that raw materials are sourced from qualified suppliers. Qualification means an established, organised and documented process that may also include supply specifications.

In the event that the supplier is not working under GMP, the manufacturer is obliged to ensure that the raw materials that he will use are suitable for producing materials and articles suitable for food contact: this verification, which must be carried out at the manufacturer's expense, may be performed either by checking the composition certificates issued by the suppliers, or by carrying out appropriate technical-analytical determinations.

Process conformity

The production process must be kept under adequate control with the help of the Quality Assurance System which must be designed in such a way as to guarantee and document that the product complies with the reference technical specifications and that these specifications comply with the product design.

The Quality Assurance System must be adapted in order to pay sufficient attention to the most critical points of the production system which can put at risk the obtaining of legislative, technical and qualitative conformity of the finished product.

Documentation of procedure/instructions

Each stage of production relevant for compliance to GMP Regulation must be regulated through appropriate documentation. Examples of documentation may be manuals, procedures, operating instructions, technical standards, and records.

The documentation required to carry out the activity must be available to the personnel concerned, it must be kept up-to-date, and its distribution must be controlled so that information that is no longer up to date will be promptly withdrawn.

B11.2.2. Quality Control System (Regulation (EC) 2023/2006, art. 6)

The producer should establish and maintain an effective Quality Control System capable of ensuring the respect of the conformity to the Regulation as laid down in the general guideline.

The system must include procedures that provide for all necessary controls, related records and actions to be taken in the event of non-compliance.

All the documentation has to be available for the Competent Authorities that demand to see it in accordance with the Regulation (EC) 2023/2006 as amended and Framework Regulation (EC) 1935/2004 as amended.

The rules and the procedures have to cover the entire production process, as described in paragraph B11.2.1.2., also including a part that deals with the handling of any non-conformities and corrective actions.

B11.2.2.1. Management of raw materials warehouses

Approved raw materials from qualified suppliers must be clearly identified. At the arrival, all raw materials that aren't in agreement with the specifications, and therefore matter of discussion with the supplier, must be segregated and clearly identified pending appropriate verification. The segregation of non-conforming material may also be carried out by means of system constraints other than physical segregation. Only the designated function within Quality Control has the authority to allow the possible use of these materials.

The environmental, storage and handling conditions of the storage areas must be such as to ensure that there is no risk of deterioration and contamination of the material.

Particular attention must be paid to the handling of raw materials to avoid damage that could make the material no longer fit for its use.

B11.2.2.2. Production controls

Quality Control System must be ruled by suitable procedures that ensure that all the necessary controls are carried out during the production process in order to grant that the product complies with technical and quality specifications defined during the project phase.

Product traceability must be ensured by means of suitable records of the batches of raw materials used, of the machine conditions set and recorded during production and of the quality controls also performed on intermediate and semi-finished products.

Warehousing of the finished product and shipment to the customer must only be possible if procedures are in place to unequivocally document that the material has been checked at all stages and that the final inspections have ascertained compliance with all requirements stipulated in the design phase.

Special attention must be paid to the control of possible contamination. Suitable procedures must take this risk into account and must document how it can be prevented (e.g. where applicable, systematic cleaning of machines and equipment, hygiene of personnel and working environments, protection against pests like insects and rodents, etc.).

B11.2.2.3. Quality Control of finished products

Quality Control System must have in place appropriate procedures for checking finished products. Evidence of controls must be properly recorded.

B11.2.2.4. Management of finished products warehouses

Approved finished products must be clearly separated or otherwise clearly labelled from those that have not yet been checked or are subject to further suitability checks.

For all products that are found to be out of specs, a procedure must be in place to stop the progress of the production phase, pending definition of the problem. All exceptions must be authorised only by the responsible function together with the Quality Control System.

Unsuitable products, clearly identified, must be separated or in any case labelled, in order to prevent them from being put into stock.

All finished products returned by customers because of a non-conformity must be stored in a predefined and clearly identified pending appropriate verification. The segregation of non-conforming material may also be carried out by means of system constraints other than physical segregation. Only the designated function within Quality Control has the authority to allow the possible use of these materials. Environmental and storage conditions of the storage areas must be such to ensure that there is no risk of deterioration of the material.

Particular attention must be paid to the handling of raw materials to avoid damage that could make the material no longer fit for its use.

B11.2.2.5. Distribution, shipment and delivery

The manufacturer, if responsible for the transport and delivery of the material to its destination, must ensure that this phase is also regulated by instructions and procedures that grant the quality of the material by preserving it from any damage and risks of contamination that may affect its use or its suitability for contact with food.

If the means of transport are owned by the manufacturer, it must be ensured, including through periodic inspections, that these are suitable for transporting goods and maintain the safety and hygiene requirements necessary to grant product integrity.

If the delivery is made through external transport companies, a procedure must be foreseen to qualify the transporter and technical specifications must be defined that establish the minimum requirements to be respected to eliminate possible risks (e.g. damage, contamination, etc.).

B11.2.2.6. Conformity of the application of the GMP and claims management, corrective and preventive actions

The Quality Control System must have in place appropriate procedures to monitor the correct implementation and full compliance with GMP.

The Quality Control System must also have procedures to document the identification of non-conformities, possible corrective measures and the monitoring of the implementation of these measures, with particular attention to the timing of their implementation.

The company's Quality Assurance System must therefore be built to include plans for audits and periodic checks on compliance with pre-established parameters and specifications, relevant to compliance with legislation on materials in contact with foodstuffs; procedures for managing non-conformities and corrective actions must be implemented.

B11.2.3. Documentation (Regulation (EC) 2023/2006, art. 7)

All the documents concerning the Quality Assurance System (procedures, specifications, formulations, etc.) and all the activity of the Quality Control System (instructions, registrations of control data, machine setup data, tolerances and measurements, etc.) have to be organized so as to constitute a paper or electronic archive, immediately accessible and easily consultable on request by the Competent Authorities.

The documents guaranteeing the traceability will also constitute an integral part of the same, as under art. 17 of the Regulation (EC) 1935/2004 as amended, the copies of the declarations of compliance issued to the customers in observance of the applicable European and national regulations and the applicable national provisions, and the supporting documentation. This documentation will also include any conditions for tests, calculations and analyses, carried out by internal and external laboratories, that serve to demonstrate conformity.

Annex B11.1

Technical glossary

Adhesive: A non-metallic chemical capable of joining materials by surface fixation (adhesion) and in such a way that the bond obtained possesses adequate internal strength (cohesion).

AVISA: AVISA is the acronym for *Associazione Italiana Vernici Inchiostri Sigillanti Adesivi* (Association, Paints, Inks, Sealants and Adhesives).

FEICA: FEICA is the acronym for *Fédération Européenne des Industries de Colles et Adhésifs*, European association of adhesives and sealants manufacturers.

Hot melt adhesive: A polymer-based adhesive that melts as effect of applied heat and solidifies by cooling. They commonly take the form of blocks, rods, granules, powders or films.

Reactive adhesive: An adhesive capable of hardening as a result of a chemical reaction (e.g. polymerisation).

Sealant: Polymeric chemical able of joining two substrates and filling the gap between them.

Water-based adhesive: Mixture composed of a solid polymer phase dispersed in an aqueous phase. The bonding process takes place with the evaporation of the water and the coalescence or film-forming of the polymer phase.

Annex B11.2

Frequently asked questions

Q1 *Is there specific European legislation regulating adhesives and sealants for food contact?*

No, only the general rules of Regulation (EC) 1935/2004 as amended apply.

Q2 *Does Regulation (EU) 10/2011 as amended cover adhesives?*

No, the field of application of the Regulation is exclusively that of plastic materials.

Q3 *Is it mandatory to issue the Declaration of Conformity for adhesives?*

No, it isn't mandatory to issue a declaration of conformity, but it is recommended to issue Adequate Information to support the supply chain in the evaluation of the finished product, as clarified by the EU document: "Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain 28/11/2013".

Q4 *Is there a voluntary technical documentation for adhesives and sealants for food contact?*

There is a voluntary technical documentation from the European Association of Adhesives and Sealants Manufacturers, FEICA, 'Guidelines for the development of a declaration of suitability of adhesive for food contact', February 2013(http://www.feica.eu/our-priorities/key-projects/food-contact.aspx)

Q5 *What is AVISA?*

AVISA is the acronym for *Associazione Italiana Vernici Inchiostri Sigillanti Adesivi* (Association, Paints, Inks, Sealants and Adhesives). It is one of the sector Associations of Federchimica (https://avisa.federchimica.it/) which protects the interests of its member companies and ensures liaison with the respective branch's European Associations (CEPE, EuPIA, FEICA).

B12. PRINTING INKS

B12.1. Characterization of the sector

B12.1.1. Field of application of 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. Applicable legislation

At present, there are only general legal provisions about printing inks for food packaging, as there is neither at European nor at national level a specific legislation regulating this kind of products.

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.[24]
- Regulation (UE) 10/2011 on plastic materials and articles intended to come into contact with food as amended.

Italian legislation

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

[24] It replaced the Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

– Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, intended to come into contact with food or substances for personal use as amended. (Field of application paper and cardboard, metal, etc.)

B12.1.3. Printing ink general description

A printing ink is composed of substances and mixtures of substances that, all in all, can be grouped into the following classes:
– colouring matter;
– fillers;
– binder;
– solvent;
– additives (plasticisers, waxes, defoamers, stabilisers, surfactants, etc.).

Above components are mixed in the quantities indicated in the specific formulations in order to obtain a finished product with the characteristics required for its correct application for the intended field.

Depending on the raw materials used, a printing ink can be:
– liquid;
– pasty.

B12.1.4. Phases of the production process: flowchart and description

B12.1.4.1. Production flowchart

Figure B12.1 illustrates the flowchart for printing inks production (the part in grey is compliant with the GMP Regulation (EC) 2023/2006 as amended).

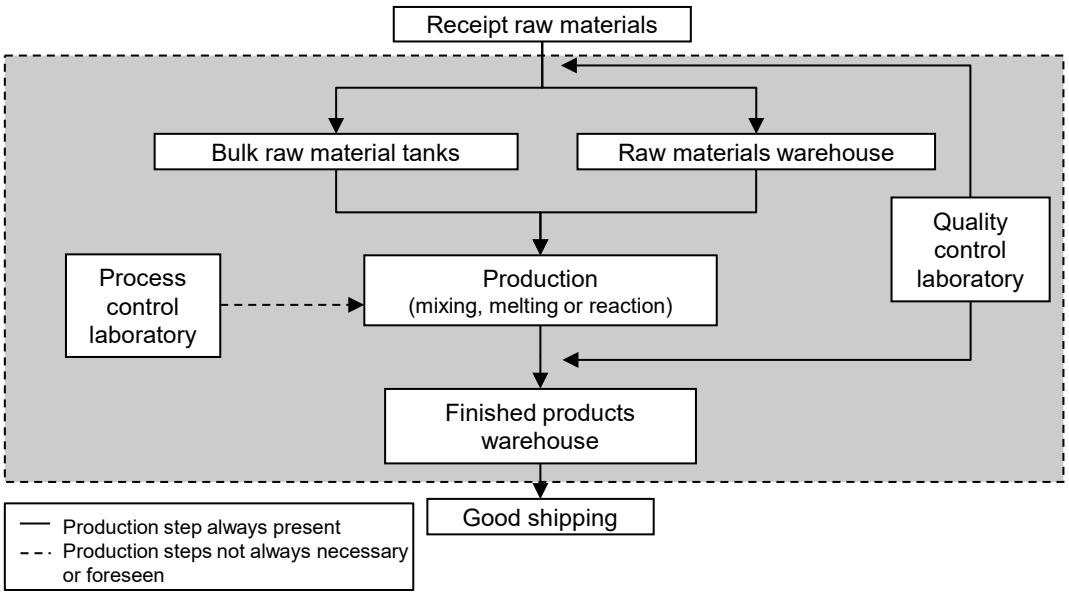

Figure B12.1. Production flowchart for printing inks

B12.1.4.2. Brief description of process phases

Raw material warehouse and bulk raw material tanks

Raw materials, at site entrance, are checked by the Quality Control Laboratory in agreement with procedures or operating instructions in force, and, if compliant, are inserted into the operational management system in order to allow their identification and location. They are then appropriately stored, depending on their hazard classification.

If a raw material doesn't comply to the specifications agreed at its qualification, it is blocked in stock by the Quality Control Laboratory until a decision is made on its destination (allow its use as an exception or ship back to the supplier).

Production and packaging

Printing inks are generally manufactured in closed, fixed or mobile equipment. The production of the ink typically takes place in a container known as a disperser, into which the solvent or, where applicable, resin solution and other liquid raw materials are loaded at first. Then solid raw materials are loaded; normally, if the first raw material loaded is the solvent or solvent mixture, the resin or resins are added. Dissolution of the resin then takes place, in order to obtain a homogeneous solution. At this point, under stirring, the pigment(s) is/are loaded. These are dusts, and are dispersed in the resin solution, always under stirring. The use of resins in solution in the first phase allows to spare time in the dispersing phase, avoiding the resin dissolution step.

Once this pigment predispersion is done (pigments are insoluble in the medium), it is milled using bead mills or three-roll mills (depending on the type of ink and raw materials used). In some cases, several grinding steps are required in order to obtain the necessary particle size (fineness). This step is necessary because the pigments, in their delivery form, consist of too big particles (or particle aggregates) that would result in a non-homogenous film, easy to fall off from the substrate. Grinding step also increases the pigment's opacity, in many cases.

From the mills or the three-roll mills, the product reaches the diluters, fixed or mobile containers inside which the finished product is brought to required specifications such as viscosity, tinting strength, etc. Filtration then takes place, depending on the grinding fineness required for the intended use. The last stage is packaging, which takes place in containers of various sizes, depending on the customer's needs.

In recent years, the category of so-called concentrates, i.e. inks with a high solids content, which are then diluted by the end customer at the time of use in the pressroom, has become increasingly popular.

Quality control laboratory

During manufacturing process, samples are taken at various stages to check ink compliance with specifications. In the event of a non-conformity, the product is processed until the specifications are met.

At the end of production process, the Quality Control Laboratory takes a sample of the finished product in order to check that the product complies to the specifications present on the technical data sheet.

In the event of a non-conformity, the Quality Control Laboratory blocks the material pending its destination (rework, other use, etc.).

Storage of finished products

Each product stored is identified by a unique trade name, a reference number and a specific *batch* number. The container used for packaging and the storage conditions are such as to grant the preservation of the characteristics of the printing inks and to protect them from external agents during transport and storage.
Products out of specs (with a non-conformity) or returned by customers for whatever problems are clearly separated and clearly identified from suitable products.

Shipping

The activities of distribution and transport must be disciplined by specific procedures in order to ensure that the product is kept intact and free from possible contamination.
If the shipment is made by an external company, specifications must be in place in order to grant that minimum requirements are met to maintain product integrity.
For products classified as dangerous from a transport point of view, internal and carrier compliance with the requirements of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) or other applicable regulations is verified.

B12.2. Fulfilments deriving from the application of the Regulation (EC) 2023/2006

This part describes the activities in place at the printing inks manufacturers' site.
The Quality Assurance System has been modified and finalised to ensure, for the part under its responsibility:

> "[...] that the materials and articles are constantly manufactured and controlled, to ensure their conformity to 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" (art. 3 paragraph a Regulation (EC) 2023/2006)

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006 as amended. Every paragraph is hence the response of the manufacturers of coating on metals to the requirements of the article in question.

B12.2.1. Quality Assurance Systems (Regulation (EC) 2023/2006, art. 5) and Size of the business

Quality Assurance Systems

The manufacturer of printing inks (hereinafter referred to as "the manufacturer") shall implement and maintain a Quality Assurance System able of ensuring that the objectives set forth in the Regulation and described in the general part of this Guideline are achieved.
The Quality Assurance Systems must be set up in such a way that audits by the competent authorities will be possible.
The Quality Assurance Systems must provide rules and procedures for operations that regulate the company's activity, concerning at least following points:

- company organisation;
- Human resources and training;
- starting materials and suppliers, including suppliers of goods and services and subcontractors;
- production (process conformity, design, documentation) maintenance and calibration plans for equipment;
- quality control;
- logistics (warehousing, handling and shipping);
- complaints, corrective and preventive actions.

The system must ensure that all pertinent legislative changes are clearly incorporated into the relevant stages of the business process.

Size of the business

Whatever the size of the company, it must be ensured that the Quality Assurance System, in analogy with the provisions of Regulation (EC) 2023/2006 as amended, is always applied.

The system must be built, applied and managed taking into account the actual size, company characteristics, as well as the technical and human resources available.

Within its own structure, the company must be able to grant the application and management of the Quality Assurance and Control System.

B12.2.1.1. Human resources and training

The *Business Operator*, for the purposes and objectives of Regulations (EC) 1935/2004 as amended and (EC) 2023/2006 as amended is responsible for managing the resources and activities necessary to ensure that Regulation (EC) 2023/2006 as amended is applied at every level of the organisation. The operational aspects inherent to the application of the provisions of Regulation (EC) 2023/2006 as amended may be entrusted by the Business Operator to competent and adequately trained persons who must in any case have adequate means at their disposal to ensure that the requirements of Regulation (EC) 2023/2006 as amended are met.

The company organisation must in any case make possible to identify the functions for the purposes of verifications by the Competent Authorities and any other interested parties.

All company personnel potentially concerned, including the highest management levels, must be informed of the principles of GMP, the obligations arising from Regulation (EC) 2023/2006 as amended, its objectives, and the policy for applying the Regulation.

The company shall have and apply procedures to identify personnel training needs and shall provide training for all personnel on tasks that may affect compliance with this Regulation.

Personnel involved in the formulation, manufacture and marketing of printing inks shall be adequately trained and informed, and documentary evidence of this training shall be available.

Training programmes and organisation shall be established to ensure that all personnel involved are fully aware of their duties and responsibilities and have the skills to carry them out. Training programmes are documented through course attendance signatures, learning checks and other documentation.

B12.2.1.2. Production

The production process, which starts from the design stage and ends with the finished product being put into stock, aims to convert the raw materials into a finished product that complies with the technical, legislative and performance requirements from the design stage and that meets the customer's specific requirements as well as guaranteeing suitability for the intended use.

A document is issued for each production *batch*, providing details of the raw materials, the quantities to be used, the equipment to be used, the manufacturing methods and the laboratory checks to be carried out at the various stages of the production process. The critical points of the process are recorded and checked by the operators.

Only raw materials that have passed quality control can be used in the quantities and proportions required to achieve the required product quality.

The equipment used must be suitable for producing the required product and kept in good working order, clean and, where necessary, maintained and/or calibrated.

For all equipment for which this makes technical sense, a scheduled maintenance plan is established.

Product design and development

The most important concept implied by GMP is that of a product designed to comply with FCMs legislative requirements.

The parameters that need to be assessed when formulating a printing ink are as follows (non-exhaustive list, as specific uses may require the assessment of additional parameters):

- Type of substrate and/or combination of packaging materials;
- Type of food to be packaged (where explicitly communicated by the processor/food industry);
- Type of printing and equipment used for printing;
- Packaging shape and filling processes;
- End-user specifications;
- Compliance with safety, hygiene and consumer health protection requirements;
- Any treatment of the finished package (sterilisation, retorting, microwave, etc.).

When properly applied, in the presence of an effective functional barrier, printing inks are formulated in such a way as to:

- have the necessary adhesion to the underlying substrate and withstand the chemical and physical stresses associated with the printing process and subsequent marketing of the packaging;
- be suitable for the application method and subsequent converting processes;
- ensure that the binder/colourant combination meets standard requirements (e.g., ISO standards) or customer specifications;
- not result in any material transfer (set off) on the reverse side of the printed surface;
- not lead to a deterioration of the organoleptic characteristics of the packaged food;
- enable compliance of the final product with existing legal provisions by minimising transfer from the printed surface to the food contact side.

Selection of starting materials, suppliers and/or services and/or third parties

The raw materials are selected in a way that, when printing ink for external printing of food packaging is applied according to good industrial practice, the printed surface is such that it does not:

- Constitute a danger to human health;
- Result in a deterioration of the organoleptic characteristics of the packaged food;
- Bring about an unacceptable change in the composition or quality of the packaged food.

By operational choice of the manufacturers, no raw materials are used in the formulation which are banned from the composition of printing inks according to the selection criteria of the *Exclusion Policy for Printing inks and Related Products* of EuPIA,[25] current version.
For the raw materials/base substances used, it is necessary to ensure that the following information is available:
– declaration of conformity/appropriate information according to the applicable European and/or national legislation;
– traceability according to Framework Regulation (EC) 1935/2004 as amended (where applicable);
– compliance with Regulation (EC) 2023/2006 as amended (where applicable).

For each raw material, a declaration of compliance with applicable national and international legislation is required or ensured in the technical documentation.
It is good practice that raw materials/starting materials are sourced from qualified suppliers. Qualification means an established, organised and documented process that may also include supply specifications.
In the event that the supplier does not operate under GMP, the printing ink manufacturer is obliged to ensure that the raw materials and/or semi-finished products it will use are suitable for producing materials and articles suitable for food contact: this verification, which must be carried out at the manufacturer's expense, may be performed either by checking the composition declarations issued by the suppliers, or by carrying out appropriate technical-analytical determinations.

Process compliance

The production process must be kept under adequate control with the help of the Quality Assurance System, which must be designed in order to grant and document the fact that the product meets the technical reference specifications and that these specifications conform to the product design.
The Quality Assurance System must be adapted in such a way as to pay sufficient attention to the most critical points of the production system that may jeopardise the achievement of legislative, technical and qualitative conformity of the finished product

Documentation of procedures/instructions

Each production step relevant to the GMP Regulation must be regulated through appropriate documentation. Examples of documentation may be manuals, procedures, operating instructions, technical standards and records.
The documentation required to carry out the activity must be available to the personnel concerned, it must be kept up-to-date, and its distribution must be controlled so that information that is no longer up to date will be promptly withdrawn.

B12.2.2. Quality Control System (Regulation (EC) 2023/2006, art. 6)

Printing inks supplier shall have implemented an efficient and demonstrable Quality Assurance System (QAS). The system shall include procedures that provide for all necessary controls, relevant records and actions to be taken in case of non-compliance.

[25] https://www.eupia.org/our-commitment/eupia-exclusion-policy-for-printing-inks-and-related-products

All documentation shall be available for the competent authorities for a check in agreement with Regulation (EC) 2023/2006 as amended and Framework Regulation (EC) 1935/2004 as amended.

The rules and procedures must cover the whole production process, as described in paragraph B12.2.1.2, including a section covering the management of any non-conformities and corrective actions.

B12.2.2.1. Management of raw materials warehouses

Raw materials must be clearly identified. Each raw material will be uniquely identified by a name, a code and a batch or consignment number. This ensures traceability in agreement with Regulation (EC) 1935/2004 as amended regarding food contact materials.

Raw materials are carefully selected to ensure that all the constituents of the printing ink formulations comply in quality and purity to the supply specifications and within the agreed technical specifications. Where necessary, critical raw materials are analysed internally in accordance with specific operating procedures and/or instructions; alternatively, certificates of analysis/conformity from the supplier can be accepted for other raw materials, stating conformity to the agreed specifications.

Any raw material out of specs must be segregated in a predefined area and clearly identified pending resolution of the issue. The segregation of non-conforming material may also be carried out through system constraints other than physical segregation in a specially designated area (computer block). Any use of such materials is subject to the authorisation of the Technical Management or other designated company function.

Particular attention must be paid to the storage and handling of raw materials in order to avoid damage that could render the materials unusable. Materials on stock are moved and used according to the *first in - first out* criterion.

B12.2.2.2. Production controls

The Quality Control System must be ruled by suitable procedures that ensure that all the necessary controls are carried out during the production process in order to grant that the product complies with the technical and quality specifications defined during the project phase.

Product traceability must be ensured by means of suitable records of the batches of raw materials used, of the machine conditions set and recorded during production and of the quality controls also performed on intermediate and semi-finished products.

Warehousing of the finished product and shipment to the customer must only be possible if procedures are in place to unequivocally document that the material has been checked at all stages and that the final inspections have ascertained compliance with all requirements agreed in the design phase.

Special attention must be paid to the control of possible contamination. Suitable procedures must take this risk into account and must document how it can be prevented (e.g., where applicable, systematic cleaning of machines and equipment, hygiene of personnel and working environments, prevention against pests like insects and rodents, etc.).

B12.2.2.3. Quality Control of the finished products

The Quality Control System must have appropriate procedures for checking finished products. Evidence of controls must be properly recorded.

B12.2.2.4. Management of finished products warehouses

Each finished product is identified by the following information, given on the commercial label:

- product reference and description;
- batch number;
- net weight;
- hygiene and safety instructions or about transport and storage, if required.

All products are stored under conditions that prevent any deterioration, the container is selected to maintain the characteristics of the printing inks and protect them from external agents during transport and storage. It complies with the applicable packaging and/or transport regulations, particularly in the case of hazardous mixtures in sense of dangerous goods transport regulations.

Non-compliant products are clearly identified and segregated to prevent accidental use.

For each product, a technical data sheet is available in which the physical data, intended uses and application methods are listed, as well as a safety data sheet, in which the toxicological and ecotoxicological indications relating to the handling of the product are given, and, if applicable, each shipment of printing inks can be supported by a declaration confirming that they conform to the agreed specifications.

Where required, the ink manufacturer will issue a "Statement of Composition" (Adequate Information) making available all the information that the customer needs to check the conformity of the finished packaging with the provisions of Regulation (EU) 10/2011 as amended, where applicable, and, more generally, through compliance with the Specific Migration Limits, to comply with Article 3 of Regulation (EC) 1935/2004 as amended. Within the Declaration of Composition, so-called *dual-use* substances are also indicated, i.e. those used both industrially and as food additives, in order to allow also in these cases, the verification of the compliance of the finished object with their respective concentration limits.

B12.2.2.5. Distribution, shipment and delivery

The manufacturer, if responsible for the transport and delivery of the material to its final destination, must ensure that this phase is also ruled by instructions and procedures that grant the quality of the material by preserving it from any damage and risks of contamination that may affect its use or its suitability for contact with food.

If the means of transport is owned by the manufacturer, it must be ensured, including through periodic inspections, that these are suitable for transporting goods and maintain the safety and hygiene requirements necessary to grant the integrity of the product.

If the delivery is made through external transport companies, a procedure must be foreseen in order to qualify the transporter and technical specifications must be defined that establish the minimum requirements to be respected to eliminate possible risks (e.g. damage, contamination, etc.).

All products are shipped in clean and appropriately labelled containers (including hazard and/or transport labelling where applicable).

B12.2.2.6. Conformity of the application of the GMP and claims management, corrective and preventive actions

The Quality Control System must have in place appropriate procedures to monitor the correct implementation and full compliance with GMP.

The Quality Control System must also have procedures to document the identification of non-conformities, possible corrective measures and the monitoring of the implementation of these measures, with particular attention to the timing of their implementation.

The company's Quality Assurance System must therefore be built including plans for audits and periodic checks on compliance with pre-established parameters and specifications, relevant to compliance with legislation on materials in contact with foodstuffs; procedures for managing non-conformities and corrective actions must be implemented as well.

B12.2.3 Documentation (Regulation (EC) 2023/2006, art. 7)

All documents relating to the Quality Assurance System (procedures, specifications, formulations, etc.) and all Quality Control System activities (instructions, control data records, machine setup data, tolerances and measurements, etc.) must be organised in such a way as to constitute an archive, as hard copy or an electronic one, immediately accessible and easy to consult if requested by the competent authorities.

Documents granting traceability, in accordance with the text of Article 17 of Regulation (EC) 1935/2004 as amended, copies of appropriate information issued to customers in compliance with applicable Italian legislation, and the required supporting documentation will also form part of the archive. This documentation will also include any test conditions, calculations and analyses, performed by internal or external laboratories, that will serve to demonstrate compliance.

Annex B12.1

Technical glossary

Printing ink: A mixture that is transferred from the printing press with the aid of a conveyor vehicle to the surface of the substrate. Printing inks usually consist of pigment, binder, solvent and additives. Printing inks must only be applied to the surface not in contact with the food (see Annex I of Regulation (EC) 2023/2006 as amended).

Statement of composition: A document that constitutes adequate information and summarises information that the customer needs in order to check the conformity of the finished packaging, in accordance with Article 3 of Regulation (EC) 1935/2004 as amended.

Varnishes: Varnishes are coating products with a composition similar to printing inks but which don't include pigments.

Annex B12.2

Frequently asked questions

Q1 *Does EU Regulation 10/2011 as amended apply to printing inks?*

No, the scope of the Regulation only covers plastics. Inks are considered among the materials for which adequate information must be provided along the *supply chain*.

Q2 *Is there a specific EU legislation regulating printing inks?*

No, reference is made to general EU legislation.

Q3 *Are there any other specific legislative reference documents?*

The only specific legislative document for inks is, at the state of the art, the "Swiss Ordinance SR 817.023.21 Ordinance of the FDHA on Materials and Objects of 23 November 2005", which at Annex 6 defines a list of substances allowed for the manufacture of packaging inks and the migration requirements relating to them. However, this list is not binding either in Italy or at EU level.

Q4 *How do you choose the right type of printing ink?*

The choice of the right type of printing ink is performed through a dialogue between ink supplier and end-user according to the following parameters:
1) type of substrate;
2) type of printing;
3) packaging filling systems;
4) end-user specifications, if any;
5) types of food to be packaged;
6) any post-packaging treatments (sterilisation, retorting, microwave, etc.);
7) storage period and conditions (*shelf life*).

Q5 *How are raw materials selected to produce inks for external food packaging printing?*

For each raw material, a declaration of compliance with current national and international legislation is requested or ensured through the technical documentation. This is necessary because for the external printing of food packaging the requirements specified in the April 2020 updated EuPIA Guideline on Printing inks applied to the non-food contact surface of food packaging materials and articles (http://www.eupia.org/index.php?id=29) are considered.

Q6 *What is AVISA?*

AVISA is the acronym for *Associazione Italiana Vernici Inchiostri Sigillanti Adesivi* (Association, Paints, Inks, Sealants and Adhesives). It is one of the sector Associations of Federchimica (https://avisa.federchimica.it/) which protects the interests of its member companies and ensures liaison with the respective branch's European Associations (CEPE, EuPIA, FEICA

Q7 *What is EuPIA?*

EuPIA is the acronym for European Printing Ink Association, a European association under CEPE umbrella that groups together the majority of European printing ink manufacturers (www.eupia.org).

Q8 *What is the Responsible Care program?*

Responsible Care is the worldwide Chemical Industry's voluntary programme based on the implementation of principles and behaviours regarding Employee Safety and Health and Environmental Protection and a commitment to communicating the results achieved, towards continuous, meaningful and tangible improvement.

Q9 *Is there a voluntary technical standard for printing inks?*

Yes, there is a voluntary technical documentation of the European Printing Ink Manufacturers' Association EuPIA defining the branch GMP (EuPIA guideline).

Q10 *Is there a voluntary industry GMP for printing inks?*

Yes, there is a specific document, the EuPIA (European Printing Ink Manufacturers Association) guideline on GMP for printing inks.

B13. COATED METAL ARTICLES INTENDED FOR COOKING

B13.1. Characterization of the sector

B13.1.1. Field of application of 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. Applicable legislation

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.[26]
- Regulation (EC) 1895/2005 on the restriction of the use of certain epoxy derivates in materials and articles intended to come into contact with food.
- Regulation (EU) 2018/213 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending.
- Regulation (EU) 10/2011 as regards the use of that substance in plastic food contact materials as amended.

[26] It replaced the Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Italian legislation

- Decree of the Italian 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.
- Italian Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- Italian 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 objects intended to come into contact with food.
- Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, intended to come into contact with food or substances for personal use as amended.

B13.1.3. Phases of the production process: flowcharts and descriptions

Figures B13.1, B13.3 and B13.5 are shown on the following pages, which, in schematic form, describe the production flows of non-stick coated metal materials and objects under the scope of this guideline.

The production process differs depending on whether:

- the metallic raw material received in the plant is coated or
- the coating is applied in the plant with diversified painting processes.

The technologies used for the application of the coating of the articles covered by this guideline are described in the dedicated paragraphs.

Technical terms are described in the glossary.

Some typical examples of products that can be obtained from the different production processes are shown in the dedicated paragraphs.

For each flowchart, those phases of the manufacturing process usually considered as critical in relation to the application field of the Regulation (EC) 2023/2006 as amended are pointed out. Beside each critical phase, a dashed box describes the specific aspects to guarantee conformity to the applicable laws.

B13.1.3.1. Production flowchart: cooking items from non-stick coated raw material

Figure B13.1 illustrates the flowchart to produce cooking items from non-stick coated raw material (the dashed part is compliant with the GMP Regulation (EC) 2023/2006 as amended).

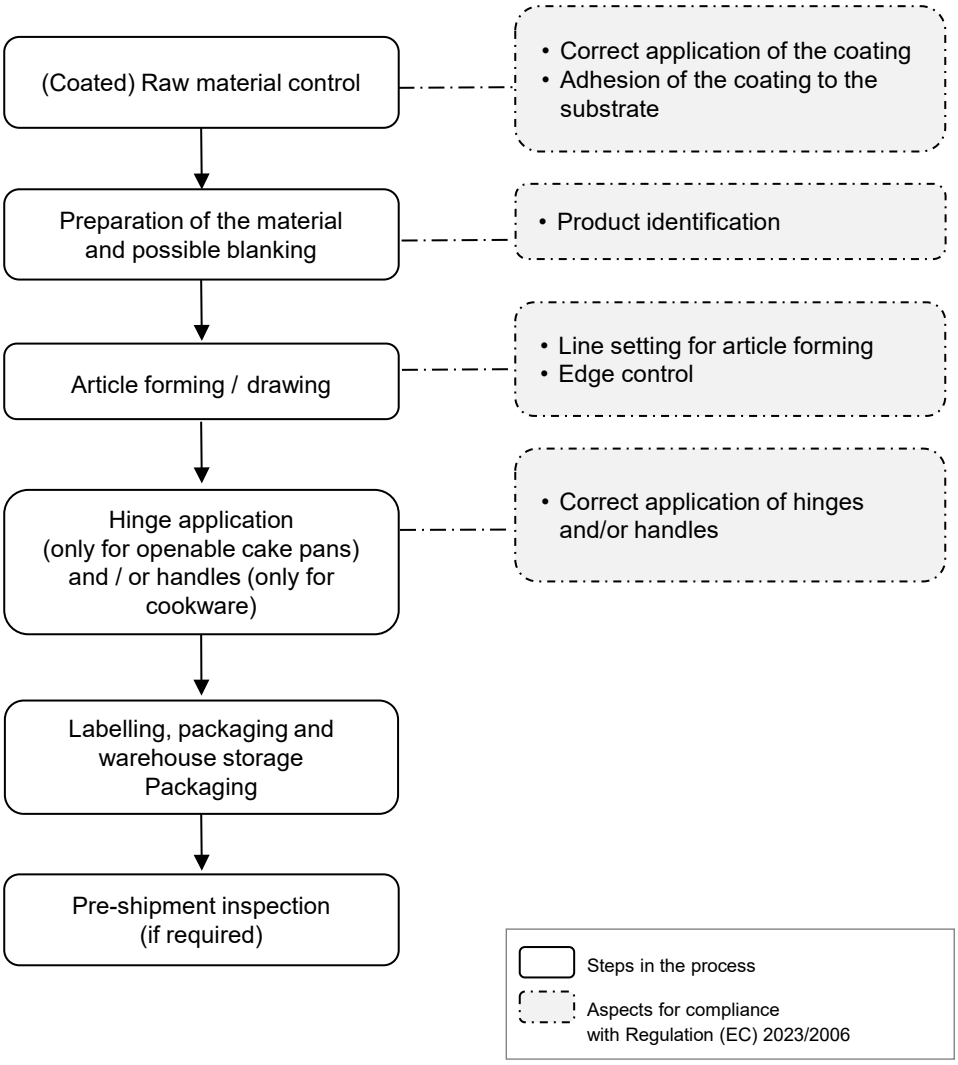

Figure B13.1. Production flowchart for cooking items from non-stick coated raw material

B13.1.3.2. Brief description of process phases

(Coated) Raw material control

It is good practice that all raw materials are purchased from previously qualified suppliers; these must provide declarations of conformity and in turn guarantee the GMP for the application of the coating on the metal substrate as agreed with their suppliers. If the supplier does not operate according to the GMP regime provided for by Regulation (EC) 2023/2006 as amended, it is the manufacturer's responsibility to ensure that the raw materials and/or semi-finished products it will use are adequate to produce materials and objects compliant with national and community legislation on FCMs.

All raw materials must be well identified and protected during the journey and also accompanied by supporting documentation.

The control consists in verifying, in addition to the correct identification and correspondence of the supporting documentation, the application characteristics of the coating according to the provisions of the various regulations and control methods.
Following this check, the raw material is accepted and sent to the storage warehouse ready for subsequent processing.

Preparation of the material and possible blanking

In case of use of coated raw material in sheets ready to be used directly in the forming/drawing phase, the preparation consists in inspecting the products in accordance with the internal control procedures and verifying the correct identification of the material ready for subsequent processing.
In the case of use of raw material already coated with coil coating technology, the preparation consists in obtaining, starting from rolled metallic strips (coils) of metal laminate of defined and well-identified thickness and characteristics, by means of blanking operations, shaped flat sheets of suitable shapes and sizes, stacked to form packs or stored in special containers.
The preparation also includes the inspection of the material and the correct orientation according to subsequent processing.

Article forming/drawing

Starting from previously cut flat sheets, forming is carried out in one or more stages in order to obtain the desired article.
The flat sheets are placed in the various production lines to carry out the forming phase and subsequently the edging on the entire perimeter of the article in order to ensure its safety.
Periodically some items (for each single coating) are sent to laboratories to perform the necessary tests to ensure the suitability for food contact required for repeated use cooking items.

Hinge application (only for springform) and / or handles (only for cookware)

In some articles (springform) the closing hinges are applied using a riveting system on the band (ring) of the article which can be of different diameters. This is done automatically; the seal and functionality of the hinge itself is also checked.
Any handles can be inserted with two different technologies: by screwing on a special support (*goujon*) welded or with riveting.
Neither of these two processes affects the state of the internal coating of the piece, but in the case of riveting it is necessary that the rivets, if not coated, are made of metal suitable for food contact. If they are coated, the rivet coating must be suitable for food contact.

Labelling, packaging and warehouse storage

The items completed with all the foreseen processes are labelled in order to make them compliant with use (traceability, pictograms and instructions for use) and packed following the requirements of the various customers' requests and / or internal production orders, and finally stored in the warehouse.
After the Quality Control verification, the final product, packaged according to the specifications agreed with the customer, is allocated in the finished products warehouse according to the procedures that regulate the storage of finished products and so that its identification is unique for traceability purposes. The data on the quantity of the product, its

location in the warehouse - in the case of a computerized warehouse - and any notations from the Quality Control are entered in the data storage system.

Pre-shipment inspection (if required)

Where required, a pre-shipment inspection is carried out and all aspects related to the finished product are checked:
- Formed product;
- Primary packaging (correctness and readability of codes);
- Traceability;
- Secondary packaging (correct identification and quantity of pieces per box);
- Tertiary packaging (type of pallet used, quantity per pallet and identification of the pallet).

Figure B13.2 shows examples of typical products obtained from coated raw material.

Figure B13.2. Example of bakeware obtained from raw material that arrives in the plant with a non-stick coating already applied

B13.1.3.3. Flowcharts: spray-coated metal cooking items with non-stick coating on the internal surface

Figure B13.3 illustrates the flowchart to produce spray-coated metal cooking items with non-stick coating on the internal surface (the dashed part is compliant with the GMP Regulation (EC) 2023/2006 as amended).

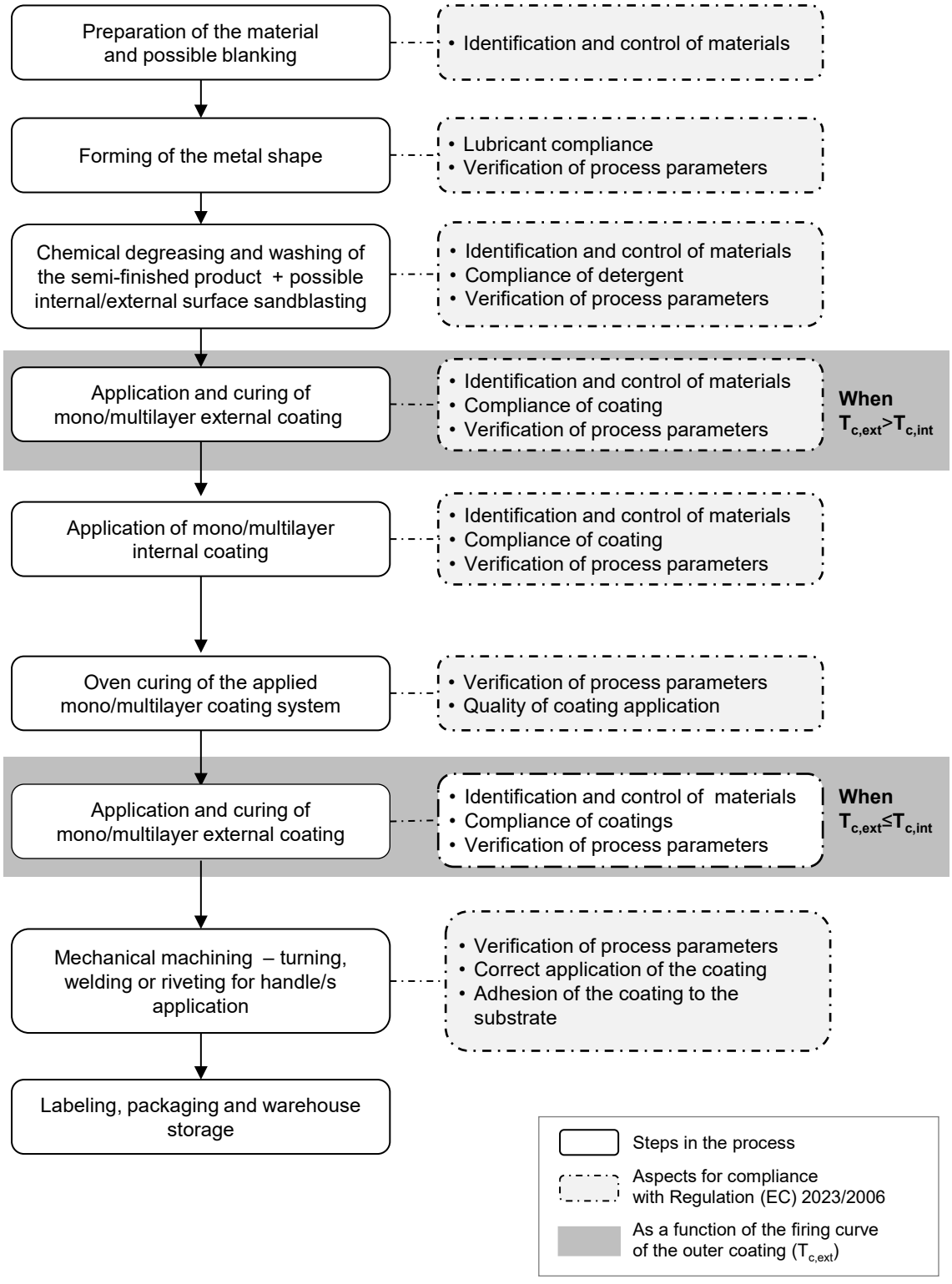

Figure B13.3. Production flowcharts for spray-coated metal cooking items with non-stick coating on the internal surface

B13.1.3.4. Brief description of process phases

Preparation of the material and possible blanking

In case of use of uncoated raw material in ready-made sheets, the preparation consists in inspecting the products in accordance with the internal control procedures and verifying the correct identification of the material ready for subsequent processing.
In case of use of uncoated raw material in rolls/coils, the preparation consists in obtaining, starting from rolled metallic strips (*coils*) of metal laminate of defined and well-identified thickness and characteristics, by means of blanking operations, shaped flat sheets of suitable shapes and sizes, stacked to form packs or stored in special containers. The material is inspected and oriented according to subsequent processing.
In the case of use as raw material of uncoated semi-finished products from moulding or casting, the preparation includes inspection of the material and correspondence to the required technical specifications. The degreasing phase then follows directly.

Forming of the metal shape

The metal shape is formed in the desired shape by means of presses or plate lathes (it becomes semi-finished product). It is good practice that the metal alloys provided for the processing of cookware are suitable for food contact; in the case of aluminium alloys their composition is strictly regulated by UNI EN 601 and UNI EN 602. Metal supplies must be accompanied by certificates of analysis certifying the percentage of the elements contained.
The lubricants used for forming must be easily removed in the subsequent degreasing phase.
The forming process is kept under control with processing lists and work instructions.
The materials and equipment to be used are described, as well as the checks that must be performed specifying responsibilities, method, frequency, instruments and reference standards to be used.
The completed control documentation is checked and archived.

Chemical degreasing and washing of the semi-finished product

The formed article (semi-finished product) is placed in a degreasing tunnel, which is carried out using suitable specific industrial alkaline detergents.
The residues of these detergents are removed in the subsequent sections of the tunnel, through several hot and cold rinses and with demineralized water.
The chemical attack, in addition to the degreasing function, helps to give the metal substrate the necessary surface roughness to prepare it for adhesion of the coating.
The degreasing/washing process is kept under control with processing lists and work instructions. The materials and equipment to be used and the system setting parameters are described, as well as the checks that must be performed specifying responsibilities, method, frequency, tools. The completed control documentation is checked and archived.

Surface sandblasting

Optional pre-treatment operation which consists of sandblasting with abrasive grit of the surface of the semi-finished product in order to increase the surface roughness of the substrate and ensure greater adhesion of the non-stick coating to the metal.

Application of mono/multilayer internal coating

On the painting line the coating is applied, with spray coating technology, on the internal surface of the semi-finished product, in one or more layers as provided in the supplier's technical data sheets. The coatings in use are guaranteed by the suppliers for suitability for food contact provided that the methods and application conditions specified in the technical data sheets of the same are followed and provided with a declaration of conformity and safety data sheets. In the case of multilayer fluoropolymer coatings, it is planned to apply, with spray technology, a first coating layer called primer that allows the adhesion of the non-stick coating to the metal substrate, and subsequent drying step in an oven; the primer will have to arrive at the next step of application of the additional layers of coating completely dry and with a certain thickness. The technical parameters of application of the primer and subsequent layers, such as the temperature range and its thicknesses, are defined on the supplier's data sheets.

Spray coating technology

The formed and degreased items are placed on a carousel catenary that makes them pass, generally in rotation, inside the painting booth equipped with suction where heating / cooling phases and phases of application of the paint through airbrushes alternate.

Oven curing of the applied mono/multilayer coating system

The items with the complete coating system are conveyed into a curing oven, set with parameters such as the speed of the transport system and the temperature of the different areas of the oven, to meet the requirements dictated by the technical data sheets or other validation documents of the curing process.

During curing, the applied liquid coating turns into non-stick coating. The items must arrive at the exit of the oven presenting a perfectly adhered coating and with a certain thickness. The oven's setting parameters and the necessary thickness of the coating are formalized on an internal work instruction, as well as the checks that must be carried out specifying responsibility, method, frequency, tools and samples to be used. The completed control documentation is verified and archived.

After this phase, further periodic checks, destructive and non-destructive, can be carried out to verify the correct execution of the production process. This evidence is also documented, recorded and archived.

For fluoropolymer coatings, the curing phase is characterized by a process called sintering, i.e. a high temperature cooking (temperatures generally in the range of 400-440°C are reached depending on the crossing time in the oven). In a first stage of curing, volatile substances (including water) evaporate from the liquid formulation of the coating. The temperature inside the oven increases progressively until a temperature, defined in the technical specifications of the supplier of the liquid coating, is reached from which the fluoropolymer particles sinter, that is, melt to form a continuous film; this process ensures that the coating is well adhered and distributed to the metal substrate.

During the curing process, residual quantities of processing aids that may be present in the coating product, including traces of non-polymeric fluorinated compounds, are eliminated by evaporation and/or thermal degradation.

Application and oven curing of mono/multilayer external coating

The articles, after the application and subsequent curing of the internal non-stick coating, are usually also coated on the external surface by means of spray application processes. The external coatings can have the same chemical base as the internal coatings, and in this case,

they can be subjected to simultaneous curing, or they can have a different chemical nature and, in this case, they are applied and cured in dedicated ovens. The sequence of application internal coating – external coating or external coating – internal coating depends on the relative curing profiles; first the coating that requires the achievement of higher cooking temperatures is applied, then the one that requires lower cooking temperatures.

Mechanical machining – turning, welding or riveting for handle/s application

Once the coating process is finished, the items move on to the subsequent stages of mechanical processing. A turning of the rim or of the outer bottom may be provided, followed by the assembly of the handle or handles. The handle/ handles can be inserted with two different technologies: with screwing on a special welded support (goujon) or with riveting. Neither of these two processes affects the state of the internal coating of the item, but in the case of riveting it is necessary that the rivets, if not coated, are made of metal suitable for food contact. If, on the other hand, the rivets are coated, the coating must be suitable for food contact.

All these process steps are kept under control with processing lists and work instructions. The materials and equipment to be used and the setting parameters of the plant are described, as well as the controls that must be carried out specifying responsibility, method, frequency, instruments. The completed control documentation is verified and archived.

Labelling, packaging and warehouse storage

The items completed with all the scheduled processes are labelled in order to make them compliant with use (traceability, pictograms and instructions for use) and packed following the requirements of the various customers' requests and / or internal production orders, and finally stored in the warehouse.

After the Quality Control verification, the final product, packaged according to the specifications agreed with the customer, is allocated in the finished products warehouse according to the procedures that regulate the storage of finished products and so that its identification is unique for traceability purposes. The data on the quantity of the product, its location in the warehouse - in the case of a computerized warehouse - and any notations from the Quality Control are entered in the data storage system.

Figure B13.4 shows examples of typical products coated with spray technology.

Figure B13.4. Example of cooking items non-stock coated with spray technology

B13.1.3.5. Flowcharts: Roller-coated metal cooking items with non-stick coating on the internal surface

Figure B13.5 illustrates the flowchart to produce roller-coated metal cooking items with non-stick coating on the internal surface (the dashed part is compliant with the GMP Regulation (EC) 2023/2006 as amended).

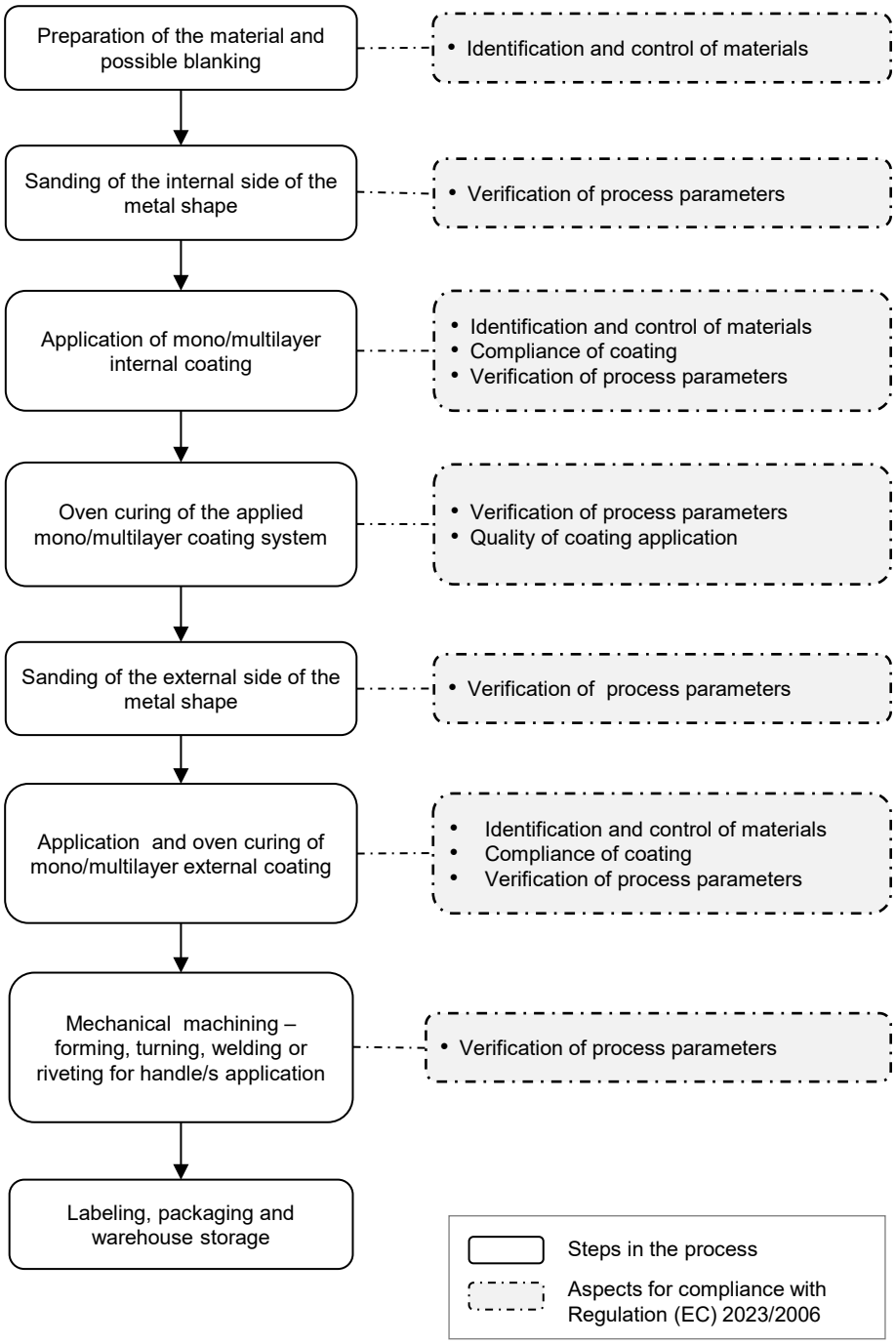

Figure B13.5. Productio flowcharts for roll-coated metal cooking items with non-stick coating on the internal surface

B13.1.3.6. Brief description of process phases

Preparation of the material and possible blanking

In case of use of uncoated raw material in ready-made sheets, the preparation consists in inspecting the products in accordance with the internal control procedures and verifying the correct identification of the material ready for subsequent processing.
In case of use of uncoated raw material in rolls/coils, the preparation consists in obtaining, starting from rolled metallic strips (coils) of metal laminate of defined and well-identified thickness and characteristics, by means of blanking operations, shaped flat sheets of suitable shapes and sizes, stacked to form packs or stored in special containers. The preparation also includes the inspection of the material and the correct orientation according to the subsequent processes.

Sandpapering of the internal side of the metal shape

The metal shape is placed on a conveyor and passed under a roller on which special abrasive paper has been grafted. The upper side (internal side) of the metal shape is therefore paper brushed; the aim is to obtain a surface roughness that favours the adhesion of the coatings to the metal. The sandpapering process is kept under control with processing lists and work instructions. The materials and equipment to be used are described, as well as the controls to be carried out specifying the responsibility, method, frequency, instruments and reference samples to be used. The completed control documentation is verified and archived.

Application of mono/multilayer internal coating

On the painting line, with roller coating technology, the liquid coating is deposited on the internal side of the metal shape, in one or more layers as provided in the supplier's technical data sheets. The coatings in use are guaranteed by the suppliers for suitability for food contact provided that the methods and application conditions specified in the technical data sheets of the same are followed and provided with a declaration of conformity and safety data sheets.
In the case of multilayer fluoropolymer coatings, it is planned to apply, with roller technology, a first coating layer called primer that allows the adhesion of the non-stick coating to the metal substrate, and subsequent drying step in a oven; the primer will have to arrive at the next step of application of the additional layers of coating completely dry and with a certain thickness. The technical parameters of application of the primer and of the subsequent layers, such as the temperature range and thicknesses, are defined on the supplier's data sheets.

Roller coating technology

The roller painting system allows the application of mono/multilayer coatings on top of metal laminates. The metallic shapes are positioned above a conveyor that makes them pass, under suction, inside painting machines called "rolling machines" where, by means of rubber rollers, each machine deposits a thin layer of coating. The alternation of heating / cooling phases and paint application phases through rolling machines allows the correct application of the coating in terms of quality and quantity.

Oven curing of the applied mono/multilayer coating system

The metal shapes with the complete coating system are conveyed into a curing oven, set with parameters such as the speed of the transport system and the temperature of the different areas

of the oven, to meet the requirements dictated by the technical data sheets or other validation documents of the curing process.
During curing, the applied liquid coating turns into non-stick coating. The items must arrive at the exit of the oven presenting a perfectly adhered coating and with a certain thickness. The oven's setting parameters and the necessary thickness of the coating are formalized on an internal work instruction, as well as the checks that must be carried out specifying responsibility, method, frequency, tools and samples to be used. The completed control documentation is verified and archived.
After this phase, further periodic checks, destructive and non-destructive, can be carried out to verify the correct execution of the production process. This evidence is documented, recorded and archived.
For fluoropolymer coatings, the curing phase is characterized by a process called sintering, i.e. a high temperature cooking (temperatures generally in the range of 400-440 °C are reached depending on the crossing time in the oven). In a first stage of curing, volatile substances (including water) evaporate from the liquid formulation of the coating. The temperature inside the oven increases progressively until a temperature, defined in the technical specifications of the supplier of the liquid coating, is reached from which the fluoropolymer particles sinter, that is, melt to form a continuous film; this process ensures that the coating is well adhered and distributed to the metal substrate.
During the curing process, residual quantities of processing aids that may be present in the paint product, including traces of non-polymeric fluorinated compounds, are eliminated by evaporation and/or thermal degradation.

Sandpapering of the external side of the metal shape

The metal shape is repositioned on the conveyor by placing the raw side upwards and passed under the roller with abrasive paper. The aim is to obtain also on the external side the surface roughness that allows a suitable adhesion of the coatings to the metal. The sandpapering process is kept under control with processing lists and work instructions. The materials and equipment to be used are described, as well as the controls to be carried out specifying the responsibility, method, frequency, instruments, and reference samples to be used. The completed control documentation is verified and archived.

Application and oven curing of mono/multilayer external coating

The metal shape continues on the line and by contact with rollers it is coated with one or more layers of coating and conveyed to the curing oven following the same method described for the curing of the internal coating. The coatings in use are supplied with completeness of conformity and safety data sheets.

Mechanical machining (forming, turning, welding or riveting for handle/s application)

Once the painting process is finished, the coated metal shapes move on to the subsequent stages of mechanical processing. The metal shapes must first be formed. It should be noted that, precisely because of this expected mechanical stress, coatings designed for roller machining have characteristics of marked elasticity compared to those designed for spray applications and therefore do not require lubrication during the forming process.
A turning of the rim or of the outer bottom may be provided, followed by the assembly of the handle or handles. The handle/ handles can be inserted with two different technologies: with screwing on a special welded support (*goujon*) or with riveting. Neither of these two processes

affects the state of the internal coating of the item, but in the case of riveting it is necessary that the rivets, if not coated, are made of metal suitable for food contact. If, on the other hand, the rivets are coated, the coating must be suitable for food contact.
All these process steps are kept under control with processing lists and work instructions. The materials and equipment to be used and the setting parameters of the plant are described, as well as the controls that must be carried out specifying responsibility, method, frequency, instruments. The completed control documentation is verified and archived.

Labelling, packaging and warehouse storage

The items completed with all the foreseen processes are labelled in order to make them compliant with use (traceability, pictograms and instructions for use) and packed following the requirements of the various customers' requests and / or internal production orders, and finally stored in the warehouse.
After the Quality Control verification, the final product, packaged according to the specifications agreed with the customer, is allocated in the finished products warehouse according to the procedures that regulate the storage of finished products and so that its identification is unique for traceability purposes. The data on the quantity of the product, its location in the warehouse - in the case of a computerized warehouse - and any notations from the Quality Control are entered in the data storage system.

Figure B13.6 shows examples of typical products coated with roller technology.

Figure B13.6. Example of cooking items non-stick coated with roller technology

B13.2. Fulfilments deriving from the application of the Regulation (EC) 2023/2006

This part describes the activities and the implementation enacted by the supply chain of objects consisting of metal base, with non-stick coating, intended for contact and cooking of food for repeated use, to conform to the Regulation (EC) 2023/2006 as amended. Since this Regulation was laid down when the quality assurance systems had already become a daily work tool in most of the manufacturing businesses, it is likely that these businesses already produce in conformity with technical specifications laid down by themselves.

However, if necessary, the Quality Assurance System and the Quality Control System must be modified and finalized to ensure:

> "[...] that the materials and articles are constantly manufactured and controlled, to ensure their conformity to 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" (art. 3 paragraph a Regulation (EC) 2023/2006).

This part deals with specific topics, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006 as amended. Every paragraph is hence the response of the manufacturers of coated cooking articles for repeated use to the requirements of the article in question. To facilitate reading, the paragraphs keep the same title as the article considered, while the subparagraphs indicate specific topics.

B13.2.1. Quality Assurance Systems (Regulation (EC) 2023/2006, art. 5) and Size of the business

Quality Assurance Systems

The producer of non-stick coated metal articles intended for cooking (hereinafter referred to as "the producer") should establish and maintain a Quality Assurance System capable of ensuring the achievement of the objectives laid down by the Regulation and described in the general guideline. The Quality Assurance System should be documented in such a way as to enable verifications by the competent authorities.

The Quality Assurance System should establish rules and procedures that regulate the company activity, at least concerning the following points:

- human resources and training;
- raw materials and suppliers including suppliers of goods and services and third parties working under contract;
- production (conformity of the process, planning, documentation);
- quality control;
- storage, handling and shipment
- complaints and corrective and preventive action.

The system must ensure that the future legislative changes are adopted in all the relevant stages of the company process.

It is recommended to implement procedures which allow any future changes to existing legislation on materials intended to come into contact with food and control methodologies to be implemented promptly.

Size of the business

Independently from the business size, it should be guaranteed that the Quality Assurance System, as required and finalised by the Regulation (EC) 2023/2006 as amended, is always applied.

The system should be established, implemented and run taking into account the actual size and complexity of the company as well as the technical and human resources available.

On its own premises the business has to at any rate be capable of guaranteeing the application and running of the Quality Assurance and Quality Control System in order to obtain finished materials and products in compliance with the legislation in force on FCMs.

B13.2.1.1. Human resources and training

The *Business operator,* in compliance with the objectives of the Regulation (EC) 1935/2004 as amended and the Regulation (EC) 2023/2006 as amended is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 as amended is applied at all levels of their organization.

The operative aspects relating to the application of the provisions laid down in the Regulation (EC) 2023/2006 as amended can be entrusted by the Business operator to competent and adequately trained people that have to at any rate have at their disposition adequate means to ensure that the requisites of the Regulation (EC) 2023/2006 as amended are respected.

The *company organization* has to in any case allow to identify the functions for the purposes of verification by the Competent Authorities.

All *company personnel* potentially involved has to be informed about the principles of GMP, the obligations deriving from Regulation 2023/2006 as amended, its objectives and the policy for the application of the Regulation.

The *Business Operator* shall have in place and enforce procedures to identify the training needs of personnel and shall provide training for all employees in relation to their tasks which may affect compliance with this Regulation.

The personnel who will have to carry out specific GMP control and verification activities will be qualified on the basis of the training and experience acquired. An appropriate record of the training process of all personnel must be kept.

B13.2.1.2. Selection of starting materials and suppliers

In this guideline "starting materials" is intended the metallic substrate, the internal coating in direct contact with the food and the external coating. The producer is called upon to use only approved starting materials, i.e. for which he has, through the supplier's information and/or through checks and verifications, all the data necessary to ensure the conformity of the final product with the legal requirements, including restrictions due to the conditions of use.

The producer should have available the following documents:

- declaration of compliance of the starting materials, according to what have been established by the applicable European and/or national legislation;
- necessary information to ensure that the supplied products comply with the requirements of compliance applicable to FCMs (for example, in the case of coating products, the producer must have supplier's information regarding the correct conditions of application of the coating, as indicated in the technical data sheets).

It is good practice that the raw/starting materials come from qualified suppliers. Qualification means a pre-established, organized and documented process conducted by the producer, which may also include supply specifications, aimed at verifying the supplier's ability to produce and / or market starting materials that correspond continuously to pre-established technical specifications.

It is advisable to verify, also through periodical inspections (audits), the Quality Assurance System of the suppliers of the starting materials or the subcontractors to ensure that it complies with the requirements expressed by Regulation (EC) 2023/2006 as amended, where applicable.

In case the supplier does not operate according to the GMP regime, the producer must ensure that raw materials or semi-finished products he will use are adequate to produce materials and articles suitable for contact with food; this verification, which is at producer's costs, could be carried out both through the verification of composition declarations issued by suppliers, and by carrying out appropriate technical and analytical evaluations.

B13.2.1.3. Production

The company production process extends from design to storage of the finished product.

The producer should implement procedures and/or instructions applicable to at least the following activities:

- design;
- receipt of raw materials;
- painting of metal laminate (where provided);
- forming of the metal shaped.

During all the phases, the complete traceability of used materials has to be ensured.

All the phases should be carried out following precise instructions indicating the required technical specifications of materials to be used, the operations order and the manufacturing and process conditions needed (for example the specific oven temperature and timing).

Specifications and characteristics of the finished product should be clearly defined.

Design of new products and conformity assessment for food contact

The most important concept implied by the GMP is that of a product designed to be compliant to the legislative requisites on materials and articles intended for food contact (FCMs).

If a producer develops a product compliant to a project for conformity of use, then the packaging material produced must:

- comply with the performances for the final use it is intended for;
- comply with the requisites of the legislation in force for materials intended for food contact.

To this purpose the product has to be produced with raw materials that, subject to controls, guarantee, at all the process phases, the compliance with the use and with legislative requirements on contact with food.

All the modifications on the original project have to be verified to control any undesired effects on the conformity of the product.

The producers have to indicate to the customer any possible change that might in any way undermine the compliance of the material with the required compliance requirements. In the development of a product, particular attention has to be paid to the test conditions adopted, which must correspond as closely as possible to the conditions of end use of the material according to the position of the product in the supply chain.

The analytical tests should always be conducted following validated methods. If these methods do not exist, an analytical method characterized by adequate performances at the established limits should be used, waiting for the development of a validated method.

Conformity of the production system

The production process has to be kept under adequate control with a Quality Assurance System that has to be conceived in such a way as to ensure and document that the product responds to the relevant technical specifications and that these specifications comply with the product design.

The Quality Assurance System has to be finalised in such a way as to pay sufficient attention to the most critical points of the production system that can put at risk the achievement of both legislative, technical and qualitative compliance of the finished product.

Documentation of procedures/instructions

Every production phase has to be regulated through adequate documentation. Examples of documentation can be: manuals, procedures, working instructions, technical rules and

registers. The documentation required to perform the activity must be at the disposition of the appointed personnel, must be kept updated and the distribution must be checked, so that so that information that is no longer updated is promptly withdrawn.

B13.2.2. Quality Control System (Regulation (EC) 2023/2006, art. 6)

The producer should establish and maintain an effective Quality Control System capable of ensuring the respect of the conformity to the Regulation as laid down in the general guideline.

The system should include procedures providing for all necessary checks, the related registrations and actions to be carried out in the event of non-compliance.

All the documentation has to be available for the competent authorities that request its vision in accordance with the Regulation (EC) 2023/2006 as amended and the Framework Regulation (EC) 1935/2004 as amended.

The rules and the procedures have to cover the entire production process, as described in paragraph B13.2.1.3, also including a part that deals with the management of any non-conformities and corrective actions.

The Quality Control System has to be applied to every phase of the production process and it does not include specific controls on the finished product to authorize its release.

In absence of non-conformities noticed in each phase, the finished product is considered compliant with the legislative requirements and so directed to the labelling phase, attesting the final conformity.

B13.2.2.1. Management of raw materials warehouses

Approved starting materials from qualified suppliers must be clearly identified and/or separated from other starting materials that have not yet been approved or that come from suppliers who are undergoing qualification or who have not been qualified.

For the latter materials a procedure must be established that authorizes their use in production only after the function in charge of Quality Control has confirmed the suitability of the material to be used in production.

Any raw materials under dispute must be segregated in a predefined zone and clearly identified pending the problem is solved. The segregation of non-compliant material can also be carried out through system constraints other than physical segregation in a specially designated area (IT block).

Only the function laid down under the Quality Control is enabled to authorize any use of these materials.

The environmental, storage and handling conditions in the storage areas must be such as to ensure that there is no risk of deterioration of the material.

Special attention should be given to the storage, warehousing and handling of raw materials to avoid any damage that can make the materials unusable.

B13.2.2.2. Production controls

The Quality Control System has to be regulated by suitable procedures that ensure that during the production process all the necessary controls are carried out to guarantee that the product complies with the legal, technical and quality specifications defined during the design phase.

The traceability of the products must be guaranteed through appropriate registration of the raw material lots used, of the machine conditions set and registered during production and of the quality controls also carried out on intermediate products and semi processed articles.

The storage of the finished product and the shipment to the customer should only be enacted against procedures that allow to unequivocally document that the material has been checked at all established phases.

This conformity should be ascertained by comparing the control data collected with the values and/or tolerances reported in the product technical specifications or in the specific legislation.

In order to complete the production controls, it is advisable to set up a plan of analytic tests to ensure the respect of global and specific migration limits applicable to FCMs and articles.

In this case it is appropriate that frequencies and methods are established / regulated by a specific operating procedure defined within the company.

Special attention must be paid to the control of possible contamination. A procedure for assessing this risk should be available and the actions established to prevent it (e.g., regular cleaning of machinery and equipment, hygiene in the workplace, prevention against insects and rodents) should be documented.

B13.2.2.3. Quality Control of finished products

The Quality Control System has to dispose of suitable procedures to verify the conformity of the finished product. In verifying the conformity of the finished product, Quality Control has to use the information available on the raw materials and on the process applied to highlight any limitations and restrictions of use for food contact.

B13.2.2.4. Management of finished products warehouses

The compliant finished products should be clearly separated from those non-compliant.

For non-compliant products, a procedure should be available that prevents their expedition (or their internal use) pending the definition of the problem. Any exceptions must be authorized only by the function in charge of Quality Control.

Non-compliant products, clearly identified, must be stored in a predefined area, in order to prevent their use, even if accidental.

Any finished products returned by customers because due to non-conformity, should be stored in a predefined area and clearly identified pending the definition of their final destination/use (sorting, scrapping, downgrading, etc.). Only the function in charge of Quality Control is allowed to authorize any use of these materials.

In any case, non-compliant products can be blocked through other system device (for example via IT system) other than physical segregation: it is fundamental that the non-compliant products are in any way not available both for the internal use and for shipment.

It is advisable to provide for a procedure for the disposal or destruction of non-compliant materials. The environmental and storage conditions of the storage areas have to be such as to ensure that there is no risk of deterioration of the material.

B13.2.2.5. Distribution, shipment and delivery

The producer, if responsible for the transport and the delivery of the material to its destination, has to guarantee that this phase is also regulated by instructions and procedures that guarantee the quality of the material, preserving it from any damage and contamination risk that might compromise its use or its suitability.

If the means of transport are owned by the producer, it must be ensured, including by periodic checks, that they are suitable for transporting goods and that they keep intact the safety and hygiene requirements necessary to guarantee the integrity of the product.

If the delivery is made through external transport companies, a procedure should be established that qualifies the transporter and a technical specification that sets the minimum requirements to be respected to eliminate possible risks (i.e. damage, contamination, etc.) must be defined.

B13.2.2.6. Conformity of the application of the GMP and claims management, corrective and preventive actions

The Quality Control System has to enact suitable procedures so as to monitor the correct implementation and total respect of the GMP.

The Quality Control System has to enact procedures for documenting the identification of lack of conformity, any corrective measures and the monitoring of the implementation of such measures, with particular attention to the timing of implementation of these measures.

The Quality Assurance System of the Business should therefore be implemented to include periodical verification and control plans on conformity to pre-established parameters and specifications, relevant to compliance with legislation on FCMs; procedures for managing nonconformities as well as corrective and preventive actions deriving from eventual claims should be implemented.

B13.2.3. Documentation (Regulation (EC) 2023/2006, art. 7)

All the documents concerning the Quality Assurance System (procedures, specifications, formulations, etc.) and all the activity of the Quality Control System (instructions, registrations of control data, machine setup data, tolerances and measurements etc.) have to be organized so as to constitute a paper or electronic archive, immediately accessible and easily consultable on request by the Competent Authorities.

Documents that guarantee traceability, according to art. 17 of Regulation (EC) 1935/2004 as amended, copies of the declarations of conformity issued to customers in compliance with applicable European and national legislation, as well as the supporting documentation provided will also be an integral part of the archive. This documentation will also include any test conditions, calculations and analyses, carried out by internal or external laboratories, that serve to demonstrate conformity.

In the event of substantial changes in production capable of changing essential requirements for compliance or when the legislative references are modified and/or updated, it should be verified whether the documentation relevant to Regulation (EC) 2023/2006 as amended needs to be updated.

Annex B13.1

Technical glossary

Blanking: Mechanical processing that allows to obtain rounded or shaped pieces of metal starting from unrolled coils or metal sheets or that allows the removal of excess metal after the forming process.

Coating (product) / liquid coating: Preparations of variable viscosity, suitable to be applied with different technologies in thin layers of a few microns in one or more steps to protect, decorate or make metal surfaces in sheets functional or applied directly on the pre-formed article.

Coil: Flat tape wrapped in overlapping regular coils, so as to form a roll with almost flat sides.

Curing profile: Thermal profile, expressed in terms of time and temperature, necessary to obtain, starting from a liquid coating, a non-stick coating suitable for contact with food that acts as a barrier to the metal substrate. Such a curve is usually obtained by oven tests using a measurement and data recording system connected to the item and represented in a time-temperature diagram.

Fluoropolymer coating: Particular type of non-stick coating based on fluoropolymers, such as PTFE (polytetrafluoroethine), which thanks to their chemical inertia, thermal stability and excellent non-stick properties are widely used for the realization of functional coatings in the cookware sector. Within these coatings, low molecular weight non-polymeric PFAS are used, along with other ingredients, as emulsifiers in the industrial production process of aqueous fluoropolymer dispersions and are eliminated together with the other volatile substances from the wet formulation of the coating during the sintering process.

Forming / drawing: Process of creating an article from a flat plate obtained by means of mechanical moulds.

Metal shape: Coated or uncoated metal sheet that can have different shapes and sizes.

Metal substrate: Metal material on which non-stick coating is applied.

Non-stick coating: Coating applied inside a cooking utensil to prevent adhesion and carbonization of food without the addition of fat and to facilitate cleaning.

Painting process: Process of technological application of paint/coating products. The most used traditional method is the application on flat sheet, followed by application on finished product. The application can be performed by roller, spray, electrostatic and electrodeposition.

Primer: First layer of a coating that favours the adhesion of the same to the substrate and to the next coating layer.

Riveting: Non-detachable joining technique used to fix the handle to the semi-finished product.

Semi-finished product: An article that has not yet completed the production process but has undergone the forming process.

Sintering: High-temperature curing process (generally in the range of 400-440 °C depending on the residence time in the oven) during which the fluoropolymer-based liquid coating is transformed into a non-stick coating. Heating fluoropolymers such as PTFE to high temperatures causes the polymer particles to fuse together to create a continuous film, eliminating voids that can cause weaknesses or defects in the polymer structure.

Traceability: The process that allows you to trace a material and / or an article through all stages of processing, use and distribution.

Turning: Mechanical processing aimed at eliminating sharp surfaces and making the rim or bottom of the articles uniform. It can also have aesthetic purposes**.**

Annex B13.2

Frequently asked questions

Q1 *What is FIAC?*

FIAC (*Associazione Fabbricanti Italiani Articoli per la Casa, la tavola e affini)* is the Italian association of manufacturers of household and table articles, and related items. It is one of the sector associations of the ANIMA Federation (www.anima.it) that protects the interests of the associated companies and guarantees the connection with the European associations (FEC).

Q2 *Is there a specific European legislation that regulates coatings applied on a metal support?*

No, in addition to the general rules of Regulation (EC) 1935/2004 as amended, the only specific legislative references applicable at European level are Regulation 1895/2005/EC which defines the migration limit of certain epoxy derivatives in plastic materials or protected by a surface coating and Regulation (EU) 2018/213 on the use of bisphenol A in paints and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as amended as regards the use of this substance in plastic materials intended to come into contact with food.

Q3 *Is there a European technical guide that regulates paints applied on a metal support?*

At European level, in the absence of specific requirements for metals and alloys used in materials and articles in contact with food, a Technical Guide has been produced by the Committee of Experts on Packaging Materials for Food and Pharmaceuticals (P-SC-EMB); Council of Europe Resolution CM/Res (2013)9.

Q4 *Do Regulation (EU) No 10/2011 and its subsequent updates regulate paints applied on a metal support?*

No, the scope of the Regulation is exclusively that of plastics and not that of coatings, even if of a polymeric nature.

Q6 *What legislation applies to coated metals*?

The applicable legislation varies according to the type of coating applied as it is only the layer in direct contact with the food that must meet the requirements of the applicable legislation. For items produced in Italy, Presidential Decree 777/82 and Ministerial Decree 21st March 1973 as amended are applied.

Q7 *Does the support metal to the non-stick coating have to comply with the regulations governing the same uncoated metal in direct contact with food?*

No, if the non-stick film performs an appropriate barrier function. FCMs of uncoated metals are regulated by additional specific regulations.

Q8 *Are there international technical standards that define the requirements for coated metal items intended for cooking?*

Yes:

- UNI EN 12983-1:2023 “Cookware - Domestic cookware for use on top of a stove, cooker or hob - Part 1: General requirements”;
- UNI CEN/TS 12983-3:2008 “Cookware - Domestic cookware for use on top of a stove, cooker or hob - Part 3: Cookware for use on induction heating sources”;
- UNI EN 13834:2020 “Cookware - Ovenware for use in traditional domestic ovens”;
- UNI EN ISO 2409:2020 “Paints and varnishes - Cross-cut test”.

Q9 *What happens during the sintering process of a fluoropolymer coating?*

During the sintering process of fluoropolymer coatings, i.e. high-temperature curing (generally in the range of 400-440°C depending on the residence time in the oven) for a few minutes, the polymer particles fuse together to create a continuous film, eliminating voids that can cause weaknesses or defects in the polymer structure. It should be noted that the coatings are supplied with the recommended time-temperature indications for obtaining a perfectly sintered coating; as the time spent in the curing oven increases, the temperature decreases and vice versa. It is therefore not appropriate to speak of sintering temperature of the coatings in a manner separate from the time spent in the oven.

Q10 *Are there any items that can be used both for baking in the oven and on other heat sources?*

Yes, there are both items with removable handles, and articles whose handles are made of material suitable for use in the oven without the need to be removed.

B14. RUBBER

B14.1. Characterization of the sector

B14.1.1. Field of application of guideline

This 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).

B14.1.2. Applicable legislation

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.[27]
- Commission Directive 93/11/EEC concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers.

Italian legislation

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

[27] It replaced the Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

450/2009 and 10/2011, concerning materials and objects intended to come into contact with food.

– Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, intended to come into contact with food or substances for personal use as amended.

B14.1.3. Phases of the production process: flowcharts and descriptions

Before proceeding to the description of the production cycles and their differentiations, it is necessary to point out some elements specific to rubber, which determine its real specificity, which has important repercussions depending on the various types of processing with regard to suitability for contact with foodstuffs.

Natural rubber is produced from natural latex, a colloidal dispersion of polyisoprene particles (35-38% on average) and small quantities of other components, such as proteins, fats, resins and sugars, which is extracted from plants belonging to the *Euphorbiaceae family*, such as *Hevea brasiliensis*. Natural latex can be sent to production processes in liquid form, after appropriate additives addition, or it can be subjected to coagulation (by dilution and subsequent acidification with formic or acetic acid), to obtain natural rubber in solid form, also known as dried.

As far as synthetic elastomers are concerned, there are various types with different chemical natures. They can also be subdivided into vulcanised and thermoplastic: the former, once they have undergone the vulcanisation process, can no longer be reshaped by means of thermo-mechanical treatment, which is what characterises the latter.

Synthetic rubber can also be used in solid form (generally in bales) or as a liquid emulsion (e.g. latex).

In view of the substantial difference in terms of chemical-physical characteristics (primarily viscosity), latex and elastomers in solid form are processed using completely different technologies, both in terms of mixing and the subsequent moulding steps.

In both cases, in order to give the finished product the required characteristics, the elastomers (in solid or liquid form) are mixed with additives of different nature and technological function (e.g. reinforcing fillers, plasticising oils, cross-linking agents, accelerators, retardants, anti-oxidants, etc.), resulting in a semi-finished product which, in the case of solid-phase processing, is generally referred to as a compound.

The semi-finished product thus obtained is then given the desired shape through processes that may make use of different technologies, depending on the physical form: moulding, extrusion, calendaring, etc. in the case of compounds, or dipping, coating, etc. in the case of latex.

At the same time, or at an immediately subsequent stage, the product undergoes vulcanisation. The latter treatment is not envisaged in the case of thermoplastic elastomers, whose transformation generally requires different processes, additives and machines than in the case of traditional rubbers.

The main technologies adopted for the processing of elastomers are described in more detail in Annex B14.1.

Technical terms are described in the glossary in Annex B14.2.

B14.1.3.1 Production flowchart

Figure B14.1 shows in a flow diagram the processes involved in the production of rubber articles intended for food contact, starting with the raw materials. The flows are differentiated according to the type of elastomers involved, which can be of natural or synthetic origin (the dashed part is compliant with the GMP Regulation (EC) 2023/2006 as amended).

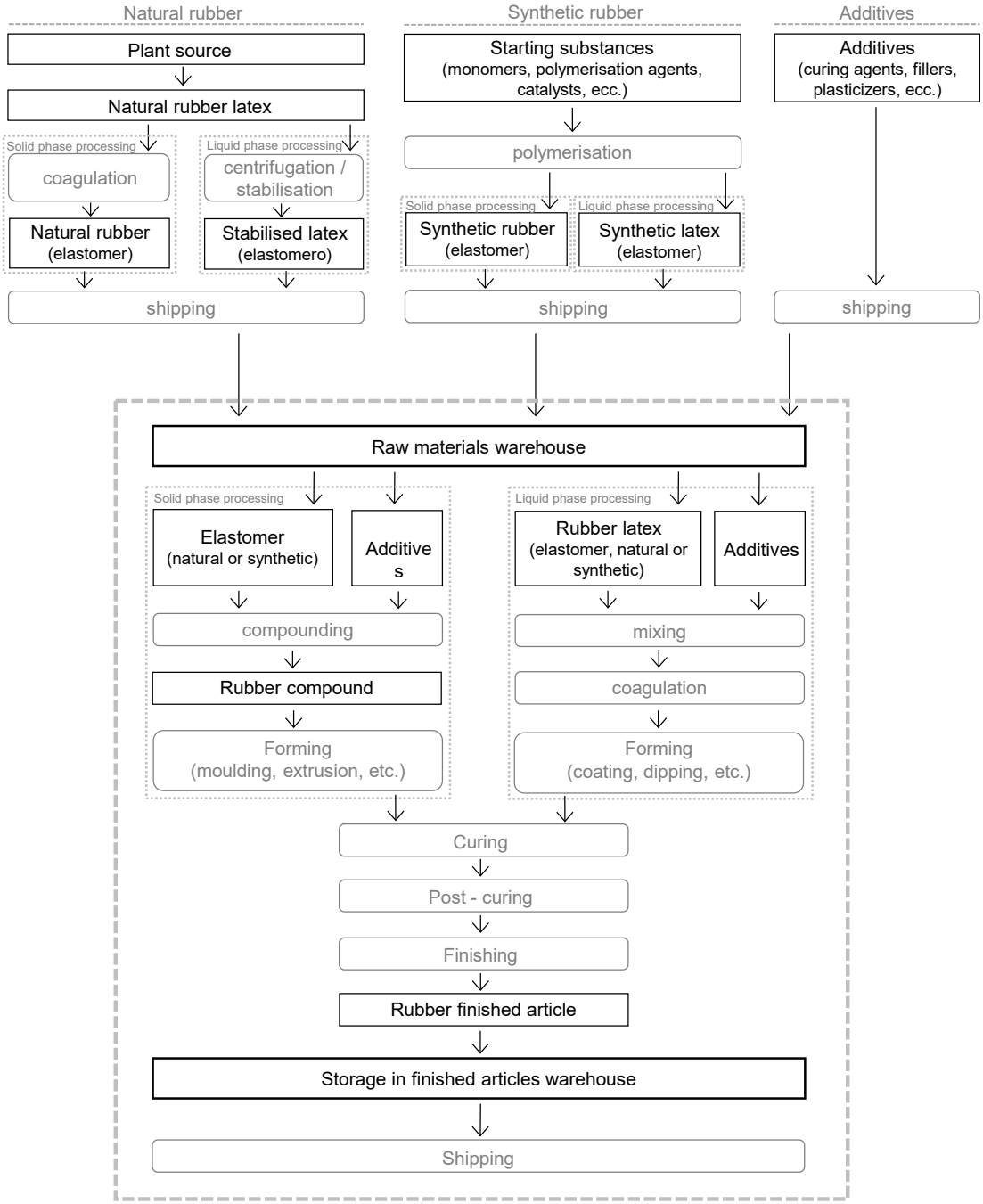

Figure B14.1. Production flowchart for rubber Food Contact Materials (FCMs)

B14.1.3.2. Brief description of process phases

Picking raw materials from the warehouse

Depending on the case, the production process can be fed from the basic raw materials (basic elastomer, fillers, vulcanising agents, etc.) or directly from a semi-finished product (rubber compound).

Mixing/Compounding

The basic elastomer – in solid or liquid form (latex) – is mixed with all the other raw materials required to make the compound (curing agents, fillers, plasticisers, etc.), according to the formulation specifically designed for the final application. In the case of solid form processing, mixing is carried out using closed or open mixers.
As expressed in the previous point, some companies carry out the mixing in-house, integrating it into their own production cycle, while others purchase the compound already produced by specialised companies.

Forming

The compound is then given the desired shape using various possible technologies, depending on the final application. At the same time, the rubber can also be coupled with other materials (e.g. textile or metal) to give the final product the desired characteristics. In the case of processing in solid form, the processing technologies can be, for example: moulding (compression or injection), extrusion, calendering. In the case of processing in liquid form (latex), the technologies typically used are dipping or coating.

Curing / vulcanisation

This is a typical process step in the rubber industry: a chemical reaction aimed at creating bonds between the elastomer chains, thus giving the material the desired properties in terms of strength and elasticity. Vulcanisation is generally thermally induced, using a variety of possible technologies, and can take place concurrently with the forming process (as in moulding) or subsequently.

Post-curing, finishing and dispatch to warehouse

In the production process, a post-curing phase may be envisaged: a heat treatment aimed at completing the vulcanisation reaction, removing any volatile residues and eliminating tensions induced in the material by the moulding processes. Finally, before packaging and sending the finished products to the warehouse, the rubber item may undergo finishing operations, such as washing, deburring, or sorting.

B14.2. Fulfilments deriving from the application of the Regulation (EC) 2023/2006

This part describes the activities and the implementations implemented by the rubber goods supply chain to comply with the Regulation (EC) 2023/2006 as amended. Since this Regulation was laid down when Quality Assurance Systems had already become a daily work tool in most of the manufacturing businesses, it is likely that these businesses already produce in conformity with technical specifications laid down by themselves.

However, should it be necessary, the Quality Assurance System and the Quality Control System should be extended to ensure:

> "[...] that the materials and articles are constantly manufactured and controlled, to ensure their conformity to 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" (art. 3 paragraph a Regulation (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006 as amended. Every paragraph is hence the response of the manufacturers of the rubber goods to the requirements of the article in question. To facilitate reading, the paragraphs keep the same title as the article considered, while the subparagraphs indicate specific subjects.

B14.2.1. Quality Assurance Systems (Regulation (EC) 2023/2006, art. 5) and Size of the business

Quality Assurance Systems

The producer should establish and maintain a Quality Assurance System capable of ensuring the achievement of the objectives laid down by the Regulation and described in the general guideline.

The Quality Assurance System should be documented so as to enable control by the competent authorities.

The Quality Assurance System should establish rules and procedures that regulate the company activity, at least concerning the following points:

- conformity to the requirements of the legislation in force;
- human resources and training;
- raw materials and suppliers including suppliers of goods and services and third parties;
- production;
- quality control;
- storage (raw materials, packaging and finished products), reception, handling and shipment;
- traceability;
- claim management;
- preventive and corrective actions.

The system must ensure adequate monitoring and implementation of the future legislative and normative changes applicable to the specific supply chain.

As regards the suppliers of raw materials and/or the third parties (tollers), it is advisable to implement an adequate qualification plan that includes also an assessment of their Quality Assurance System, to ascertain that, where applicable, it complies with the requirements of Regulation (EC) 2023/2006 as amended.

It should be recalled, in fact, that the production of the starting substances for the manufacturing of elastomers (e.g. monomers, catalysts, additives, etc.) is excluded from the scope of the GMP Regulation, as is the production of the additives added to elastomers to produce rubber compounds (such as reinforcing fillers, stabilisers, protective agents, plasticisers, curing agents, accelerating agents, etc.) unless they are in the form of predispersions or mixtures. On the other hand, the production of elastomers themselves, as well as the manufacture of rubber compounds

or other semi-finished products, are included in the scope of the Regulation and require the application of GMP.

Size of the business

Independently from the business size, it should at any rate be guaranteed that the Quality Assurance System, as demanded and finalised by the Regulation (EC) 2023/2006 as amended, is always applied. The system should be established, implemented and managed taking into account the actual size, peculiarities and complexity of the company as well as the technical and human resources available, without being an excessive burden on the company. At any rate the business, in its own premises, must be able to guarantee the application and management of the Quality Assurance and Quality Control System in order to obtain materials or finished products that comply with the legislation in force on FCMs.

B14.2.1.1. Human Resource and Training

The *Business Operator,* in compliance with the objectives of the Regulation (EC) 1935/2004 as amended and the Regulation (EC) 2023/2006 as amended is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 as amended is applied at all levels of their organization. The operational aspects inherent to the application of the provisions laid down by Regulation (EC) 2023/2006 as amended can be entrusted by the Business Operator to competent and adequately trained people who must, however, have adequate means at their disposal to ensure that the requirements of Regulation (EC) 2023/2006 as amended are met.

The *Company Organisation* must in any case make it possible to identify the functions for the purposes of verification by the Competent Authorities.

All potentially involved *company personnel* whose activities may affect product quality shall be informed about the principles of GMP, their obligations under Regulation (EC) 2023/2006 as amended, its objectives and how to apply it.

The *Company* shall have and implement appropriate training plans for employees whose duties may affect compliance with this Regulation.

Personnel who are to carry out specific GMP control and verification activities are to be qualified on the basis of their training and experience.

Appropriate records of the training process of all personnel shall be maintained.

B14.2.1.2. Production

The company production phase extends from design and planning to storage of the finished product.

The production process encompasses all the company phases that contribute to ensuring that the finished product complies with the technical, legislative and performance requirements envisaged at the design stage to guarantee suitability for its intended use.

When product design and development activities are carried out by or in collaboration with the customer, responsibility for defining the technical, legislative and performance requirements applicable to the product (mandatory or voluntary) must be clearly assigned.

Hence the Quality Assurance System should comprise procedures that regulate all the phases listed hereafter:

- Design and development of the product (if it is the producer's responsibility);
- Selection of starting material and suppliers;
- Acceptance of raw material and storage;

- Quality control of raw material;
- Production processes and traceability of the raw materials used;
- Control of process parameters;
- Quality control during production;
- Quality control of the finished product and storage.

Selection of the starting materials and substances, of the suppliers and/or third parties

All starting materials and substances should be procured from approved and/or qualified suppliers. Qualification is meant a pre-established, organized and documented process that can also include supply specifications and the implementation by the supplier company of a Quality Assurance System conceived so as to be able to guarantee the constant fulfilment of the pre-defined requirements. The manufacturer should ascertain that, where applicable, the following requirements are met:

- traceability according to the Framework Regulation (EC) 1935/2004 as amended;
- declaration of compliance according to what established by DM 21.03.73 as amended;
- compliance to Regulation (EC) 2023/2006 as amended.

In the event that suppliers have not yet undergone the approval or qualification process, the starting materials must still be characterised; in any case, supply specifications must be established. The customer has to be sure that the supplier is always able to guarantee consistency of production and conformity with the agreed supply specifications.

Process compliance

The production process has to be kept under control with a Quality Assurance System that has to be conceived so as to be able to guarantee and document that the rubber goods produced comply with the applicable legislative and technical provisions.

Documentation of procedures/instructions

Every production phase that may influence the final compliance of the product to the relevant food contact legislation has to be regulated through adequate documentation. Examples of documentation can be: manuals, procedures, working instructions, technical standards and records. The documentation required to perform the activity must be available to the appointed personnel, must be kept updated and the distribution of the same must be controlled, so that non updated information is rapidly withdrawn.

B14.2.2. Quality Control System (Regulation (EC) 2023/2006, art. 6)

Regulation (EC) 2023/2006 as amended requires that a Quality Control System is in place and maintained to ensure compliance with the Regulation as described in the general guideline of this document.

The system should include procedures that envisage all necessary controls, related records and actions to be taken in the event of non-compliance.

All documentation relevant to the implementation of corrective actions shall be available to Competent Authorities on demand in accordance with Regulation (EC) 2023/2006 as amended and Framework Regulation (EC) 1935/2004 as amended.

The rules and procedures must cover the entire production process, as described in paragraph B14.2.1.2, including a section covering the management of any non-conformities and corrective actions.

B14.2.2.1. Management of raw materials warehouses

The starting materials from qualified suppliers or approved supplies must be clearly separated from other starting materials that have not been homologated (or approved) or that are from suppliers who are in the process to be qualified or who have not been qualified yet.

For the latter substances, or mixtures, a procedure must be established that authorizes their use in production only after the responsible function has confirmed the suitability of the material for use in production.

At the arrival of the supply, any starting material non-compliant with the specification, and then subject to a claim, has to be segregated in a predefined area and clearly identified pending suitable verification. The segregation of non-compliant material can also be carried out through system procedures other than that of physical separation in an especially defined area (IT blocking).

To demonstrate the correct management of the above materials, businesses should implement a procedure to manage the materials after the verifications.

Storage conditions must be such as to ensure that there is no risk of contamination or deterioration of the material.

B14.2.2.2. Production controls

Products traceability must be ensured through suitable registration of the batches of starting materials used, of the operating conditions of the machinery, recorded during production and the quality controls performed.

Storage of the finished product and shipment to the customer should only be enacted against procedures that enable the unequivocal documentation that the material has been controlled in all the established phases and that the final controls, whether planned, have ascertained the conformity to all the requirements identified in the production phase.

This conformity should be ascertained through the comparison between the control data collected and the values and/or ranges listed in the product specifications or in the applicable legislation.

B14.2.2.3. Quality Control of finished products

The Quality Control System has to include suitable procedures to control finished products, taking into account the position in the supply chain. In verifying the conformity of the finished product, Quality Control has to use the information available on starting materials and on the process applied to highlight any limitations and restrictions of use.

Particular attention should be paid to the test conditions used for carrying out the controls, which have to be suited to the verification of the intended final use of the material. The analyses should always be carried out using validated methods of analysis. If these methods are not available, an analytical method with performance characteristics adequate to the verification of the specific parameter may be used pending the availability of a validated method.

The equipment for tests and analysis must be properly calibrated and the calibration operations must be adequately recorded.

B14.2.2.4. Management of finished products warehouses

In the warehouse, depending on the classification given by the Quality Control, the approved finished products must be clearly separated from those that still have to be controlled or identified as unsuitable. This distinction can also be made through the use of appropriate software or management systems.

For any unsuitable product, a procedure should be in place that prevents their commercialization as FCMs.

Unsuitable products, clearly identified by physical and/or electronic means, must be segregated in a predefined area of the storage areas.

Any finished products returned by customers due to non-conformity must be clearly identified by physical and/or electronic means and segregated in a predefined area pending definition of the claim.

A procedure for handling non-conforming materials is recommended; such products do not necessarily have to be disposed of as it may be possible to recover/recycle them in different application areas.

The environmental and storage conditions of the storage areas must be such as to ensure that there is no risk of contamination or deterioration of the material.

B14.2.2.5. Distribution, shipment and delivery

The manufacturer, if responsible for the transport and the delivery of the material to its destination, must ensure that this phase is also regulated by instructions and procedures that guarantee the quality of the product by preserving it from possible alterations and risks of contamination that could affect its use or suitability.

If the means of transport is owned by the manufacturer of rubber goods, it must be ensured, including through periodic checks, that they are suitable for transporting goods and maintain the safety and hygiene requirements necessary to guarantee the integrity of the product.

If the delivery is made via external shipping companies, a procedure should be established that qualifies the shipping company and technical specifications must be defined that establish the minimum requirements to be respected to remove possible risks (e.g. alterations, contamination, etc.).

If transport is managed by the customer, it will be the customer's responsibility to guarantee the requirements necessary to maintain the integrity of the product.

B14.2.2.6. Conformity of the application of the GMP and claims management, corrective and preventive actions

The Quality Control System must have appropriate procedures to monitor the correct implementation and full compliance with GMP.

The Quality Control System must also have procedures to document the identification of non-compliance, eventual corrective measures and the monitoring of the implementation of these measures, with particular attention to the timing of their implementation.

The company's Quality Assurance System must therefore be structured to include plans for audits and periodic checks on compliance with the pre-established parameters and specifications relevant to compliance with food contact materials legislation; procedures for managing non-compliances and corrective actions must be implemented.

B14.2.3. Documentation (Regulation (EC) 2023/2006, art. 7)

All documents relating to the Quality Assurance System (procedures, specifications, formulations, etc.) and all activities of the Quality Control System (instructions, control data records, machine setup data, tolerances and measurements, etc.) must be organised in such a way as to constitute an archive, hard copy or electronically, which is readily accessible and easy to consult.

This documentation must be made available to the competent authorities if requested.

Documents guaranteeing traceability in accordance with Article 17 of Regulation (EC) 1935/2004 as amended, copies of declarations of compliance issued to customers in accordance with Article 16 of Regulation (EC) 1935/2004 as amended and applicable national provisions, and the required supporting documentation will also form part of the archive.

This documentation, which must be kept up-to-date, shall also include test conditions, calculations and any analyses, performed by internal or external laboratories, that serve to demonstrate conformity.

In the event of substantial changes in production that may alter essential requirements for conformity, or when legislative references are changed and/or updated, it must be verified whether the documentation relevant to Regulation (EC) 2023/2006 as amended needs to be updated.

Annex B14.1

Elastomers transformation technologies

Main types of elastomers

Rubber, both in solid and liquid (latex) form, is classified and coded into the following groups based on the chemical composition of the main polymer chain, as stated in ISO 1629:2013 and ASTM D1418-22 technical standards:

M Group rubbers having a saturated carbon chain of the polymethylene type
N Group rubbers having carbon and nitrogen in the polymer chain
O Group rubbers having carbon and oxygen in the polymer chain
Q Group rubbers having silicon and oxygen in the polymer chain
R Group rubbers having an unsaturated carbon chain, e.g. natural rubber and synthetic rubbers derived at least partly from conjugated dienes
T Group rubbers having carbon, oxygen, and sulphur in the polymer chain
U Group rubbers having carbon, oxygen, and nitrogen in the polymer chain
Z Group rubbers having phosphorus and nitrogen in the polymer chain

Table B14.A1 shows examples of rubbers belonging to some of the groups with their respective acronyms.

Table B14.A1. Examples of nomenclature of rubbers listed in ISO 1629:2013 and ASTM D1418-22 standards

Group and acronym		Chemical composition of the main polymer chain
M	ACM	copolymer of ethyl acrylate (or other acrylates) and a small amount of a monomer which facilitates vulcanization (usually known as acrylic rubber)
	AEM	copolymer of ethyl acrylate (or other acrylates) and ethylene
	ANM	copolymer of ethyl acrylate (or other acrylates) and acrylonitrile
	CSM	Chlorosulfonylpolyethylene
	EPDM	terpolymer of ethylene, propylene, and a diene with the residual unsaturated portion of the polymerized diene in the side chain
	EPM	ethylene-propylene copolymer
	EVM	ethylene-vinyl acetate copolymer
	FEPM	copolymer of tetrafluoroethylene and propylene
	FFKM	perfluoro rubber in which all substituent groups on the polymer chain are fluoro, perfluoroalkyl, or perfluoroalkoxy groups
	FKM	fluoro rubber having substituent fluoro, perfluoroalkyl, or perfluoroalkoxy groups on the polymer chain
O	CO	polychloromethyloxirane (usually known as epichlorohydrin rubber)
	ECO	copolymer of ethylene oxide (oxirane) and chloromethyloxirane (also known as epichlorohydrin copolymer or rubber)
Q	FVMQ	silicone rubber having methyl, vinyl, and fluorine substituent groups on the polymer chain
	MQ	silicone rubber having only methyl substituent groups on the polymer chain, such as dimethyl polysiloxane
	PMQ	silicone rubber having both methyl and phenyl substituent groups on the polymer chain
	PVMQ	silicone rubber having methyl, vinyl, and phenyl substituent groups on the polymer chain
	VMQ	silicone rubber having both methyl and vinyl substituent groups on the polymer chain
R	BIIR	bromo-isobutene-isoprene rubber (usually known as bromobutyl rubber)
	BR	butadiene rubber
	CIIR	chloro-isobutene-isoprene rubber (usually known as chlorobutyl rubber)
	CR	chloroprene rubber
	ENR	epoxidized natural rubber
	HNBR	hydrogenated NBR (some unsaturation remains)
	IIR	isobutene-isoprene rubber (usually known as butyl rubber)
	IR	isoprene rubber, synthetic
	NBIR	acrylonitrile-butadiene-isoprene rubber
	NBR	acrylonitrile-butadiene rubber (usually known as nitrile rubber)
	NR	natural rubber
	SBR	styrene-butadiene rubber
	XNBR	carboxylic-acrylonitrile-butadiene rubber
U	AU	polyester urethane
	EU	polyether urethane

A) PROCESSING IN SOLID FORM

Compounding

Rubber, fillers, plasticizers, vulcanizing agents and other additives, dosed according to a specific recipe, are mixed together.

For this process, the two basic machines are generally the open (cylinder) mixer and/or the closed mixer.

The open mixer consists mainly of two steel cylinders arranged horizontally opposite each other at a distance that can be adjusted as needed.

The cylinders rotate in the opposite direction with different speeds. This difference in speed allows the rubber to spread out better as it passes through the space between the two cylinders, so that the piled ingredients are mixed more intensely and faster.

In order to control the temperature, which must not exceed a given threshold, the cylinders are equipped with a cooling system.

The mixers are equipped with a braking device with return movement so as to ensure the safety of the operator.

Vapours and dust that develop during mixing are generally extracted by extraction hoods. The mixing process is carried out as follows: rubber is introduced between the two cylinders and allowed to slide around the front cylinder. The rubber is strongly deformed by friction within the space between the cylinders. At this point, the other ingredients are distributed across the width of the leaf in a predetermined sequence and with regular flow. Ingredients that have fallen through the space between the cylinders are collected as much as possible and reintroduced into the mix.

Once the mixing process is completed, the leaf is cut and pulled out of the cylinders, depending on the required shaping specifications. The open mixer is sometimes used downstream of the closed mixer, with or without the addition of additional ingredients.

The closed mixer consists of a coolable and heatable closed mixing chamber, inside which two rotors run in the reverse direction. The chamber is provided with two hermetically sealed feed and discharge openings. Vapours and dust that develop with heat are extracted. Some types of enclosed mixers are equipped with a pneumatically driven piston, which presses the ingredients into the range of the rotors during mixing, speeding up mixing.

While in the open mixer the individual ingredients are mixed by the action of friction, in the closed mixer they are pressed against each other. In this way, mixing proceeds more intensively and much faster than in the open mixer. The processed material is discharged into machinery suitable for cooling, shaping, possible further homogenization (e.g., open mixers and twin-screw extruders).

The final step for both processes may be passage through a cooling bath, with or without the presence of anti-adhesive agent, and subsequent drying.

Compound storage and retrieval

The compounds, usually delivered in the form of continuous rolls or strips, once checked during acceptance, are stored in rooms with controlled conditions in relation to the type of compounds stored. The appropriate employees pick up, when necessary, the compound scheduled for production in the quantities indicated on the production documents. The picking phase, which should take into account the FIFO system (use the oldest compound first) can be facilitated by using identification systems using barcodes and/or RFiD.

Transformation technologies

Hoses extrusion (without rigid/flexible mandrel)

A rubber hose consists of an inner layer, which is responsible for containing the conveyed fluid, a reinforcement, which is responsible for ensuring operating pressure, and an outer layer for external protection. Extrusion without mandrel is a technology used to continuously produce rubber hoses with inner diameters ranging from 4 mm to 32 mm. In general, an extrusion line consists of:

- Feeding system
- Extruder (cylinder + screw)
- Head
- Reinforcement textiles laying system
- Cooling system
- Calibration system
- Collection system
- Vulcanization system
- Winding and cutting system

The *feeding system* features a hopper (feeding funnel) through which cold raw rubber compound in the form of strips is fed into the inlet of the extruder barrel. The *extruder* consists of a cylinder and a screw rotating inside it: their combined action pushes the rubber compound toward the head. This process takes place at temperatures generally between 70 and 90°C. The necessary heat is provided by electrical resistors, as well as by the friction generated by the moving compound. The *head* is the part through which the compound takes shape and size. The shape of the die that makes up the head generates a tube of raw compound of the desired diameter.
This hose is cooled immediately after exiting the head through the *cooling system* (e.g., cold water/nitrogen). The hose then passes to the *reinforcing textile laying system*, where, using different technologies, it is covered with reinforcing textiles. The hose+textile subassembly then passes into a second extrusion head to be covered by the outer rubber protection layer.
The various passes are monitored by a *calibration system*. The assembly thus constructed is collected in a *collection system* and then moved on to the *vulcanization system*, where, with the aid of heat, the chemical process of cross-linking between the polymers constituting the compound takes place, resulting in the viscoelastic properties characteristic of rubber. The rubber hose is thus ready for subsequent cutting and packing operations.
The *winding and cutting system* consist of a series of machines capable of winding vulcanized hoses into rolls and packing them in lengths as per customer requirements.

Handmade hose construction on rigid mandrel

Many special hoses ranging in size from 8 mm to 800 mm in diameter are hand-built on rotating rigid mandrels inside large lathes. Each layer, from the sublayer to the textile reinforcement to the rubber cover, is laid by hand using special equipment. Steel wire helixes are incorporated, spiralling them into place, when they are required to prevent collapse of the hose under suction/bending conditions. In general, a production line consists of:

- Rigid mandrel;
- Rigid mandrel lathe;
- Vulcanization system;
- Hose extraction system;
- Winding and cutting system.

The *rigid mandrel* is a steel tool with lengths of up to 60 m, suitable for being hooked into a lathe and rotating, allowing the operator to lay on it helically a rubber sheet of various thicknesses, suitable for building up the inner layer and outer layer. Reinforcing textiles and any steel spirals are also laid on the rotating spindle. To finish, a nylon bandage is laid over the assembly thus composed, which is intended to protect the hose in subsequent stages.
A *rigid spindle lathe* is a machine that allows spindles to be housed, rotated, and, by means of special equipment, the various components to be laid out by an operator.
The *vulcanization system* is a machine capable of housing the rigid mandrels, on which the tubes are built, bandaged with nylon, and supplying heat in order to ensure the cross-linking process of the polymers constituting the compound.
The *hose extraction system* is a machine that can extract the vulcanized hose from the rigid mandrel.
The *winding and cutting system* consist of a series of machines capable of winding vulcanized tubes into rolls and packing them in lengths as per customer request.

Calendering

The calender is a machine designed to produce strip articles of indefinite length and having a predefined thickness and width.
The calender consists of cylinders with parallel axes, placed at adjustable distances, heated and rotating at low speeds.
There are calenders with 3 or 4 cylinders arranged in line, L-shaped, S-shaped or Z-shaped.
Each cylinder is individually heated/cooled and is driven by its own individually regulated motor.
The calender cylinders are supported by two strong shoulders.
Uncured rubber is fed continuously and passes through pairs of rollers and is laterally contained by a pair of sheaths to obtain sheets or plates of desired thickness and width.
During the calendering process, it is possible to couple the rubber to a textile backing.

Injection moulding

Injection moulding technology turns out to be by far the most widely used and well-known process.
Polymer-based compound in the form of a strip is introduced into the injection moulding machine through a feeding system, into a heated barrel in which a continuous screw rotates. Due to the heat produced by the heaters on the barrel and the shear stress exerted on the material trapped between the barrel and the profile of the screw, the compound changes to a "plastic" state, that is, its viscosity is drastically reduced, thus being able to flow.
The polymer-based compound is previously formulated and mixed to accommodate the specific end-use requirements of the part. Due to the rotation of the screw, the plasticized mass is advanced near the injection point (screw head); when the machine has loaded enough material (previously set by the operator on the control panel) to fill the mould, the screw translates longitudinally. At this point the plasticized compound undergoes the process step called injection, which will bring it into the mould, which has a number of cavities depending on the size of the individual part. This action is provided by the pressure and flow that the screw translation imposes on the plasticized compound so that it can fill the mould before the material solidifies.
Once inside the mould, the compound is kept under pressure until it is deemed to have reached a sufficient curing degree, constituting the moulded product, which will later be extracted. Throughout the injection of the molten material into the mould, it is kept clamped by the clamping unit to which it is attached. This machine unit has the task of counteracting the force generated by the material injection pressure, which tends to open the two half moulds as a side effect. In traditional construction systems, the clamping unit consists of a fixed platen to which one half-mould is secured, a movable platen to which the other half-mould is attached (so as to allow clamping, opening, and extraction operations), a system for supporting and guiding the movable platen (usually 4 cylindrical-section columns), and a mechanism for closing the mould (usually a toggle actuated by hydraulic pistons or actuators and linear electric motors).The sequence of operations just described is performed on a single automatic machine with hydraulic and/or electric drives (injection moulding machine). The characteristic time for executing a cycle obviously varies from case to case but is rarely more than a few minutes. The productivity of the process is very high considering that a mould can contain a large number of impressions of the same product.
There are hydraulic, hybrid and fully electric injection moulding machines. Process innovation has led to the market having machines on the market with electric movements of the different units for movement, mould opening/closing, etc. instead of the traditional pneumatic (hydraulic) movements.

Liquid silicone rubber injection moulding

In its raw material state, this type of silicone rubber is in liquid form at room temperature. Nevertheless, the technology used for its processing is similar to that typically used for processing in solid form and is therefore described in this section.
The processing of liquid silicone rubber is characterised by the fact that mixing is completed at the same time as the moulding process. In fact, a two-component system is used, plus a possible colouring agent, which are accurately dosed by a pumping unit and mixed just before moulding, which takes place using

appropriately designed injection moulding machines. The temperature is kept low throughout the process in order to avoid triggering cross-linking, which must only occur inside the mould, where the temperature typically reaches values of 140-200°C.
In order to remove residues of volatile substances and make the silicone more suitable for contact with food and/or to complete the cross-linking process, the articles could be subjected to *post-curing*, which consists of heating in ovens at a temperature of around 200°C, with air circulation, for a few hours. This process also improves the mechanical properties of the artefact.
The latest generations of platinum catalysts make it possible to reduce the cross-linking temperature and increase the speed, improving the overall efficiency of the process. On the other hand, the use of such catalysts requires the mixtures to be stored at lower temperatures (around 20°C) and for short periods of time.

Compression moulding

This section describes the operations required to obtain articles from elastomer compounds using "compression" presses, which are generally used for the manufacture of large articles, small series or particularly complex composite articles (rubber-metal, textile rubber or other).
Compression presses are defined as presses which, due to the pressure exerted by the piston and the heating, obtain the finished article with the aid of moulds which, due to their nature, must be fed with semi-finished and preformed compound, to be introduced into the various cavities of the mould before vulcanisation. The presses differ essentially in the positioning of the piston, which may be above the upper platen (which becomes the movable platen) or below; the choice of type depends on the type of article to be produced and the mould used. Temperature is obtained with steam, diathermic oil or electrical resistances embedded in the platens and is transferred by contact and pressure.
The pre-forming of the semi-finished product is essential for the success of the part and is carried out either with the aid of special machinery (pre-forming machines, calenders, granulators, die-cutters) or with manually pre-packaged parts.
Generally, compression presses have movable platens to facilitate mould loading and are equipped with devices that, suitably calibrated, automatically perform the degassing for the escape of air and the established curing. They can have several working compartments.
The moulds used have one or more figures and if necessary are fixed by means of special brackets to prevent them from moving from their seat during opening/closing. Sometimes they have permanent anti-adhesive treatments and no release agent is used.
There are also moulds known as 'transfer' moulds, which have a (generally) upper collection chamber, which is filled with a defined amount of raw compound. During pressing, the compound, passing through holes, fills the figure(s) below.
The temperatures used during compression moulding are lower than in injection moulding technology and clearly the demoulding times are significantly longer.
All compression-moulded parts, once cured and removed from the machines, must necessarily be stripped of burrs and processing scrapes.

Adhesive application for bonding to metals or other materials

Adhesion of inserts of any material prior to moulding and vulcanisation serves to ensure a strong and durable bond between the elastomer and the insert material.
The following operations form the complete process:

- Cleaning the surfaces of any pollutants remaining from previous work;
- The creation of a suitable roughness to ensure the best adhesion, e.g. by sandblasting;
- Surface activation and eventual drying;
- The adhesive is applied and dried, either at room temperature or by means of a thermal cycle in an oven, suitable for materials that come into contact with foodstuffs;
- Stabilisation and storage time in a contaminant-free environment.

Vulcanisation

Semi-finished elastomers must go through successive transformations, possibly be bonded together (or with other elements) and then be fixed in their final form through the process of vulcanisation. Vulcanisation is a process used in the production of elastomers, which consists of the formation of a molecular lattice obtained by bonding polymer chains together through the presence of other substances. In order to be carried out, the vulcanisation process requires, in addition to the possible conformation, a considerable amount of heat, generally under pressure.

Depending on the type of article, curing can take place discontinuously (on individual moulded parts) or continuously (e.g. on drawn or calendared parts), by transmitting heat through the metal walls of presses, moulds or rollers or directly through fluids (hot air, steam, etc.).

In-mould vulcanisation

In-mould vulcanisation is the most widely used system for the production of rubber articles; a certain amount of compound is compressed inside a metal mould and takes on its shape while being heated under pressure for a suitable time.

Autoclave vulcanisation

The autoclave is a large, cylindrical, watertight vessel into which saturated steam (at high pressure and temperature) can be fed; the articles to be cured are loaded into it for the time required to complete the process.

The pressure required to ensure proper curing is provided by the steam itself or by inert fluids (nitrogen, water, etc.) or by devices such as bandaging or the use of inflatable air chambers (with steam or hot water) that press the article against the walls of any counter-moulds.

Vulcanisation with hot air

Many products (extruded products, calendered products) can be vulcanised by passing through hot-air ovens. The pressure can be ensured by means of product-specific measures; the heat exchange, for a certain time under pressure, allows vulcanisation to take place.

Vulcanisation in rotocure

Rotocure vulcanisation is a continuous vulcanisation system for obtaining vulcanised sheets from calendered material. The rotocure is a machine consisting of a heated vulcanising cylinder (e.g. by diathermic oil or steam) around which a belt is wound, tensioned by deflection cylinders. The tension generates the pressure required for the vulcanisation process between the vulcanising cylinder and the belt. The calendared material passes between the belt and cylinder and is cured by temperature and pressure. The required vulcanisation time is ensured by setting an appropriate feed rate for the entire system.

Post-curing

In some cases, in order to ensure that the required standards are achieved, further heat treatment following vulcanisation is necessary in order to

- complete the curing process;
- ensure a significant technical and mechanical improvement;
- eliminate previously created residues and volatile waste;
- eliminate surface and bulk tensions created in the various process steps.

Post-curing is carried out using ovens with forced air circulation, in which the products are arranged in such a way as to avoid deformations, using hooks or trolleys with horizontal shelves or rotating baskets, which are loaded to about half their maximum volume.

At the end of the cycle, the trolleys are removed and placed in special cooling zones under fume hoods. The rotating carriages are kept rotating during both the oven cycle and the cooling phase in order to limit deformations.

Finishing

Deburring

The operation, which consists of separating the article from the system of channels (sprues) that serve to distribute the rubber throughout the mould cavities, or from burrs, is carried out by cryogenic machines for most articles, while the remainder is processed manually (simple tearing and separation operations).

Manual treatment is necessary for those workpieces on which cold treatment would not allow discrimination between the scrap and the article, resulting in many pieces breaking.

Cryogenic deburring allows separation through the mutual impacts of articles and scrap when brought to very low temperatures within rotating containers; sometimes separation is supported by the use of steel balls whose impacts shorten the process. The necessary low temperature is provided by the expansion of liquid nitrogen from an external tank that is charged at rather low pressures.

The cryogenic deburring phase is followed by an initial screening operation, to separate the parts from the coarser scraps, which may be followed by a fine screening operation to remove the smaller scraps. Screening is conducted on vibrating perforated tables that are part of the deburring machine or on other vibrating screens.

Grinding

It is necessary to differentiate between the so-called tumbling or centrifugal grinding and cryogenic grinding: both are performed in order to eliminate residual burrs still present on the workpieces after deburring operations, but cryogenic grinding, also known as a nitrogen grinding, applies to all products with burrs of significant length, which tumbling grinding would not be able to eliminate.

Cryogenic grinding uses machines consisting of a rotating container in which the workpieces are brought to temperatures around -70°C, by means of nitrogen, and are pelted with steel shot (small spheres with a diameter of 0.4-0.6 mm) thrown from a turbine; this is combined with a small screen for separating the workpieces from the shot.

For smaller articles, machines called tumblasts are used, in which the steel shot is replaced by a finer shot made of polyester, glass or other material.

Tumbler grinding uses machines with rotating baskets that are filled with a certain amount of workpieces, a certain volume of abrasives and water at room temperature, which is usually recovered and filtered at the end of the cycle or replaced with fresh water (open cycle).

Cycle time and rotation speed are set on the tumblers and the grinding operations are started, which go on without workers' assistance. At the end of the cycle, the tumblers are emptied into a perforated container, assisting the operation with pressurised water jets, so that no workpieces remain inside the tumblers; the container is then handed over to the separating machine, where a jet of water allows the workpieces to be transferred to the drying basket, while the abrasives separate by gravity. When sufficient load is reached in the drying basket, it is set in rotation and the drying system, consisting of a fan and electric heating elements, is activated.

Part treatment times are variable depending on the type of material and its hardness, the ratio of part diameter to thickness, or chord, the level of burrs existing and whether or not cryogenic finishing was previously carried out. As an approximation, however, treatment times ranging from 6-8 hours up to 18 hours can be considered. The amount of material for each cycle depends on the same factors affecting the cycle time; generally, the amount of abrasives and water used is kept fixed.

Sorting

Once cooled, the parts are subjected to a quality control and then, if required, to a sorting operation. The sorting operation can take place either with the aid of special machines or manually by trained operators.

The sorting operation is normally carried out on all articles produced and consists of an electronic or visual check of each piece in order to separate the defective ones created during the various stages of the process as well as to eliminate all foreign matter present. Based on a sample investigation of the defects that may have affected the production batch, the most appropriate sorting methods are defined, which may concern one or more sides of the product and/or its edges (external and/or internal).

Packaging, storage and shipping

Standard packaging is performed using polyethylene bags of various sizes, which are filled with pieces in an easily manageable number, counted by means of sample weighing systems or in some cases by means of special piece-counting machines. Larger products are generally packed using polyethylene film.

The bags are normally equipped with UV filters and hermetically sealed.

The bags are then normally placed inside corrugated cardboard boxes in such a quantity as to ensure adequate storage for the level of deformation permitted on the product. As far as possible, the boxes are filled to their full volume to prevent sagging when placed on top of each other and sealed with strips of adhesive tape.

Packaging containing the product must be identified with the necessary information, including through the use of barcode or RFiD systems, both for proper traceability and for proper storage.

Packaged products are delivered to the finished goods warehouse, from where they can be shipped directly to the customer or end up in storage.

B) PROCESSING IN LIQUID FORM (LATEX)

Generalities

Natural latex

Natural latex consists of an aqueous phase, the so-called serum, and a solid phase, the finely divided negatively charged rubber particles stabilised by an outer protective layer of proteins and natural sodium resinate. Chemically, latex is a complex emulsion consisting of water (60%), 'poly-isoprene' rubber (35%), proteins and enzymes (3%) and others such as resins, hydrocarbons, starch granules, secondary metabolites (alkaloids), and inorganic salts (2%).

A few hours after extraction, the latex can coagulate, due to the action of enzymes and bacteria. To prevent coagulation, a certain amount of ammonia is added as a preservative or a secondary preservative is also dosed to use less ammonia.

Immersion-treated latex is used in a variety of application fields ranging from the production of technical articles and foam rubber and hoses to more specific areas such as water-based adhesives, door and window profiles, hoses for irrigation and food transfer, flooring and gaskets for the automotive industry, gaskets and hoses for the aviation industry, carpet and textile coating, paper waterproofing, the binding of cork and leather scraps and bitumen upgrading for road pavements.

Synthetic latex

Synthetic latex is an aqueous colloidal dispersion of synthetic rubbers (e.g. SBR, NBR and CR), obtained through the emulsion polymerisation of one or more monomers. The polymerisation mixture contains, in addition to the monomer(s) and water, a number of additives, such as emulsifiers, activators, regulators, inhibitors and other chemical agents. After polymerisation, unreacted monomers are removed. Finally, stabilisers are added in order to protect the latex from the oxidising action of atmospheric oxygen.

At the end of emulsion polymerisation, the synthetic latex has a concentration of around 25-35%, which is insufficient to allow them to be processed directly. Further concentration is therefore carried out by skimming or evaporation.

Most synthetic latexes are 'anionic', which means that their particles have a negative electric charge. In contrast, latexes whose particles have a positive charge, so-called 'cationic' latexes, are very suitable

for impregnating and coating textiles or paper with a negative electrical charge. Anionic latexes are not suitable for these applications, as their particles are repelled by the also negatively charged particles of textiles.
The use of synthetic latex has led to the development of important new applications, such as carpet backing, paper processing, bitumen processing, etc.

Latex compounds - formulation

The latex compound formulation is designed specifically for the intended application. A series of ingredients are added to the raw material (latex) in order to make the latex vulcanisable.
In addition to the normal solid rubber chemicals, such as sulphur, vulcanisation accelerators, anti-aging agents, fillers, pigments, softeners, flame retardants, etc., which are also available in dispersion or emulsion form for latex, various special latex chemicals are also required for the production and processing of latex compounds, e.g. emulsifiers, dispersants, stabilisers, thickeners, humectants, foaming agents, foam stabilisers, coagulants, heat-sensitisers and preservatives. All compounding ingredients are added to the latex in the form of an aqueous solution, emulsion or dispersion.
For direct processing, the latex must have a higher rubber content. The main concentration processes are centrifugation, evaporation and skimming.
Centrifugation is the most common process. With this process a latex with a 60% concentration can be obtained. Most of the non-rubber components of the latex are removed along with the whey during centrifugation.
By diluting the centrifuged latex with water and centrifuging it a second time, a very pure latex concentrate is obtained. Depending on the low content of non-rubber components, articles obtained from latex centrifuged two or more times are very transparent, have good insulating properties and low moisture absorption.
Latex obtained by evaporation, with approximately 72% dry matter, is very stable against chemical and mechanical influences. For this reason, this grade is very suitable for the production of water-based adhesives.
For skimming, which is carried out in a similar manner to the skimming of milk, the latex is mixed with skimming agents. These substances cause a reversible agglomeration of the rubber particles, which, due to their low specific weight, rise to the surface. The underlying whey layer is drained off; what remains is a concentrated latex with a rubber content of about 66%, with a low percentage of non-rubber components, which is an advantage in the production of rubber threads.
Other methods of concentration are electrodecantation and filtration. For the latter, filters with pores smaller than the smallest rubber particles are used.
In addition to the concentrated latex grades described, there are other special modified grades, such as, for example, prevulcanised latex and grafted latex.
Pre-vulcanisation is done by simply heating the latex with vulcanising agents and then centrifuging it. This removes the unprocessed vulcanising agents and enables the production of pre-vulcanised latexes with different moduli. These latexes are used in the manufacture of articles by dipping, especially game balls.
Grafted latex, known commercially as Hevea plus MG, consists of natural latex onto whose elastomeric chains methyl methacrylate is polymerised by grafting. The percentage of methyl methacrylate is usually 30% or 40%. Grafted latex is used for specific applications, e.g. for the production of adhesives.
All the ingredients of the mixture are added to the latex in the form of separately prepared aqueous solutions, emulsions or dispersions.
Notable exceptions from this general rule are the addition of certain dry substances (fillers) in certain latex foam compounds and the direct addition of certain plasticising substances.
The complex of operations relating to this stage of processing can be summarised as follows:

a) withdrawal of latex from the storage-homogenisation tank by vacuum, its automatic dosing and transfer of the quantity to the packaging tank;
b) dosing of individual components in appropriately sized containers;
c) introduction, by gravity, of the semi-finished products into the packaging tank, in the order of the formulation;

d) these containers are left in the room for the time necessary to give the mixture the desired degree of seasoning;
e) compound filtering and transfer to production lines.

Components

Emulsifiers

Emulsifiers are substances used in the production of stable emulsions, i.e. the suspension of tiny droplets of a liquid in another liquid, which can be divided into three groups:
– anionic emulsifiers;
– cationic emulsifiers;
– non-ionic emulsifiers.

Anionic emulsifiers are mainly alkali salts of fatty acids, resin acids, aliphatic and aromatic sulphonic acids.
Cationic emulsifiers are mostly hydrochlorides of long-chain fatty amines.
Non-ionic emulsifiers are mainly condensation products of long-chain alcohols or fatty acids with alkyl oxides, mainly ethylene oxide.
All liquid compounding ingredients that are not soluble in water are added to the latex in emulsion form. Anionic emulsifiers are used for anionic latexes, cationic emulsifiers for cationic latexes; non-ionic emulsifiers can be used for both anionic and cationic latexes.

Dispersants

Dispersants, in the form of an aqueous solution, at as low a concentration as possible, have the task of preventing the agglomeration of fillers or other solid substances. A 1-2.5% ammonia solution of casein (the most important protein substance in milk) is used as a dispersant.

Stabilisers

Stabilisers are defined as those substances used to prevent premature coagulation of latex compounds. Stabilisers give the latex compound a certain stability against chemical and mechanical influences as well as the effects of temperature. Almost all emulsifiers are also good stabilisers.

Thickeners

Thickeners are substances that increase the viscosity of latex compounds, e.g. textile coating compounds. They are high molecular weight substances, and can be either natural or synthetic. Natural thickeners are e.g. glue, gelatine, agar-agar, etc. Synthetic thickeners are e.g. sodium polyacrylate, ammonium polyacrylate and polyvinyl alcohol. Many thickeners are at the same time skimming agents, and may cause a certain degree of skimming in latex mixtures that are not very concentrated; the danger of skimming is less in more concentrated mixtures.

Coagulants

Coagulation is an important stage in the processing of many articles, e.g. in dipping and production of porous articles. To achieve coagulation, coagulants are used, which can be divided into two groups:
– coagulants that act spontaneously and energetically;
– coagulants that act progressively, weakly or only when heated.

The first group includes organic acids (formic acid, acetic acid, lactic acid), polyvalent metal salts (calcium and aluminium chlorides or nitrates) and organic salts (cyclohexylamine acetate).
The second group includes ammonium salts, zinc oxide, sodium fluosilicate, polyvinylmethylether, as well as certain siloxanes. Coagulants that act only when heated are also called heat-sensitising agents, because with their help it is possible to produce “thermosensitive” latex compounds.
Such mixtures can be stored for several hours at room temperature without coagulating, but coagulate spontaneously when heated to a certain temperature.

Humectants and foaming agents

For latex compounds intended for impregnation and coating of textiles and other materials, humectants are required. For synthetic latexes, the addition of humectants is superfluous, as synthetic latexes already have good wetting properties. Alkali salts of fatty acids are often used as foaming agents.

Foaming stabilisers

In the processing of latex foam, there is often the problem of the foam coming apart even before coagulation begins. The pores become enlarged and eventually burst. By adding a foam stabiliser to the latex mixture, this problem can be remedied.

Preservatives

Latex compounds often contain protein substances such as casein and certain skimmers and thickeners. These natural products tend to putrefy with prolonged storage, giving latex an unpleasant odour. With the help of suitable preservatives (e.g. sodium-o-phenylphenolate), putrefaction can be prevented.

Vulcanising agents

Sulphur with accelerators and zinc oxide is usually used for vulcanising latex compounds. Normal sulphur for vulcanisation is very difficult to disperse, as it tends to clump easily. For this reason, only sulphur with a very high state of subdivision, so-called colloidal sulphur, can be used, which enables perfect vulcanisation due to its even distribution.

So-called ultra-quick curing agents are usually used as accelerators, with the aim of quickly completing the curing process at temperatures as low as possible.

Zinc oxide acts as an activator for accelerators. For the vulcanisation of latex articles, zinc oxide is indispensable: it carries out the cross-linking and at the same time serves as an ‘absorbent’ for the hydrochloric acid that is released. Zinc oxide also has a special function in the case of special latexes with reactive carboxyl groups: it reacts with the carboxyl groups contained in the rubber molecule and performs cross-linking without accelerants and without sulphur.

Anti-ageing

In order to improve the ageing resistance of latex articles, anti-ageing agents are added to the compound. The use of highly effective, non-staining anti-ageing agents is of particular importance in the production of foam articles, where large surfaces are in contact with air.

Fillers

Active fillers do not have the same reinforcing effect in latex compounds as in solid rubber technology. For this reason, only light inactive fillers such as chalk, kaolin and silica chalk are usually used. Carbon black is generally only used to dye articles black. By increasing the amount of fillers, vulcanised articles become harder, less elastic and with lower tensile strength.

Pigments

For the colouring of latex articles, mainly lightfast organic dyes, specially created for latex compounds, are used.

Inorganic dyes used in the processing of solid rubber are rarely used in latex compounds, as they sediment quickly due to their high specific weight and, in the event of a possible electrolyte content, could cause the compound to coagulate.

Plasticisers

Plasticisers are not as important for latex compounds as they are for solid rubber compounds; they are generally not even necessary. However, in order to achieve certain characteristics, such as a low modulus, plasticisers are also added to latex compounds.

Tackifiers

To improve the adhesive properties of latex compounds, so-called tackifiers must be added to them several times. Suitable tackifiers are certain coumarone resins, rosin or modifications of rosin.

Preparing emulsions

Liquid products that are not soluble in water, such as softeners, are made into a 50% or more concentrated emulsion, as the case may be, by vigorously mixing them with an emulsifier in a 5-10% aqueous solution. The emulsion can be added to the latex directly, while continuing to mix it.

Waxy or resinous ingredients are melted or dissolved with a suitable solvent and are then emulsified in an emulsifying solution at the same temperature by stirring vigorously.

Another difficulty is the hydrolysis of certain substances, resulting in increased turbidity and sedimentation. This can be solved by adding alkali to inhibit turbidity.

Preparation of aqueous dispersions

Solids that are not soluble in water are added to the latex in the form of dispersions. An aqueous dispersion is prepared by grinding the solid to be dispersed in an aqueous medium with a dispersing agent. Ball mills, which operate with porcelain balls of different diameters, have proved successful. The grinding of the pastes takes 24 to 48 hours; after this time, there is a dispersion, which can be added directly to the latex by mixing it.

The object of this processing is to obtain a semi-finished product that allows the introduction of water-insoluble solids into the mixture; this semi-finished product consists of a very fine aqueous dispersion of the solid substance.

The processing basically consists of the following steps:

– dosing of ingredients;
– wetting of powders and their coarse dispersion (we have previously referred to this as predispersion);
– grinding the coarse dispersion in jars or mills containing the right amount of grinding beads until the desired dispersion level is obtained (usually below 2 microns);
– control of dispersion characteristics.

Storage of natural and synthetic latexes

Storage must be particularly careful. The principles are:

– extreme cleanliness;
– very low light radiation;
– room temperature not exceeding 26°C.

General conservation criteria

The general principles regarding the criteria for storing latexes in storage and usage tanks can be summarised as environmental conditions, storage duration, tank size:

a1) It is always good to keep latexes from different batches separate and it is never convenient to mix a fresh batch with an old one. Any blending between different batches should only be done in special cases and with good reason.

a2) It is a good idea to fill the reservoirs up to the maximum possible level, so as to minimise the amount of air above the free surface of the latex; this reduces the formation of skin on the free surface of the latex.

a3) Tanks should be kept at a constant temperature of 5°C, either by cooling the walls of the tanks with running water or by burying the tanks deeply.
These precautions, which tend to preserve the characteristics of latex, are indispensable during the warm months and in the case of prolonged storage over several months: latex must not go below 5°C and above 20°C under any circumstances.

a4) In order to avoid stratification and deposits at the bottom of the tank or any unevenness in solids content between the various latex levels in the tank, it is advisable, especially in the case of large tanks, to subject the latex to periodic homogenisation treatments. (Every 12/24 hours, for 1 hour). If the tanks are not equipped with agitators, the latex can be completely recycled by taking it from the bottom and putting it in from the top using a diaphragm pump.

Maturation of latexes before industrial use

NR latexes undergo a maturation period before their industrial use. Taking into account what explained above, maturation is of great importance. Indeed, during the maturation process, an attempt is made to bring the MST (*Mechanical Stability Time*) to an ideal value for processing.
It should be emphasised that if the "degree of maturation" (seasoning) of an NR latex influences the pre-curing time of a compound, at the same temperature, relative humidity and pressure, there will be considerable variations in the production process.

Latex processing technologies

The rationale of any production from natural and synthetic rubber latex is based on rigorous research into the stability of the compounds for processing, culminating in their controlled stabilisation to achieve the desired products.

Each production system is extremely complex, not only because of the normal difficulties of the processes and their details, but above all because of the variability of certain factors, linked to the fact that latex, whether synthetic or natural, is a 'living' raw material.

Impregnation technology (*dipping*). The main processes

The impregnation process for the manufacture of "seamless articles" is one of the oldest processes. According to this procedure, aluminium, porcelain or glass moulds with the shape of the article to be produced are dipped in a vulcanisable latex compound; the moulds are then slowly pulled out, covered with a thin film and left to dry. Dipping and drying are repeated until the film has reached the desired thickness. The film is then solidified by curing in hot air and peeled off the mould. Several articles can be manufactured in this way, such as surgical gloves, household gloves, industrial gloves, electrician's gloves, baby bottle nipples, dummies, toys, play balls, weather balls, footballs, condoms, overshoes, etc.

The moulds are then extracted and the latex dried and cured. The thickness of the layer deposited on the moulds depends essentially on the temperature of the moulds themselves, the immersion time and the degree of concentration of the compound.

All coagulated films contain a number of water-soluble substances, such as coagulants, dispersants, electrolytes, etc., which then adversely affect not only the 'touch' but also the ageing resistance of the finished product. For this reason, articles produced by dipping are normally washed, with treatments of varying intensity depending on the intended use of the finished product. Washing, which usually takes place before curing, removes most of the water-soluble substances in a few minutes. The total elimination of these substances, however, requires a much longer washing process, which can only take place after curing and after separating the article from the mould.

Simple deposition

A simple immersion production process is defined as a process aimed at obtaining a finished article on an aluminium, glass or porcelain mould, with gelation of the compound on the mould itself not controlled by additional external or internal chemical compounds, and with fixing of the gel controlled by temperature

and ventilation with forced air in suitable dryers. The uniformity of the thickness, corresponding to the homogeneous distribution of the compound on the mould, is guaranteed by an appropriate mechanical action of rotation of the moulds, implemented immediately upon exiting the compound.

This immersion system is used to produce items of reduced thickness. A few examples are: condoms, surgical gloves for inspection, peon roses (special drainage tubes), sheaths for soil drainage measurements (used in pedology), rubberised threads, impregnation of textiles.

In other cases, as in the past, such a system has been used to obtain even very high thicknesses (2-3 mm) by making a proportional number of simple dips on synthetic core.

The factors that regulate this process are:

- the mould and compound temperature: the higher the temperature, the thicker the item will be;
- the viscosity of the compound: the higher the viscosity of the compound, the thicker the finished articles will be;
- the density of the compound: the greater the density of the compound, the greater the thickness of the finished articles;
- the total solid content (TSC) of the compound: this factor is decisive on the thicknesses for all production systems, whether immersion, thermoextrusion, coating, etc., since a low solid content will give greater shrinkage by virtue of the higher liquid content, which will be evaporated during processing, while a high solid content corresponds, all things being equal, to relatively greater thicknesses;
- the cross-linking density: a pre-cured compound will give higher thicknesses than a non-pre-cured compound;
- the speed at which the moulds exit the compound during immersion: increasing this speed will increase the thickness of the article;
- the presence of stabilising soaps as they increase the surfactant activity of the mixture.

Deposition with coagulant

A production process by immersion with coagulant is defined as a process aimed at obtaining a finished article on an aluminium, glass or porcelain mould, with gelation of the compound on the mould itself controlled by additional external chemical compounds (such as calcium nitrate in aqueous or alcoholic solution of varying concentration) and with fixing of the gel controlled by temperature and ventilation with forced air in appropriate dryers. The uniformity of the thickness, corresponding to the homogeneous distribution of the compound on the mould, is guaranteed by an appropriate mechanical action of rotation of the moulds, implemented immediately upon exiting the compound but, unlike the previous system, the presence of the coagulant favours rapid gelation, at least partial, with the achievement of relatively greater thicknesses.

In reality, in this process the immersion in the compound is preceded by an immersion in a calcium nitrate solution, in order to homogeneously distribute a thin nitrate film that will destabilise the compound during the actual immersion phase, forming the gel. It is in this sense that the coagulant in this case is said to be external (outside the compound).

This immersion system is used to produce articles of medium thickness, varying from around 0.3 mm to 1.3-1.5 mm. Greater thicknesses can also be obtained in this case with multiple immersions.

The factors that regulate this process are:

- the mould and compound temperature: the higher the temperature, the thicker the item will be;
- the viscosity of the compound: the higher the viscosity of the compound, the thicker the finished articles will be;
- the density of the compound: the greater the density of the compound, the greater the thickness of the finished articles;
- the total solid content (TSC) of the compound: this factor is decisive on the thicknesses for all production systems, whether immersion, thermoextrusion, coating, etc., since a low total solid content will give greater shrinkage by virtue of the higher liquid content, which will be evaporated during processing, while a high total solid content corresponds, all things being equal, to relatively greater thicknesses;

- the cross-linking density: a pre-cured compound will give higher thicknesses than a non-pre-cured compound;
- the speed at which the moulds exit the compound during immersion: increasing the speed will increase the thickness of the article;
- the presence of stabilising soaps, as they increase the surfactant activity of the mixture;
- last but not least: the concentration of calcium nitrate in the solution - the greater the concentration, all other things being equal, the greater the gel thickness - and the residence time in the mixture after it enters the tank: the greater the residence time in the mixture, the greater, all other things being equal, the gel thickness.

Thermal deposition (thermodeposition)

A thermal immersion production process is defined as a process aimed at obtaining a finished article on an aluminium, glass or porcelain mould, with gelation of the compound on the mould itself controlled by additional internal chemical compounds (such as polyvinylmethylether in an aqueous solution of varying concentration) and with fixation of the gel controlled mainly by temperature.

The uniformity of the thickness, corresponding to the homogeneous distribution of the compound on the mould, is guaranteed by a suitable mechanical action of rotation of the moulds, implemented immediately upon exiting the compound, but unlike the previous systems, the presence of the internal coagulant favours rapid gelation, at least partially, resulting in very high thicknesses: even up to 3 cm.

The factors that regulate this process are:

- the mould and compound temperature: the higher the temperature, the thicker the item will be;
- the viscosity of the compound: the higher the viscosity of the compound, the thicker the finished articles will be;
- the density of the compound: the greater the density of the compound, the greater the thickness of the finished articles;
- the total solid content (TSC) of the compound: this factor is decisive on the thicknesses for all production systems, whether immersion, thermoextrusion, coating, etc., since a low solid content will give greater shrinkage by virtue of the higher liquid content, which will be evaporated during processing, while a high solid content (TSC) corresponds, all things being equal, to relatively greater thicknesses;
- the cross-linking density: a pre-cured compound gives higher thicknesses than a non-pre-cured compound;
- the speed at which the moulds exit the compound during immersion: increasing this speed will increase the thickness of the article;
- the presence of stabilising soaps as they increase the surfactant activity of the mixture;
- the concentration of the sensitiser in the solution: the higher this concentration, all other things being equal, the thicker the gel will be;
- the residence time in the compound after entering the tank: the longer the residence time in the compound, the thicker the gel will be, other things being equal;
- zinc oxide concentration: higher thicknesses for higher ZnO content.

Extrusion

Elastic thread extrusion

One of the production processes is the extrusion of drawn elastic wire in tanks containing acetic acid (CH_3 COOH), which is directly responsible for the gelling of the compound. The compound is brought into the acetic acid bath by means of suitable glass dies immersed slightly below the surface of the liquid: the speed of the compound flow is regulated by pressure obtained from the difference in the head.

Immediately after gelation in acetic acid, the threads (about 400) pass into a hot water bath for washing and are collected on rollers of different diameters, resulting in a calculated stretching. This is followed by drying in appropriate ovens with counter-current air and the actual vulcanisation in the last stage of the ovens. At the exit of the oven, the wires are collected in bands and put in containers after an anti-adhesive treatment.

Thermoextrusion

Thermoextrusion is a special drawing system that exploits the thermal sensitivity of heat-sensitive compounds, which are passed through glass dies equipped with a heating jacket to obtain, for example, a tube, elastic wire or elastic strip.

Casting process

If a latex compound is poured onto a porous plaster surface, much of the water is absorbed by the plaster; a film remains on the surface, which can already be peeled off after partial drying. This is the principle on which hollow moulded articles such as toy animals and decorative figures are manufactured. Hollow moulds of porous material, usually plaster, are used for this purpose. The moulds, filled with the latex compound, absorb some of the water; over time, an increasingly thicker film is deposited on the inner wall. Once the desired thickness has been reached, the mould is emptied of the excess compound, which is still liquid, and dried at 70-100°C. The article can now be removed from the mould, dried completely and cured in hot air. Curing is usually followed by varnishing of the article. This process allows the use of a large quantity of fillers (e.g. up to 300 parts of clay or kaolin for 100 parts of rubber): as a result, the manufactured articles can vary greatly in hardness.

Manufacture of sealants

Sealants serve to hermetically seal the space between the pleated metal walls of a container, preventing air from entering. They are also used for glass containers with screw caps: the sealant is sprayed onto the inside wall of the cap in this case. Sealants used for tins of meat, olives and canned food in oil must have good resistance to fat and oil.

Impregnation

The name impregnation, or *dipping*, refers to a technique of depositing a rubber solution on a substrate, which can be a textile or non-woven.

The substrate passes into a tank in which there may be one or more cylinders; the excess of solution is removed with a series of knives (scrapers) inclined with respect to the substrate or by means of a foulard in which pressure is applied that pushes the solution into the fabric.

The substrate thus treated subsequently passes through a drying oven.

Generally, with this operation, a small amount of rubber is applied to the substrate and in a single pass the treatment is applied to both faces of the substrate.

The rubber solutions used can be solvent-based or water-based and the total solid content can vary from 5% to 30%.

Coating

Coating refers to various techniques by which a layer of rubber-based solution is deposited on a substrate, which may be a fabric, film, non-woven or metal.

The procedure consists of sliding the substrate on a roller into a bath of the solution to be deposited, then through squeezing cylinders into a drying and curing plant. This plant may consist of heated drums of large diameter, hot air dryers with good air circulation or infrared radiation.

The rubber solutions used can be solvent-based or water-based and the total solid content can vary from 10% to 60%. The concentration of the solution, the speed at which the fabric is led into the bath and the pressure exerted by the squeeze rolls on the impregnated fabric determine the amount of rubber deposited on the substrate.

In order to achieve better wetting, wetting agents can be added to the solutions, but these usually have the disadvantage of decreasing the adhesion between rubber and fabric. Alternatively, it is possible to dilute the solution in order to reduce its viscosity.

In particular, blade coating is the most widespread and, depending on the geometry of the coating head, allows the penetration of the solution into the substrate to be controlled, as well as the amount of material deposited, guaranteeing great precision in terms of weight and thickness.

In blade-on-cylinder coating, the substrate is in contact with a cylinder, usually made of metal, which acts as a driver for the substrate and is placed in contrast to the coating blade. The carrier passes through the gap between the cylinder and the blade, so that it is covered by a layer of solution before entering the drying oven.

In suspended blade coating, the blade rests on the fabric, which is bound by two cylinders: one placed before and one after the blade.

Annex B14.2

Technical glossary

Activation: Preparation of the insert surface to optimise adhesive adhesion

Adhesivation: Surface treatment of an insert to ensure a strong and durable bond between the elastomer and the insert.

Adhesive application: Creation of an adhesive layer that guarantees both good cohesion of the adhesive and optimal adhesion to the elastomer and the insert.

Base elastomer: Polymeric product in primary form (bales, granules, flakes, etc.) not yet cured or mixed with additives, dyes or fillers, or otherwise processed.

Calibration: Measurement aimed to verify the correct dimensions of the article.

Compression moulding: The process of producing rubber articles by moulding and subsequent vulcanisation of preformed semi-finished products using compression moulding presses.

Control equipment: Device governing all stages of closing, curing and opening of the injection moulding machine.

Cover: Rubber outer layer of a hose.

Deburring: An operation that consists of separating the article from the system of channels (sprues) that serve to distribute the rubber throughout the cavities of the mould; it is carried out depending on the type of article or mould, either by machine or manually.

Degassing: Operation to remove air trapped in the raw rubber compound inside the mould.

Elastomer: A macromolecular material that rapidly recovers its initial shape and size after the release of an imposed and relatively high deformation.[28]

Finishing: operation consisting in the detachment of excess material from workpieces. In the case of parts obtained by moulding, finishing is the detachment of excess material along the entire contour of the part, at the parting plane of the mould.

Impregnation: A technique also known as dipping, imbibition or *dipping*.

Injection moulding: The process of producing articles by pre-melting the material and pressure-injecting it into a multi-plate mould.

Latex: Colloidal dispersion of an elastomer in water.

Masterbatch: Well-dispersed mixture of rubber and one or more ingredients in known proportions, used as raw material for the production of the final compound [29] .

Mixing: The mechanical process of preparing a compound by means of a mixer.

Mould: Shaped container capable of withstanding moulding pressure to obtain defined parts in the desired shape.

Natural rubber: Cis-1,4-polyisoprene obtained from the botanical source *Hevea brasiliensis*, or other plant species.

Plate (in injection moulding machine): Movable or fixed, transmits the pressure and, if necessary, the required heat, via heating elements.

Post-curing: Heat treatment following vulcanisation.

[28] See standard UNI 7406:2020
[29] See ISO 1382:2020 'Rubber Vocabulary'.

Preformed semi-finished product: This may be raw compound moulded into various shapes or a special composite, such as rubber/metal, rubber/canvas or others.

Reinforcement: Layers of textiles or steel wire with a defined tensile strength.

Rubber: Depending on the context, for:
- *finished articles*: both flexible and elastic;
- *semi-finished products*: synonym for mixing or blending;
- *raw materials*: elastomer of natural or synthetic origin, used for the production of mixtures or compounds.

Rubber article: A finished article which may also require further processing (e.g. shearing / cutting from sheet) designed for a specific use and manufactured from rubber or rubber latex by mixing and/or moulding, extrusion, coating, dipping or other methods. A rubber article may consist almost entirely of rubber, such as a glove for medical use, or it may be coupled with reinforcing components other than rubber, such as a rubberized textile, a tyre, an elastomeric bearing or a rubber hose.

Rubber compound: An intimate mixture of one or more elastomers with other ingredients.

Spindle: Solid tube or steel cable of defined lengths and diameters with suitable ends for coupling.

Third-party processing: Processing carried out by a third-party company on behalf of a client company that retains ultimate responsibility for it (sometimes referred to as ‘tolling’ or ‘subcontracting’).

Transfer mould: A mould equipped with a pot to contain the compound required for the moulding process, which fills the cavities through holes and channels.

Underlayer: Inner layer in a rubber hose.

Vulcanisation: Chemical transformation, promoted by specific agents (e.g. sulphur) and generally activated by means of temperature and pressure, aimed at modifying the chemical structure of rubber, by cross-linking, giving it or emphasising its elastic properties.

Vulcanised rubber: Product of the vulcanisation of a rubber compound.

Annex B14.3

Frequently asked questions

Q1 *What is the specific property of rubber*?

The most important – and best known – property of rubber is elasticity, i.e. the ability to quickly recover its original shape and dimensions after being subjected to deformation (e.g. elongation), even to a great extent.

Q2 *What is meant by natural rubber?*

Natural rubber is a white, milky, complex aqueous emulsion obtained from the coagulation of the cortical secretions of certain tropical plants of the Euphorbiaceae family (the best known are *Hevea Brasiliensis* and *Hevea Guaianensis*). It is composed of approximately 60% water, 35% elastomer (rubber), 5% proteins, sugars, amino acids, mineral salts, enzymes and some carbohydrates that coagulates on exposure to air.

Q3 *What is meant by liquid natural rubber (latex), dry rubber and solid rubber?*

Liquid natural rubber (latex) is obtained directly from plants and then through concentration, skimming and centrifugation methods is used directly in formulations for various production processes.
Dry rubber, on the other hand, is obtained by dilution of the latex to 15% and acidification with formic acid and subsequent coagulation with precipitation at the bottom. A subsequent passage through a calender with rotating cylinders gives it the form of smooth or creped sheets, which are then heat-dried. The rubber is also marketed in the form of bales.
Solid rubber is the residue of evaporation at a temperature of 70°C of natural rubber latex.

Q4 *What is an elastomer***?**

The term elastomer refers to natural or synthetic substances that have the chemical-physical properties typical of natural rubber, the most peculiar of which is the ability to undergo elastic deformation, only to recover its dimensions once the stress has been removed.

Q5 *What is meant by masterbatch?*

A masterbatch, technical term for "non-accelerated compound", refers to a well-dispersed mixture of rubber and one or more ingredients in known proportions to be used as a starting material for the preparation of the final compound. Masterbatches can be used to facilitate processing or improve the properties of the final product, or both, and above all to enable it to be transported, thus reducing the risk of scorching, i.e. triggering the curing process.

Q6 *Do global migration tests with food simulants apply to rubber articles?*

Yes, according to the requirements set out in Ministerial Decree 21.3.73 as amended.

Q7 *What tests do companies perform to ensure the suitability of rubber articles intended for food contact?*

Companies are obliged to carry out both global and specific migration testing, in accordance with the provisions of Ministerial Decree 21.3.73 and subsequent amendments and additions. Migration tests must be performed according to the intended use of the articles, in accordance with the provisions of Ministerial Decree 21.3.73 as amended.

Q8 *Are there technical standards defining requirements for rubber?*

Yes, there is an English language version:

- ASTM D1418-22 Standard Practice for Rubber and Rubber Latices -Nomenclature

- ASTM D5538-13R18 Standard Practice for Thermoplastic Elastomers-Terminology and Abbreviations
- ISO 1629:2013 Rubber and latices - Nomenclature *(last reviewed and confirmed in 2018).*
- ISO 1382:2020 Rubber Vocabulary: a trilingual (English/French/Russian) vocabulary containing the definitions of approximately 400 terms in general use in the rubber industry.
- ISO 35:2004 Natural rubber latex concentrate - Determination of mechanical stability *(last reviewed and confirmed in 2020).*
- ISO 123:2001 Rubber, latex - Sampling.
- ISO 124:2014 Latex, rubber - Determination of total solids content *(last reviewed and confirmed in 2019)*.
- ISO 125:2020 Natural rubber latex concentrate - Determination of alkalinity.
- ISO 126:2005 Natural rubber latex concentrate - Determination of dry rubber content *(last reviewed and confirmed in 2018)*.
- ISO 506:2020 Natural rubber latex concentrate - Determination of volatile fatty acid number.
- ISO 706:2004 Rubber latex - Determination of coagulum content (sieve residue) *(last reviewed and confirmed in 2018)*.
- ISO 2027:1990 (EN) Natural rubber latex concentrate, evaporated, preserved - Specification *(last reviewed and confirmed in 2021)*.

Q9 *Are there international guidelines for the rubber industry?*

There is the Council of Europe Resolution: Resolution ResAP (2004) 4 on rubber products intended to come into contact with foodstuffs: https://rm.coe.int/09000016804e9fce.
Furthermore, there is a similar resolution concerning silicones: Resolution ResAP (2004) 5 on silicones to be used for food contact applications: http://rm.coe.int/09000016804e206f.

B15. FOOD PACKAGING MACHINES

B15.1. Characterization of the sector

B15.1.1. Field of Application of Guideline

This guideline applies to companies that produce food packaging machines[30].

B15.1.2. Applicable legislation

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.[31]
- Directive 2006/42/EC implemented by Legislative Decree 27th January 2010 n. 17 relating to machinery and which modifies Directive 95/16/EC (recast).
- Regulation (EU) 2020/1245 amending and correcting Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food.

Italian legislation

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

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

[31] It replaced the Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

- Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, intended to come into contact with food or substances for personal use as amended.
- Ministerial Decree No. 76/2007 on regulation regarding the hygienic discipline of materials and articles of aluminium and aluminium alloys intended to come into contact with foodstuffs.

The following references may be helpful:

- Ministry for Health Circular 24th January 2006 on materials and articles intended to come into contact with food: companies and food industry responsibilities[32]
- Note DGSAN 20072-P 20/05/2014 with indications for checks on objects made of metal alloys and on objects coated with porcelain enamel intended for contact with food.

B15.1.3. Phases of the production process: flowchart and description

For the manufacturing process of food packaging machines, many companies resort to subcontracting for the manufacture of custom-made parts, others purchase groups of machines, and still others purchase complete machines to complete food packaging lines.

The flowchart shown below is intended to schematically represent the machine manufacturing process.

Each company will assign executive tasks and responsibilities according to its own technical and organizational structure, bearing in mind that it is in any case responsible for placing machines on the market that comply with the applicable laws.

The production process of food packaging machines illustrated below is described without attribution of task execution.

B15.1.3.1. Production flowchart

Figure B15.1 illustrates the flow diagram for the creation of food packaging machines (the part in grey is compliant with the GMP Regulation (EC) 2023/2006 as amended).

B15.1.3.2. Brief description of process phases

Issuance of user company requirements specifications (URS)

The Specifications (called User Requirement Specifications, URS) constitute an integral part of the customer's purchase order. For example, they detail:

- foods to be packaged and the chemical, physical and dimensional conditions of the food;
- format of each package to be produced: dimensions, weight, hourly production;
- shape of packaging material, such as: reel, die, cardboard, etc.;
- environmental conditions of the production site: ambient temperature range, relative humidity, technical gases, power supply;
- possible list of commercial systems to be installed on the machine: printers, cameras, quality control devices, etc.;
- other information of a technical-organizational nature.

[32] The circulars of the Italian Ministry for Health are tools that are issued in support of particular legislative aspects.

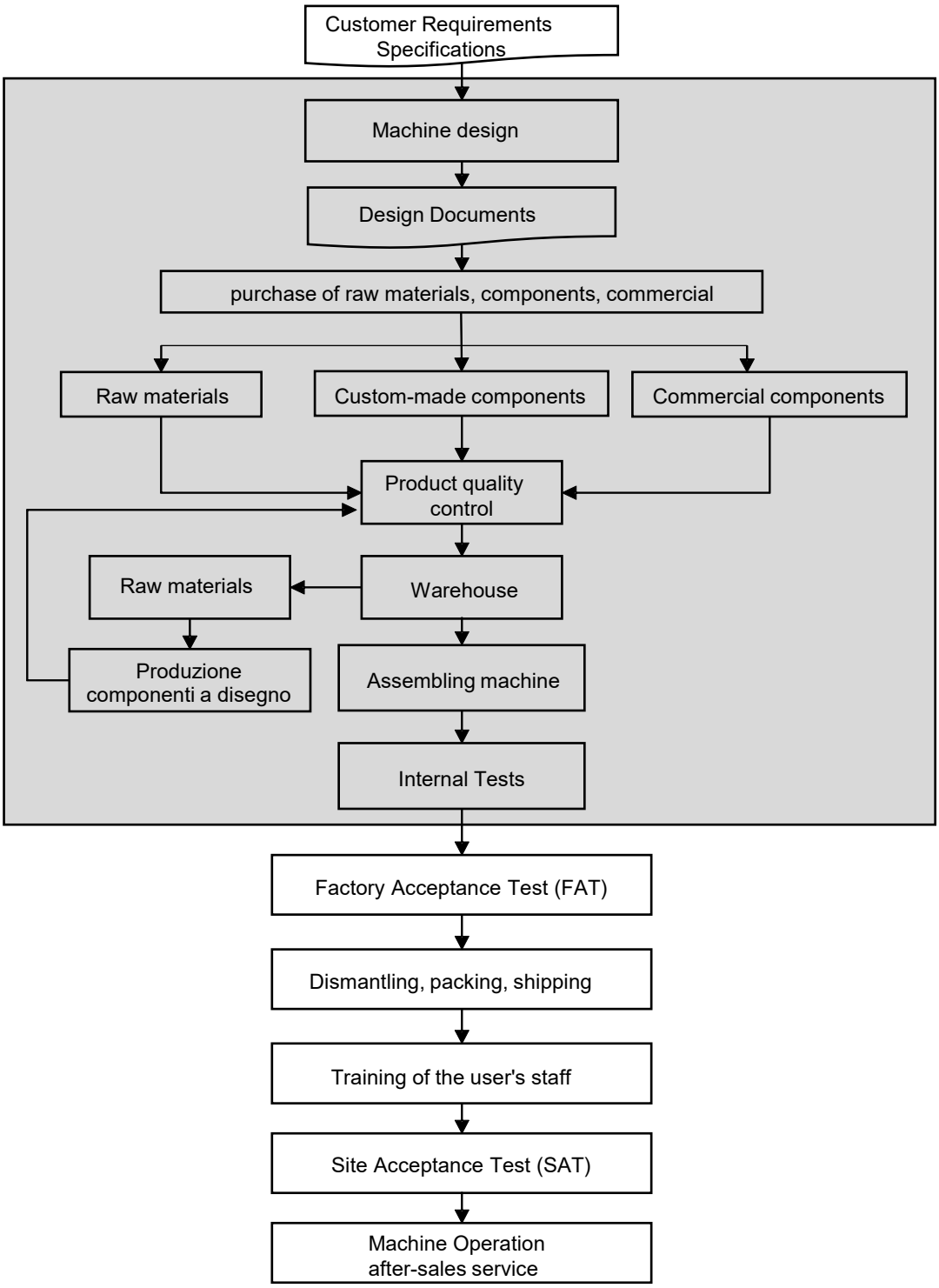

Figure B15.1. Production flowchart for the construction of the machines for food packaging

Machine design

The packages to be produced vary from product to product, from user company to user company and often from point of sale to customer point of sale, since, as is known, the packages represent a secondary marketing factor in the consumer's choice. To reduce the variety of machines, manufacturers divide the machines into two distinct sections:

- *Basic machine*: includes the operating mechanisms, the command-and-control part. It is generally standardized, i.e. it is repeated the same, or almost identical, for each similar supply and normally has no parts in contact with food.
- *Customization*: the customized machine part is built specifically on the packages requested by the user company, taking advantage of past creations, where possible. This area normally contains the parts in contact with food.

The design documents relating to the parts in contact with food contain information on the materials to be used, supply specifications for raw materials and commercial components and possibly other information depending on the company organization.

Supplying

In the procurement phase, we acquire what is necessary to build the machine according to the design specifications. In detail:

- raw materials to obtain customized components in the internal workshops, for example metal alloys, silicone tubes, Teflon sheets, etc.;
- custom components from the subcontracting system;
- commercial components and systems, such as solenoid valves, pumps, instrumentation, etc.

The customized components are made in the manufacturer's internal workshops, or by subcontractors with direct purchase of materials or with the supply of materials on contract from the clients, or more often with mixed internal and external procurement.

Quality control of supplied products

All supplied products are subjected to quality control to ensure compliance with design and manufacturing specifications. The control is extended to the documentation required by each specification: certificates, instruction manuals, drawings, etc.

Warehouse

Warehousing has the purpose of neatly setting aside what has been supplied until all the components according to the drawing, all the components and commercial systems have been acquired, protecting their quality.

Montaggio della macchina

Completato l'approvvigionamento, si provvede al montaggio della macchina secondo gli schemi di progettazione. Si esegue il montaggio meccanico, il montaggio elettrico e pneumatico**,** preservando le caratteristiche, compresa la rintracciabilità.

Assembly of the machine

Once the procurement is complete, the machine is assembled according to the design diagrams. Mechanical assembly, electrical and pneumatic assembly is carried out, preserving the characteristics, including traceability.

Internal tests

The internal tests have the purpose of verifying that the operation of the machine complies with the design specifications and requirements of the user company. In detail, electrical and pneumatic energy is supplied to the machine, the movements are fine-tuned, the instruments are calibrated, the productivity and quality of the packages are checked, and compliance with the machine safety regulations is verified.

The internal tests are conducted in temporary conditions: the packaging materials are generally original; the foods are almost always replaced by temporary products that adequately represent the final foods (for example water replacing liquid foods).

Factory Acceptance Test (FAT)[33]

FAT is carried out in the presence of representatives of the user company and has the purpose of verifying that the machine meets the minimum requirements to be successfully shipped and installed. In this phase, the functionality and compliance with the productivity, safety, materials and hygiene requirements of the machine are verified.

FAT is also conducted under temporary conditions.

Disassembly, packaging and shipping

If FAT has been passed, the user company authorizes the shipment of the machine to its installation site. In this phase, the machine is dismantled if its dimensions do not allow for easy transport and it is protected with packaging suitable for the type of transport.

Reassembly at the user company's premises

The purpose of the reassembly is to install the machine in the operating conditions foreseen by the contractual specifications.

Training of the user company's staff

The training has the aim of making the user company's staff suitable for equipping and operating the machine in safe conditions, carrying out routine maintenance and cleaning. This activity is part of the user's GMP and is required by the Machinery Directive (Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 relating to machinery and which modifies Directive 95/16/EC).

Site Acceptance Test (SAT)

SAT represents the final testing of the machine and is carried out by the user company's personnel (in the presence of the machine manufacturer), in the production operating environment, with final packaged and packaging materials. It has the purpose of verifying the satisfaction of all contractual requirements, including binding and supporting documents. Passing the SAT marks the transfer of ownership of the machine from the machine manufacturer to the user company. The test is part of the user's GMP.

Machine operation and after-sales assistance

At this stage the machine produces the specified products. The machine manufacturer supplies the spare parts agreed or requested by the user company and carries out preventive

[33] In some cases, it is not possible to carry out internal tests and FAT in such detail, due to the technical structure and boundary conditions (for example, modeling or low-temperature packaging machines).

maintenance or on request. In this phase, if required, more or less substantial modifications to the machine can be carried out. This activity must be conducted in accordance with the user's GMP.

B15.2. Fulfilments deriving from the application of the Regulation (EC) 2023/2006

In this part are described the activities and the implementation enacted by the supply chain of manufacturers of machines intended for food packaging to conform to the Regulation (EC) 2023/2006 as amended. Since this Regulation was laid down when the quality assurance systems had already become a daily work tool in most of the manufacturing businesses, it is likely that these businesses already produce in conformity with technical specifications laid down by themselves.

All the same, should it be necessary, the Quality Assurance System and the Quality Control System should be extended to ensure:

> "[...] that the materials and articles are constantly manufactured and controlled, to ensure their conformity to 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" (art. 3 paragraph a Regulation (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006 as amended. Every paragraph is hence the response of the manufacturers of machines intended for food packaging to the requirements of the article in question. To facilitate reading, the paragraphs keep the same title as the article considered, while the subparagraphs indicate specific subjects.

B15.2.1. Quality Assurance Systems (Regulation (EC) 2023/2006, art. 5) and Size of the business

Quality Assurance Systems

The manufacturer of machines intended for food packaging should establish and maintain a Quality Assurance System capable of ensuring the achievement of the objectives laid down by the Regulation and described in the general guideline.

The Quality Assurance System should be documented so as to enable control by the competent authorities.

The Quality Assurance System should establish rules and procedures that regulate the company activity, at least concerning the following points:

- conformity to the requisites of the legislation in force;
- human resources and training;
- design;
- raw materials and suppliers including suppliers of goods and services;
- production;
- quality control;
- storage, handling and shipment;

– complaints and corrective and preventive actions.

The system must ensure that the future legislative changes are adopted in all the phases of the company process also including the specifications and any contracts with qualified suppliers.

It is recommended to prepare a procedure that allows for the implementation of changes resulting from updates to current legislation relating to materials intended to come into contact with food.

Size of the business

Independently from the business size, it should at any rate be guaranteed that the Quality Assurance System, as demanded and finalised by the Regulation (EC) 2023/2006 as amended, is always applied.

The system should be established, implemented and run taking into account the actual size and complexity of the company as well as the technical and human resources available.

On its own premises the business has to at any rate be capable of guaranteeing the application and running of the Quality Assurance and Quality Control System in order to obtain finished materials and products in compliance with the legislation in force on FCMs.

B15.2.1.1. Human resources and training

The *Business operator,* in compliance with the objectives of the Regulation (EC) 1935/2004 as amended and the Regulation (EC) 2023/2006 as amended is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 as amended is applied at all levels of their organization.

The operative aspects relating to the application of the provisions laid down containing in the Regulation (EC) 2023/2006 as amended can be entrusted by the Business operator to competent and adequately trained people that have to at any rate have at their disposition adequate means to ensure that the requisites of the Regulation (EC) 2023/2006 as amended are respected.

The *company organization* has to at any rate enable the location of the functions to enable inspection by the Competent Authorities.

All *company personnel* potentially involved have to be informed on the principles of GMP, on the obligations that derive from the Regulation (EC) 2023/2006 as amended, on its objectives and on the policy for applying the Regulation.

The *business* should operate and implement procedures for identifying personnel training requirements and has to see to the training of all staff regarding the tasks that might affect the compliance to the said Regulation.

The *personnel* assigned to GMP control activities should be qualified on the basis of the training and the experience acquired.

An appropriate registration of the training process of all personnel must be kept.

B15.2.1.2. Production

The company production phase extends from design and planning to storage of the finished product.

The production process includes all the company phases that combine to guarantee that the end product complies with the legislative, technical and performance requisites laid down at the planning phase to guarantee the suitability for intended use.

Hence the Quality Assurance System should comprise procedures that regulate all the phases listed hereafter:

- design and development of the machine;
- selection of starting material and suppliers including suppliers of goods and services;
- arrival of raw material and storage;
- control of raw material/starting materials;
- production processes and traceability;
- control of process parameters, where applicable;
- control during production;
- control of the finished machine.

Design and development of the product

The most important concept implied by the GMP is that of a product designed to be compliant to the legislative requisites on materials and articles intended for food contact (FCMs).

Distinctions can be made between the design of a machine and the adaptation of a machine to the needs of the user company; that is, you have a machine developed for a specific use (e.g. filling a creamy food) which is subsequently adapted to the precise requests of a user company, such as filling a jar or bottle.

In any case, the machine must:

- meet the performance requirements for the end use for which it is intended;
- meet the requirements of current legislation for materials intended to come into contact with food to be packaged.

For this purpose, the machine must be made with raw materials which, after checking, guarantee compliance with the legislative requirements regarding contact with food in all phases of the process.

To enable the development of a machine design that complies with the mandatory requirements, the following information (by way of example and not limited to) on foods must be known and available:

- the type of food to be packaged;
- the conditions of the food, such as: temperature, humidity, acidity, presence of surface fats, etc.;
- any additional processes necessary for the preservation of the food, such as: modification of the atmosphere inside the package, injection of brines or other substances.

Selection of the starting materials and the suppliers of goods and/or services and/or third parties

The machine manufacturer is required to use only approved starting materials, for which he has, through the supplier's information and/or through checks and verifications carried out during the design phase, all the data necessary to guarantee the conformity of the packaging product meets legal requirements, including restrictions due to conditions of use.

Observance of the following requisites should also be ensured:

- declaration of compliance according to what has been established by the applicable European and/or Italian legislation;
- traceability according to the Framework Regulation (EC) 1935/2004 as amended (where applicable);
- conformity to the Regulation (EC) 2023/2006 as amended (where applicable).

Any supply of starting material has to be kept under adequate control.

It is good practise that the starting materials are procured from qualified suppliers. By qualification is meant a pre-established, organized and documented process that can also include supply contracts.

One is also advised to verify, also through periodical visits of inspection (audits) the Quality Assurance System of the supplier of starting materials or third parties to ascertain whether it is compliant with the requisites as laid down by the Regulation (EC) 2023/2006 as amended, where applicable.
In the event that the subcontractor does not operate under GMP, the machine manufacturer is required to ensure that the raw materials and/or semi-finished products he will use are suitable for producing materials and objects suitable for contact with food: this check, which must be carried out at the expense of the machine manufacturer, can be carried out both by verifying composition certifications issued by suppliers and by carrying out appropriate technical-analytical determinations.

Conformity of the production system

The production process has to kept under adequate control with a Quality Assurance System that has to be conceived so as to be able to guarantee and document that the product responds to the relevant technical specifications and that these specifications comply with the product design.
The Quality Assurance System has to be finalised so as to proffer sufficient attention to the most critical points of the production system that might endanger the attainment of both legislative, technical and qualitative conformity of finished machine.

Documentation of procedure/instructions

Every production phase relevant to the GMP Regulation has to be regulated through adequate documentation. Examples of documentation can be: manuals, procedures, working instructions, technical rules and registrations. The documentation required to perform the activity must be at the disposition of the appointed personnel, must be kept updated and the distribution of the same must be controlled, so that non updated information is speedily withdrawn.

B15.2.2. Quality Control System (Regulation (EC) 2023/2006, art. 6)

The machine manufacturer should establish and maintain an effective Quality Control System capable of ensuring the respect of the conformity to the Regulation as laid down in the general guideline.

The system should include procedures that envisage all the necessary controls, the relative registrations and actions to be carried out in the event of lack of conformity.

All the documentation has to be available for the Competent Authorities that demand to see it in accordance with the Regulation (EC) 2023/2006 as amended and Regulation (EC) 1935/2004 as amended.

The rules and the procedures have to cover the entire production process, as described in paragraph B15.2.1.2., also including a part that deals with the handling of any non-conformities and corrective actions.

B15.2.2.1. Management of raw materials warehouses

Approved raw materials and components coming from qualified suppliers must be segregated from other raw materials that have not yet been verified or that come from suppliers in the qualification phase or not qualified.

For these latter materials, a procedure must be established that authorizes use in production only after the relevant function within the Quality Control System has confirmed the suitability of the material for use in production.

The machine manufacturer must establish the designated Quality Control function that has the authority to authorize any use of these materials.

The environmental, storage and handling conditions of the storage areas must be such as to guarantee the quality of the materials.

Particular attention must be paid to the handling of raw materials and components to avoid damage that can make the material unusable, including maintaining traceability.

B15.2.2.2. Production controls

The Quality Control System must be regulated by suitable procedures that guarantee that during the production process all the necessary controls are carried out to ensure that the components comply with the legal, technical and quality specifications defined during the design phase. The traceability of the product must be guaranteed through suitable registration of the batches of raw materials used, of the manufacturing and production processes. The flow diagram (Figure B15.2) proposes a traceability scheme that machine manufacturers will adapt to their production and organizational structure.

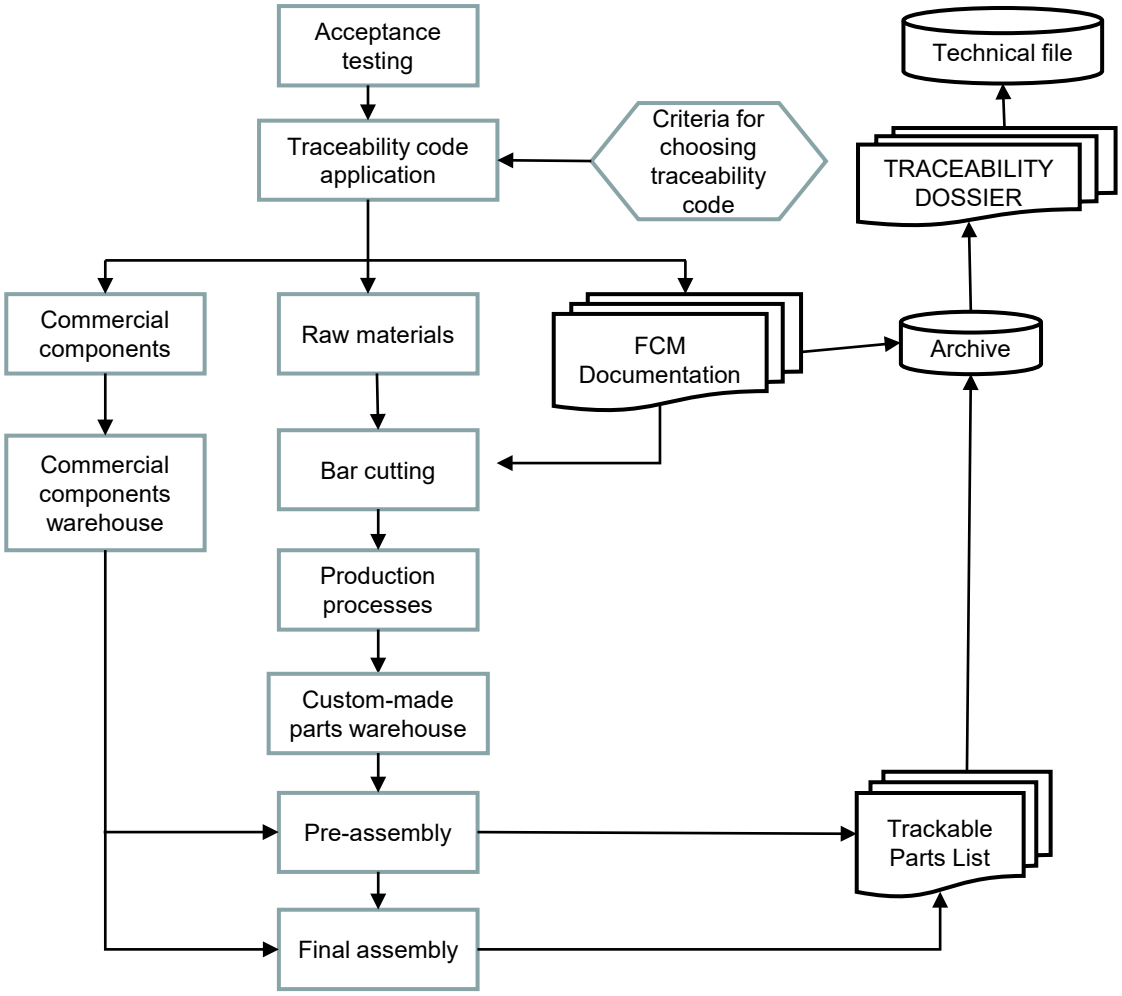

Figure B15.2. Traceability scheme for the construction of the machines for food packaging

The manufacturer has the task of establishing a system of unique codes to be applied to raw materials and components.

The application of the traceability code can make use of appropriate techniques, such as: engraving, photoengraving, laser, tags, or computerized procedures. The traceability code must be maintained in all processing phases.

During assembly of the groups and final assembly of the machine, the recording of the traceability codes of each component in contact with food and the subsequent archiving in the Technical File guarantees the identification of components and machines that could be involved in recalls due to violation of the legal requirements.

Shipping the machine to the user company must be possible only following procedures that allow it to be unequivocally documented that the material has been checked in all the planned phases and that the final checks have ascertained compliance with all the requirements envisaged in the design phase.

This conformity must be ascertained by comparing the control data collected and the values and/or tolerances reported in the technical specification of the product or in the reference legislation.

By way of example, some characteristic parameters that can be kept under control are listed:

- mechanical characteristics (UNI EN 546 part 2);
- dimensional tolerances (UNI EN 546 part 3);
- particular characteristics (UNI EN 546 part 4).

Storage conditions, if applicable, must be such as to ensure that there is no risk of contamination and deterioration of the material.

B15.2.2.3. Quality Control of finished products

The Quality Control System has to dispose of suitable procedures for controlling the finished product.

In verifying the conformity of the finished product, Quality Control must use the information available on the raw materials and the process applied to highlight compliance with the design and process specifications (see B15.2.2.2).

Particular attention should also be paid to the test conditions used for carrying out the controls, which have to be suited to the verifications of the intended final use of the material.

The analyses must always be carried out using validated methods of analysis. If these methods do not exist, an analytical method with performance characteristics adapted to the specified limits may be used pending the drawing up of a validated method.

B15.2.2.4. Management of finished product warehouses

The Quality Assurance System must provide a procedure that authorizes the storage/shipment of finished products. The authorization for storing the products and shipping them to customers must be given by the relevant function within the Quality Control system, or by a delegated person, after all the checks required by the control procedures for ascertain the final suitability for the use for which the finished products are intended.

If, by agreement with customers, the storage of spare parts is envisaged, the Quality Assurance System must prepare specific procedures.

B15.2.2.5. Distribution, shipment and delivery

The producer, if responsible for the transport and the delivery of the material to its destination, has to also guarantee that this phase is regulated by instructions and procedures that guarantee the

quality of the material preserving it from any damage and contamination risk that might compromise its use or suitability.

If the means of transport are the property of the packaging producer, it must be ensured, also by periodic checks, that these are suited for transporting goods and that maintain the requisites of safety and hygiene required to guarantee the integrity of the product.

If the delivery is via external couriers, a procedure should be established that qualifies the courier and a technical contract should be defined that sets the minimum requisites to be respected to eliminate possible risks (i.e., damage, contamination, etc.).

If transport is the responsibility of the user company, transport instructions must be prepared.

B15.2.2.6. Conformity of the application of the GMP and claims management, corrective and preventive actions

The Quality Control System has to enact suitable procedures so as to periodically monitor the correct implementation and total respect of the GMP.

The Quality Control System has to enact procedures for documenting the identification of lack of conformity, the enacting of any corrective measures and the monitoring of the implementation of the said measures, with particular attention to the time frame envisaged.

The manufacturer's Quality Assurance System must therefore be built to include verification and control plans on compliance with pre-established parameters and specifications, relevant to compliance with the legislation on materials in contact with food; procedures for managing non-conformities and corrective actions must be implemented.

B15.2.3. Documentation (Regulation (EC) 2023/2006, art. 7)

All the documents concerning the Quality Assurance System (procedures, specifications, formulations, etc.) and all the activity of the Quality Control System (instructions, registrations of control data, machine setup data, tolerances and measurements etc.) have to be organized so as to constitute a paper or electronic archive, immediately accessible and easily consultable on request by the Competent Authorities.

The documents that guarantee traceability will also form an integral part of the archive, according to the dictates of the art. 17 of Regulation (EC) 1935/2004 as amended, copies of the declarations of conformity issued to customers in compliance with the applicable national provisions, and the required supporting documentation.

This documentation will also include any conditions for tests, calculations and analyses, carried out by internal and external laboratories, that serve to demonstrate conformity.

In the event of substantial changes in production liable to change the essential requirements regarding compliance, or when the legislative benchmarks are modified and/or updated, it should be verified whether the documentation relating to the Regulation (EC) 2023/2006 as amended should be updated.

Annex B15.1

Technical glossary

Factory Acceptance Test (FAT): Testing of the machine in the manufacturing plant before delivery with the aim of showing that the system works adequately to be installed and tested on the user's site. Generally, the test is conducted with temporary products due to the difficulty in handling food in the manufacturers' factories.

Manufacturer: Natural or legal person who designs and manufactures a machine and is responsible for the conformity of the machine with the Machinery Directive for the purpose of placing it on the market under its own name or trademark. It is synonymous with "producer" or "builder".

Site Acceptance Test (SAT): Tests of the machine in the user's factory aimed at showing that the system works in its final operating environment and that it interfaces correctly with other systems and peripherals. The test is conducted by the user's personnel with final products.

User: Organization that uses the machine to produce saleable food. It can be distinguished from the "customer" if the latter acts as a commercial buyer.

Annex B15.2

Frequently asked questions

Q1 *Do supplies of machines to non-European countries have to comply with European regulations?*

No, machines intended for non-European customers must comply with the mandatory provisions of the user's country.

Q2 *In the case of food packaging machines, what materials are in direct contact with food?*

These are the materials constituting the surfaces intended for direct contact with the food product.

Q3 *Should materials that can come into indirect contact with food be treated the same as materials that come into direct contact?*

Materials in indirect contact with food are those that (for example):

- come into contact with the side of the packaging materials that is in direct contact with the packaged foods.
- receive food splashes, condensation or other draining, dripping materials that spread or are sucked (spontaneously returned) to the food container.
- are in contact with technical fluids that come into contact with food (modified atmosphere gases, compressed air)

Therefore, indirect contact materials are subject to the same rules as direct contact materials.

Q4 *How to choose the tracking code?*

By way of example, the traceability code could consist of the order number and order line, the number of the goods receipt note, the number of the warehouse loading note, a pure progressive code, etc. The code must be associated with the components and control and testing documents in all production phases. Again, by way of example:

- raw material and chemical analysis of the casting;
- commercial component and declaration of conformity;
- semi-finished product and chemical analysis of the casting of the raw material used;
- supplier's raw material and production batch.

B16. FOOD GASES DISTRIBUTION EQUIPMENT

B16.1. Characterization of the sector

B16.1.1. Field of application of guideline

This 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. Applicable legislation

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.[34]
- Regulation (EC) 10/2011 on plastic materials and articles intended to come into contact with food.
- Directive 2014/68/EU on the harmonization of the laws of the Member States relating to the making available on the market of pressure equipment

Italian legislation

- Decree of the Italian 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.
- Italian Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- Italian 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 objects intended to come into contact with food.
- Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, intended to come into contact with food or substances for personal use as amended.
- Ministerial Decree No. 76/2007 on regulation regarding the hygienic discipline of materials and articles of aluminium and aluminium alloys intended to come into contact with foodstuffs.

B16.1.3. Phases of the production process: flowchart and description

The manufacturing process of a food additive gas distribution equipment consists in the assembly – at the user's site – of specific components such as:

- cryogenic tanks and/or cylinders for gas storage
- vaporization systems
- pressure reducing systems
- pipes and fittings
- valves and accessories.

B16.1.3.1. Production flowchart

Figure B16.1 illustrates the flowchart for the production of food gases distribution equipment (the dashed part is compliant with the GMP Regulation (EC) 2023/2006 as amended).

[34] It replaced the Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

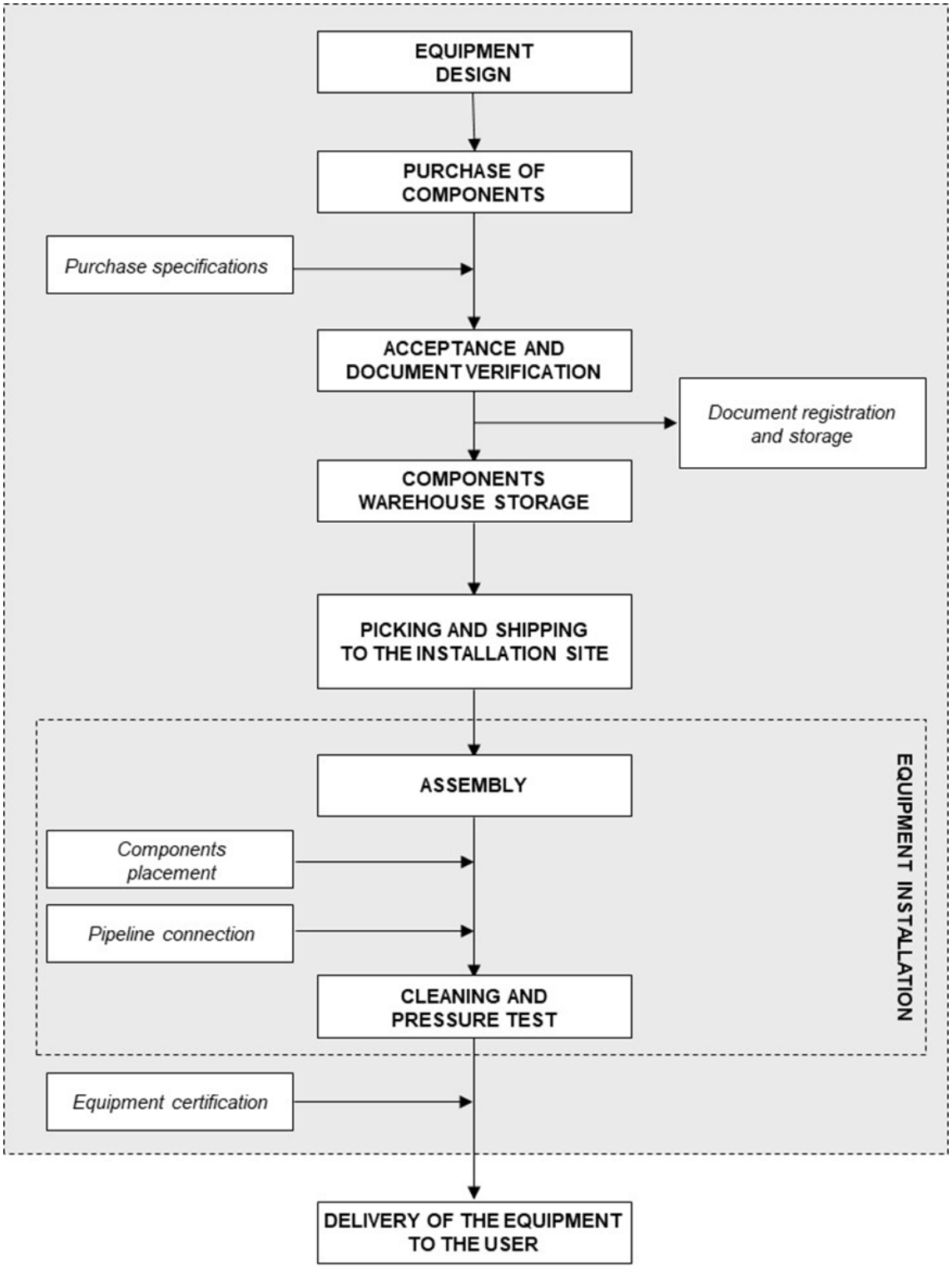

Figure B16.1. Production flowchart for the construction of food gases additives distribution equipment

B16.1.3.2. Brief description of the phases of the process

Equipment design

The equipment project is created on the basis of the user's needs. The project contemplates an equipment scheme, the choice of materials, the assembly methods and the accompanying technical documentation.

Purchase of components

The equipment components are purchased from qualified suppliers according to predefined purchase specifications. These specifications include the request for the qualification of the components both from a technical and food safety point of view, but also with respect to compliance with current regulations (Regulation (EC) 2023/2006 as amended, Regulation (EC) 1935/2004 as amended, PED Directive (EU) 2014/68).
It is also verified the presence of the requirements related to the traceability of the components themselves.

Acceptance and document verification

The purchased components are taken over by the producer and verified as regards the accompanying documentation and compliance with the order together with the integrity of the packaging.
At the same time, the information aimed at guaranteeing traceability of the components is recorded and archived.

Components warehouse storage

The incoming materials, suitably identified by type, are stored in the component warehouse in accordance with company procedures.
Data on quantity, location and traceability are entered into the management systems.
Storage includes the need to keep the component supplier's original packaging intact to preserve integrity and maintain adequate hygienic conditions.

Pickup and shipment to the installation site

Depending on the equipment design, the components are picked from the warehouse and shipped to the installation site.
Also, in this phase the traceability of the single component is guaranteed.
The integrity of the packaging is further checked upon arrival of the material.

Assembly

The components that are part of the food gases distribution equipment are unpacked and positioned according to the equipment design.
Subsequently, the interconnection pipes between the system components are assembled, in such a way to guarantee a single and functional whole.
The assembly phase involves the creation of permanent joints (welding), or connections with threaded or compression fittings.

Cleaning and pressure testing

Once assembled at the installation site, each distribution equipment is subjected to a flushing with inert food gas, in order to eliminate traces of impurities deriving from the processes during the assembly phase.

Subsequently, the system is subjected to a pressure test (testing) with inert food gas in order to verify the goodness of the assembly according to the operating pressure.

Delivery of the equipment to the user

Once the equipment has been completed and tested, the Declaration of Conformity to FCMs legislation is drafted together with the documentation required by current regulations.

With the transmission of the aforementioned documents to the user, the producer formally "delivers" the equipment.

B16.2. Fulfilments deriving from the application of the Regulation (EC) 2023/2006

In this part are described the activities and the implementation enacted by the manufacturing process of food gases distribution equipment to conform to the Regulation (EC) 2023/2006 as amended. Since this Regulation was laid down when the quality assurance systems had already become a daily work tool in most of the manufacturing businesses, it is likely that these businesses already produce in conformity with technical specifications laid down by themselves.

All the same, should it be necessary, the Quality Assurance System and the Quality Control System should be extended to ensure:

> "[...] that the materials and articles are constantly manufactured and controlled, to ensure their conformity to 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" (art. 3 paragraph a Regulation (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006 as amended. Every paragraph is hence the response of the manufacturers of food gases distribution equipment to the requirements of the article in question. To facilitate reading, the paragraphs keep the same title as the article considered, while the subparagraphs indicate specific subjects.

B16.2.1. Quality Assurance Systems (Regulation (EC) 2023/2006, art. 5) and Size of the business

Quality Assurance Systems

The producer of food gases distribution equipment should establish and maintain a Quality Assurance System capable of ensuring the achievement of the objectives laid down by the Regulation and described in the general guideline. The Quality Assurance System should be documented so as to enable control by the competent authorities.

The Quality Assurance System should establish at least concerning the following points:

- purchase specifications;
- supplier qualification;
- human resources and training;
- equipment installation;
- management of the technical file;
- FCMs Declaration of Conformity.

The system shall ensure that the future legislative changes are adopted in all the phases of the company process also including the specifications and any contracts with qualified suppliers.
It is recommended to implement a procedure which enables the company to adopt the changes deriving from updates of the applicable legislation on FCMs, for example through one's own trade association.

Size of the business

Independently from the business size, it should at any rate be guaranteed that the Quality Assurance System, as demanded and finalised by the Regulation (EC) 2023/2006 as amended, is always applied.
The system should be established, implemented and run taking into account the actual size and complexity of the company as well as the technical and human resources available.
On its own premises the business has to at any rate be capable of guaranteeing the application and running of the Quality Assurance and Quality Control System in order to obtain finished products (food gases distribution equipment) in compliance with the legislation in force on FCMs.

B16.2.1.1. Human resources and training

The *Business operator,* in compliance with the objectives of the Regulation (EC) 1935/2004 as amended and the Regulation (EC) 2023/2006 as amended is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 as amended is applied at all levels of their organization.

The operative aspects relating to the application of the provisions laid down in the Regulation (EC) 2023/2006 as amended can be entrusted by the Business operator to competent and adequately trained people that have to at any rate have at their disposition adequate means to ensure that the requisites of the Regulation (EC) 2023/2006 as amended are respected.

The *company organization* has to at any rate enable the location of the functions to enable inspection by the Competent Authorities.

All *company personnel* potentially involved, including the highest managerial levels, have to be informed on the principles of GMP, on the obligations that derive from the Regulation (EC) 2023/2006 as amended, on its objectives and on the policy for applying the Regulation.

The *Business operator* should operate and implement procedures for identifying personnel training requirements and has to see to the training of all staff regarding the tasks that might affect the compliance to the said Regulation.

The *personnel* assigned to GMP control activities should be qualified on the basis of the training and the experience acquired.

An appropriate registration of the training process of all personnel must be kept.

B16.2.1.2. Production

The production process includes all phases in the business that together guarantee that the finished equipment complies with technical, legislative and performance requirements conceived right from the design phase to guarantee suitability for its intended use.

Therefore, the Quality Assurance System must have procedures that regulate the phases listed below:

- Equipment manufacturing;
- Selection of components and suppliers of goods and/or services and/or subcontractors;
- Documentation of procedures/instructions;
- Traceability;
- Labeling.

Equipment manufacturing

The most important concept implied by the GMP is that of an equipment designed to be compliant to the legislative requisites on materials and articles intended for food contact (FCMs).
The distribution equipment is designed ad hoc on the basis of the user's needs.
This equipment should therefore:

- meet the requirements for their final destination of use;
- meet with applicable legislative requirements on materials and articles intended for food contact.

To this aim, they have to be produced with components that, through control, guarantee in any phase of the process respect for final use and legislative requirements on materials and articles intended for food contact.
In order to allow the development of a project for an equipment which is compliant with the user's requests, the following information must be known and made available by the user himself:

- type of application (food process);
- food gas used for the application;
- technical conditions of use (gas pressure and flow rate, metric calculation, etc.);
- gas storage conditions (liquid or gaseous).

The executive project contains the technical choice of the components, the risk analysis in the FCMs field, the assembly operating methods, the equipment lay-out (at the user's site).
The entire planning phase is properly documented.
The manufacturing process has to be kept under adequate control with a Quality Assurance System that has to be conceived as to be able to guarantee and document that the equipment complies with the provisions of the project.
The Quality Assurance System has to be finalized so as to proffer sufficient attention to the most critical points of the production system that might endanger the attainment of both legislative and technical conformity of the assembled equipment.
A fundamental phase of the production process is assembly, which generally takes place at the end user.
The producer of the equipment shall appear in the list of FCMs producers, as required by Legislative Decree no. 29 of 10/02/2017.

Selection of components and suppliers of good and/or services and/or subcontractors

The producer of the equipment is called upon to use only components conforming to the design.
It must be ensured that the following requirements are met:

1. Declaration of Conformity to FCMs legislation as established by applicable European and/or national legislation
2. Instructions for use in Italian or in the language of the user country, as required by article 4 of Decree no. 29 of 10 February 2017
3. Traceability according to the Framework Regulation (EC) 1935/2004 as amended
4. Compliance with Regulation (EC) 2023/2006 as amended.

The reference to Regulation (EC) 2023/2006 as amended may be present on the Declaration of Conformity to FCMs legislation, even if it is not mandatory.
Each supply of components must be kept under adequate control.
The material shall be supplied in packaging that preserves the integrity of the components and maintains adequate hygienic conditions.
It is good practice that the starting materials come from qualified suppliers. Qualification means a pre-established, organised and documented process, which may also include supply specifications, aimed at verifying the supplier's ability to provide and/or market components that correspond continuously to pre-established technical specifications.
We can distinguish:
– component suppliers;
– services providers (installers).

The company shall clearly identify in its list of suppliers those eligible for the two categories above and verify that they are able to provide a Declarations of Conformity for the components. In the case of the provision of services only, compliance with Regulation (EC) 2023/2006 as amended is also verified.
On the basis of the company Quality Assurance System, the requirements of the suppliers envisaged for operating in the food sector shall be periodically checked.
Control evidence shall be appropriately recorded.

Documentation of procedures/instructions

Every production phase has to be regulated through adequate documentation. Examples of documentation can be: manuals, procedures, working instructions, technical rules and registrations. The documentation required to perform the activity must be at the disposition of the appointed personnel, must be kept updated and the distribution of the same must be controlled, so that non updated information is speedily withdrawn.

Traceability

For each FCMs equipment, the traceability of the components shall be ensured at all stages to facilitate control, the collection of defective elements and the attribution of responsibility; it allows to uniquely identify the components from the acceptance of the material up to the end of the useful life of the equipment itself.
The details for managing traceability are given in the instructions and procedures of the individual companies.
In the event of a defective component, the company shall apply its own recall procedure.

Labelling

At the time of placing on the market, the FCMs equipment shall be equipped with the following:
- the word «for food contact» or a specific indication as to their use or the symbol reproduced in Annex II of Regulation (EC) 1935/2004 as amended;

- the name or trade name and, in either cases, the address or registered office of the manufacturer, processor, or seller responsible for placing on the market established within the Community;
- adequate identification to ensures traceability.

This information shall be reported on the accompanying documentation (e.g., FCMs Declaration of Conformity to FCMs legislation, installation manual).

B16.2.2. Quality Control System (Regulation (EC) 2023/2006, art. 6)

The producer should establish and maintain an effective Quality Control System capable of ensuring the respect of the conformity to the Regulation as laid down in the general guideline.

The system should include procedures providing for all necessary checks, the related registrations and actions to be carried out in the event of non-compliance.

All the documentation has to be available for the competent authorities that request its vision in accordance with the Regulation (EC) 2023/2006 as amended and the Framework Regulation (EC) 1935/2004 as amended.

The rules and the procedures have to cover the entire production process, as described in paragraph B16.1.3, also including a part that deals with the management of any non-conformities and corrective actions.

B16.2.2.1. Management of raw material warehouses

Incoming components intended as raw materials shall be checked for:

- order compliance;
- presence of suitable protective packaging, if required;
- conditions of integrity;
- completeness of the accompanying documentation (FCMs Declarations of the components).

In the event of non-compliance, the material shall not be accepted but managed according to the company's non-compliance procedures.

Adequate registration forms for incoming material and archiving of reference documentation must be provided for appropriate traceability.

All FCMs scomponents, managed at warehouse level, shall be identifiable with a company traceability code.

In case of purchase of non-coded materials (specific purchase on order) traceability is managed at the level of technical documentation accompanying the project.

Particular attention shall be paid to the storage and handling of the components to avoid damage that could make the material unusable.

B16.2.2.2. Production controls

The Quality Control System has to be regulated by suitable procedures that guarantee that during the production process all the necessary controls are carried out to guarantee that the equipment conforms to the legal, technical and quality specifications defined during the design phase.

The components shall be shipped to the user keeping the original packaging conditions intact and guaranteeing the conditions contemplated by the supplier (temperature, degree of humidity, handling conditions, etc.).

At the user's site the installer shall check the following:

- the integrity of the material received
- the correspondence between the Bill of Materials (identification of the components) and the materials received
- the presence of the system diagram (P&ID - Piping and Instrumentation Diagram)
- pressure test with food gas.

B16.2.2.3. Quality control of finished product

The Quality Control System has to dispose of suitable procedures to verify the compatibility of the delivered equipment (finished product) with the project and the effectiveness for its intended final use. In verifying the conformity of the delivered equipment, the function in charge of the Quality Control System must use the information (technical documentation accompanying the project) on the materials and the applied process to highlight any non-compliance with food contact as envisaged by the project. The evidence of the controls must be properly recorded.

B16.2.2.4. Management of finished products warehouses

The production process does not contemplate for the finished product (delivered equipment) to be stored in a warehouse.

B16.2.2.5. Shipment and delivery

Generally, the production process does not contemplate the shipment of the entire finished product (delivered equipment) as it is assembled directly at the user's premises.

Once the equipment has been assembled and tested, the Declaration of Conformity to FCMs legislation is drawn up together with the documentation required by current regulations.

With the transmission of the aforementioned documents, the producer formally "delivers" the system to the user.

B16.2.2.6. Conformity of the application of the GMP and claims management, corrective and preventive actions

The Quality Control System has to enact suitable procedures so as to monitor the correct implementation and total respect of the GMP.

The Quality Control System has to enact procedures for documenting the identification of lack of conformity, any corrective measures and the monitoring of the implementation of such measures, with particular attention to the timing of implementation of these measures.

The Quality Assurance System of the Business should therefore be implemented to include periodical verification and control plans on conformity to pre-established parameters and specifications, relevant to compliance with legislation on FCMs; procedures for managing non-conformities as well as corrective and preventive actions deriving from eventual claims should be implemented.

B16.2.3. Documentation (Regulation (EC) 2023/2006, art. 7)

All the documents concerning the Quality Assurance System (procedures, technical specifications, etc.) and all the activity of the Quality Control System (instructions, registrations of control data, equipment test data, etc.) have to be organized so as to constitute a paper or electronic archive, immediately accessible and easily consultable on request by the Competent Authorities.

Documents that guarantee traceability, according to art. 17 of Regulation (EC) 1935/2004 as amended, copies of the declarations of conformity issued to customers in compliance with applicable European and national legislation, as well as the supporting documentation provided (e.g., user and maintenance manual) will also be an integral part of the archive. This documentation will also include any test conditions, calculations and analyses, carried out by internal or external laboratories, that serve to demonstrate conformity.

In the event of substantial changes in production capable of changing essential requirements for compliance or when the legislative references are modified and/or updated, it should be verified whether the documentation relevant to Regulation (EC) 2023/2006 as amended needs to be updated.

Annex B16.1

Technical glossary

Carbonation of beverages: Carbonation, i.e. the process of dissolving carbon dioxide in beverages to make them fizzy, is also a natural method for obtaining greater healthiness thanks to the bacteriostatic property of carbon dioxide.

Cooling and freezing: In the food sector, the control - or better still the elimination - of bacterial activity is pursued with cryogenic cooling and freezing. The latter - carried out with liquid nitrogen and carbon dioxide - is a consolidated practice which is based on the use of these gases at extremely low temperatures when they come into contact with food.

Cryogenic storage: storage method using a high vacuum insulated container suitable for containing liquefied gases under pressure, commonly called "cryogenic tank".

Delivery: taking charge of the equipment by the user.

Equipment: Food gases distribution system made up of elements interconnected to each other so as to create a single and functional whole, with the aim of supplying the food gas to the point of use.

Flushing: "washing" operation of the pipe and accessories, performed with a food gas.

Food gas: It is defined as a food and it is used in various applications in the food and beverage industry. Food gases, in liquid, gaseous or solid form, shall therefore meet the strict requirements of the food law (labelling, purity and hygiene criteria).

Gas storage: storage method using a receptacle suitable for containing pressurized gas, commonly called a "cylinder".

Inert gas: A gas that has poor reactivity characteristics; by reactivity we mean the ability of the gas to interact with other substances which could give rise to a chemical reaction.

Inerting process: Inerting is a technique which, through the use of inert gases, allows to preserve the products from contact with the oxygen and humidity contained in the air. It is used in the storage, preservation and handling of food products subject to oxidation processes.

Installation site: Place where the equipment is assembled and used.

Installer: subject who carries out the assembly of the system at the user's site according to the indications and the design provided by the producer.

Manufacturing: production process which includes all phases of the equipment assembly: from design to delivery to the user.

Modified Atmosphere Packaging (MAP): Modified Atmosphere Packaging (MAP) is a technique used to modify the composition of the internal atmosphere of a package by introducing a single gas or a mixture of gases (such as for example nitrogen, oxygen or carbon dioxide) which, by replacing the air inside the package, eliminate or reduce the deterioration of the product by increasing its shelf life.

Pipes and Fittings: set of pipes and related fittings used to convey the food gas to the point of use.

Pressure reducing systems: set of one or more devices designed to reduce and maintain the gas pressure at the required value.

Producer: the subject responsible for the design, assembly and marketing of the equipment. The producer can entrust the assembly operation at the user's site to other subjects (installer), while remaining responsible and owner of the supply of the equipment.

User: subject who make use of the equipment according to its intended use and where the equipment is assembled. The user is therefore the food company operating in the food&beverage sector which

makes use of the food gas distribution equipment in its industrial processes (e.g. packaging in a protective atmosphere, freezing and cooling, beverage carbonation, inerting processes).

Valves and accessories: devices used for the interception, protection, measurement and regulation of the food gas.

Vaporization systems: set of one or more equipment used to facilitate the transition from liquid to gaseous state, by means of heat exchange.

Annex B16.2

Frequently asked questions

Q1 *What is the industrial and trade association context in which the producers of food additive gas distribution equipment operate?*

The Regulation (EC) 178/2002 equates food additives to a food and, in this logic, food additive gases shall comply with the same legislation applicable to food. As to Italian Legislative Decree No. 29/2017, companies that provide food gases distribution equipment are therefore configured as FCMs producers and shall therefore comply with the provisions of Regulation (EC) 1935/2004 as amended. These activities must also be carried out in accordance with the provisions of the company GMP, as per Regulation (EC) 2023/2006 as amended.

Producers of food gases distribution equipment are represented in Italy by Assogastecnici, the National Association of manufacturers of technical, special and medical gases, which is part of Federchimica, the National Federation of the Chemical Industry.

Q2 *What is the function of a food additive gas?*

The main food additive gases – carbon dioxide, nitrogen, argon and oxygen – are used in the Food& Beverage industry. Their function is to preserve the organoleptic qualities of the products and extend their shelf life. Food additive gases are mainly used to reduce food oxidation (effect of oxygen present in the atmosphere), microbial development, preserve the colour of particular foods, carbonate drinks.

Q3 *What is the contribution made by the studies of the CNR of Florence to the knowledge of the phenomena of migration of metal and non-metal elements in food gases?*

With regard to the suitability of materials in contact with food gases, the National Research Council (CNR) of Florence, an expert and equipped Institution, on the analysis of metal migration from materials and alloys, has conducted various studies with the aim of:

- define a protocol for sampling and measuring contaminants in food gases whose presence is caused by migration from cylinders, tanks or food gases distribution equipment;
- evaluate the effective impact of the migration processes on the quality of the food gas.

The results of the experimentation on a food gas distribution equipment show migration phenomena with concentration values at least two orders of magnitude lower than the legal limits used as a reference for this study (Legislative Decree No. 31 of 2001).

Q4 *Are there any reference documents for the production of a food gas distribution equipment?*

Yes, the main document is the Study on the "Migration processes of metal and non-metal elements in the food gas distribution equipment" carried out by the CNR of Florence, 2019.

Q5 *Is it possible to issue the Declaration of Conformity to FCM legislation for a distribution equipment that has components without a FCM Declaration of Conformity?*

It is possible, but it is necessary to carry out a risk assessment that considers each individual component on the basis of the positive lists in force and of the supporting scientific studies conducted on a standard distribution equipment.

In this regard, the National Research Council (CNR) has carried out scientific studies to verify the suitability of the components assembled in an equipment representing the standards used.

Based on these scientific studies, Assogastecnici has drawn up the "Guideline for the application of Regulation (EC) 2023/2006 as amended on Good Manufacturing Practice in the food gas sector", July 2019. This document provides the method for carrying out risk assessment.

Q6 *Is the installer of a food gas distribution equipment required to draw up the FCMs Declaration of Conformity?*

No; the release of the FCMs Declaration of Conformity is in charge of the equipment producer.
In some cases, the subject of the producer and the installer correspond.

Q7 *Which other regulations affect a food gases distribution equipment?*

The main reference legislation for a distribution equipment is the Directive (EU) 2014/68 (PED) on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (recast). This standard applies to the design, manufacture and conformity assessment of pressure equipment and assemblies with a design pressure greater than 0.5 bar.

PART C
Use of non-legislative documents in the evaluation process

Introduction

The verification of the aspects of the quality assurance connected with the quality standards adequate for food contact use should ensure that the finished product will not endanger human health, or bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties.

Therefore, the business operator should always perform an evaluation of compliance of the product both to the legislative requirements applicable for FCMs and to the general requirements of art. 3 of the Regulation (EC) 1935/2004 as amended.

It is desirable that this evaluation involves also the food industry.

In the evaluation process, when specific issues are afforded for which a specific EC or Italian legislation does not exist or it is not complete, non-legislative documents may be used, too, as useful supporting tools. Some examples are:

- Opinions of the Scientific Committee of Food of the EC Commission and Opinions of the European Food Safety Authority;
- Council of Europe Resolutions;
- Opinions of National, EU or not EU Authorities on food safety (e.g., BfR, FSA, FDA, etc.);

Relevant documents, wherever possible officially adopted by National and/or European industrial associations.

A non-exhaustive exemplificative list is the following:

- Alliance for beverage cartons and the environment, CEPI Container Board, Confederation of European Paper Industries, International Confederation of Paper and Board Converters, European Tissue Symposium, European Carton Makers Association, European Federation of Corrugated Board Manufacturers. *Food contact guidelines for the compliance of paper and board materials and articles*. Brussels: ACE, CCB, CEPI, CITPA, ETS, ECMA, FEFCO; 2019.
- Assovetro. *Codice di comportamento dell'Industria del vetro da imballaggio in adempimento degli obblighi per i materiali e gli oggetti a contatto con gli alimenti.* Edizione 3. Roma: Assovetro; 2018 (Quaderno Assovetro n. 4).
- Bundesinstitut für Risikobewertung. *Recommendation XXI. Commodities based on natural and synthetic rubber*. Berlin: BfR; 2023.
- Confédération Européenne du Liège - Europen Cork Confederation. *CIPB - Codice Internazionale delle pratiche per la produzione di tappi in sughero (ai sensi del Regolamento (CE) n. 2023/2006 della Commissione del 22 dicembre 2006 sulle buone pratiche di fabbricazione dei materiali e degli oggetti destinati a venire a contatto con prodotti alimenti) – Versione 7.00.* Milano: Assolegno; 2018.
- Confederation of European Paper Industries. *Good manufacturing practice guideline for the manufacture of paper and board for food contact*. Bruxelles: CEPI; 2023.
- Confederation of European Paper Industries. *Guidelines for responsible sourcing and supply of recovered paper*. Brussels: CEPI; 2006.
- Consiglio Nazionale delle Ricerche-Istituto di Geoscienze e Georisorse. *Studio sulla migrazione di elementi metallici e non metallici in impianto di distribuzione gas alimentari.* Firenze: CNR-IGG; 2019.

- Council of Europe. *Resolution CM/Res (2020)9 on the safety and quality of materials and articles for contact with food.* Adopted by the Committee of Ministers on 7 October 2020 at the 1385th meeting of the Ministers' Deputies; 2020.
- CRL-NRL-FCM. *Guidelines on testing conditions for articles in contact with foodstuffs (with a focus on kitchenware).* 1st edition 2009. EUR 23814 EN. Luxembourg: Office for Official Publications of the European Communities; 2009. (JRC51601)
- European Metal Packaging. *Guide to good manufacturing and hygiene practices for metal packaging in contact with food*. Bruxelles: EMPAC, SEFA; 2009.
- European Printing Ink Association. *EuPIA Guideline on printing inks applied to food contact materials.* Brussels: EuPIA; 2020.
- European Printing Ink Association. *Exclusion policy for printing inks and related products.* Brussels: EuPIA; 2021.
- European Printing Ink Association. *Good Manufacturing Practice (GMP). Printing inks food contact materials.* Brussels: EuPIA; 2016.
- Fédération Européenne des Industries de Colles et Adhésifs. *FEICA Guidance Paper 2015 - Guideline for Good Manufacturing Practice of food packaging adhesives.* Disponibile anche in italiano.
- FederlegnoArredo. *Legno-Sughero-Arredo*. *Imballaggi ortofrutticoli: linea guida per la caratterizzazione delle prestazioni e lo sviluppo di un sistema di rintracciabilità.* Milano: FederlegnoArredo; 2004.
- Flexible Packaging Europe, CIPTA. *Code for good manufacturing practice for flexible and fibre-based packaging for food*. Dusseldorf: FPE; 2011.
- Plastic Europe Association of Plastic Manufacturers. *Guidelines for good manufacturing practice for plastic materials and articles intended for food contact applications*. Bruxelles: Plastic Europe, Cefic-FCA, EUPC; 2011.
  This recommendation does not constitute a legal provision, however it represents the current state of scientific and technical knowledge for the conditions under which consumer products consisting of polymeric substances such as silicones, paper and natural or synthetic rubber, meet the requirements of § 31, paragraph 1 of the German Food and Feed Code (Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch, LFGB) as well as those of Article 3, paragraph 1, letter a) of Regulation (EC) 1935/2004 as amended in relation to their health safety.

CEPE Document

The following documenti are avaiable on *Conseil Européan de l'Industrie des Peintures, des Encres d'Imprimerie et des Couleurs d'Art* (CEPE) (https://cepe.org/food-contact/documents/) website; last consultation 15/09/2022:

- 2004 *Industrial Guidelines on Traceability of Materials and Articles for Food Contact*
- 2004 *Resolution ResAP (2004) 4 on rubber products intended to come into contact with foodstuffs*

- 2004 *Resolution ResAP (2004)5 on silicones used for food contact applications* (Adopted by the Committee of Ministers on 1 December 2004 at the 907th meeting of the Ministers' Deputies) (replacing Resolution AP (99) 3
- 2006 *Guide to Good Hygiene and Manufacturing Practices for Metal Cans, Packaging and Closures for Foodstuffs*.
- 2007 *Code of Practice for coated articles where the food contact layer is a coating – Annexes II & III: inventory list for coatings intended to come into contact with food - compiled lists approved by the Council of Europe.*
- 2009 *Coated Articles Where the Food Contact Layer is a Coating - Declaration of Compliance*.
- 2009 *Framework Resolution RESAP (2004)1 on Coatings Intended to Come Into contact with Foodstuffs - Version 3*
- 2010 *Code of practice for coated articles where the food contact layer is a coating - Annex X(a): Good Manufacturing Practice (GMP) Food Contact Coatings.*
- 2012 *Code of Practice for Coated Articles where the Food Contact Layer is a Coatings - Annex X(b): Good Manufacturing Practice (GMP) for the production of heavy-duty coatings intended to come into contact with food.*
- 2016 *Code of Practice for Coated Articles where the Food Contact Layer is a Coating - Annex XI: List of dual use substances*.
- 2017 *TSC34 Migration Testing Guidelines for Rigid Metal Packaging Coated with Organic Coatings Intended for Direct Food Contact for Discussion with Member States and JRC*.
- 2019 *TSC33 NIAS guidelines for coated rigid metal packaging intended for direct food contact*.

UNI Standard

The official document adopted by national and/or international standardization bodies is only the UNI EN ISO 9001:2015 "Quality management systems - Requirements" standard.

Note

Taking into account that the mentioned documents are not legally binding, the final evaluation will in any case remain under the responsibility of the *producer/business operator* that has to ensure that the product is in conformity with the declared compliance requirements.

APPENDIX
Other aspects relating to food safety in the practices of food packaging chains

Introduction

This Appendix (already present in the first version of the 2009 CAST guidelines – Rapporto ISTISAN 23/4 Rev.) deals with some aspects that, while not directly regarding the field of application of the Regulation (EC) 2023/2006 as amended, are strictly connected to the practises of the food packaging chains.

These aspects regard:

– food industry and food packaging;
– hygiene;
– use of non-legislative documents.

The contents of the following paragraphs, while logically not part of the guideline on the general or specific application of the Regulation (EC) 2023/2006 as amended, in consideration of the importance of the aspects dealt with, stands as an important integration for users of this document.

Food industry and food packaging

The field of application of the Regulation (EC) 2023/2006 as amended does not extend to the food industry, for which a specific legislation exists. All the same for the food industry packaging is a strategic element not only in terms of safety but also in terms of the quality and image of the products.

Considering the multiple functions packaging is called upon to perform, the food industry deals with packaging as a raw material in terms of its specificities. Hence any integrated action directed at increasing the level of safety of packaging represents an important contribution in the common efforts of the entire chain towards the objectives of final safety of the food product. In this view, the adoption of the Regulation (EC) 2023/2006 as amended and the application of the GMP described in the same constitute an important step.

It should what is more be highlighted that the tools most in use in the systems for managing Food firms (i.e., purchasing contracts, declarations of compliance, qualification of the suppliers, tracking and tracing of the raw materials etc.) interface well with the GMP system introduced by the Regulation (EC) 2023/2006 as amended and described in this guideline, as well as with what has been laid down in terms of traceability of packaging (Regulation (EC) 1935/2004 as amended).

It is also important to underline that, in practise, the sharing of pertinent information between the packaging and food industry is recognised as the most effective approach for consolidating the cooperative relations that have to be set up between the parties and to guarantee the exchange of data and knowledge relevant to conformity, as under what has been laid down by the applicable legislation.

In order to contribute effectively to improve the level of safety of the packaged food product, the food industry is hence ready to make the appropriate information available covering the product to be packed and/or covering the process, that enable the packaging supplier /producer to follow suitable design and planning procedures and/or select the materials suited to their intended use. In consideration of the variety of potential and foreseeable situations (in terms of material/objects, food and process and contact conditions), the necessary information cannot be indicated beforehand. All the same, especially in the preliminary phases, the dialogue between the parts can contribute to highlighting the truly indispensable points for guaranteeing a finished product that is safe and that conforms to the applicable legislation for each specific case.

Obviously, in the absence of this information it transpires that the packaging supplier/producer cannot be considered responsible for the related aspects.

Established that the laws in force on materials and objects for food contact demand that the so called "supporting documentation" is only made available to the Competent Authorities, it is at any rate indispensable that the parties exchange the information necessary to guarantee the conformity of the packaging to the applicable legislation.

The transparency and the cooperation within the chain would enable the food industry to gain knowledge of the packaging used, adequate for guaranteeing the conformity and the safety of the end product, understood as food product including its packaging.

Hence the information provided by the packaging industry should be pertinent and such as to enable the food industry to gain knowledge of the packaging used, adequate to guaranteeing its conformity to the applicable legislation.

The food industry is bound to use the materials and objects for packaging the product in the conditions of use as laid down, subject to previous verification as to their conformity to the applicable legislation.

The support from the packaging chain is indispensable to the food industry and hence to be able to guarantee the safety of the products that it places on the market, it is desirable that, where suitable, the dialogue with the packaging supplier might also be extended to important complementary aspects not directly considered in the Regulation (EC) 2023/2006 as amended, such as for example the declaration of compliance of the packaging, and/or the reinforcing of the traceability chain of the packaging within the food company.

Hygiene

Regulation (EC) 2023/2006 as amended does not prescribe a Hygiene Control System; the existing voluntary standards such as ISO 22000, UNI EN 15593, BRC are valid examples of systems that can be used to ensure the respect of the hygiene requisites in packaging and semifinished products.

At any rate the analysis of the hygienic requisites, whether important in terms of position in the production chain, should consider:

- hygiene of the personnel and cleanliness of the workplace;
- risks of material contamination.

The possible cause of contamination of the materials and the articles during storage, processing and handling have to be identified, kept under control, minimized, or completely removed where possible, this through adequate measures.

For example, these measures should include:

- prevention of risks of contamination from insects, rodents and/or other animals
- a company policy of cleanliness of the environments and equipment;
- rules for respecting hygiene during the storage, handling and shipping of materials and objects;
- specific training of the personnel;
- definition of eating areas separates from the production sections.

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