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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

ISSN 1123-3117

Edited by
M.R. Milana, M. Denaro, R. Feliciani,
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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

Edited by
Maria Rosaria Milana, Massimo Denaro, Roberta Feliciani,
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Dipartimento di Ambiente e Connessa Prevenzione Primaria

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In the frame of the CAST Project (Contatto Alimentare Sicurezza e Tecnologia) 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 section for general application and in a section for specific applications, in particular the chains of aluminium, paper and boards, flexible packaging, plastics, coated and not-coated metals and alloys, wood, cork, glass.
Key words: Regulation (EC) 2023/2006; Good manufacturing practice; Materials; Contact; Food

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Progetto CAST. Linee guida per l'applicazione del Regolamento 2023/2006/CE alla filiera di produzione dei materiali e oggetti destinati a venire in contatto con gli alimenti.
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Nell'ambito del Progetto CAST (Contatto Alimentare Sicurezza e Tecnologia) sono state sviluppate linee guida per l'applicazione del Regolamento 2023/2006/CE 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, materie plastiche, legno, metalli e leghe metalliche rivestiti e non, sughero, vetro.
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The following associations took part in the CAST project:

AIDI
Italian Association of Confectionery Industries (Rome)

AIIPA
Italian Association of Food Producer Industries (Milan)

AIPE
Italian Expanded Polystyrene Association (Milan)

ANFIMA
Italian Association of Manufacturers of Metal Packaging and like products (Milan)

ASSOBIBE
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
National Italian Graphics Paper&Cardboard manufacturing and converting industry (Milan)

Assografici- GIFASP
Italian Group of Folding Case and Box Manufacturers (Milan)

Assografici- GIFLEX
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
Aluminium Packaging Consortium (Milan)

Assorimap
National Association of plastics recyclers and regenerators (Milan)

Assovetro (Rome)

Avisa Federchimica
National Association of Producers of lacquers, inks, sealers and adhesives (Milan)

PVC Information Centre (Milan)

Federalimentare
Italian Food Industry Federation (Rome)

Federazione Gomma Plastica (Italian Rubber Plastic Federation) (Milan)

Federchimica - PlasticsEurope Italia (Milan)

III (*contracting partner)*
Italian Institute of Packaging (Milan)

ISS (*scientific coordinator*)
National Institute of Health (Rome)

Unionzucchero (Rome)

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INTRODUCTION 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 2023/2006/CE alla filiera di produzione dei materiali e oggetti destinati a venire in contatto con alimenti", published in 2009 in the series *Rapporti ISTISAN*.

This English version is now 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 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 translation is faithful to the original Italian version, 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), 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;
- plastics;
- metals and metal alloys both coated and not-coated;
- cork;
- glass.

Each Working group has drawn up a guideline document for the application of the Regulation (EC) 2023/2006 regarding GMPs 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/EC.

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. During the development of the guidelines it appeared increasingly evident that, independently of what has been achieved and the operational choices made, the correct implementation of the GMPs cannot take place without a real dialogue between all the players in the food packaging chain (from materials through conversion to the food industry itself). This is made explicit both in the correct selection of the starting materials as well as the transfer of a specific body of information for each stage (ie. declaration of compliance, declaration of composition, indications for use, etc.) that really enable the flow and maintenance throughout the entire chain of the required information, ensuring the conformity of the food product and the continuous improvement of food product safety.

The following associations took part in the CAST project:

- AIDI (Italian Association of Confectionery Industries)
- AIIPA (Italian Association of Food Producer Industries)
- AIPE (Italian Expanded Polystyrene Association)
- ANFIMA (Italian Association of Manufacturers of Metal Packaging and like products)
- ASSOBIBE (Italian Association of Soft Drinks Industrialists)
- Assocarta (Italian Association of Paper, Board and Paper Pulp Industrialists)
- Assocomaplast (National Italian Association of machine and mould builders for plastics and rubber materials)
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- Federchimica
- PlasticsEurope Italia
- III (The Italian Institute of Packaging) (*contracting partner*)
- ISS (The National Institute of Health) (*scientific coordinator*)
- Unionzucchero

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 are closely connected to the practise of the *food packaging* chain.

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

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) n. 2023/2006 of the Commission 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 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.

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: wood fruit & vegetable packaging and/or wood fibre, and/or plywood, wood blocks and stumps;
- B6. Plastics;
- B7. Metals and metal alloys both coated and not coated;
- B8. Cork;
- B9. Glass.

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 a Italian level have remained valid in that they are not superseded by harmonized regulations. The list of the Regulations is as follows:

European legislation:

Regulation (EC) 1935/2004 of the European Parliament and of the Council of 27th October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/CEE and 89/109/CEE.

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

Regulation (EC) 2023/2006 of 22nd December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Regulation (EC) 882/2004 of the European Parliament and of the Council of 29th April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal heath and animal welfare rules.

Italian national legislation:

Decree of the Italian President of the Republic No. 777 of 23rd August 1982 on implementation of the Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs and subsequent revisions.

Italian Legislative Decree No. 108 of 25th January 1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.

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 and Regulation (EC) 2023/2006):

- *Good Manufacturing Practises 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 (from the Regulation (EC) 2023/2006, 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 GMPs.

- *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, 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 (from the Regulation (EC) 1935/2004, art. 2).

- *Business operator*
  The natural or legal person responsible for ensuring that the requirements of this Regulation (EC) 1935/2004 are met with in the business under his/her control (from the Regulation (EC) 1935/2004. art. 2).[1]

- *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, 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.

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

- *Specifications*
  As understood under Regulation (EC) 2023/2006 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 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, at art. 3 only demands in general terms that "Materials and articles, … should be manufactured in compliance with good manufacturing practice so that …". Hence no way of guaranteeing the fulfilment of the GMPs is made explicit, while Regulation (EC) 2023/2006 gives basic indications and the essential tools for responding to the above. The underlying concept is indeed the very implementation (or extension) of the quality system, with requisites described in the articles and in the 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 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 does *not* implicate the obligatory adoption of ISO standards, nor the certification of the system.

It should also be reiterated that, in the field of regulated obligations for FCM, the implementation of a quality system, even if certified, does not automatically entail the fulfilment of the requisites of the Regulation (EC) 2023/2006.

This document is aboveall intended as orientative, 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 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 and Regulation (EC) 2023/2006.

A3.2. Analysis of the articles

The following text illustrates the key concepts of the Regulation (EC) 2023/2006, 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:

> "The Regulation lays down the rules on GMP for the groups of materials and articles intended to come into contact with food (hereafter "materials and articles") listed in Annex I of the Regulation (EC) n. 1935/2004 and the combinations of these materials and articles as well as the recycled materials and articles used in those materials and articles"

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

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

Article 2: Field of application

Art. 2 reads:

> "The present Regulation applies 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 should 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, specific dispositions are defined for processes concerning the use of printing inks and the use of recycled plastic materials (updated in the Regulation (EC) 282/2008).

Article 3: Definitions

Art. 3 reads:

> "Under the present Regulation the following definitions are adopted:
> a) «GMPs or Good Manufacturing Practises»: 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 GMPs constitute 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 Systems»: 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»: 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 specifications 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 GMPs

Art. 4 reads:

> The business operators 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

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

Article 5: Quality Assurance System

First part

Art. 5, comma 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 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 comma 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 [...]."

Reg. (EC) 1935/2004 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 Reg. (EC) 1935/2004).

Reg. (EC) 2023/2006 introduces the novelty of the process control: to obtain the guarantee demanded by Reg. (EC) 1935/2004 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 GMPs. The starting materials have to be appropriately selected on the basis of the knowledge and control of ones 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 comma 3 reads:

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

Reg. (EC) 2023/2006 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 procedurialization 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.

All the same the amount of processes and activities within a company and the interconnection of the same can be 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 correlatable, 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 operators 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.
> The sector operators have to implement an effective Quality Control System."

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 GMPs".

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, 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 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 under art. 16. The obligation is what is more reiterated in art. 7 comma 1 of the Regulation (EC) 2023/2006. 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, semiprocessed 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 (see art. 5, comma 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 conforming to the preset requisites and hence to the applicable standards.
- *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 semiprocessed 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.

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

Q1 *What does GMP mean?*

It is short for Good Manufacturing Practises.

Q2 *How are the GMPs defined ?*

GMPs are 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 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 GMPs 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 GMPs?*

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

Q8 *Can one demand the application of the Regulation (EC) 2023/2006 applied to the production of semiprocessed 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.

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 does not lay down any obligation of system or product certification.

Q11 *Are the GMPs 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) stands as an excellent basis for implementing the GMPs, that all the same should not be confused with the Quality System in itself. These systems can what is more already include the GMPs 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 do not consider the size of the business but, in the foreword (comma 6) it is stated that "The rules on GMPs should be applied proportionately to avoid undue burdens for small businesses". As well as that, in art. 5 ("Systems of quality assurance" it is laid down that "the system has to [...] be applied considering the size of the business, so as not to constitute and excessive burden for the business").

Q14 *What is FCM traceability?*

Traceability (defined in art. 17 of the Regulation (EC) 1935/2004) 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 GMPs, 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 GMPs 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 GMPs?*

For the correct application of the GMPs 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 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 GMPs?*

No, the Regulation demands that the business operator guarantees that Regulation (EC) 2023/2006 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 no mention is made of the obligation to draw up a manual but a "Documentation (in art. 7 mention is made of "adequate documentation on paper or in electronic format").

Q24 *What should one do to manage GMPs 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 (ie 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 semiprocessed 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 GMPs 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 GMPs?*

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

Q29 *Who checks the application of the GMPs?*

The implementation of controls as to the application of the GMPs, in the Regulation (EC) 2023/2006 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: http://www.ministerosalute.it/imgs/C_17_normativa_745_allegato.pdf

Q31 *Where does one find clarification on the application of the traceability in the sector of production of materials and objects intended for food contact (art. 17 Reg. 1935/2004/EC)?*

The document on the application of art. 17 of the Regulation (EC) 1935/2004 specifically for each food packaging sector "Industrial Guidelines on traceability of materials and articles for food contact" is available on the website Joint Research Centre – Community Reference Laboratory for Food Contact Materials (CRL-FCM).

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, are to make to guarantee conformity to the requisites of the Regulation (EC) 2023/2006.

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

All the same, 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 cardboard: production;
- B3. Paper and cardboard: processing;
- B4. Flexible packaging;
- B5. Wood: wood fruit & vegetable packaging and/or with wood fibre, and/or plywood, wood blocks and stumps;
- B6. Plastics;
- B7. Metals and metal alloys both coated and not-coated;
- B8. Cork;
- B9. Glass.

Each specific guideline includes a description of:

- the production process, both in graphic diagram and in a 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 of the European Parliament and of the Council of 27th October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/CEE and 89/109/CEE.

Regulation (EC) 2023/2006 of 22nd December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Regulation (EC) 882/2004 of the European Parliament and of the Council of 29th April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal heath and animal welfare rules.

Italian national legislation:

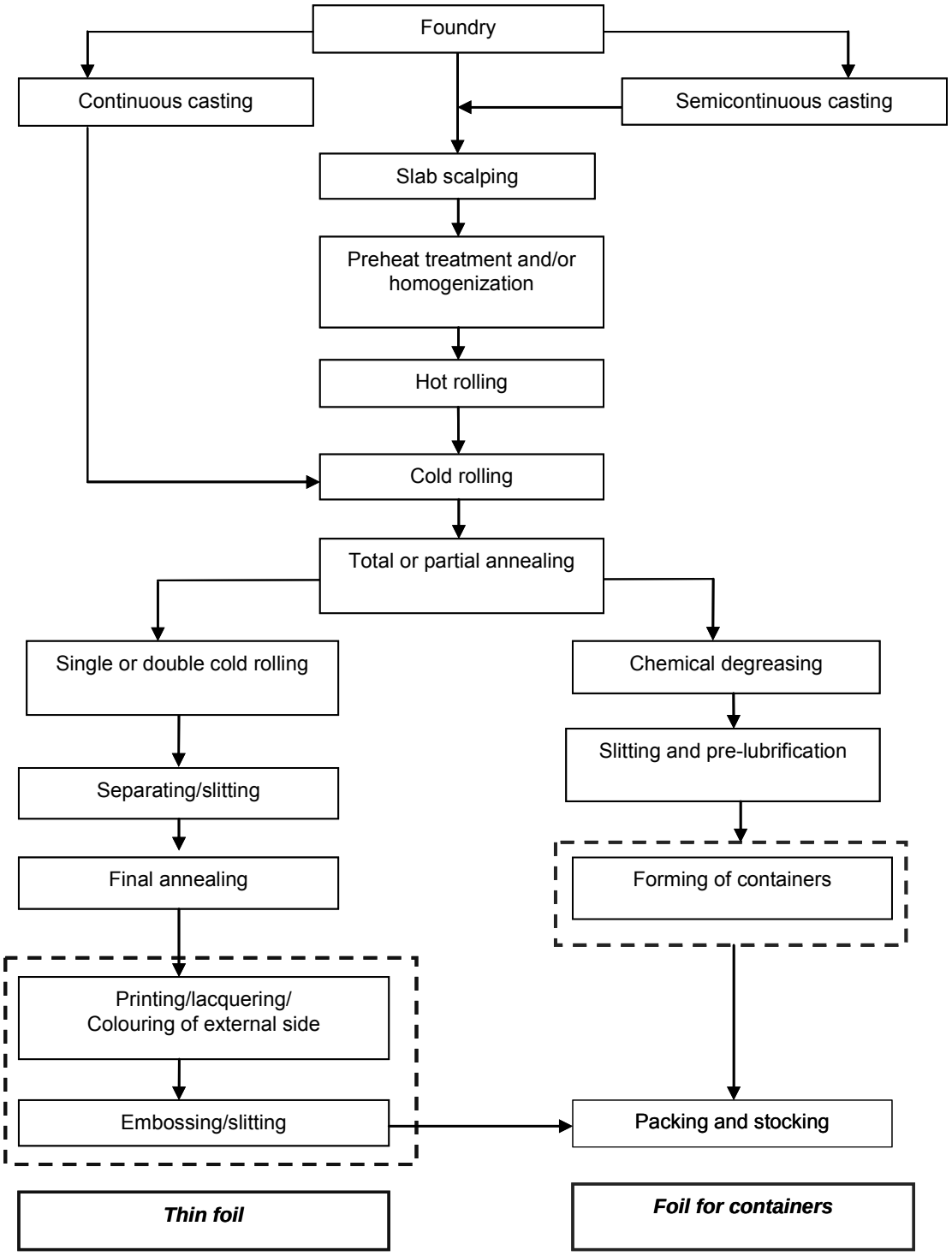
Italian Ministerial Decree No. 76 of 18th April 2007 on regulation regarding the hygienic discipline of materials and articles of aluminium and aluminium alloys intended to come into contact with foodstuffs.

Decree of the Italian President of the Republic No. 777 of 23rd August 1982 on implementation of the Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs and subsequent revisions.

Italian Legislative Decree No. 108 of 25th January 1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.

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

Production flowchart



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 channeled 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 channeled 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 millimeters 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 $\geq$ 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 operations 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 liddings 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. Since this Regulation was laid down when the quality assurance systems had already become a daily worktool 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:

> "[..omitted..] 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 comma a Reg. (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006. 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 (Reg. (EC) 2023/2006, art. 5) and Size of 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, 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 and the Regulation (EC) 2023/2006 is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 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 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 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 GMPs, 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.

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 GMPs 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 recontrolled 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 (where applicable);
- conformity to the Regulation (EC) 2023/2006 (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, 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 (Reg. (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.

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 semiprocessed 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 avilable 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 GMPs.

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, relevants to compliance with legislation on FCMs; procedures for managing non conformities and corrective measures should be implemented.

B1.2.3. Documentation (Reg. (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, 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.

EN ISO 6886. *Animal and vegetable fats and oils -- Determination of oxidative stability (accelerated oxidation test)*. Geneva: International Organization for Standardization; 2009.

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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.

Aluminum alloy: Aluminum 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: Duo Mill, fourth or multirulli (six over), 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 mold 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 mold 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 solidid 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 Al bath.

Doubling: Preparatory phase to final step of thin foil rolling passes, it consists of coiling together (doubled) two aluminium foil 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 aluminum (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 Triglicerides) 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 (http://www.ministerosalute.it/attualita/pacomunicati.jsp)

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 No. 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) 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.

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 recovered paper until the development of sheet and its setting up in reels or sheets.

B2.1.2. Applicable legislation

European legislation:

Regulation (EC) 1935/2004 of the European Parliament and of the Council of 27th October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

Regulation (EC) 2023/2006 of 22nd December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Italian national legislation:

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.

Presidential Decree No. 777 of 23rd August 1982 on implementation of Directive 76/893/EEC on materials and articles intended to come into contact with food and following updatings.

Legislative Decree No. 108 of 25th January 1992 on implementation of Directive 89/109/EEC on materials and articles intended to come into contact with food.

The following references may be helpful:

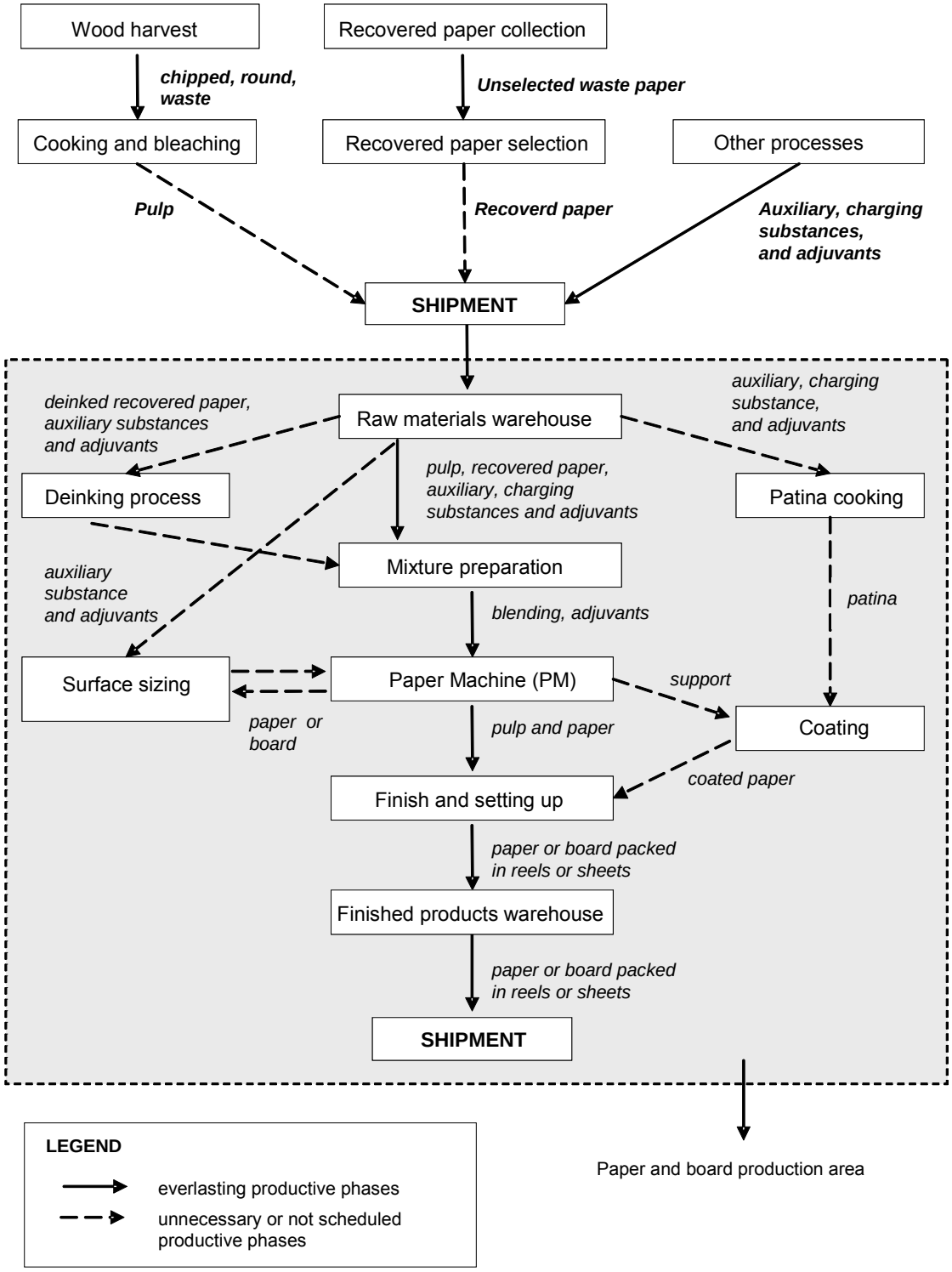
Ministry for Health Circular 24th January 2006 on materials and articles intended to come into contact with food: companies and food industry responsibilities[2]

Joint Research Center-Community Reference Laboratory for Food Contact Materials (CRL-FCM) - Industrial Guidelines on traceability of materials and articles intended to come into contact with food

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

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

Production flowchart



Brief description of process phases

Raw materials warehouse

Raw materials (pulp, selected recovered paper, 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 recovered paper is firstly sent to the kneader (or 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 obtanined, so to allow fibers to increase capacity of binding when forming the sheet.

When using recovered paper, 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 fibers 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, recovered paper 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 fiber 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 fibers 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 calenders (moist press) just before being dried in the dry end, composed by a number of high temperature calenders 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.

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, labeled, sometimes palletized ready to be sent to the finished products warehouse ready to be delivered to customer.

Finished products warehouse

Finished product, duly lableled, 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 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. Since this Regulation was laid down when the quality assurance systems had already become a daily worktool 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:

> "[..omitted..] 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 comma a Reg. (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006. Every paragraph is hence the response of the 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 (Reg. (EC) 2023/2006, art. 5) and Size of 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, 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 and the Regulation (EC) 2023/2006 is responsible for the management of the resources and the

activities required to guarantee that Regulation (EC) 2023/2006 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 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 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 GMPs, 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.

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 GMPs 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[3].

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 recovered papers 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.

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

[3] Applicable Italian legislation

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 (Reg. (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.

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 semiprocessed 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 GMPs.

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, relevants to compliance with legislation on FCMs; procedures for managing non conformities and corrective measures should be implemented.

B2.2.3. Documentation (Reg. (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, the copies of the declarations of compliance issued by the customers in observance of art. 16 of the Regulation (EC) 1935/2004, 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 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 vegetals, in significant quantities in wood and annual plants. Fiber is constituted of an 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 gathers also 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". Recovered papers are 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, chemi- 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 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) it is enclosed a list regarding paper and board materials and articles intended to come into contact with food, 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 recovered paper

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 (bobina madre) as also indicated in the *Industrial Guidelines on traceability of materials and articles for food contact by Joint Research Center – Community Reference Laboratory for Food Contact Materials (CRL-FCM)*

Q5 *Are GMPs to be applied also to tissue papers?*

For tissue papers, GMPs are 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 of the European Parliament and of the Council of 27th October 2004 on materials and articles intended for contact with food products and repealing Directives 80/590/EEC and 89/109/EEC.

Regulation (EC) 2023/2006 of the Commission of 22nd December 2006 on good manufacturing practice for materials and articles intended for contact with food products.

Italian national legislation:

Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, for contact with foodstuffs or substances for personal use and subsequent updates.

Decree of the President of the Republic No. 777 of 23rd August 1982 on implementation of Directive 76/893/EEC covering materials and articles intended for contact with food products and subsequent updates.

Legislative Decree No. 108 of 25th January 1992 on implementation of Directive 89/109/EEC on materials and articles for contact with food products.

The following references 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[4]

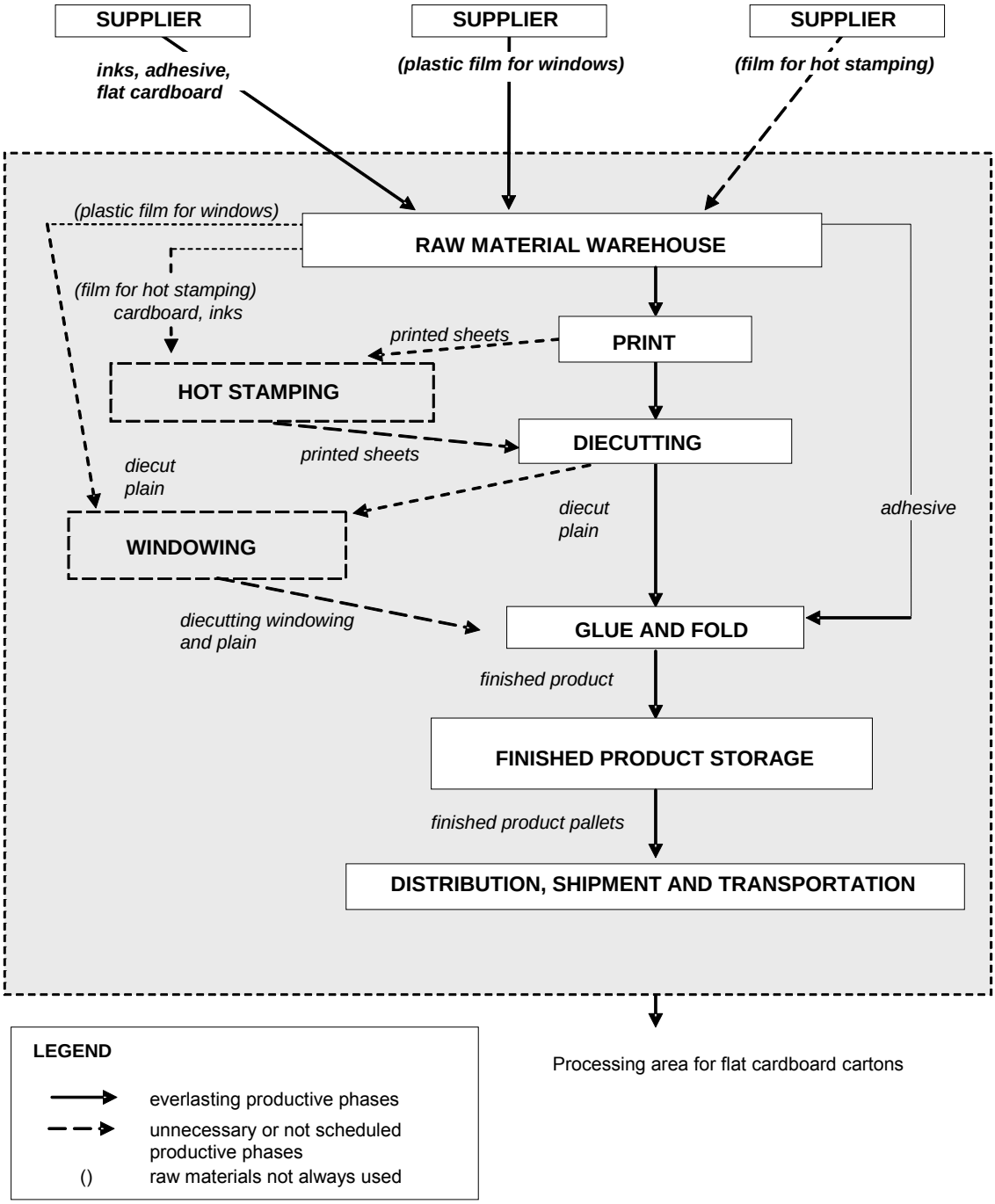
Industrial Guidelines on traceability of materials and articles for food contact of the Joint Research Centre - Community Reference Laboratory for Food Contact Materials (CRL-FCM).

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

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

B3.1.3.1. Flat cardboard cartons

Production flowchart



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 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 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 stretchfilm 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 (countergraphisms) – 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’ ie 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 color, 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 (color) and polymeric matrix (depending on the print substrate). The print techniques differ depending on the type of inks that have been chosen:

- waterbased 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 color (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.

Diecutting and glue-n-fold

After printing the sheets are passed through a diecutting machine in order to be cut, creased and subsequently folded in order to obtain the finished product. The print and diecutting 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.

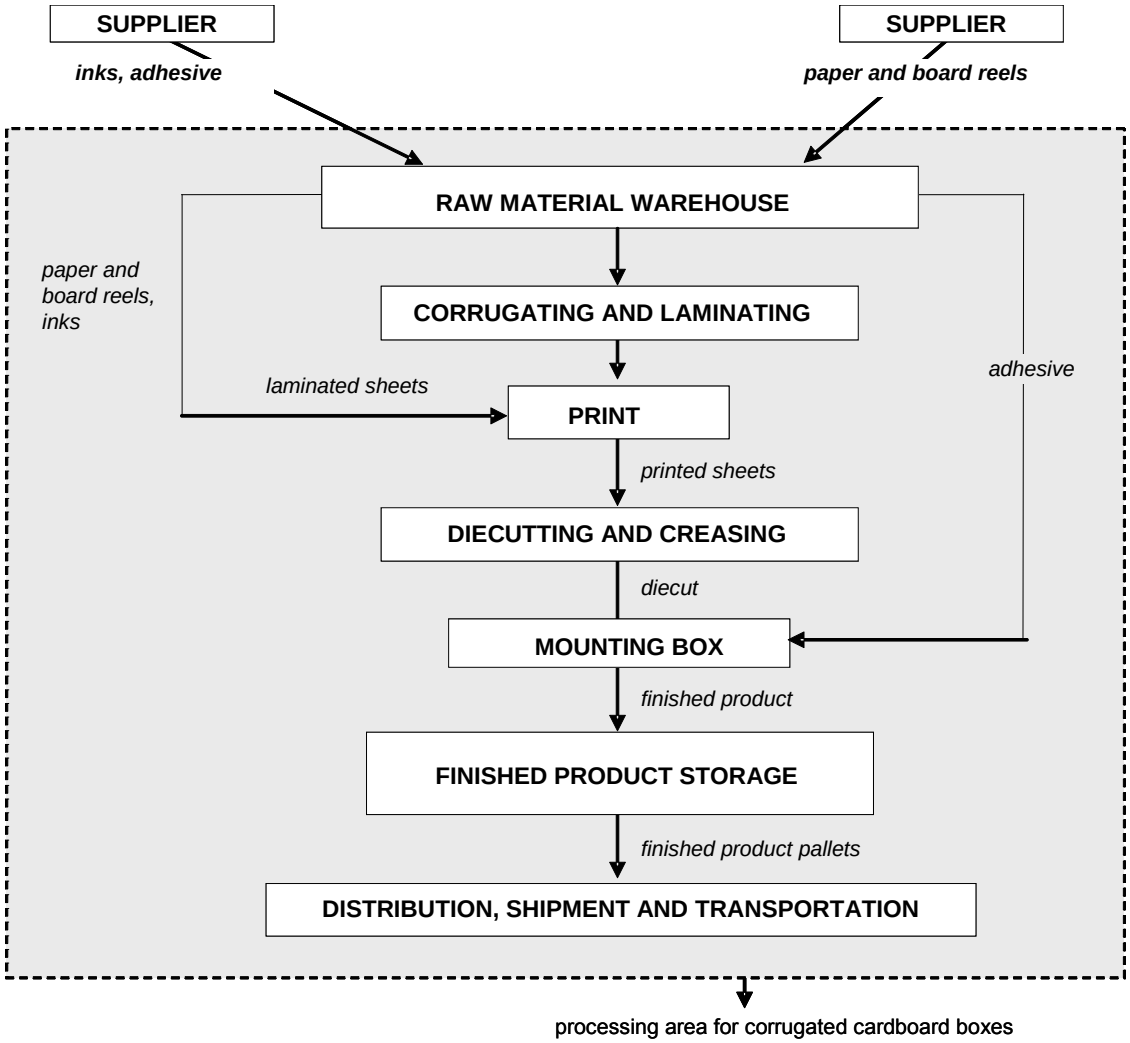
If the customer sees to retrieving the goods, except for the accompanying documents that are laid down by law, the responsibilities as to the homologation of the shipper come under the obligations of the final customer.

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.

B3.1.3.2. Corrugated cardboard boxes

Manufacturing flowchart



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 stretchfilm 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.

Diecutting and creasing

As already described diecutting 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 diecutting 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 diecutters can be manual (here on more often speaks of platens) or automatic (called diecutters or autoplatens).

Mounting the box

After having removed the swarf from the diecut 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 (waterbased vynilic) 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.

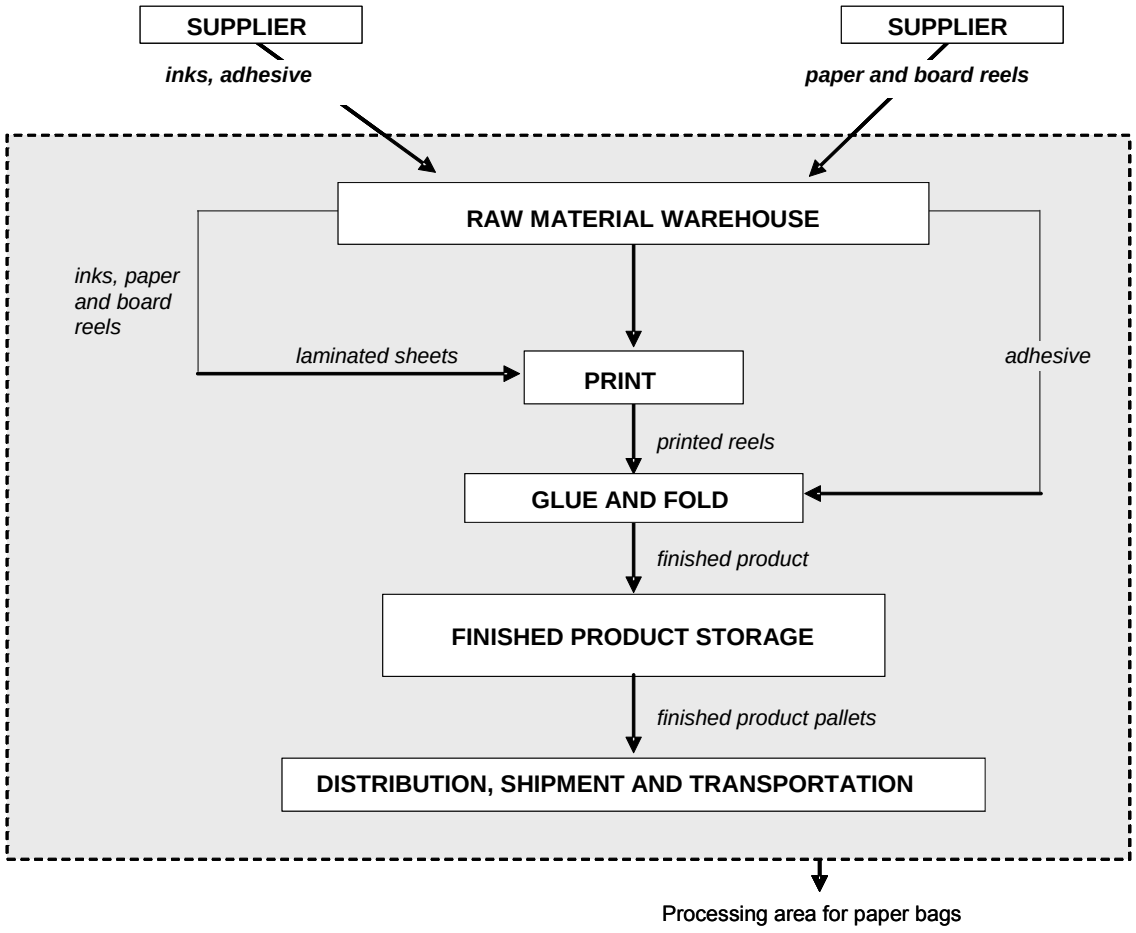
Distribution, shipment and transportation

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.

B3.1.3.3. Paper bags

Manufacturing flowchart



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 stretchfilm 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 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 caseine) or waterbased 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. Since this Regulation was laid down when the quality assurance systems had already become a daily worktool 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:

> "[..omitted..] 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 comma a Reg. (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006. Every paragraph is hence the response 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 (Reg. (EC) 2023/2006, art. 5) and Size of 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 Reg. (EC) 2023/2006, 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 and the Regulation (EC) 2023/2006 is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 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 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 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 GMPs, 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.

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 GMPs 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 producer 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 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 recontrolled 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 ont he 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 (where applicable);
- conformity to the Regulation (EC) 2023/2006 (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, 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 (Reg. (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.

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 semiprocessed 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.);
- color 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 GMPs.

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 (Reg. (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, the copies of the declarations of compliance issued by the customers in observance of art. 16 of the Regulation (EC) 1935/2004 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 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.

Diecutting: Diecutting 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 diecutting 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 diecutters can be manual (here one more often speaks of platens) or automatic (called diecutters or autoplatens).

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 diecut and creased blank is assembled into a container or carton (from the blank to the box).

Gloss: The greater the quantity of light reflect 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 (waterbased vinilic) 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: Colored 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 color images are formed by small dots (called halftone dots, that create a screen). The size of the dots determine the intensity of the color. The combination of different colors creates the entire color range.

Register: The situation that occurs when all the print inks are perfectly lined up in respect to each other (ie. as in the case of four different colored images in a four colored print, or in the diecutting, cutting and embossing sequence). Hence the print is out of register when the four colored images are not perfectly overlapping, in that the resulting image is not clear and has color 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 is capable of offering 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 heatshrink 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 of the European Parliament and Council of 27th October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

Regulation (EC) 2023/2006 of the Commission of 22nd December 2006 on the good manufacturing practises of materials and articles intended to come into contact with food.

Directive 2002/72/EC of the Commission of 6th August 2002 on materials and articles in plastic intended for contact with food products and subsequent updates (currently Directive 2004/1/EC, Directive 2004/19/EC, Directive 2005/79/EC, Directive 2007/19/EC, Directive 2008/39/EC)[5][6].

Regulation (EC) 882/2004 of the European Parliament and Council of 29th April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

Regulation (EC) 1895/2005 of the Commission of 18th November 2005 on the restriction of the use of certain epoxy derivates in materials and articles intended to come into contact with food.

[5] Directives are regularly transposed as amendments to Ministerial Decree of 21st March 1973

[6] Since 1st May 2011 the Regulation (EU) 10/2011 is in place. Articles 20-23 lay down the transition periods for the full implementation of this Regulation. The reference to the Regulation (EU) 10/2011 is not present in the original Italian version of these guidelines (*Rapporti ISTISAN* 9/33) because their publication was in 2009.

Italian national legislation:

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 and subsequent updates.

Decree of the President of the Republic No. 777 of 23rd August 1982 on implementation of Directive 76/893/EEC on materials and articles intended to come into contact with food and subsequent updates.

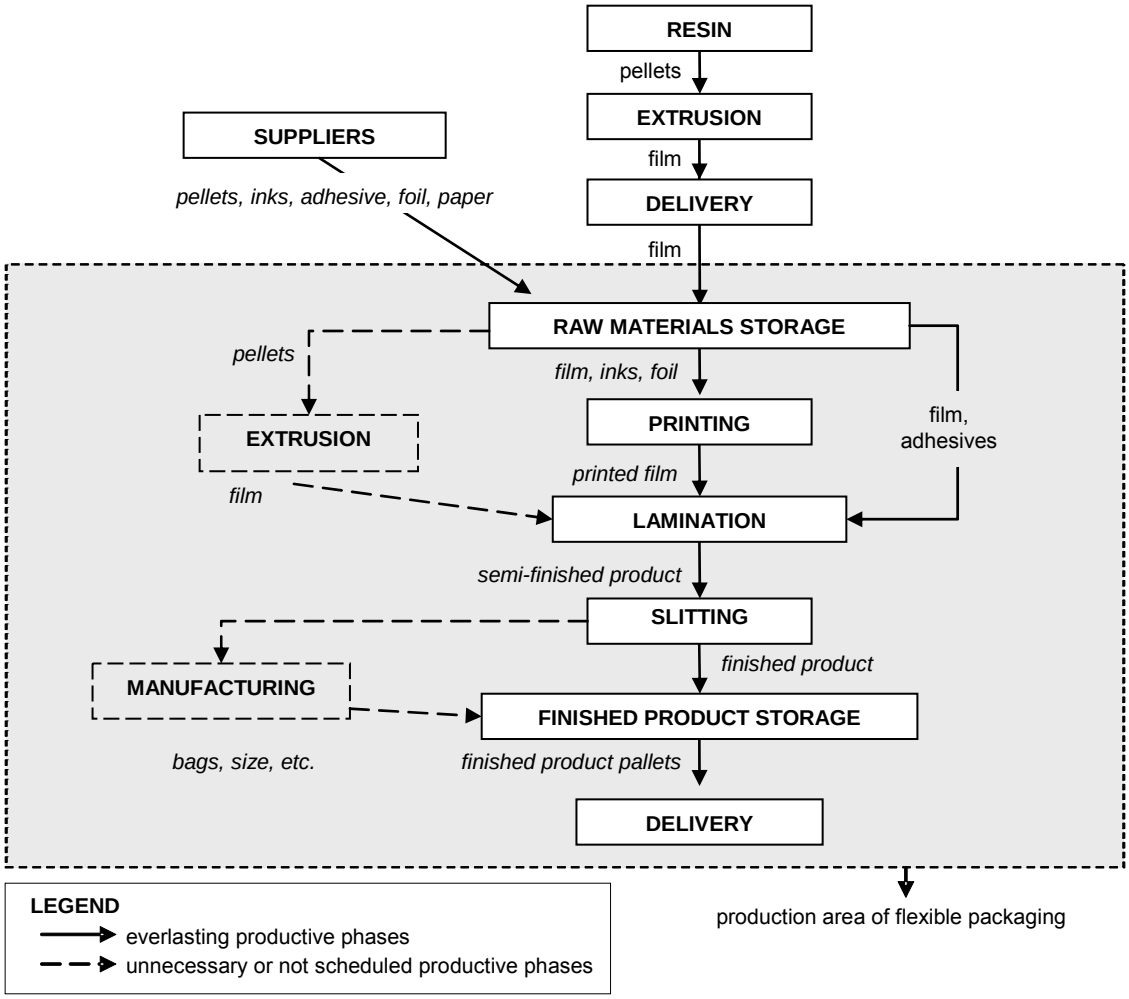
Legislative Decree No. 108 of 25th January 1992 on implementation of Directive 89/109/EEC concerning materials and articles intended to come into contact with food.

The following reference may be helpful:

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[7].

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

Production flowchart



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

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 multicolor printing (up to 10 or 11 colors) also involving different substrates, the printer can choose from numerous inks that differ in terms of pigment (color), 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 color (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 selfsame substrate.

Flexographic printing

The cylinders (sleeves), complete with engraved plates, mounted on the flexographic print machine via the pans that supply the color, transfer the ink to the substrate to be printed.
Dealing with multicolor printing (up to 10 colors) also involving different substrates the printer can choose from numerous inks that differ in terms of pigment (color) 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 companyitself 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.), heatformed containers (tubs and trays) or formats of different sizes (ie. 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. Since this Regulation was laid down when the quality assurance systems had already become a daily worktool 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:

> "[..omitted..] 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 comma a Reg. (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006. Every paragraph is hence the response 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 (Reg. (EC) 2023/2006, art. 5) and Size of 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, 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 and the Regulation (EC) 2023/2006 is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 is applied at all levels of their organization.

The operative aspects relating to the application of the provions laid down containing in the Regulation (EC) 2023/2006 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 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 GMPs, on the obligations that derive from the Regulation (EC) 2023/2006, 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 GMPs 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 recontrolled 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 (where applicable);
- conformity to the Regulation (EC) 2023/2006 (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, 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 (Reg. (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.

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 semiprocessed 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 GMPs.

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 (Reg. (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, the copies of the declarations of compliance issued by the customers in observance of art. 16 of the Regulation (EC) 1935/2004 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 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 (ie. 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: WOOD, AND/OR WOOD FIBER AND/OR PLYWOOD FRUIT & VEGETABLE PACKAGING, WOOD CUTTING BOARDS, CHOPPING BLOCKS AND BOARDS

B5.1. Characterisation of the sector

B5.1.1. Field of application of the guideline

This guideline is applicable to companies of wood producing fruit & vegetable packaging, and/or wood fiber and/or plywood, cutting boards, chopping blocks and boards 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 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 of the European Parliament and of the Council of 27th October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

Regulation (EC) 2023/2006 of 22nd December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Regulation (EC) 882/2004 of the European Parliament and of the Council of 29th April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Italian national legislation:

Italian President of the Republic Decree No. 777 of 23rd August 1982 on implementation of Directive 76/893/EEC on materials and articles intended to come into contact with food as updated.

Legislative Decree No. 108 of 25 January 1992 on implementation of Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.

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

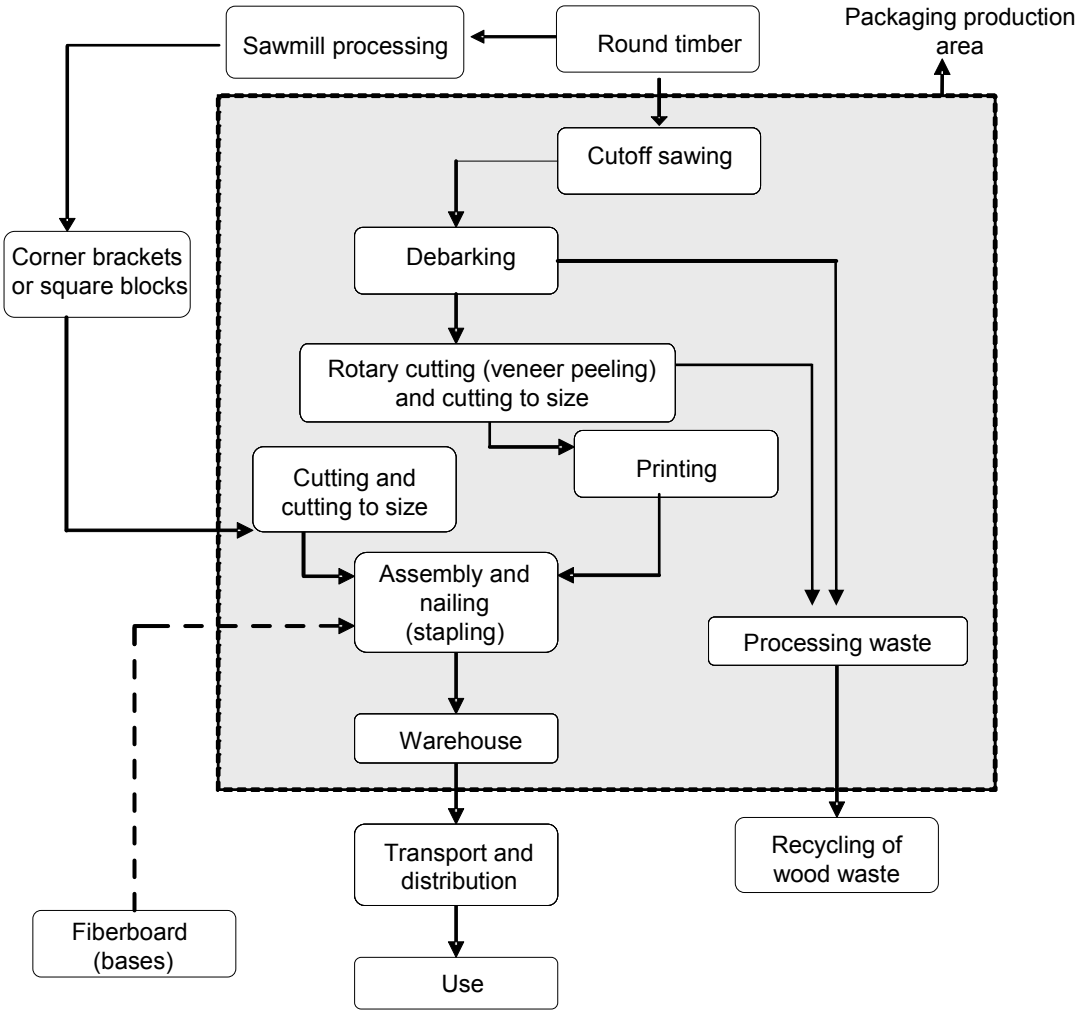
B5.1.3.1. Wood, and/or wood fiber, and/or plywood fruit & vegetable packaging

In the manufacture of solid wood fruit & vegetable packaging, three wood species are generally used: poplar (70%), beech and pinewood (the remaining 30%).

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



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:

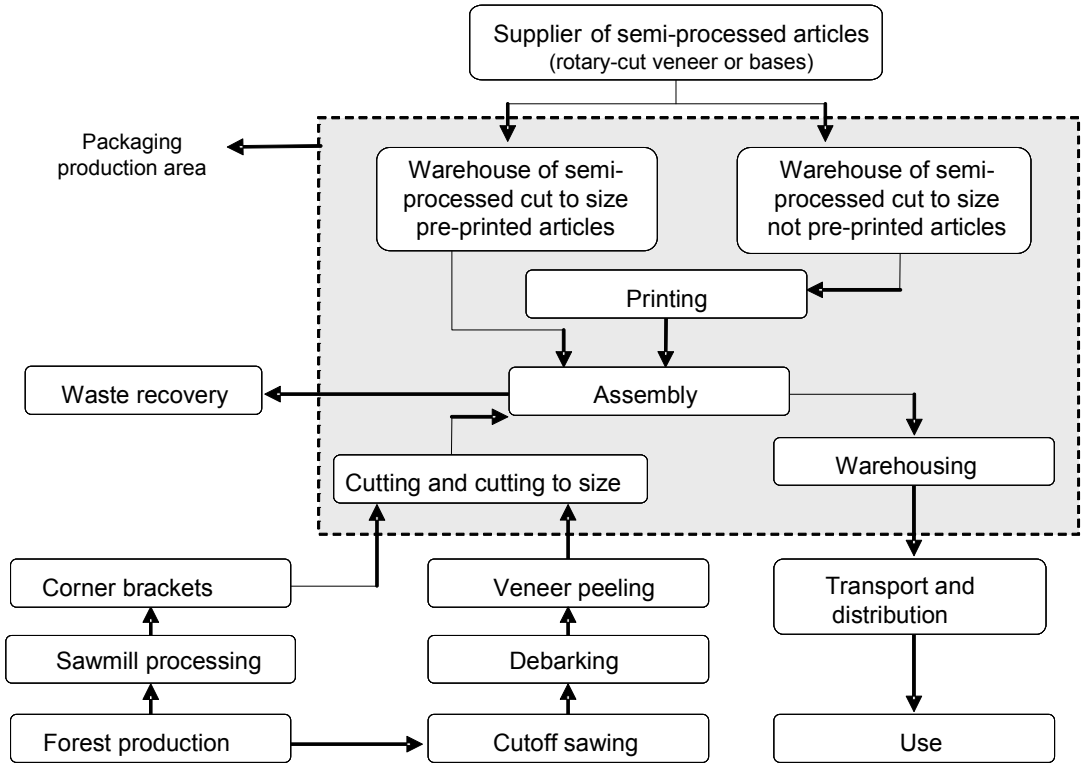
- *Cutoff sawing* → cutting in a direction perpendicular to the wood fiber to produce;
- *Debarking*
- *Rotary cutting (veneer peeling) and cutting to size* → rotary cutting is performed on regular-sized logs that are suited for this kind of treatment. The product obtained is a kind of wood sheet of 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 together 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.

B5.1.3.1.2. Semi-processed articles production flowchart



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 fiber 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.

B5.1.3.1.2.a. Wood fiber panels

Under standard EN 316, wood fiber 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 fiber panels (from UNI EN 316 Wood fiber panels. Definition, classification and symbols)

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

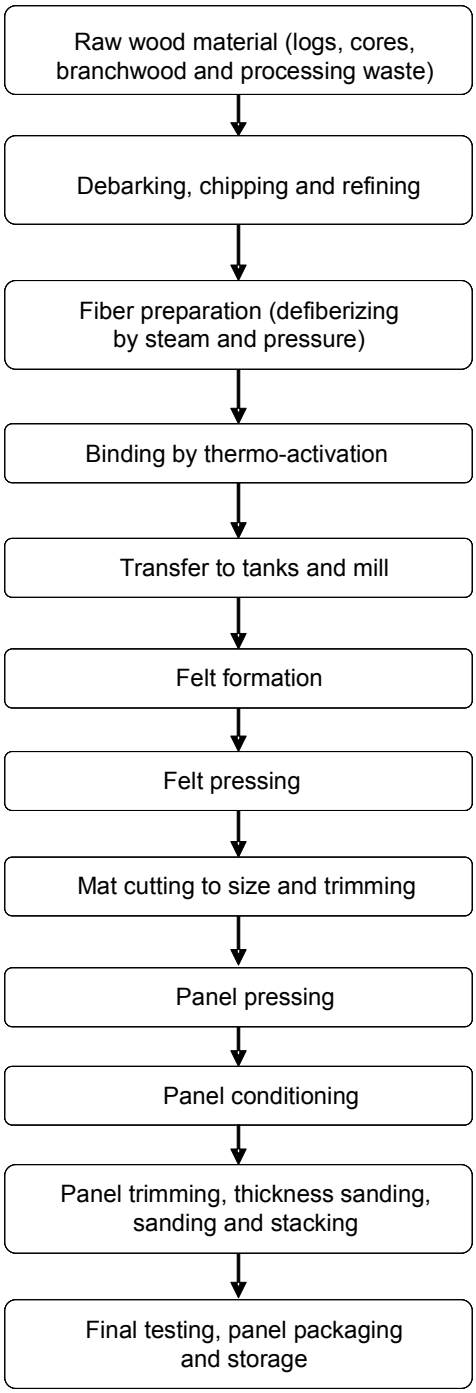
Wood fiber panels are obtained by defiberizing the raw wood material which becomes lignocellulosic fibers when heat and/or pressure are applied.

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 fiber aggregates and, only partially, of isolated fibers suspended in a black liquor made of products deriving from the thermo-hydrolysis of the cellulose.

Wood fiber panels using the wet method (Masonite)

Production flowchart



Brief description of stages in the process

Defiberizing creates a mass of fiber aggregates and, only partially, of isolated fibers 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[8] 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 fibers contain a sufficient percentage of lignin and if the latter does not alter during the defiberizing 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 fiber that have not been penetrated by the steam and which, as a result, are not defiberized. It is then homogenized in cone mills and collected in special containers.

This is followed by felt formation during which the mix of fibers 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 fiber 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.

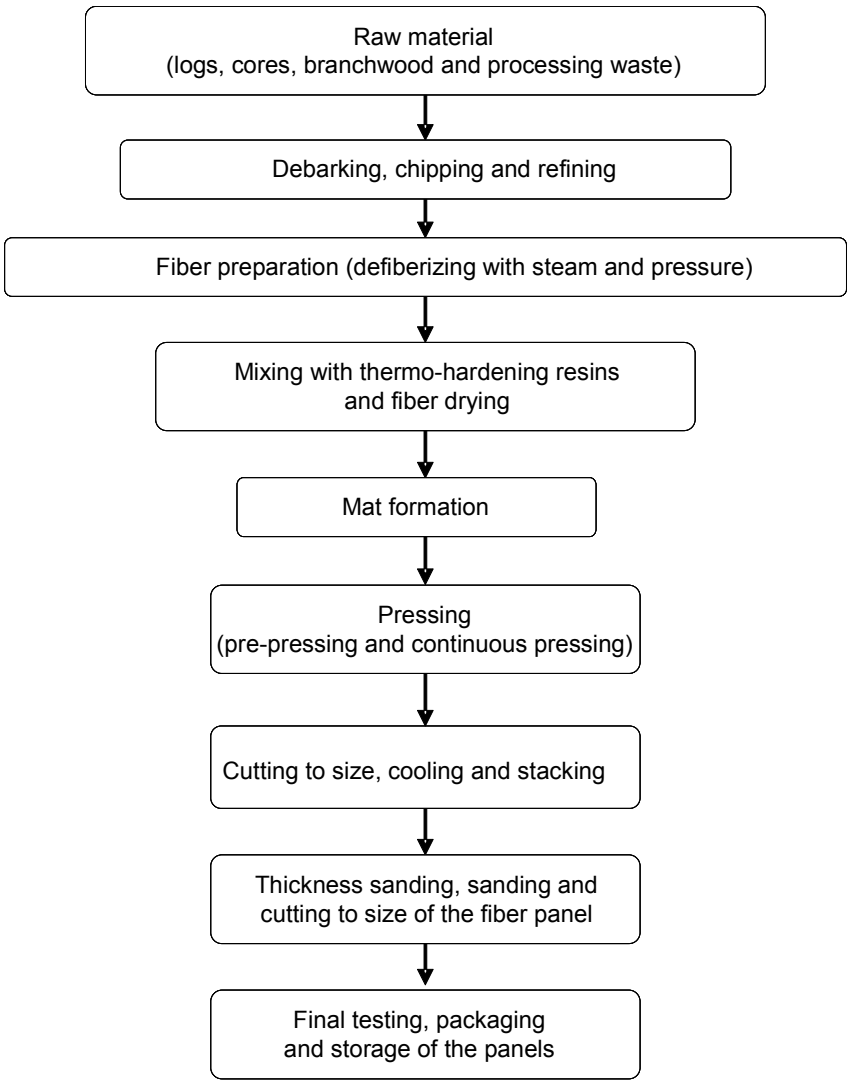
After pressing, the panels have a very low moisture content, less than 1.5%, and require a period of conditioning in a controlled atmosphere to reach a well-balanced moisture content close to 8%.

The panels are then trimmed, thickness sanded, sanded and stacked in areas that are possibly well ventilated.

[8] 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.

Wood fiber panels using the dry method (MDF)

Production flowchart



Brief description of stages in the process

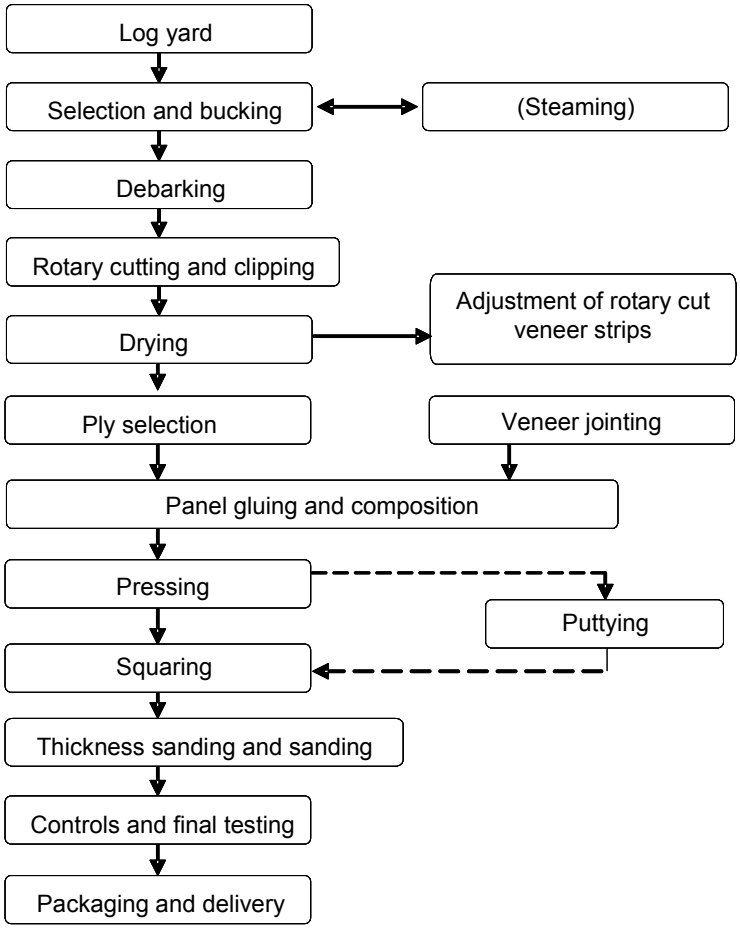
The dry method produces fiberboard with a lower volumic mass and excellent mechanical characteristics, called MDF (Medium Density Fiberboard).

In the "dry" manufacture of MDF panels, the fibers are dried before forming the "mat" (the moisture content of the fibers is less than 20% in the felting phase) and pressed at lower temperatures than when pressing "wet" felts.

In this case, since fiber cohesion by means of the natural wood components only, particularly the adhesive properties of lignin is not sufficient, for dry process production of fiberboard it is necessary to add a binding mix of thermo-hardening synthetic resin.

B5.1.3.1.2.b. Plywood panels

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 centered 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 fiber to obtain sheets of the same size as the finished panels.

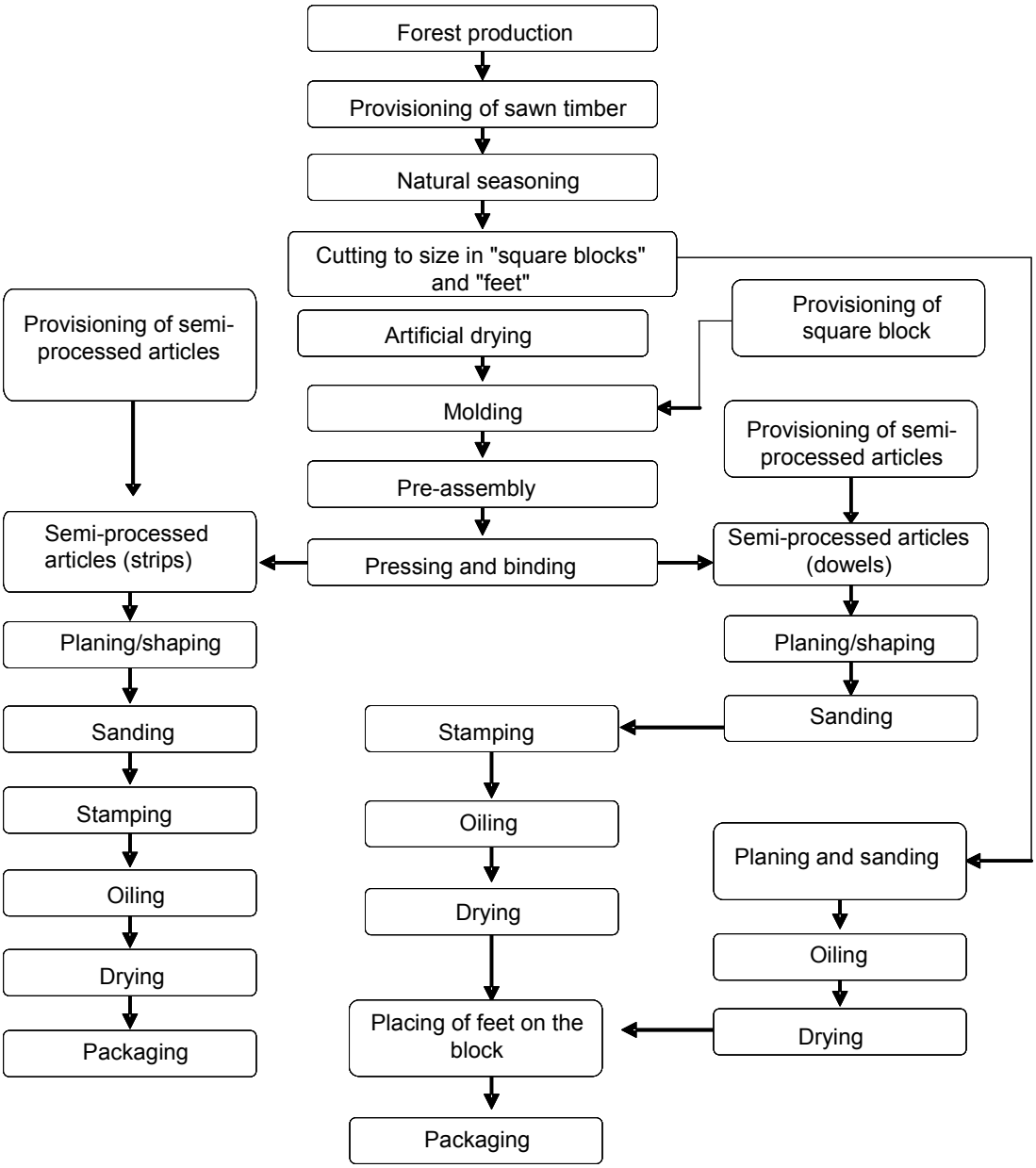
The plies produced from the clipping are then stacked separately according to size, quality and moisture content (ply selection).

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 sanding is performed to obtain an even panel thickness, and usually comes before the sanding (which confers smooth surfaces). The controls and final testing are the last stage before the panel is packed and shipped.

B5.1.3.2. Wood cutting boards, chopping blocks and boards.

Production flowchart



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 (*Carpìnus 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 for the production of 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.

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 molding 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, sanding, 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, planing, sanding, 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 planed 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.

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. Since this Regulation was laid down when the quality assurance systems had already become a daily worktool 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:

> "[..omitted..] 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 comma a Reg. (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006. Every paragraph is hence the response of the production chain 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 (Reg. (EC) 2023/2006, art. 5) and Size of 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, 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 and the Regulation (EC) 2023/2006 is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 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 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 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 GMPs, 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.

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 storege 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 GMPs 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.

In the event that a producer 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.

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 (where applicable);
- conformity to the Regulation (EC) 2023/2006 (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, 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 (Reg. (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.

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 semiprocessed 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 GMPs.

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, relevants to compliance with legislation on FCMs; procedures for managing non conformities and corrective measures should be implemented.

B5.2.3. Documentation (Reg. (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, the copies of the declarations of compliance issued by the customers in observance of art. 16 of the Regulation (EC) 1935/2004 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 should be updated.

B5.2.4. Bibliography

Studio legno - *Wood Consulting. Imballaggi ortofruttìcoli: lìnea guida per la caratterizzazione delle prestazioni e lo sviluppo dì un sistema di rintracciabilità (Fruit and vegetable packaging: Guidelines for performance features and the development of a traceability system).* Milano: Assoimballaggi FederlegnoArredo, Lampi di Stampa; 2004.

Assoimballaggi FederlegnoArredo. *Procedura operativa per la gestione della rintracciabilità per le imprese produttrici dì imballaggi ortofruttìcoli in legno (Operating procedure for traceability management for producers of wood fruit and vegetable packaging).* Milano: Assoimballaggi; 2006.

Useful sites

European Federation of Wooden Pallets and Packaging Manufacturers:
www.fefpeb.org

FederlegnoArredo:
www.federlegnoarredo. it

Wood Cork Service Consortium:
www.conlegno.org

Annex B5.1

Technical glossary

Adhesive: A substance to bind two elements of the same or different material by forming an interface surface to favor 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 (polyvinylactetate 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, branchwood, 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.

Debarker: 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 debarkers (the bark is eliminated by short chains that extend out by centrifugal force from a rotating container); rotor or ring debarkers (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 debarkers (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.

Defiberizing: Mechanical, chemical or thermo-mechanical action by means of which, particles, sawdust, or various kinds of wood waste can be made into bundles of fibers.

Drying: Operation that is performed by passing the cutting boards and chopping blocks in a special chamber to remove any excess oil (after oiling).

Drying: 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.

Dry-process manufacture fiberboard (MDF): Wood fiber panel (EN 316) produced from ligno-cellulosic fibers 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 isocianic) may be added.

Feet: Elements made of solid wood (polyhedron shape), with a support function, to be assembled together with the block or board.

Fiberboard: Two kinds of fiberboard are often used in the fruit and vegetable packaging industry: dry-process manufacture fiberboard (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 thermofusible 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 thermofusible 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) fiberboard 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.

Molding: 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.

Planing: Operation which consists in obtaining a flat surface (thin planing) and possibly in bringing sawn timber to the desired thickness (thick planing).

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 has 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 hydrolyzable 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 fibers 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 centered, 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 centering 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 center, 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. Can be bucked or not.

Sanding: 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 sanding 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 color; harmonize or reduce any differences in color 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 sanding: Operation that generally precedes the sanding of a wood-based panel and that involves leveling 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 ligno-cellulosic fibers by applying heat and/or pressure. Binding is achieved by means of fiber felting which exploits the adhesive properties or by adding a thermo-hardening synthetic adhesive (phenolic, aminoplastic, ureic, melaminic or isocianic). Other additives can be used in the production of wood fiber panels.

Annex B5.2

Frequently asked questions

Ql *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

Q2 *Is GMP required in the production of fiberboard 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 fiberboard 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 1935/04/EC, of which Regulation (EC) 2023/2006 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 fiberboard for the production of fruit and vegetable boxes required to comply with GMP?*

Yes. Assemblers of fiberboard, 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 *Do these guidelines apply to "boxes for seafood"?*

No, these guidelines do not apply to producers of wood packaging for seafood products, but they can be a good reference.

Q8 *Do these guidelines apply to other sectors?*

These guidelines apply to fruit and vegetable packaging made of wood and/or wood fiber and/or plywood, wood cutting boards, chopping boards (or blocks) and are a valid example that can be a reference for producers of wood fiber panels and plywood used in fruit and vegetable packaging.

Q9 *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.

Q10 *If a company produces bases and/or corner brackets intended for assembly in the production of 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).

Q11 *Do the GMP obligations apply to companies which – in the production of fruit and vegetable boxes – are only involved in assembly?*

Yes, they do.

Q12 *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.

Q13 *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.

Q14 *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.

Q15 *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 does not refer to any obligation to prepare a manual but to "Documentation"(Article 7 refers to "appropriate documentation in paper or electronic format").

Q16 *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.).

Q17 *In the production of wood articles, how should hygiene-related issues be addressed?*

Although Regulation (EC) 2023/2006 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.).

Q18 *Do the obligations of the Regulation (EC) 2023/2006 remain the same for small businesses?*

The obligations set by the Regulation (EC) 2023/2006 do not consider the size of the business but the premise (para 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 ".

Q19 *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);
- Framework Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food;
- Regulation (EC) 2023/2004 on Good Manufacturing Practice (GMP);
- Regulation (EC) 882/2004 on official controls of food products.

Q20 *Are there any specific requirements for special sectors?*

Italy has issued some specific regulations for wood for specific fields of application. A special field of application is work tops and blocks in meat processing facilities, where wood, for microbiological reasons given the difficulty with reclamation, is prohibited (DPR N.312 dated 10.9.1991 and EEC Directive 91/497). There is also a specific regulation (Law No. 128 Art.l comma 1 let.b, dated 10.4.91) 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.

Q21 *Are those engaged in the trade of MDF or Masonite required to comply with GMP?*

Yes, in terms of traceability obligations (under Regulation 1935/04/EC, of which Regulation (EC) 2023/2006 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.

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.

Multilayer multimaterial 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 of the European Parliament and Council of 27th October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

Regulation (EC) 2023/2006 of the Commission of 22nd December 2006 on the good manufacturing practice of materials and articles intended to come into contact with food.

Directive 2002/72/EC of the Commission of 6th August 2002 on materials and articles in plastic intended for contact with food products and subsequent updates (currently Directive 2004/1/EC, Directive 2004/19/EC, Directive 2005/79/EC, Directive 2007/19/EC, Directive 2008/39/EC)[9][10].

Regulation (EC) 882/2004 of the European Parliament and Council of 29th April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Regulation (EC) 1895/2005 of the Commission of 18th November 2005 on the restriction of the use of certain epoxy derivates in materials and articles intended to come into contact with food.

[9] Directives are regularly transposed as amendments to Ministerial Decree of 21st March 1973

[10] Since the 1st May 2011 the Regulation (EU) 10/2011 is in place. Articles 20-23 lay down the transition periods for the full implementation of this Regulation. The reference to the Regulation (EU) 10/2011 is not present in the original Italian version of these guidelines (Rapporti ISTISAN 9/33) because their publication was in 2009.

Council Directive 82/711/EEC of 18th October 1982 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 of 19th December 1985 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.

Italian national legislation:

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 and subsequent updates.

Decree of the President of the Republic No. 777 of 23rd August 1982 on implementation of Directive 76/893/EEC on materials and articles intended to come into contact with food and subsequent updates.

Legislative Decree No. 108 of 25th January 1992 on implementation of Directive 89/109/EEC on materials and articles intended to come into contact with food.

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.

Table 6.1. Production steps and processes related to raw materials

	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

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 are reported in Annex B6.2.

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. Since this Regulation was laid down when the quality assurance systems had already become a daily worktool 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:

> "[..omitted..] 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 comma a Reg. (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006. Every paragraph is hence the response of the plastic 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.

B6.2.1. Quality Assurance Systems (Reg. (EC) 2023/2006, art. 5) and Size of 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.

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, 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 and the Regulation (EC) 2023/2006 is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 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 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 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 GMPs, 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 adequate training plans 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.

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;
- declaration of compliance according to what has been established by the Directive EC/2002/72 and further amendments[11];
- conformity to the Regulation (EC) 2023/2006.

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.

[11] The Regulation (EC) 10/2011 should be now taken into account.

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 (Reg. (EC) 2023/2006, art. 6)

The Regulation (EC) 2023/2006 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 and the Framework Regulation (EC) 1935/2004.

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 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 controling 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 equipments 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 GMPs.

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 (Reg. (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, the copies of the declarations of compliance issued by the customers in observance of art. 16 of the Regulation (EC) 1935/2004 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 should be updated.

Annex B6.1

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 plastisols 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.

Annex B6.2

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 ($-NH_2$) 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 mold 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 axis, 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.

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-pieces cans and aerosols with electro-welded body;
- caps and closures;
- 2-pieces 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 of the European Parliament and Council of 27th October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

Regulation (EC) 2023/2006 of the Commission of 22nd December 2006 on the good manufacturing practice of materials and articles intended to come into contact with food.

Regulation (EC) 882/2004 of the European Parliament and Council of 29th April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Regulation (EC) 1895/2005 of the Commission of 18th November 2005 on the restriction of the use of certain epoxy derivates in materials and articles intended to come into contact with food.

Directive 2002/72/EC of the Commission of 6th August 2002 on materials and articles intended to be used in contact with food products and subsequent updates (Field of Application: Caps' garnishes)[12][13]

Italian national legislation:

Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, intended to come into contact with food or substances for personal use and subsequent updates.

Decree No. 777 of 23rd August 1982 on implementation of Directive 76/893/EEC on materials and articles intended to come into contact with food and subsequent updates.

Decree No. 405 of 18th February 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).

Decree No. 243 of 1st June 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 are pointed out.

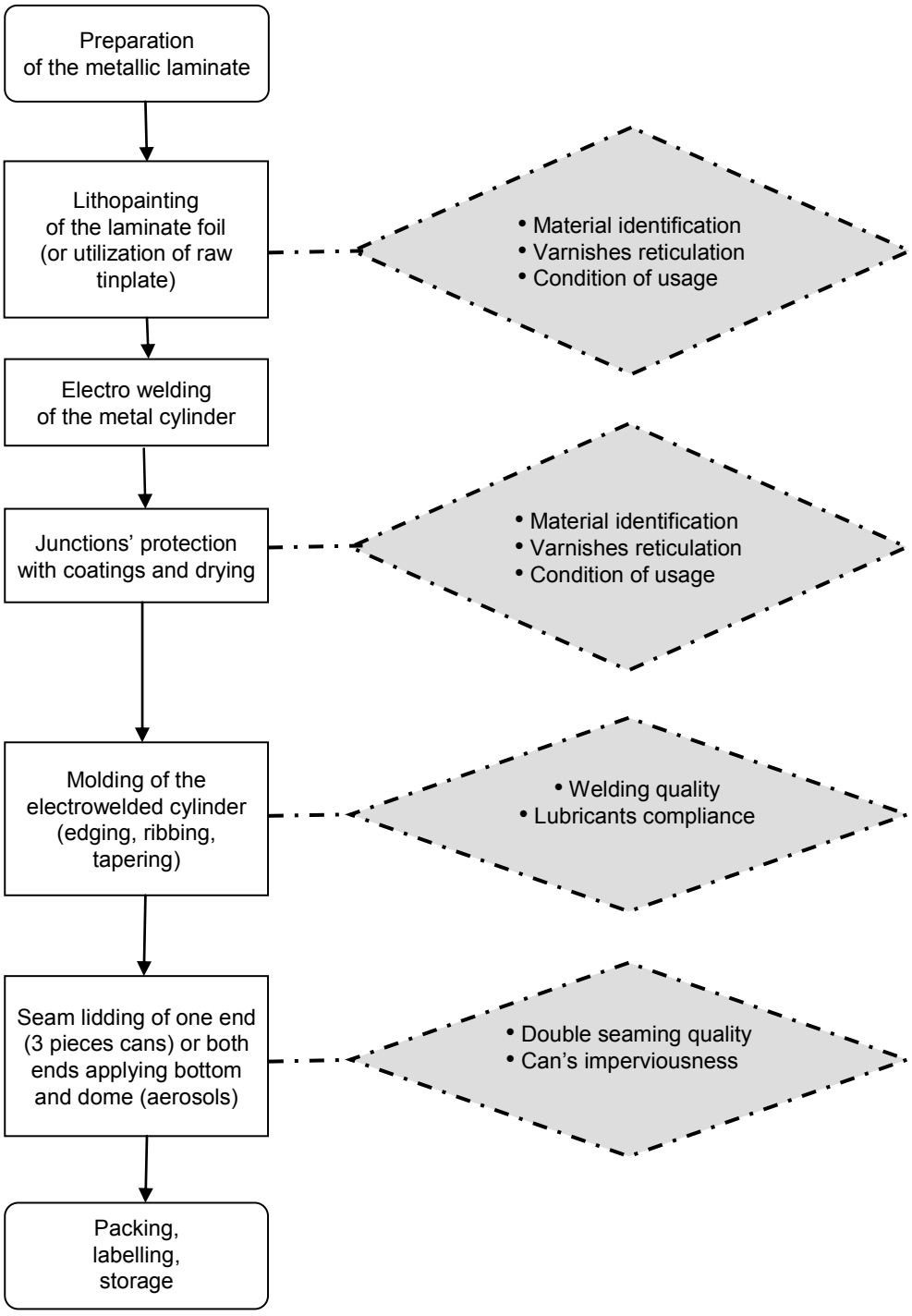
Beside each critical phase, a dashed box describes the specific aspects to guarantee conformity to the applicable laws.

[12] Directives are regularly transposed as amendments to Ministerial Decree of 21st March 1973.

[13] Since 1st May 2011 the Regulation (EU) 10/2011 is in place. Articles 20-23 lay down the transition periods for the full implementation of this Regulation. The reference to the Regulation (EU) 10/2011 is not present in the original Italian version of these guidelines (Rapporti ISTISAN 9/33) because their publication was in 2009.

B7.1.3.1. Three pieces cans and aerosol cans with electrowelded body

Production flowchart



Brief description of process phases

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 charateristics 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 and external application of protection varnishes and inks (only external) on the metallic plane laminate, followed by reticulation through thermic processes (conventional) 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.

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 then a minute).

Molding 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 pieces 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 are conducted by the canmaker (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.

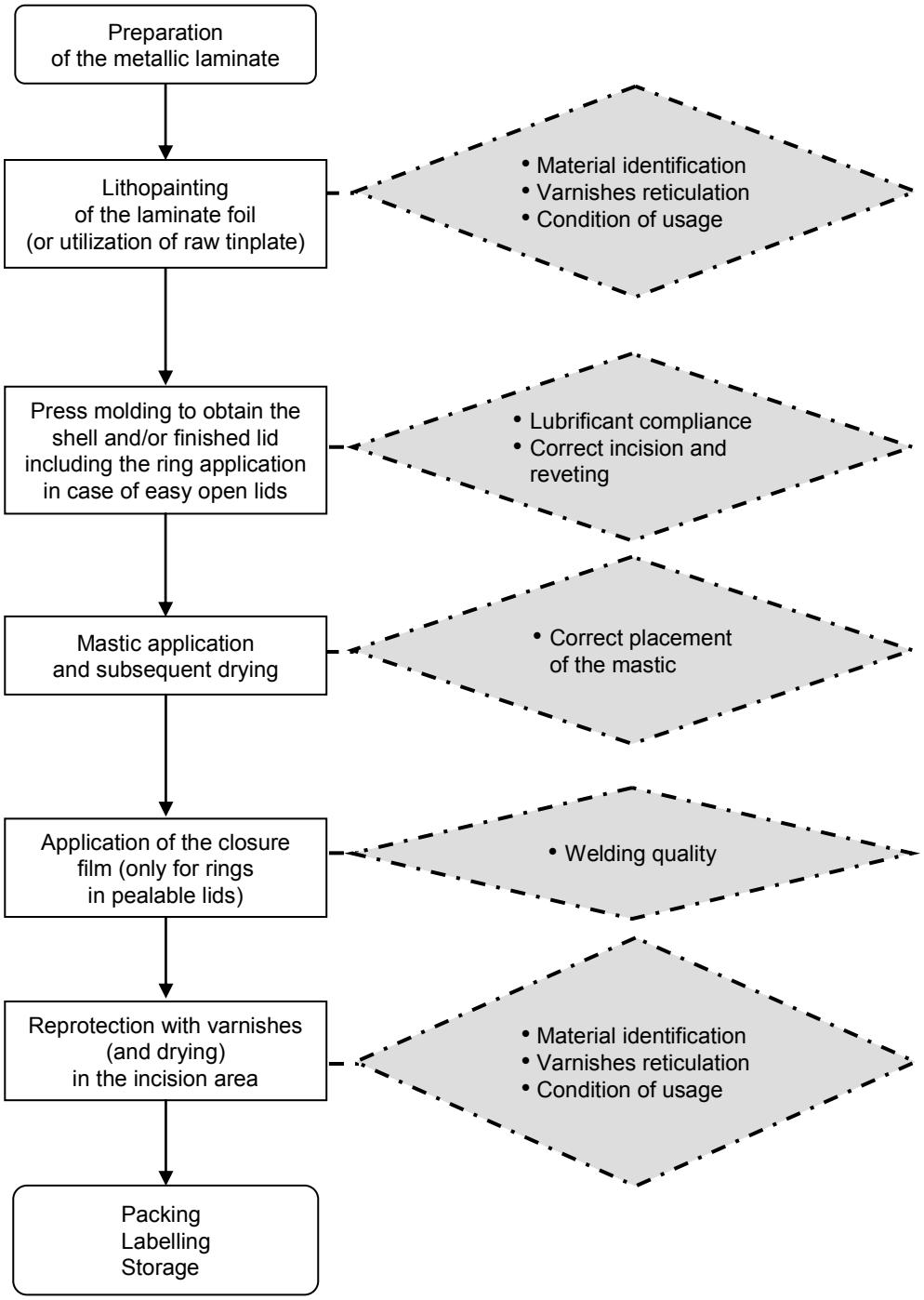
These platforms in the warehouse are usually piled forming stowed columns.

Figure B7.1 shows examples of typical products.

Figure B7.1. Example of 3 pieces cans

B7.1.3.2. Open top, easy open and peelable lids

Product flowchart



Brief description of process phases

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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 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 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) molding

The foil has to be previously cut in stripes of defined dimensions. After this operation, the lids are created by press molding: using one (if the cutting and printing operations are conducted in the same time) or two dies, the lids are cut out and shaped.
Then follows the curling operation: the edge of the lids are curled inside.
In the case of easy open lids the manufacturing operations of the lid include other steps such as the "conversion" (press molding to obtain the shell and/or finished lid including the ring application)
In case of peelable lids the molding operations include also 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 furnaces. 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).

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 B7.2 shows some examples of lids.

pealable lids

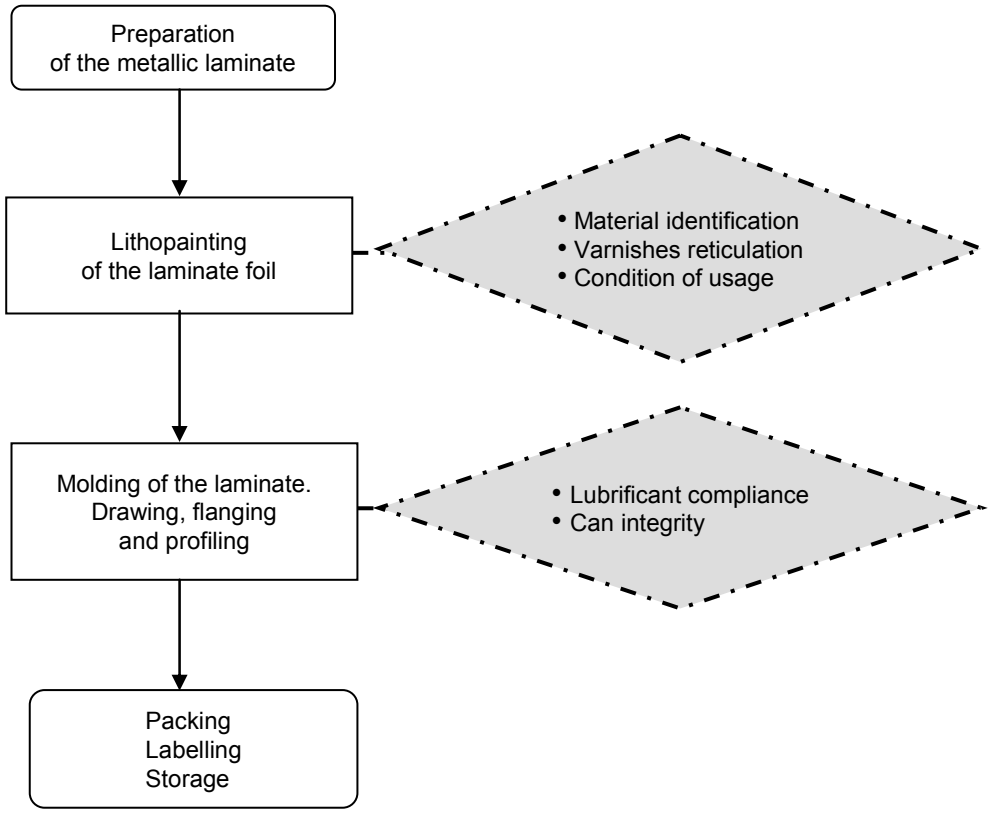
open top lids

easy open lids

Figure B7.2. Examples of different typologies of lids

B7.1.3.3. Drawn and redrawn metal cans (2 piece can DRD)

Production flowchart



Brief description of process phases

Preparation of the laminate

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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

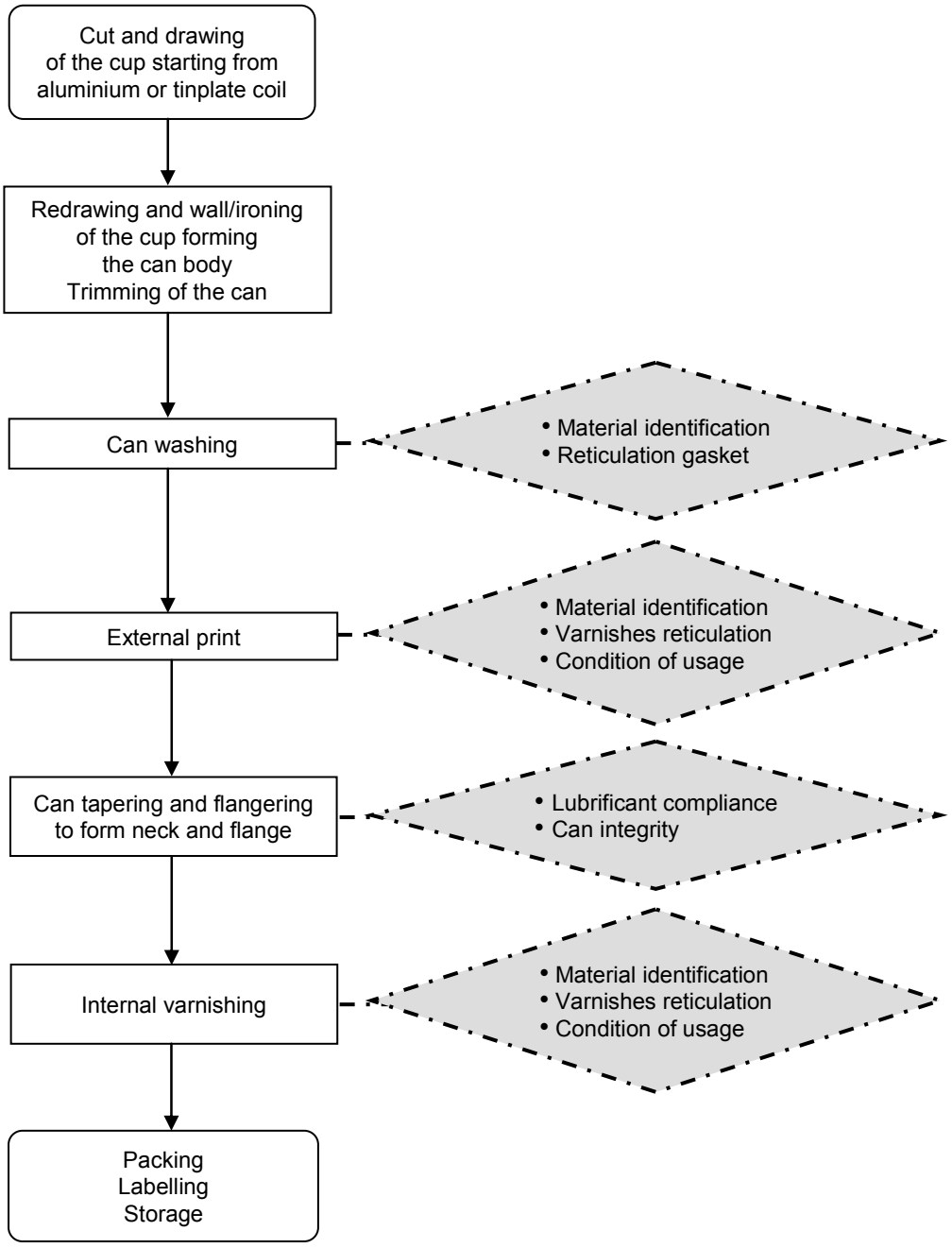
Disposition of the cans on ordered plans inside carton-boxes (or other kinds) so that they are disposed in deliverable units called pallet, clearly identifiable by labels and codes placed on each side of the platform.
Usually pallets are wooden or plastic platforms, allowing handling, charge and discharge operations using forklifts.
These platforms are usually piled forming stowed columns.

Figure B7.3 shows some examples of typical products.

Figure B7.3. Examples of 2 piece can DRD

B7.1.3.4. Drawn and wall-ironed (DWI)

Production flowchart



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

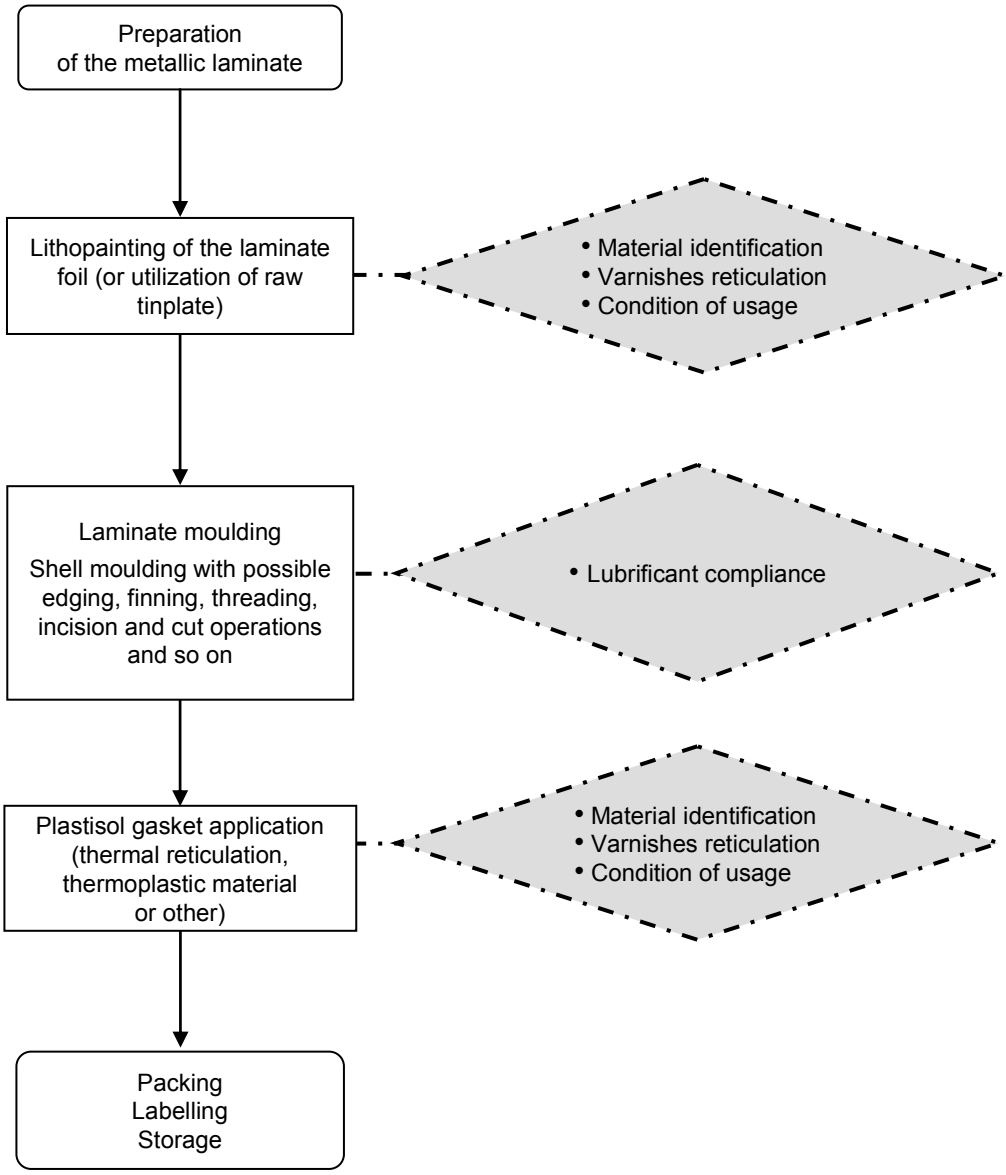
An internal protective spray varnish is applied and then thermically reticulated passing the can into a oven.

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.

B7.1.3.5. Closures (capsules with fins, PT capsules, crown caps)

Production flowchart



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 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 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 molding 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' molding in case of capsule production).

Gasket application

This operation consists of the application (spray or by deposition) of the gasket mastic, consisting of a highly flexible thermoplastic polymer. Then, the thermal reticulation process in a oven is performed.

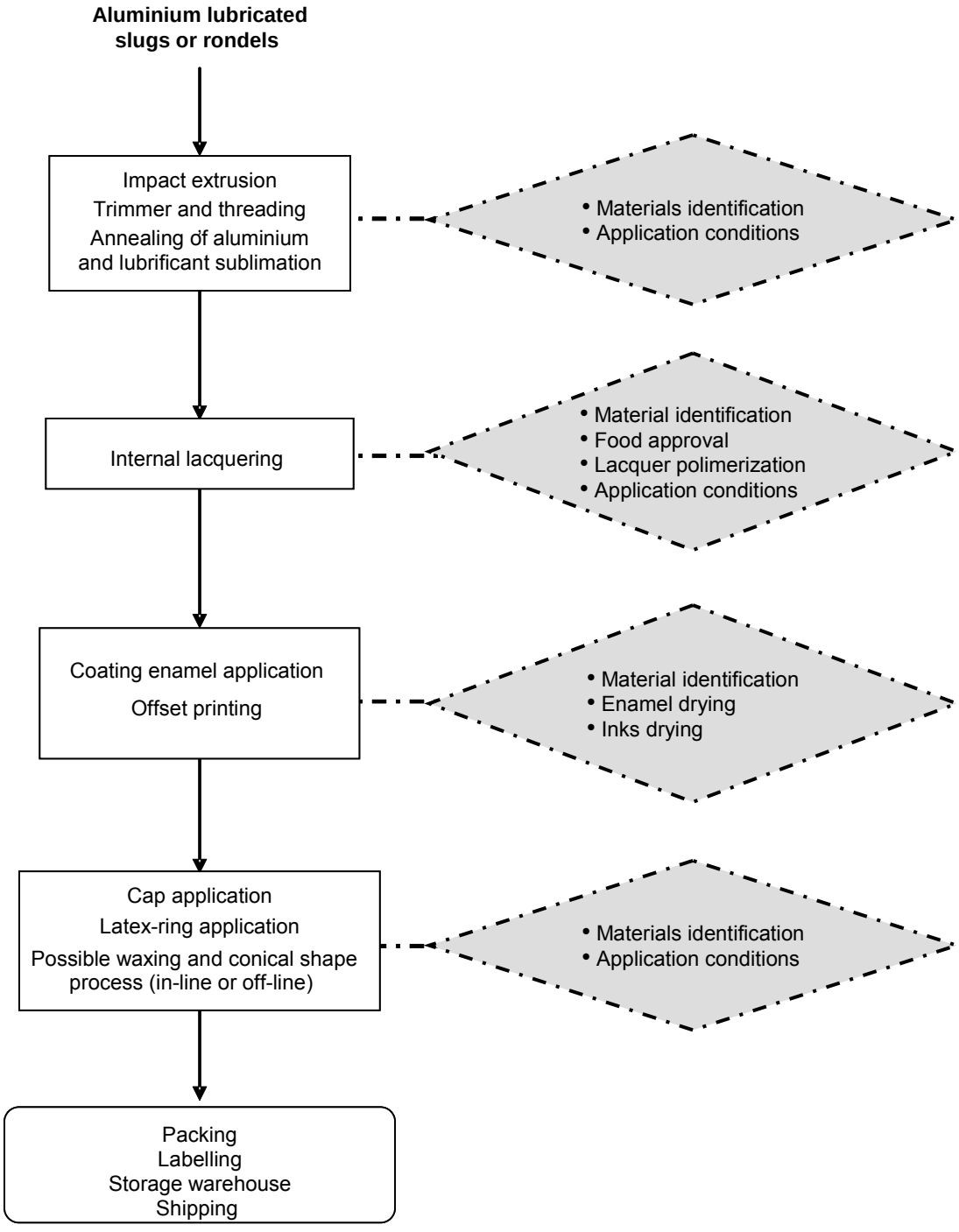
Packing, labelling, storage

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.

B7.1.3.6. Flexible tubes, not deformable



Brief description of process phases

Blank lubrification

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 aluminum 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 aluminum 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 colored, 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

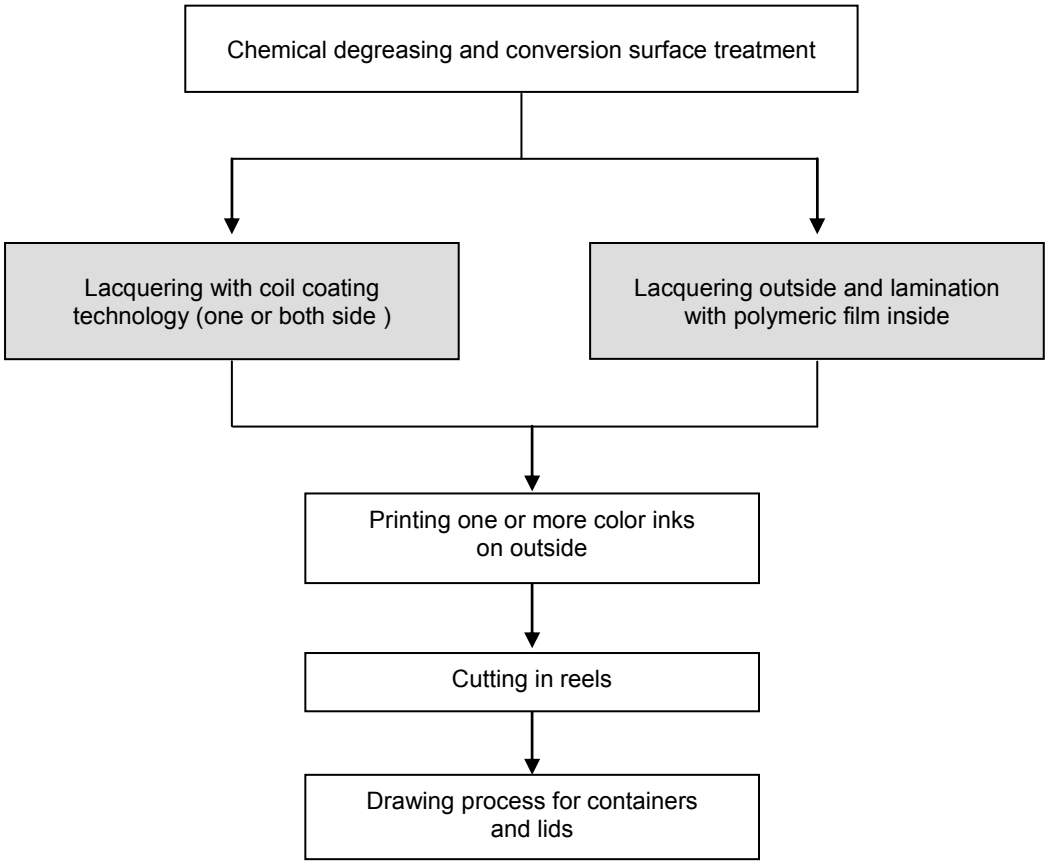
This phase consists into 3 operations:

- 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).

B7.1.3.7. Semi-rigid containers lacquered or coupled with polymer films

Production flowchart



Synthetic description of the process' phases

Coil coating technology

The aluminium coil, after being chemically degreased and submitted to surface conversion treatment (as for example 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 rewinded 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 sinergically the multiple features of a single polymer.

Figures B7.4a-B7.4e show some examples of semirigid containers of coated aluminium with different types of closures.

Figure B7.4a. Typical tray used by air line companies with wrapped lid

Figure B7.4.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 B7.4.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 B7.4.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 B7.4.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. Since this Regulation was laid down when the quality assurance systems had already become a daily worktool 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:

> "[..omitted..] 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 comma a Reg. (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006. Every paragraph is hence the response of the the metal packaging (coated and not-coated) 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.

B7.2.1. Quality Assurance Systems (Reg. (EC) 2023/2006, art. 5) and Size of 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, 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 and the Regulation (EC) 2023/2006 is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 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 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 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 GMPs, on the obligations that derive from the Regulation (EC) 2023/2006, 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 informations 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, 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 GMPs 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 producer 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 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 these informations, 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 a 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 recontrolled 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 informations 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 these informations, 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 exists, 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 (Reg. (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 and the Framework Regulation (EC) 1935/2004.

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 semiprocessed 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 fondamental 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 GMPs.

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, relevants 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 (Reg. (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, 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 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 bodymaking 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 bodymaking 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.

Dimentional finishes: Obtain the final dimensions of the tube by turning.

Drawing and wall ironing DWI: Metal forming process 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.

DRD: 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.

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 chromiumadjacent to the steel substrate with a top layer of hydrated chromium oxides or hydroxides.

Electrolytic tinplate: 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 incororation 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 aluminum layer lacquerd 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.

Lubrification by tumbling: lubrification of alluminium slugs and rondels by lubrificants usually solid (Zinc Stearate or Zinc Arachinate) to facilitate the impact extrusion. The lubrificant 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.

Pelable 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 consist 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 alluminium

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).

Traceability: The ability to trace and follow a material or article through all stages of manufacturing processing and distribution.

Waxing: Hot application by sprying of natural wax to avoid the interaction between the aluminum and the alkaline substances.

Annex B7.2

Frequently asked questions

Q1 *Do the Directive 2002/72/CE and its further amendments apply to the metal packaging sector?*

No, they apply to plastic materials only, not to metal coating.

Q2 *Is there a specific European legislation for metal coatings?*

No, the general principles and criteria of the frame Reg. (EC) 1935/2004 are applicable to metal coatings. Then the Reg. (EC) 1895/2005 that defines the migration limits for some epoxy derivatives from plastic materials or metal coatings is applicable, too.

However It is available a voluntary GMP (CEPE guidelines) from the European metal coatings producers.

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 - Tin and tin alloys-Ingot tin; EN 10202:2001 (AC: 2003) - Electrolytic tinplate and electrolytic chromium/chromium oxide coated steel (UNI EN 10202 del march 2004); 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 avaialable a voluntary GMP (APEAL guidelines) from the European tinplate producers.

Q4 *Is there a specific European legislation for ECCS?*

No, but some technical standards are available such as: EN 10202:2001 (AC: 2003) - Electrolytic tinplate and electrolytic chromium/chromium oxide coated steel (UNI EN 10202:2004). 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?*

No, when the lacquer film acts as an appropriate barrier between the foodstuff and the metal.

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.

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. On the basis of such information, the most proper coating is selected, suitable for the food to be preserved and the cooking conditions that will be used.

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[14]. Exclusion from the application of this guideline does not automatically imply exclusion from the Regulation (EC) 2023/2006.

The cork 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 of the European Parliament and of the European Council of 27th October 2004 on materials and articles intended to come into contact with food and repeal Directives 80/590/EEC and 89/109/EEC.

Regulation (EC) 2023/2006 of the European Commission of 22nd December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Regulation (EC) 882/2004 of the European Parliament and the European Council of 29th April 2004 on official controls designed to verify compliance with regulations regarding feed and food and rules on animal health and welfare.

Italian national legislation:

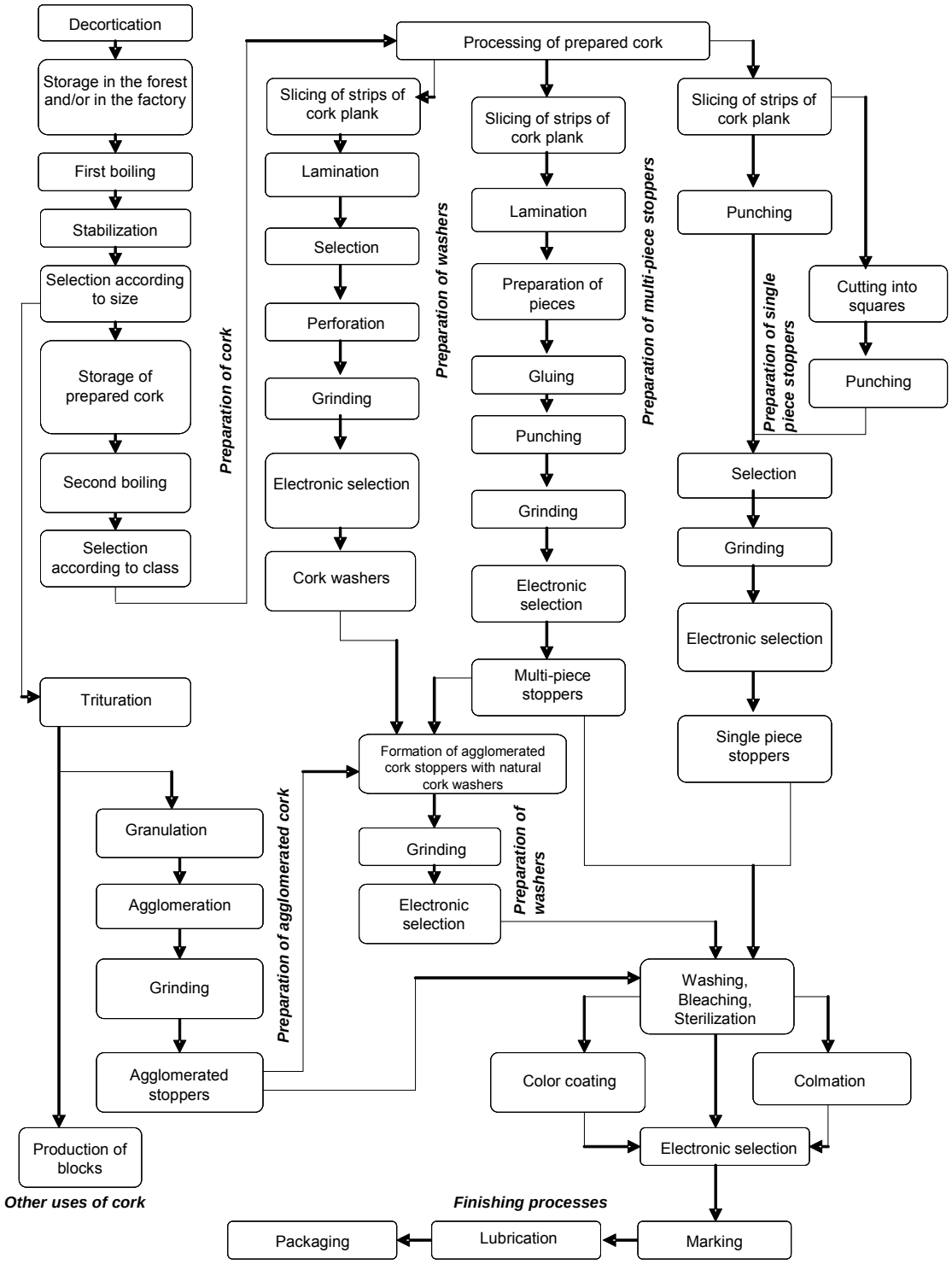
Decree of the President of the Republic No. 777 of 23rd August 1982 on implementation of Directive 89/109/EEC and 76/893/EEC on materials and articles intended to come into contact with food as amended.

Legislative Decree No. 108 of 25th January 1992 on implementation of Directive 89/109/EEC on materials and articles intended to come into contact with food.

[14] 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".

B8.1.3. Phases of the production process: flowchart and description

Production flowchart



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.

Generally speaking, cork is *produced in blocks,* however, not for the production of 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 of all, 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 as a result of the iron tannates). After further rinsing with clean water, the stoppers may be colored (*color 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, odors, dust, microorganisms, which may contaminate the closures.

Jute, of vegetable origin, can contaminate the closures with flavors 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. Since this Regulation was laid down when the quality assurance systems had already become a daily worktool in most of the manufacturing businesses[15], it is likely that these businesses already produce in conformity with technical specifications laid down by themselves.

[15]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:

> "[..omitted..] 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 comma a Reg. (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006. Every paragraph is hence the response of the the cork stopper manufacturing industry 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.

B8.2.1. Quality Assurance Systems (Reg. (EC) 2023/2006, art. 5) and Size of 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, 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 and the Regulation (EC) 2023/2006 is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 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 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 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 GMPs, 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 GMPs 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 producer 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..

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 (where applicable);
- conformity to the Regulation (EC) 2023/2006 (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, where applicable.

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 (Reg. (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.

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 semiprocessed 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 GMPs.

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, relevants to compliance with legislation on FCMs; procedures for managing non conformities and corrective measures should be implemented.

B8.2.3. Documentation (Reg. (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, 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 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 releaseable 2, 4, 6, - trichloroanisol (TCA).* Geneva: International Organization for Standardization; 2007.

ISO 21128:2006: *Cork stoppers – Determination of oxidizing residues – Iodometric 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

Stazione Sperimentale del Sughero. *Disciplinare sulla produzione ed utilizzo del tappo di sughero in enologia.* Tempio Pausania (Sassari): Stazione Sperimentale del Sughero; 1996.

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Assoimballaggi Federlegno furniture. *Lìnee guida per la realizzazione dì un manuale aziendale dì autocontrollo/HACCPper 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

Riboulet JM, Alegoet C. *Aspetti tecnici della tappatura dei vini.* Chaintré: Burogne Publications sarl; 1997.

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 molding: Cork stopper obtained by agglutination of cork granules with binders from a process of molding, 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.

Color coating: Application of a colored film on the surface of the stoppers.

Coloring: 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 color, 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 colors 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 molding, 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 caliber (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 enological 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 for the production of 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.

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 CE. Liege code?*

The CE. 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 Reg. (EC) 2023/2006. 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 "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 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 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:

- DPR 777/1982 and DL.vo 108/1992 (in force regarding declarations of conformity and applicable sanctions);
- Framework Regulation (EC) 1935/2004 on materials and articles in contact with food;
- Regulation (EC) 2023/2006 on good manufacturing practices (GMP);
- Regulation (EC) 882/2004 on official controls of food.

B9. GLASS

B9.1. Characterization 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 of the European Parliament and of the European Council of 27th October 2004 on materials and articles intended to come into contact with food and repeal Directives 80/590/EEC and 89/109/EEC.

Regulation (EC) 2023/2006 of the European Commission of 22nd December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Regulation (EC) 882/2004 of the European Parliament and the European Council of 29th April 2004 on official controls designed to verify compliance with regulations regarding feed and food and rules on animal health and welfare.

Italian national legislation:

Decree of the President of the Republic No. 777 of 23rd August 1982 on implementation of Directive 89/109/EEC and 76/893/EEC on materials and articles intended to come into contact with food as amended.

Legislative Decree dated No. 108 of 25th January 1992 on implementation of Directive 89/109/EEC on materials and articles intended to come into contact with food.

Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, intended to come into contact with food or substances for personal use and subsequent updates.

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, devoid 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 a chemical structure similar to 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 assume its own stable form.

In the melting phase, at high temperature, a sequence of chemical reactions takes place unhinging the raw materials' crystalline structures. During the subsequent rapid cooling, the chemical elements reform into amorphous and isotropic structures (vitrification). Silica dioxide, for example, coming from sand where it is present in its regular structure, becomes the main component of the glassy framework, however other elements (Ca, Mg, Na, etc.) coming from different raw materials (soda, marble, dolomite, etc.) will also be present in the silica network for the purpose of obtaining the glassy materials most suitable to the end use (containers and home articles).

In other words, the chemical reactions of the raw materials produce a new homogeneous material.

A particular fundamental element is the fact that once the glass formula 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 working temperature limit values, the machine speed, the softening and annealing temperatures, and the chemical resistance of the glass to the food it will contain.

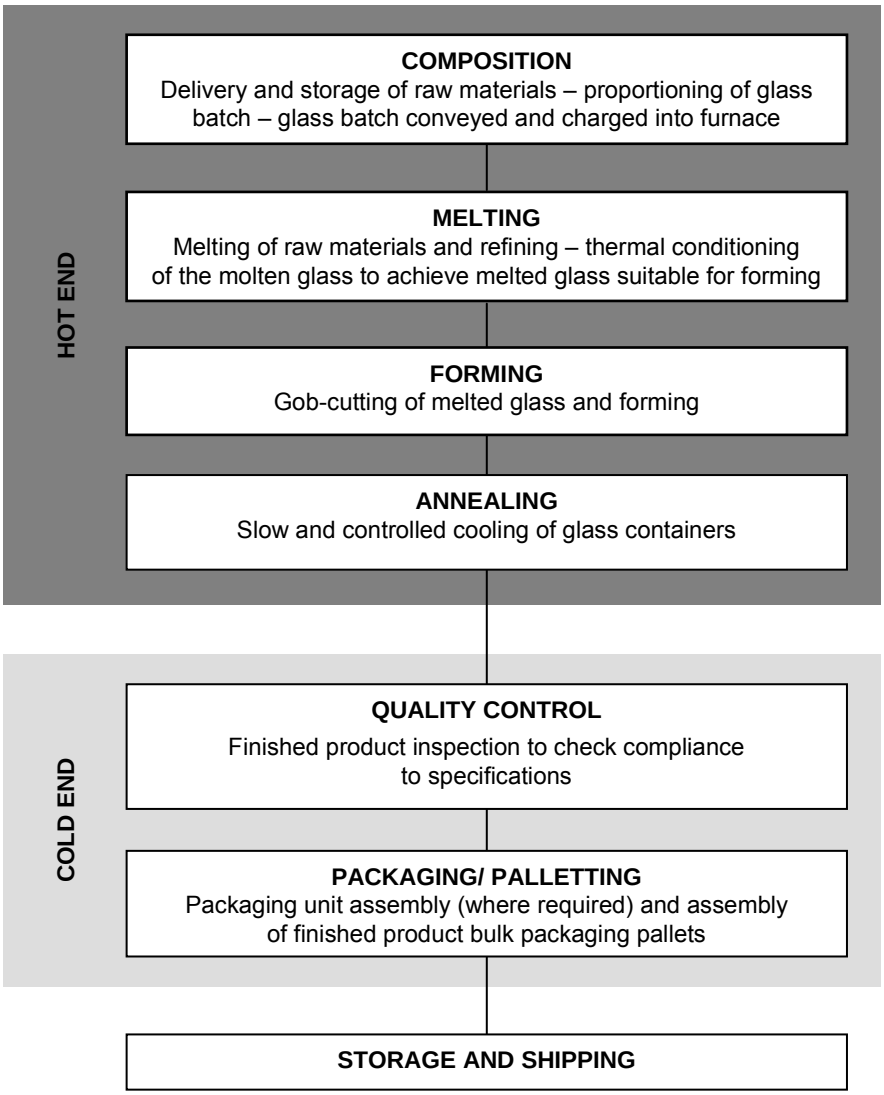
In a glass-factory, each step of the process has quality controls carried out to assure the consistency and efficiency of the whole production process.

Possible deviations from the standard production process parameters, due to glass formulation error, cause conditions that make impossible the regular production process.

Eventual glass formulation errors compromising food contact suitability are responsible for containers manufacturing impossibility because the whole production process, from melting to forming, could be compromised.

Therefore, many process controls, required to assure continuity, are to be regarded as controls related to the Regulation (EC) 2023/2006.

Production flowchart



Brief description of process phases

The glass packaging sector of containers for foods 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/palletting.

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

Hot-End

Composition

The batch composition is the first hot-end sub-process and concerns receiving and storage of raw materials and the preparation of a batch mixture that can be melted into glass. Raw materials (silica sand, soda, lime, dolomite, etc.), mainly stored in silos, are appropriately weighed, mixed and humidified in order to obtain a certain mixture that can be melted into glass (*batch*).

The batch, having a total weight in the range of between 500 and 2000 kg, is directly sent to the furnace with conveyor belts and furnace chargers.

Another important component of the mixture is glass cullet from the internal manufacturing process and from outside differentiating recycling collection, which, after being properly checked, is made suitable for the melting process.

Melting

The melting and refining process is composed of a complex sequence of chemical and physical reactions, 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 gas free. 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 specifications.

The melting and refining processes take place in the furnace tank, built with refractory material and so able to resist to the above mentioned high temperatures for many years. The glass manufacturing plant operates round the clock 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 cooling of the glass to the gob temperature, normally the temperatures go down 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 flow into gobs of suitable weight, shape and temperature;
- Gob delivery to 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.

Subsequently, the two processes are named, respectively "press and blow" and "blow and blow".
The first one is more suitable for wide mouth containers (jars) and 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 can be applied both at the exit of the forming machine, when the ware still has a temperature of about 500°C (*hot-end coating*) and, afterwards, at the exit of the annealing lehr (*cold-end coating*).
It is common a combined treatments because the hot-end treatment represents the ideal substrate for anchoring the subsequent cold-end treatment.
The first one enhances the mechanical resistance of the container, while the cold one reduces friction, improving their flow on automatic packaging and filling lines and reducing micro-stretches that 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 ware 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, for example, need welding between two parts subsequent to a superficial re melting operation. The two components are separately obtained through the above mentioned technologies. For example, the bowl is manufactured through the press-blow while the disc is obtained through pressing and the two parts are subsequently welded on a rotary machine.
Drinking vessels, manufactured with the press and blow process, also require cutting the upper part 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 valuable drinking vessels. In this latter case, the rim must be finished by grinding and blazing 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 and then is slowly cooled to avoid new tensile stress.
In the case of certain glass articles, thermal treatment is replaced by tempering; the application 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 qualitative check is carried out manually or automatically to verify the container conformity to agreed specifications. Unsuitable containers are taken off the packing line and immediately recycled in the same process in order to be re-melted down 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 is usually the "pallet" and is composed of a wood pallet, a layer pad, a covering lid, and a thermally shrunk down to size plastic hood cover, which represents the factory's sale unit after labelling and marketing.

This pack is able to 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 staked completed, the pallet is wrapped with polyethylene elastic tubular or covered with a polyethylene hood which again is shrunk wrapped on to and over the entire bulk pallet. The glass companies have adopted the standard procedure to label and so clearly identify the single sale unit to the client, in order to fulfil the requirement of traceability required for food containers. The single unit consists of a pallet if the manufacturer produces glass containers or, American boxes, or baskets, if the manufacturer produces household or table ware goods.

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. Since this Regulation was laid down when the quality assurance systems had already become a daily worktool 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:

> "[..omitted..] 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 comma a Reg. (EC) 2023/2006).

This part deals with specific subjects, respecting the numerical sequence of the articles of the Regulation (EC) 2023/2006. Every paragraph is hence the response of the the glass container

industry 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 (Reg. (EC) 2023/2006, art. 5) and Size of 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, 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 and the Regulation (EC) 2023/2006 is responsible for the management of the resources and the activities required to guarantee that Regulation (EC) 2023/2006 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 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 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 GMPs, 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

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 the flowchart B9.1), while others are necessary to guarantee that the containers respect the quality standards suitable for their intended use.

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.

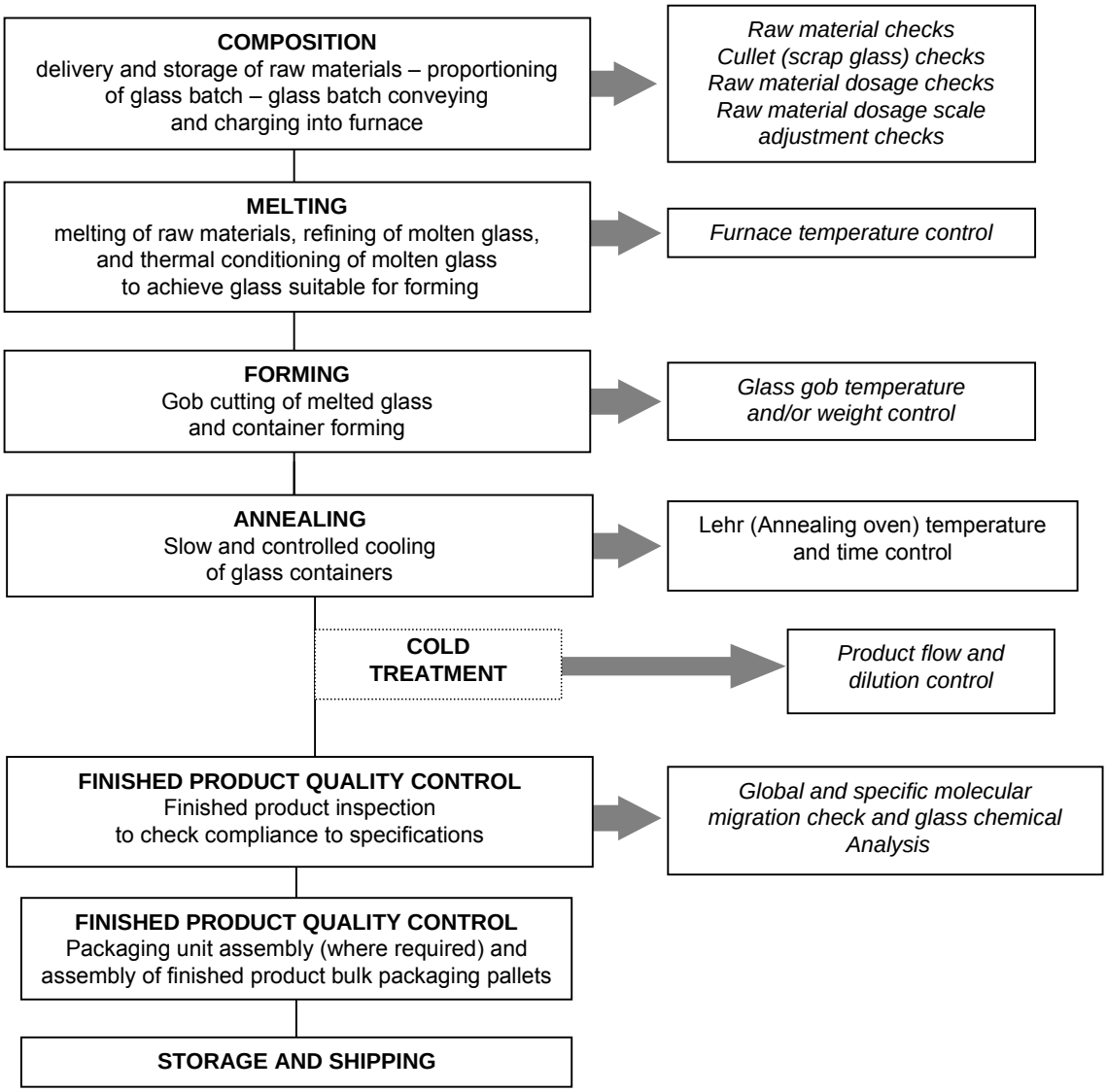


Figure B9.1. Product and production process control chart
(checks directly related to food contact suitability are in italics)

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.

It is important to underline that the viscosity of the glass, and therefore the ability to shape it, is related to its chemical composition, consequently, any 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 any 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 made. 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 and updates);
- glass chemical analysis of the finished container.

Please Note: 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.

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 (Reg. (EC) 2023/2006, art. 7)

All the documents related to the Quality Assurance System and all the activities of the Quality Control System to fulfill the obligations of the Regulation (EC) 2023/2006 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 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 strengthen 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 staking 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: pre formed 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 its changeability for its weight.

Vitrification: process of transformation of the batch raw materials into glass.

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 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 a oggetti a contatto con gli alimenti – Assovetro, 2009), that is, Italian Glass Packaging Industry Behaviour Code (obligations concerning food contacting materials and articles – Assovetro 2009) which includes a subject type format which can be provided to customers. It is in any case the responsibility of a the company to issue a declaration in accordance with the Italian Decreto Ministeriale 21.3.73.

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 as per the Italian DM 21.3.73 and the migration test have to be performed in accordance with the method detailed this same DM 21.3.73. In the case of lead glass, also, the migration has to be carried out in accordance with DM 21.3.73. 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 a glass research center).

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, marble, dolomite, sodium sulphate, internal glass cullet, and outside glass cullet coming from waste collection 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 etc.

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 and Regulation (EC) 1935/2004 do not provide for a fixed system. Useful references and label prototypes are provided in the sale unit and may be found in the Codice di comportamento dell'industria italiana del vetro da imballaggio (Obblighi per materiali a oggetti a contatto con gli alimenti – Assovetro, 2009), that is, Italian Glass Packaging Industry Behaviour Code (obligations concerning food contacting materials and articles – Assovetro 2009). According to this document, if the customer retains the label supplied with the goods, the traceability of the product can be guaranteed.

APPENDIX
Other aspects relating to food safety in the practices of food packaging chains

Introduction

This Appendix deals with some aspects that, while not directly regarding the field of application of the Regulation (EC) 2023/2006, 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, 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/ 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 and the application of the GMPs 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 and described in this guideline, as well as with what has been laid down in terms of traceability of packaging (Reg. (EC) 1935/2004).

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, 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 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 separate from the production sections.

Use of non legislative documents in the evaluation process

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 FCM and to the general requirements of art. 3 of the Regulation (EC) 1935/2004.

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:
  - Confederation of European Paper Industries. *Guidelines for responsible sourcing and supply of recovered paper*. Bruxelles: CEPI; 2006.
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- 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.

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.

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