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CAST Project

Guidelines for supporting documentation for the declaration of compliance with legislation on materials and articles in contact with food

English version of Rapporto ISTISAN 24/29

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

AMBIENTE E SALUTE

ISTITUTO SUPERIORE DI SANITÀ

CAST Project

Guidelines for supporting documentation for the declaration of compliance with legislation on materials and articles in contact with food

English version of *Rapporto ISTISAN* 24/29

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Edited by Cinzia Gesumundo, Maria Rosaria Milana, Giorgio Padula, Silvia Giamberardini, Fabiana Vanni, Marco De Felice, Massimo Denaro, Roberta Feliciani, Michele Massara, Veruscka Mannoni
2025, xviii, 273 p. Rapporti ISTISAN 25/23

In the frame of the CAST Project (*Contatto Alimentare Sicurezza e Tecnologia:* Food Contact, Safety and Technology) general and specific guidelines on supporting documentation to the declaration of compliance to the legislation on 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 for the chains of in aluminium, paper and cardboard, flexible packaging, wood, plastics, metals and coated metal alloys, cork, glass, coated products, sealing adhesives, printing inks. In addition, four new supply chains have been included in this edition: coated metal articles for cooking, rubber, food packaging machines, gas distribution systems food additives. Working sheets were elaborated for each chain. In this new guideline four chains have been considered.
Key words: Supporting documentation; Declaration of compliance; Materials; Food contact

Istituto Superiore di Sanità
Progetto CAST (Contatto Alimentare Sicurezza e Tecnologia). Linea guida sulla dichiarazione di supporto per la dichiarazione di conformità alla legislazione sui materiali e oggetti a contatto con alimenti. Versione inglese del Rapporto ISTISAN 24/29.
A cura di Cinzia Gesumundo, Maria Rosaria Milana,Giorgio Padula, Silvia Giamberardini, Fabiana Vanni, Marco De Felice, Massimo Denaro, Roberta Feliciani, Michele Massara, Veruscka Mannoni
2025, xviii, 273 p. Rapporti ISTISAN 25/23 (in inglese)

Nell'ambito del Progetto CAST (Contatto Alimentare Sicurezza e Tecnologia) sono state sviluppate linee guida sulla documentazione di supporto alla dichiarazione di compliance alla legislazione sui materiali e oggetti destinati a venire in contatto con gli alimenti. Le linee guida sono strutturate in una parte di applicazione generale e in una parte di applicazione specifica, distinta per le filiere dei materiali e oggetti in alluminio, carta e cartone, imballaggi flessibili, legno, materie plastiche, metalli e leghe metalliche rivestiti e non rivestiti, sughero, vetro, prodotti verniciati su metalli (*coating*), adesivi sigillanti, inchiostri da stampa. Inoltre, in questa edizione sono state inserite quattro nuove filiere: articoli in metallo rivestito destinati alla cottura, gomma, macchine per il confezionamento degli alimenti, impianti di distribuzione di gas additivi alimentari.
Parole chiave: Documentazione di supporto; Dichiarazione di Conformità; Materiali; Contatto; Alimenti

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The following associations took part in the present guideline:

ANFIMA
Italian National Association of Metal Packaging Manufacturers (Milan)

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

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

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

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

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

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

Assovetro
National Association of Glass Manufacturers (Rome)

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

Federchimica
National Federation of the Chemical Industry (Milan)

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

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

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

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

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

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

The following associations collaborated in the drafting of the guidelines published in the previous volume (Rapporto ISTISAN 18/24):

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

AIDI
Associazione Industrie Dolciarie Italiane
Italian Association of Confectionery Industries (Rome)

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

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

ANFIMA
Italian National Association of Metal Packaging Manufacturers (Milan)

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

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

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

Assografici
Associazione nazionale italiana industrie grafiche cartotecniche e trasformatrici (Milano)

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

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

Assorimap
National Association of plastics recyclers and regenerators (Milan)

Assovetro
National Association of Glass Manufacturers (Rome

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

CENTROAL
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Italian Aluminium Center (Milan)

Centro di Informazione sul PVC
PVC Information Center (Milan)

ConLegno
Wood-Cork Service Consortium (Milan)

Federalimentare
Italian Food Industry Federation (Rome)

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

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

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

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Italian Association of Plastic Converters (Milan)

Unionzucchero
National Union of Sugar Industrialists (Rome)

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PREFACE TO THE ENGLISH VERSION

This document is the English version of "Progetto CAST (Contatto Alimentare Sicurezza e Tecnologia). Guideline on supporting documentation for the declaration of compliance with legislation on materials and articles in contact with food", published in 2024 in the series *Rapporti ISTISAN* (*Rapporto ISTISAN* 24/29) (1).

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

The CAST guidelines represent a distinctive collaboration between public and private stakeholders within the European Union (EU). They provide an accessible and user-friendly resource especially designed for Small and Medium Enterprises (SMEs), while simultaneously serving as an effective enforcement tool for Public Inspectors.

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

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

PRESENTATION

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

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 compliance 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 first *ad hoc* Working Groups have drawn up specific documents on the individual nine supply chains of aluminium, paper and cardboard (both production and processing), flexible packaging, wood, plastics, metals and metal alloys, cork and glass, and have had as the first result of the Project the publication in 2009 of the 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" (*Rapporto ISTISAN* 09/33) (2), which, at the request of the European Commission Services DG Sanco (now DG Santé), and at the request of representatives of several Member States of the European Union, was subsequently translated into English (*Rapporto ISTISAN* 11/37) (3).

In addition to the previous guidelines, the Project has drawn up documentary feedback sheets on the implementation of Regulation (EC) 2023/2006 as amended on GMP (Good Manufacturing Practice) for FCMs in the various supply chains (*Rapporto ISTISAN* 13/14) (4)[1].

Subsequently, the three supply chains of paints, adhesives and sealants, and printing inks were added to the Working Groups of the CAST Project. Additional guidelines on the application of Regulation (EC) 2023/2006 have therefore been published as amended (*Rapporto ISTISAN* 16/42) (5) and on the document confirmation sheets on implementation in the aforementioned supply chains (*Rapporto ISTISAN* 16/43)[1] (6).

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

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

[1] *Rapporto ISTISAN* 13/14 (4) and *Rapporto ISTISAN* 16/43 (6) are reports published as *Rapporto ISTISAN* 24/36: Gesumundo C, Milana MR, Vanni F, Padula G, Giamberardini S, Denaro M, Massara M, De Felice M, Feliciani R, Mannoni V (Ed.). *Linee guida per il riscontro documentale sull'applicazione del Regolamento (CE) 2023/2006. Edizione 2024*. Roma: Istituto Superiore di Sanità; 2024.

additive gas distribution systems. In view of the new supply chains and the issuance and update of other regulations, an update of the *Rapporto ISTISAN* 09/33 (2), which is therefore currently replaced by the document *Rapporto ISTISAN* 23/4 Rev. (8). Therefore, even the *Rapporto ISTISAN* 11/37 (3) in English has been updated and is therefore currently replaced by the *Rapporto ISTISAN* 24/8 (9).

This document represents a further step forward in the document *Rapporto ISTISAN* 18/24 (7) on the SD updated with the inclusion of the four above-mentioned supply chains and with the new legislative references.

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

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

For the development of this guideline, a specific document has been developed for each supply chain.

The different materials and articles covered by the scope of the guideline have been identified in greater detail, as well as the different phases of the supply chain so that operators in the sector can easily recognize themselves.

The basic idea in the development of the CAST guidelines was to enhance what already existed at company and sector level, while aiming at the legislative compliance of the supporting documentation for FCMs.

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

INTRODUCTION

This document represents a further advancement of the CAST (*Contatto Alimentare Sicurezza e Tecnologia*: Food Contact, Safety and Technology) Project as a guideline and shared document available to all stakeholders and updates and integrates the *Rapporto ISTISAN* 18/24 (7).

The guideline presents fundamental aspects of the supporting documentation, both of a general nature applicable to all food packaging supply chains, and specific aspects, peculiar to each supply chain and relevant for maintaining the compliance of products along the supply chain. In fact, the supporting documentation accounts for the activities carried out by the economic operators in the supply chain in support of the Declaration of Compliance (DoC) of materials and articles in contact with foodstuffs (Food Contact Materials, FCMs). Since the beginning of the Project, it has become increasingly evident that, regardless of the achievements and operational choices, there can be no disregard for a real dialogue between all the players in the food packaging supply chain, and more generally in the supply chain of FCMs, and in the food industry itself. This is made explicit, both in the correct implementation of Good Manufacturing Practice (GMP) as defined by Regulation (EC) 2023/2006 as amended (e.g., selection of starting materials, supplier qualifications, traceability, etc.) and in the transfer of the relevant corpus of information for each stage (e.g. DoC, substances with migration limits, assessments, indications on use, etc.) that really allow, throughout the supply chain, the flow and maintenance of the information necessary to ensure and maintain the conformity and safety of the food product. The information transmitted along the supply chain must of course be part of the supporting documentation.

However, the value of communication along the supply chain cannot be considered exclusively in relation to the construction of supporting documentation. Proactive communication is in fact an integral part of the collaboration between supplier and customer to increase shared awareness of safety aspects. In this way, a cohesion of fundamental importance for the achievement of food safety objectives is built and consolidated and the quality control and assurance requirements, in terms of conformity, provided for in the context of Regulation (EC) 2023/2006 as amended on Good Manufacturing Practices, are also given concreteness.

The contributors to this edition of the guideline include:

- ANFIMA (Italian National Association of Metal Packaging Manufacturers);
- Assocarta (Italian Association of Pulp, Paper and Board Industry);
- Assogastecnici – Federchimica (Italian Association of Technical, Special and Medical Gases Industry);
- Assogomma - Federazione Gomma Plastica (National Association of Rubber, Electrical Cables, and Related Industries);
- Assografici (Italian Association of Printing and Paper Converting Industries);
- Assoimballaggi - FederlegnoArredo (National Association of Wood, Pallet, Cork Packaging Industries, and Logistics Services);
- ASSOMET/CIAL (*Associazione Italiana Industrie Metalli non Ferrosi/Consorzio Nazionale Imballaggi Alluminio*, Italian Association of non-ferrous metal industries/Aluminium Packaging Consortium);
- Assovetro (National Association of Glass Manufacturers);
- AVISA – Federchimica (*Associazione nazionale Vernici, Inchiostri, Sigillanti e Adesivi*, National Association, Paints, Inks, Sealants and Adhesives);
- Federchimica (Italian food industry federation);

- FIAC (ANIMA) (*Associazione Fabbricanti Italiani Articoli per la Casa, la tavola e affini,* Italian association of manufacturers of household and table articles, and related items);
- III (contracting partner) (*Istituto Italiano Imballaggio*, the Italian Institute of Packaging);
- ISS (scientific supervisor) (*Istituto Superiore di Sanità*, the National Institute of Health in Italy);
- PlasticsEurope Italia – Federchimica (Italian Association of Plastics Producers);
- UCIMA (*Unione Costruttori Italiani Macchine Automatiche per il confezionamento e l'imballaggio,* Italian Association of Manufacturers of Automatic Packaging Machines);
- Unionplast - Federazione Gomma Plastica (Italian Association of Plastics Converters).

The present document is divided into three parts

- *Part A. General guidelines*
  Section on supporting documentation valid for all supply chains (legislative references and applications from a general point of view).
- *Part B. Specific guidelines*
  Section on supporting documentation for each supply chain (implementations that supply chains carry out to ensure compliance with legislative requirements).
- *Part C. Use of non-legislative documents in evaluation processes*

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

PART A
General guideline

A1. GENERAL ASPECTS

A1.1. Purpose of the guideline

This document represents a guideline on the preparation of the Supporting Documentation (SD) to the Declarations of Compliance (DoC) for materials and articles in contact with foodstuffs (Food Contact Materlials, FCMs). Reference is made to the EU and national legislation governing the sector and sometimes to other existing documents, applicable to FCMs, in which comments and application interpretations are also provided.

This guideline, although not binding for companies operating in the FCMs sector, can be a useful tool in the construction or improvement of their own SD with the aim of giving evidence of the compliance of FCMs with current legislation.

A1.2. Field of application of the guideline

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

The guidelines relating to the supply chains considered are:

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

A1.3. European and Italian legislation on DoC and SD on FCMs

A1.3.1. List of legislative references

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

European legislation

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

Italian legislation

- DPR 777/1982 - Decree of the President of the Republic No. 777 of 23rd August 1982 on implementation of the Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs as amended.
- DL.vo 108/1992 - Legislative Decree No. 108 of 25th January 1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- DL.vo 29/2017 - Legislative Decree No. 29 of 10th February 2017 on Sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food.

A1.3.2. Basic principles on European and Italian legislation

A1.3.2.1. Introduction

The DoC and SD are fundamental instruments in both national and EU legislation on FCMs. Although the discipline relating to the DoC and the SD is affected by the differences between EU law and national law, and in some cases also suffers from regulatory gaps, the fundamental principles and the application consequences of this discipline are common among the different legislative bodies of harmonized legislation and the parts on specific materials in force only in Italy. The DoC are in fact key points both in the assumption of responsibility of the producers of FCMs, and in the correct transfer of information between companies in the supply chain, while the SD are a means of demonstrating the compliance of a FCMs competent authority, in the case of inspections or controls. While for the DoC there are legislative indications or in any case guidelines deriving from legislative indications, for the SD a shared strategy of approach for the preparation of the SD itself has not yet been defined, except in general.

Since the SD is always closely connected to the DoC, both conceptually and operationally, in order to better introduce the study of the DoC, the subject of this guideline, it is appropriate to first illustrate some fundamental legislative aspects for the DoC.

A1.3.2.2. European and Italian legislation on DoC

Regulation (EC) 1935/2004 as amended applies to all FCMs and lays down general provisions. The basic principles that govern the entire rule and provide the rationale for any other specific rule are reported in art. 3 which reads:

> "Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:
> a) endanger human health;
> b) bring about an unacceptable change in the composition of the food;
> c) bring about a deterioration in the organoleptic characteristics thereof".

According to art. 16 of Regulation (EC) 1935/2004 as amended, FCMs for which specific measures exist at EU level must be accompanied by a written DoC, issued by the company, certifying that the FCMs complies with the requirements of the applicable legislation.

In fact, art. 16 of Regulation (EC) 1935/2004 as amended, reads as follows in paragraph 1, first subparagraph:

> "The specific measures referred to in Article 5 shall require that materials and articles covered by those measures be accompanied by a written declaration stating that they comply with the rules applicable to them.".

Currently, the specific measures on FCMs at European level relate to:

- *Plastics*: Regulation (EU) 10/2011 as amended,
- *Ceramics*: EEC Directive 84/500 as amended,
- *Regenerated cellulose*: EEC Directive 2007/42,

but there are specific indications concerning the DoC also for the following FCMs:

- *Recycled plastics*: Regulation (EC) 1616/2022[2],
- *Active and intelligent materials and articles*: Regulation (EC) 450/2009,
- *Polyamide and melamine plastic from China and Hong Kong*: Regulation (EC) 284/2011.

As regards the Italian legislation provisions on FCMs, Regulation (EC) 1935/2004 as amended and additions in paragraph 2 of art. Article 16 provides:

> "In the absence of specific measures, this Regulation shall not prevent Member States from retaining or adopting national provisions for declarations of compliance for materials and articles."

For areas not harmonised by specific European laws, Member States are therefore allowed to maintain or adopt their own national legislation.

In Italy, as extensively illustrated in the Ministry of Health note DGSAN.VI/ 32249-P-11/10/2011 "Declaration of Compliance of materials and articles intended to come into contact with foodstuffs" (indicated below as Note of the Ministry of Health no. 32249), there is a body of legislation that gives specific provisions on the DoC for the following FCMs:

[2] It replaces Regulation (EC) 282/2008 on recycled plastic materials and articles intended to come into contact with food and amending Regulation (EC) 2023/2006 as amended.

- "by the Ministerial Decree of 21 March 1973 as amended, for: rubber, regenerated cellulose, paper and cardboard, glass, stainless steel, as well as in force for the materials referred to in Article 9, paragraph 9 (surface coatings, silicones, etc.) and to a transitional extent for migration tests on plastics for which Regulation (EU) 10/2011 and subsequent amendments has come into force.
- by Decree no. 405 of 18 February 1984 and 13 July 1995 for tinplate
- by Decree no. 243 of 1 June 1988 for chrome strips
- by Decree of 4 April 1985 and 1 February 2007 for Ceramics
- by Decree no. 76 of 18 April 2007 for Aluminium".

For materials not included in the previous list, the Italian legislation applicable for this aspect is Legislative Decree 108/1992 which in art. 5 reads:

> "The following shall be added after Article 5 of Presidential Decree No 777 of 23 August 1982:
> Article 5-bis.
> 1. The industrial or commercial use of materials and articles intended to come into contact with foodstuffs shall be subject to ascertaining that they comply with the provisions of this decree and that they are technologically suitable for the purpose for which they are intended.
> 2. The company must be provided with the declaration of compliance referred to in Article 4, paragraphs 5 and 6, and always be able to allow the competent control bodies to identify the supplier or manufacturer of the materials or articles used."

In paragraph 5 of Article 4 and paragraph 2 of Article 5-bis of Presidential Decree 777/1982 cited above, the following is written:

> "5. Materials and articles intended to come into contact with foodstuffs must be accompanied, at phases other than by sale to the final consumer, by a declaration attesting to conformity with the rules applicable to them issued by the manufacturer.
> 2. In the absence of the declaration referred to in paragraph 5, the declaration of conformity must be issued by a public analysis laboratory."

Therefore, it follows that in Italy, even for materials and articles for which there is no specific legislation, both at Italian legislation and EU level, the DoC is still required certifying compliance with the requirements of Regulation (EC) 1935/2004 as amended.

In this regard, attention has grown, both at the level of companies and at the level of public authorities, on the documentary part inherent to the compliance of FCMs and many supply chains have developed their own documentation or guidelines[3] in order to provide FCMs producers useful elements to prepare the documents necessary to prove the declared compliance to the competent authority.

A document of particular importance and reference is the guideline for plastic FCMs published in 2013 by the Directorate-General for Health and Food Safety of the European Commission "Union Guidance on Regulation (EU) No 10/2011 on plastic FCMs as regards information in the supply chain" (hereinafter referred to as DG Sanco 2013) (10) and developed by a mixed group (representatives of the European Commission) industry associations and experts in the FCMs sector). In this guideline, the obligations for the different roles in the production chain are differentiated, providing indications on the DoC relating to each position in the supply chain (producers of substances, semi-finished products, etc.).

[3] For further information, *see* Part C in this guideline and the Appendix of the *Rapporto ISTISAN* 23/4 Rev. (8).

It should be emphasized, however, that each FCMs supply chain has its own peculiarities and characteristics and that therefore what is detailed for plastics (and for what is defined in the guideline as "non-plastic" e.g. inks and adhesives) may not be relevant for the other supply chains, but in any case some concepts of general applicability can be borrowed from DG Sanco 2013.

In this regard, as a framework of applicability and general reference, it is also useful and necessary to mention the Note of the Ministry of Health no. 32249 of 2011, which highlights the obligations for the different roles, also taking into account those FCMs that are not harmonized at EU level and existing national laws.

In summary, from the content of the applicable legislation, as clarified in DG Sanco 2013 and the aforementioned Ministerial Note, it emerges that the DoC must be issued by all those who are part of the production chain up to the finished object, including the final producer of this object who issues the final declaration. The DoC must not be issued by the food industry.

Please note that all companies that produce FCMs are subject to Regulation (EC) 2023/2006 as amended and therefore must have implemented and maintain a quality management system. Therefore, documentation must be available to demonstrate the roles, functions and responsibilities of personnel within the company. In this context, it is mandatory to identify who is responsible for issuing and signing the DoC. In the DoC, the role (producer, importer, etc.) must be defined. If the issuer of the DoC does not coincide with the producer or importer, the identity and address of the person who produces and/or imports the good must also be indicated. To support this, relevant documentation must be made available, e.g. commercial documents, specifications or supply agreements, etc. The documentation on traceability provided for by art. 17 of Regulation (EC) 1935/2004 as amended.

The various figures involved in the production chain are listed below, as a useful example of identification, definition and assignment of roles in the supply chain, specifying the possible obligation to draw up and issue the DoC (for more details they will be discussed in the specific chapters for each supply chain):

- *Raw material manufacturers*[4]
  They are obliged to issue the DoC, where required by law (for the differences between the different roles, see the specific chapters).
- *Manufacturers of materials and intermediates intended to be processed into finished products*
  They have the obligation to issue the DoC.
- *Finished product manufacturers* (ready to come into contact with food) hey have the obligation to issue the DoC.
- *End users* (food industry, but also retailers or food sellers including catering, restaurants, shops, etc.)
  They have the end consumer as a user and therefore do not have to issue the DoC.
- *Distributor* (economic operator who distributes substances, materials, intermediates and finished products to another economic operator without intervening in the manufacture of the same)

[4] Raw materials in general are understood as starting substances (monomers, additives, catalysts, pulp, etc.) used in the production of a particular material (plastic, glass, paper, etc.)

You can forward your supplier's DoC to your customer (with a cover page or page identifying your role in the supply chain) or you can issue your own DoC, including the relevant information contained in your supplier's document.[5]

- *Distributor who sells directly to the final consumer*
  He takes on the role of a retail trader. It does not have to issue its DoC.
- *Distributor who intervenes on finished products (e.g. by applying an ink)*
  From distributor to producer and must issue the DoC.
- *Distributor acting as an importer*
  It must issue its DoC.
- *Importer* (economic operator who places substances, intermediates or finished products from non-European countries on the European market)
  He has the obligation to issue his own DoC.
- *Retailer* (sells only to the consumer)
  If it sells to an economic operator, it is also configured as a distributor. They can also be importers and in this case they must assume all the obligations of the importer.
- *Consumer* (private person who has the instructions for use available)
  Its role is to follow the instructions provided for the appropriate use of the item.

With regard to the obligations attributable to importers of FCMs from non-EU countries (European Union), it is also considered useful to report the reference made in the Note of the Ministry of Health no. 32249 of 2011 on the DoC of applicability to all FCMs:

> "In the case of imported products, therefore, the declaration of compliance of the FCMs can also be issued by a person other than the producer, such as the importer established in the European Union, responsible for introducing the consignment into the territory. This is in consideration of the fact that EU regulations have clearly defined the so-called supply chain that involves not only production, processing, but also distribution where the import of the materials and articles in question is included.
> In this circumstance, the importer becomes the person responsible for compliance with the aforementioned provisions (general and specific reference legislation) and must have the appropriate supporting documentation, ensuring that the materials and articles intended to come into contact with food comply with the requirements. In this way, not only the companies that produce and the industrial users of materials and articles intended to come into contact with food are required to issue and/or be provided with the declaration of compliance, as prescribed by the Ministerial Decree of 21 March 1973 and by Presidential Decree no. 777/82, amended by Legislative Decree no. 108/92, but the entire supply chain of the sector, including imports, which is responsible for its part of competence. Retail sales are excluded from this provision".

For exported products, we operate in accordance with art. 6 of DPR 777/1982 which reads:

> "Without prejudice to the prohibition referred to in Article 2 above, the production of materials and articles intended for export with characteristics that differ from those established by the ministerial decrees referred to in Article 3 is subject to the obligation of prior notification to the competent health authority on the basis of regional regulations".

[5] In any case, the distributor must transfer the information that allows the consumer to use the object correctly (art.15 Regulation (EC) 1935/2004 as amended) and transfer the information relevant to maintaining compliance along the supply chain.

The DoC must refer to a specific product and/or supply. The goods covered by the DoC must be clearly identified by trade name (or catalogue number, or batch number, code, etc.) and type of material (e.g. aluminium tray, glass cup, box or other wooden packaging, polypropylene film, pizza box, carton for dry food, etc.). Traceability documents, trade agreements, etc. can also be useful to support this.

This does not necessarily mean that the DoC must be reissued for every delivery, batch, or production batch, but that the link between the product and/or supply and the DoC must be clear and unambiguous. Therefore, reference could be made to a contract, or to a supply specification, etc., provided that no significant changes occur in the production process or in the product that affect the declared conformity. Indeed, the DoC must be updated when there are substantial changes in production that lead to changes in migration, when new scientific data are available or when legislative changes occur that affect the conformity of the product in question.

For further information, please consult the document *Rapporto ISTISAN* 23/4 Rev. "CAST Project (Food Contact, Safety and Technology). Guidelines for the application of Regulation (EC) 2023/2006 to the production chain of materials and articles intended to come into contact with food. 2023 edition" (8).

A1.3.2.3. European and Italian legislation on SD

Article 16 of Regulation (EC) 1935/2004 as amended reads as follows in paragraph 1, second paragraph:

> "Appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to the competent authorities on demand.".

This article contains the concept of SD at EU legislation. The SD is the collection of the information necessary to "support" the compliance declared in the DoC. The company issuing a DoC must therefore have appropriate documentation demonstrating that compliance has been declared on a well-founded, verifiable basis and in line with scientific knowledge and legal requirements. It is mandatory to show the SD to the competent authority upon request.

However, article 16 of Regulation (EC) 1935/2004 as amended, applies only to the above-mentioned materials, which are specifically regulated at EU legislation, while the provisions of paragraph 2 of article 16 (*see* paragraph A1.3.2.2 of this guideline) allow national provisions to be applied also to the SD, which by its nature is closely related to the DoC.

At the national level, in the specific regulations mentioned above, the concept of SD refers to the "demonstration" of compliance provided for in italian legislation.

Consider the following articles of the DM 21/03/1973 as amended:

> "art. 6
> Companies that produce articles in contact with foodstuffs [...] are required to check their compliance with the regulations [...] and to demonstrate at all times that they have adequately provided for the necessary checks and inspections. Each batch must be accompanied by a declaration from the manufacturer certifying that the articles [...] comply with the regulations in force.
>
> art. 7
> Their use in an industrial or commercial setting [...] is subject to the verification of their compliance with the regulations in force as well as their technological suitability for the purpose for which they are intended. The company must therefore be provided with the declaration of compliance issued by the manufacturer, [...] and always be able to allow the health authority to identify the supplier or manufacturer of the object used".

These articles, although with different terminology, for 40 years have already contained the concept of "demonstration" of the activities carried out by the company to check compliance with the rules, which can be completely superimposed on the concept of SD of EU standards. The text of art. 6 and 7 is taken up or referred to by the other specific national laws mentioned above and therefore the concept of SD related to the DoC also fully applies to non-harmonized materials, but only subject to Italian provisions. In this regard, the Ministry of Health's Note no. 32249 mentions the SD as a fundamental part of the documentary analysis that must be carried out in control activities.

For those materials that are not regulated by specific provisions at national level (e.g. wood, ferrous alloys, non-stainless steel, etc.), the provisions of Legislative Decree 108/1992 apply. It should be noted that in art. 5 of Legislative Decree 108/1992 there is no part on "demonstration" and therefore a SD would not seem to be required as for materials regulated at EU or national level. However, Regulation (EC) 2023/2006 as amended, applicable to all materials and all sectors of FCMs, intervenes on this aspect, which provides for the preparation of extensive documentation to support the conformity of the finished product in compliance with the requirements of art. 3 of Regulation (EC) 1935/2004 as amended. It is therefore required by rules of good production practice that SD is present and available also for materials not subject to specific legislation at national level.

In conclusion, in Italy, all FCMs must be accompanied by the DoC, in support of which an adequate SD must be prepared to demonstrate, only to the competent authorities, how the conformity of a given product with the relevant legislation has been declared. This obligation seems to be extendable also at EU level by Regulation (EC) 2023/2006 as amended.

A1.3.2.4. Relations between SD and DoC

The SD is the collection of information that contributes to providing evidence of the compliance declared in the DoC. When a company issues the DoC, it must therefore already have an appropriate SD available. The SD should include any kind of information or data that is relevant and useful to demonstrate the declared compliance, e.g. technical information, declarations from suppliers, certificates of analysis, test reports, scientific arguments, calculations, reference to operating procedures, etc. The SD does not accompany the goods, nor does it have to be delivered to the customer, but it must be available and shown, upon request, to the competent authorities, for example during inspections or checks. In fact, the purpose of the SD is precisely to provide evidence to the competent authorities of the correct management and verification of the compliance of an FCMs. The law, both at national and EU level, does not provide for the SD to be compulsorily shown or transferred to customers. This possibility can be contemplated in the context of private bargaining between the partners in the supply chain, using the typical methods in use for the exchange of sensitive information (e.g. non-disclosure agreements). In fact, SD often contain confidential information, which can form an integral part of company know-how, and as such must be adequately protected. The SD is in fact maintained in-house (or in pre-established and/or agreed and identifiable third-party locations), while the DoC is transferred.

The information that must be transferred to customers is that which allows the actors of the successive links in the supply chain to comply with the applicable restrictions, or in other words, the information without which the compliance of the FCMs along the supply chain could no longer be demonstrated or even not maintained. Consider the following example: if a substance with compositional restrictions or migration limits is used in the manufacture of a semi-finished or finished product, all the information necessary to enable the user of the semi-finished or finished product to comply with the relevant legislation must be included in the DoC. That is, the identity of the restricted and/or specific substance should be known, e.g. at least by the trade name

or number assigned by the Chemical Abstracts Service (CAS) or the chemical name of the substance.

The DoC may also contain, if necessary or expressly required by legislation, specifications relating to the use of the material or articles, such as*:*

- types of food products with which it is intended to come into contact;
- duration and temperature of treatment and storage in contact with the food product;
- ratio of the contact surface of the food product to the volume used to determine the conformity of the material or articles.

In the corresponding SD, there will therefore be, for example:

- DoC (or the appropriate information[6]) received from the suppliers of the raw materials/starting materials and/or semi-finished products used;
- technical reports or technical documentation on the tests carried out (theoretical calculations, composition tests, migration tests, modelling, etc.) with details of the test conditions and the ratios /surface volume in support of the stated indications or restrictions of use;
- technical data sheets;
- other.

The above is a clear example to illustrate the fundamental principle, valid for all FCMs, according to which anyone who produces a semi-finished or finished product of any material intended to come into contact with food (wood, glass, paper, etc.), must provide the relevant information to the subsequent parties in the supply chain so that those who use such semi-finished or finished product (final processor or food industry) can in turn comply with the provisions legislative legislation in force.

Obviously, the quality and quantity of the "relevant" information depends strictly on the nature of the material of the artifact and its intended use. Therefore, the different applications will be discussed separately for each material, in the chapters of the specific parts.

A further important concept of general validity concerns the possession and conservation of the SD. There are no pre-established indications, nor legislative references on the period of time for the minimum storage of the documents and acts that make up the SD. Since the SD proves the conformity of an asset, it is considered appropriate for each company, in its management system, to estimate the shelf life of the SD for its products and to include this indication in its Quality Assurance System (QAS[7]).

There is no specific requirement to physically store the SD within the Company. The SD, or parts of it, may be maintained by third parties (e.g., laboratories, legal departments, etc.) following an agreement between the parties. However, regardless of any possible solution applied, the SD must be easily accessible to the competent authorities upon request and linked to the FCM(s) for which a DoC has been issued.

It should be noted that the SD may be required to demonstrate compliance with specific requirements (materials or aspects with specific regulation) and/or with the general requirements of Article 3 of Regulation (EC) 1935/2004 as amended. The organisation issuing the DoC for regulated materials must consider in its SD the specific rules and requirements in force for those materials and prepare documentation on compliance with existing requirements. The company that issues the DoC for materials not regulated by a specific EU or national regulation, or for aspects not covered by

[6] as defined in DG Sanco 2013 (10)

[7] There are some references agreed between Associations, including the "Guidelines for declarations of compliance of raw materials for food contact packaging" of the Italian Packaging Institute (2009) which indicate the minimum time of 5 years for the storage of the DoC.

specific limits, must possess as a SD the documentation that highlights how compliance has been demonstrated. In both cases, always considering the position in the supply chain, there can be, for example, composition tests, risk assessments, analytical screenings, etc.

Finally, it should be remembered that the SD of the suppliers does not necessarily have to be together with the DoC received.

A1.3.2.5. Relationships between GMP, SD and DoC

The GMP system, as described by Regulation (EC) 2023/2006 as amended, concerns the Quality Management System (QMS) which must be implemented in the enterprises involved in the production of FCMs, in all sectors and at all phases of production, processing, and distribution, up to and excluding the starting substances. All operations and data relevant to demonstrate compliance with GMP regulation must be documented and archived.

The documentation generated within the GMP system for FCMs is therefore part of the SD required to demonstrate compliance with art. 3 of Regulation (EC) 1935/2004 as amended. In some cases, not all the components of a GMP system are developed by companies exclusively to comply with the requirements of Regulation (EC) 2023/2006 as amended, but they can also be generated in an area related to quality management systems and company operational choices. For example, traceability is a goal that companies can pursue for all the materials they produce and not just for FCMs. In fact, there are various possibilities of connection and different operational options between the various documentation produced and declarations required to demonstrate and support compliance.

An example is shown in Figure 1.

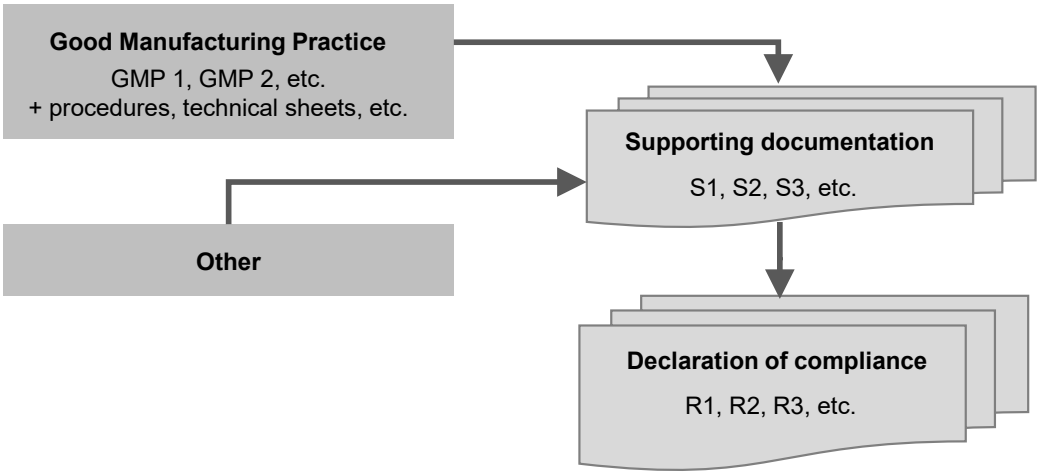

Figure 1. Diagram of connection between the various documentation and declarations required to demonstrate and support compliance (R: legal requirements, S: documentation)

In the diagram of Figure 1 the relationships between the DoC and the related SD are schematically represented. It is displayed how the SD can consist of documents of very different origin, relating directly to the GMP system of Regulation (EC) 2023/2006 as amended (e.g. procedures or instructions) or independent of it (e.g. analysis reports or studies carried out at external or internal organizations of the company). The nature and content of these documents depends on the nature of the supply chain concerned and the subject matter. To clarify the concept, by way of illustration, consider the following example: a DoC, prepared for a plastic FCMs to which three R requirements relating to compliance R1, R2 and R3 apply; these must correspond

respectively to the S documents (or the collections of documents) S1, S2 and S3. The collection of S1, S2 and S3 will therefore constitute the SD. To continue with the example, it can be assumed that the R1 requirement is compliance with the migration limit of a plastics additive. Consequently, S1 (its SD) will consist in the collection of the technical documentation to demonstrate that the migration of the additive complies with the R1 requirement.

Therefore, it can be observed that, in general, it is the nature of R1 and its influence on the compliance of the FMCs that define the composition of S1 which, depending on the case, may contain for example (non-exhaustive list):

- laboratory test reports;
- results of calculations carried out by the company or external bodies;
- supplier's DoC to a particular specification;
- manufacturing recipe;
- collection of information;
- procedure or instruction within the scope of the GMP regulation;
- other

Therefore, at the basis of S1 there may be data of a different nature, as the documentary collection can come both from analytical tests or calculations, and from the application of the GMP system. In the latter case, the relevant GMP system documentation for compliance with the R1 requirement (GMP 1) will also be an integral part of the S1 supporting documentation.

It may also be the case that the company develops a new material or produces it, without allocating it *ab initio* to the production of FCMs. During this phase, the company will generate a number of documents, and many of these may obviously not relate to food suitability. If, however, the new material were to be used at a later stage for the creation of an FMC, the company, having to compose the relevant SD, could find useful or necessary to resort to some of the documents originally drawn up during development. Consequently, both newly prepared documents to meet the requirements of Regulation (EC) 1935/2004 as amended and additions, and pre-existing documents, i.e. prepared during the development of the material and regardless of food compliance, can enter the SD.

The demonstration of suitability for contact with food and the consequent preparation of the related SD must therefore be carried out on a case-by-case basis.

The above is intended to be just one example of the many situations that can be encountered in the examination of the different supply chains. As will be seen in the specific sections by supply chain, for some of them the SD is directly and inextricably linked to the GMP documentation of Regulation (EC) 2023/2006 as amended (e.g., producers of flexible packaging and/or manufacturers of some glass packaging), while in others "mixed" situations such as the one exemplified above may occur (e.g., for plastics manufacturing companies).

Finally, it should be emphasized that whatever operational choice is implemented, it remains the responsibility of the company, in compliance with its position in the supply chain, to declare and demonstrate the compliance of the FCMs produced with art. 3 of Regulation (EC) 1935/2004 as amended, comply with the obligations of Regulation (EC) 2023/2006 as amended, and be able to show the competent authority documentary evidence of what has been implemented.

A1.4. Intra-supply chain relations

The production chains of FCMs are different not only in the type of finished products, but also in the methods, technologies and phases of their production. There is therefore a typicality for each supply chain, and within each supply chain a different operation for the different subjects,

depending on their role. However, there are some fundamental roles, corresponding to life phases of the FCMs, similar in each supply chain:

- manufacturer/supplier of starting materials, raw materials or substances;
- processing phases, more or less articulated;
- production phase of the finished articles and its marketing/distribution;
- use in contact with food.

A fixed point is that in any case, at each point of the supply chain, the relevant technical work (documentary, design, analytical, calculation, experimental, etc.) must have been carried out to prove compliance. In DG Sanco 2013 this technical work is defined as compliance work. Anyone who declares compliance with a requirement (e.g. use of substances on lists, migration limit or limitation of use, etc.) must therefore have technical support, obtained from suppliers or produced and maintained in house.

The DoC therefore confirms that the compliance work has been carried out. The concept, well clarified in DG Sanco 2013, that the compliance work (*see* annex to chapter) which can be carried out also depends on the position of the operator in the supply chain and the information available to that operator. It is also evident that it is rarely possible to carry out all the compliance work in a single position in the supply chain. In fact, the information available is often not exhaustive. For example, the producer of a semi-finished product may not know the final destination of the FCMs, just as an end-user may not know the by-products generated by upstream operations. Therefore, intra-supply chain collaboration is an essential aspect to identify what information is really essential to adequately design and carry out your compliance work.

According to the approach of the EU guideline, if the economic operator does not provide a specific description of the compliance work to its client, it automatically assumes responsibility for carrying out the compliance work. This is an approach that, despite the difficulties of application in the daily reality of industrial relations, should nevertheless constitute the most desirable and correct evolution of the shared and conscious approach to food safety.

DG Sanco 2013 also points out that intra-supply chain collaboration builds trust in business partners, which is essential as the DoC does not include all the information contained in the supplier's SD. A particular aspect of the compliance work concerns the risk assessment, defined in Regulation (EC) 178/2002 as (11):

> "A science-based process consisting of four steps: hazard identification, hazard characterization, hazard exposure assessment, and risk characterization".

Risk assessment as a tool to support a DoC is expressly mentioned in the Plastics Regulation (Art. 19). However, the concept underlies all legislation on FCMs, for which art. 3 of Regulation (EC) 1935/2004 as amended, requires the identification of a "quantity such as" not to constitute a danger to human health. This obviously implies knowledge of the danger (in the case of FCMs then the identification of migrating substances and their toxicological profile), exposure assessment and risk characterisation. In some cases, the risk assessment has already been carried out by the legislator (when in the legislation on FCMs exposure assessment and risk characterisation. In some cases, the risk assessment has already been carried out by the legislator (when in the legislation on FCMs on a scientific basis (experimental or *in silico*) to verify its compliance with the requirements of the aforementioned Article 3. Obviously, the relevant risk assessment documentation for the DoC goes into the composition of the SD.

As regards the possible transmission of parts of the SD, please refer to the previous considerations. However, the need of the packaging supply chain to protect its wealth of knowledge and skills must be guaranteed without diminishing the need for food safety assessment and documentation and, likewise, food companies should be willing to communicate the intended use of the packaging and comply with the conditions and limitations of use provided by the

packaging supply chain. These aspects can be adequately considered in the confrontation between the parties at the contractual level and possibly formalized through non-disclosure agreements.

Obviously, even if the obligations to issue the DoC and to maintain an adequate SD apply indiscriminately to all the actors in the supply chains, the content of these documents is different precisely according to the typicality of each supply chain and its position in it. Therefore, in consideration of the peculiarities of each supply chain, the SD guideline has been developed in Part B for each of them respecting these specificities. In order to standardize the approach, however, the different roles will be distinguished where possible, defining the different requirements for the SD.

A1.5. Food industry and SD on FCMs

The food industry is responsible for the packaged food product (packaging + food) to the authorities and consumers. This responsibility is shared with the individual players in the supply chain who are each responsible for the part of competence.

The food industry receives the DoC from its suppliers of packaging materials and is obliged to hold them but is not obliged to issue any guaranteed documents to its customers.

The DoC certifies that the packaging material meets all the requirements of the applicable legislation and is the tool through which suppliers certify that the so-called compliance work has been carried out adequately[8]. The compliance work includes activities aimed at meeting the requirements of applicable legislation, both specific, where existing, and Regulation (EC) 1935/2004 as amended, in particular art. 3.

If the compliance work has not been completed by the FCMs chain, the DoC must contain the necessary information to allow the user to clearly identify any activities to be carried out to complete the verification of the suitability of the FCMs. Accordingly, the DoC must confirm that a risk assessment of any Non-Intentionally Added Substances (NIAS) has been carried out or relevant information must be reported to enable the completion of the compliance work. The level of detail and depth can be evaluated with the logic called “case by case”. In some cases, to guarantee the know-how of the supply chain, it may be useful to define specific agreements (contracts, confidentiality documents).

In order for the DoC to allow the recipient to decide on any activities to be undertaken, it is essential that a collaborative relationship is established between the parties so that effective and efficient communication is generated that guarantees the necessary level of reliability with regard to information of a specific technical nature.

The food industry must ensure the safety of the packaged product. Therefore, an assessment of the completeness and adequacy of the information received should be carried out. For this reason, it may be necessary that even at this level (end user) a collection of information and evidence is available that can be defined as a whole as SD.

Finally, to allow the food industry to give precise and timely answers to the competent authority, the availability of a SD that is not limited to the collection of DoC alone, in some cases, can certainly prove useful and appropriate. This may also include information concerning, for example, barrier properties, the effect of the entire packaging system of a product (primary, secondary, etc.), evidence on the technological suitability of materials. This may require an in-depth knowledge complementary to the compliance work carried out by the FCMs supply chain.

[8] *See* chapter A1.4 for further information on the compliance work

As a result, the food industry will be able to repeat some assessments related to specific critical issues, or carry out targeted in-depth studies to cover particular requirements (e.g. migration and/or composition tests, risk assessments; sensory tests, etc.).

The test conditions adopted must necessarily take into account the actual conditions of use, the treatments to which the packaging must be subjected and the shelf life of the food product. However, where it may be deemed appropriate and/or technically applicable, more severe test conditions than the real ones (worst case conditions) may be applied.

Therefore, the specific SD of the food industry consists of the DoC of the suppliers, possibly supplemented by analysis results and documentary evidence (e.g. opinions of the EFSA-European Food Safety Authority, toxicological assessments, information obtained confidentially from the supply chain, etc.).

Annex to the chapter A1

Compliance work: some basic concepts

Excerpt from *DG Sanco's Union Guidance on Regulation (EU) No 10/2011* (2013) (10)

PRINCIPLES FOR SHARING COMPLIANCE WORK THROUGHOUT THE PRODUCTION CHAIN

1. Avoid duplication of compliance work

Producers performing the same compliance work on the same material should be avoided. In order to minimize duplications and costs, as much compliance work as possible should be concluded at an early stage.

2. Responsibility of business operators for their manufacturing step with a view to compliance of the finished article under the intended or foreseeable uses

The compliance of the finished article can only be ensured if all business operators in the chain, from the manufacturer of starting substances down to the food packer, assume the necessary responsibility for their manufacturing step, with a view to the compliance of the finished article. This follows from the obligation that the whole manufacturing process respects GMP. It means that only components suitable for use in food contact materials can be used. This also excludes the possibility that a business operator can transfer to his customer all responsibility for compliance work arising from his manufacturing step (general disclaimers).

3. Responsibility of the business operator that introduces or generates a substance in the manufacturing process

A business operator introducing or generating a substance in a product (raw material, intermediate or finished material or article) is responsible for compliance of this substance. This includes the impurities of the substance and degradation and/or decomposition products linked to its intended use which may be formed at this or a later manufacturing step under the specified use.

All aspects of compliance work linked to the introduction or generation of a substance may not be finalised at the manufacturing stage at which the substance is introduced. Therefore, the DoC or Adequate Information serves as means to inform on the aspects of compliance work that have been performed by the business operator issuing the DoC or Adequate Information and on which aspects still need to be performed by the downstream business operators.

4. Conclude compliance work as early as possible in the manufacturing chain

Compliance work should be concluded as high up in the manufacturing chain as possible. As an example, in case of addition of a small quantity of a substance with a high SML, it may be possible at the plastic manufacturing stage to ensure compliance and conclude that part of the compliance work, e.g. based on the calculation that, even with complete migration, the SML would not be reached. However, in particular in multilayers, it has to be taken into account that a substance can originate from several layers and compliance has to be ensured for the final article, taking into account contribution from all layers.

5. Information from customer to supplier on intended use

Through communication between customer and supplier, the customer may already provide necessary information to his supplier that will enable the supplier to complete the compliance work at this stage. For example, if the plastic converter informs the plastic manufacturer on the exact shape or size, food contact conditions and contacting food of his final article, the plastic manufacturer may already conclude relevant aspects of the compliance work.

6. Specific description of compliance work transferred to the customer

The description of the compliance work that is transferred to the customer must be specific and allow him to perform the compliance work. There are some cases which oblige the supplier to disclose the identity of substances and it may be also necessary to disclose their concentration in the material. Information passed from customer to supplier in the supply chain can help to identify relevant information that allows the supplier to adequately perform his compliance work. The customer is also obliged to critically assess the information provided by the supplier.

7. Responsibility of compliance work not transferred to the customer

A business operator automatically accepts responsibility for compliance work if he is not providing a specific description of compliance work transferred to the customer.

A2. DEFINITIONS

The following definitions, most of which have already been given in the document *Rapporto ISTISAN* 23/4 Rev. (8), illustrate the most important terms used in this text. When they exist, these definitions are taken verbatim from the relevant legislation, i.e. from Regulation (EC) 1935/2004 as amended, from Regulation (EC) 2023/2006 as amended and from Regulation (EU) 10/2011 as amended:

- *Functional barrier*
  Barrier consisting of one or more layers of any type of material, capable of guaranteeing that the finished material or article complies with Article 3 of Regulation (EC) 1935/2004 as amended. and the provisions of this regulation (by Regulation (EU) 10/2011 as amended).

- *Good Manufacturing Practice* (GMP)
  Those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof (Regulation (EC) 2023/2006 as amended, art. 3).

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

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

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

- *Business operator*
  The natural or legal person responsible for ensuring that the requirements of this Regulation (EC) 1935/2004 as amended are met with in the business under his/her control (Regulation (EC) 1935/2004 as amended, art. 2).[9]

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

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

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

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

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

PART B
Specific guidelines

INTRODUCTION

In this Part B, the specific chapters describe the Support Documentation (SD) that the supply chain must prepare to comply with the requirements of Regulation (EC) 1935/2004 and subsequent amendments concerning materials and articles intended to come into contact with foodstuffs. Legislative references specifically applicable at Community level, where they exist, or at national level in the absence of harmonised legislation have been considered.

The description is divided into separate and independent chapters for each supply chain, reflecting and respecting the peculiarities of the supply chains themselves. However, for the sake of clarity of reading and interpretation, an attempt has been made to maintain homogeneity in the structure and terminology of the text wherever possible.

The specific guidelines are set out as follows:

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

Each specific guideline includes a description of flow chart of the activities of each supply chain by correlating it, in the critical points that require documentary evidence, to the relevant documents for that specific step of the production activity itself.

In addition, the specific documentation that must be prepared by each operator in the supply chain has been identified depending on its role and position in the supply chain itself.

Where possible and relevant, an attempt has also been made to describe separately some topics of the SD necessary to demonstrate compliance with the requirements set out in Regulation (EC) 1935/2004 as amended, but which may not necessarily be managed directly in the GMP system provided for by Regulation (EC) 2023/2006 as amended.

Whatever the operational choice implemented by the Company, it remains the responsibility of the economic operators in the sector to ensure the compliance of the product with art. 3 of Regulation (EC) 1935/2004 as amended, to operate in accordance with Regulation (EC) 2023/2006 as amended and to demonstrate to the competent authority that it has fulfilled these obligations.

B0. WORK SHEETS FOR SUPPORTING DOCUMENTATION

In order to make this guideline applicable, *ad hoc* work sheets have also been prepared for each supply chain.

In fact, the present guideline proposes some practical sheets that link the Support Documentation (SD) both with the main requirements considered by the Declaration of Compliance (DoC) of each supply chain, and with the specific chapters of this guideline. At the same time, the type of documentation that can be prepared to comply with the legal obligation is illustrated. Where necessary, the rationale behind the operational choice is also commented on, in the parts relating to each supply chain, which remains the responsibility of the company.

The format of the sheets, considered useful and uniform for practical purposes, is in any case secondary to their content, which instead constitutes from an application point of view a set of commented suggestions for the preparation or verification of the SD.

The forms, attached to each chapter for the specific supply chains, must therefore not be considered as classic pre-filled checklists, used by the inspector/auditor (public inspector or company personnel, or third party) to verify the presence of documentation, but as an operational tool that must always be used together with the general part of present guideline (Part A) and the specific part for the supply chain considered (Part B).

For each supply chain, the nine sheets identified by lowercase letters (from “a” to “i”), which follow the numbering coinciding between the supply chains considered in the guideline, are preceded by a summary of the legislation applicable to the specific supply chain. In fact, to harmonize the format of the sheets of all the supply chains, the nine points (requirements) contained in Annex IV of Regulation (EU) 10/2011 as amended, although this regulation is not of general applicability, but specific to plastics. The sheets of each supply chain therefore specify the applicability or otherwise of the point considered.

In each sheet are listed the following fields:

- *Requirement n.*
  where the requirement in the DoC is described.
- *Support documentation*
  where the type of documentation proving compliance with the requirement is summarized.
- *Present guideline*
  where the corresponding chapter of present guideline is indicated, which illustrates what is summarized in the sheet.
- *Applicable legislative reference*
  where the applicable Community or national legislative reference is indicated, with details on the article in question.
- *Regulation (EC) 1935/2004 as amended*
  where the reference to the applicable article of the Regulation is indicated
- *Notes*
  where clarifications, explanatory comments, etc. are reported.

The facsimile sheet used is shown in the Annex to this chapter.

It should be noted that each sheet filled in in Part B does not describe, except briefly, the technical content of the document, but focuses is on its type (e.g. test report, declaration of composition, etc.) which will then correspond to a more extensive specific documentation for each company.

The peculiarity of each supply chain, but even more so the size and organization of the company, could also involve operational choices that are often different, but which can be equally valid and meet legal requirements.

Annex B0. Facsimile sheet for Supporting Documentation (SD)

Work Sheet BX ……..

INDICATION	DESCRIPTION
Requirement	
Supporting documentation	
Present guideline	
Applicable legislative reference (specific or general if non-existent)	
Regulation (EC) 1935/2004 as amended	
Notes	

B1. ALUMINIUM

B1.1. Characterization of the sector

B1.1.1. Field of application of the guideline [10]

The present guideline on the Supporting Documentation (SD) for the Declaration of Compliance (DdC) applies to companies that produce the following products intended to come into contact with food:

- thin rolled aluminium foil;
- thin foil of transformed aluminium (painted and/or lacquered);
- finished products in aluminium as it is or coated.

For thin foil and/or finished products in aluminium laminated to paper and/or plastic films, with the side laminated side in contact with food, the provisions for flexible packaging in point B4 of this guideline apply.

B1.1.2. Applicable legislation

B1.1.2.1. Aluminium rolled products, thin foil and finished products

European legislation

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

Italian legislation

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

[10] It should be noted that the scope of the document *Rapporto ISTISAN* 23/4 Rev. (8), was as follows: "thin and laminated sheets intended for the manufacture of aluminium trays" thus including only FCMs of not-coated aluminium. Coated products were instead considered in point B7. For better rationalization, coated aluminium FCMs are considered in this Chapter B1 together with not-coated aluminium FCMs in this chapter. However, beverage cans and the like remain under the scope of point B7.

- DL.vo 108/1992 - Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- DL.vo 29/2017 - Legislative Decree No. 29/2017 on sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food.
- DM 76/2007 - Ministerial Decree No. 76/2007 on regulation regarding the hygienic discipline of materials and articles of aluminium and aluminium alloys intended to come into contact with foodstuffs.

B1.1.2.2. Thin aluminium converted foil

In addition to the references in the previous point:

European legislation

- 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.

Italian legislation

- DM 21/03/1973 - 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 as amended.

B1.1.3. Relationships between GMP, SD, DoC

Present guideline analyses the content and correlation between SD and DoC with reference to Good Manufacturing Practice (GMP) with regard to the production phases of rolled products and products in aluminium and its alloys, bare or processed, intended for contact with food.

Figures B1.1 to B1.3 represent, for illustrative purposes, the correlation flows between activities and documents relating to the various phases of product development and implementation. For a more in-depth description, however, see chapter B1.2.

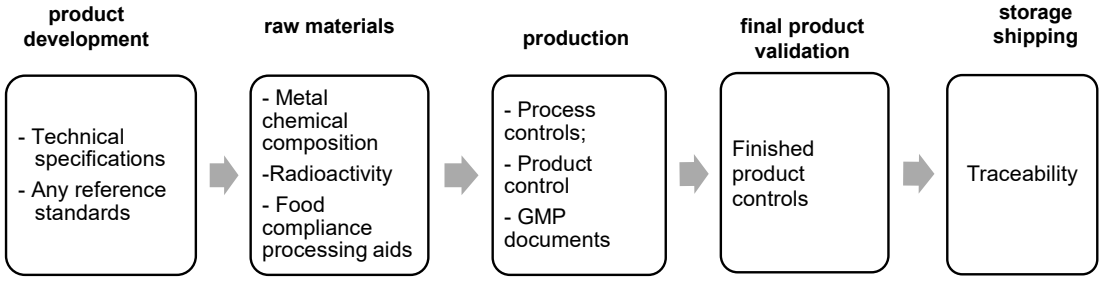

Figure B1.1 ALUMINIUM ROLLED THIN FOIL: production work steps and correlation with the SD for the DoC

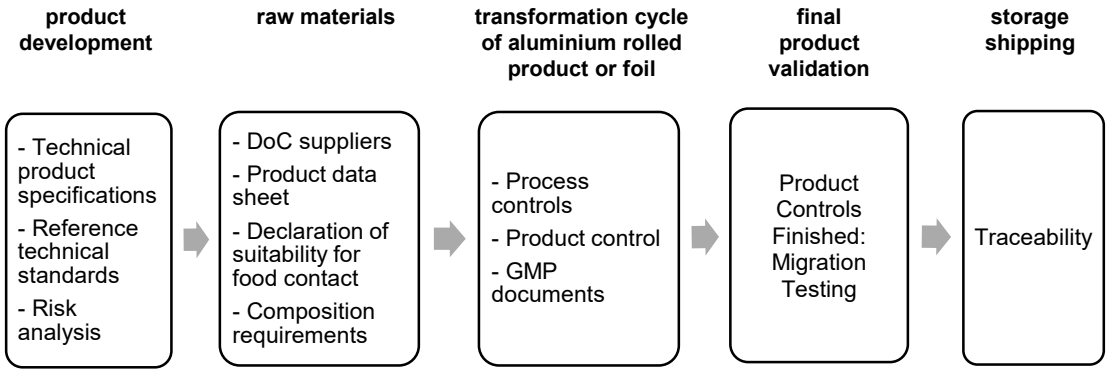

Figure B1.2 THIN FOIL OF TRANSFORMED ALUMINIUM PAINTED AND/OR LACQUERED: production phases and correlation with the SD for the DoC

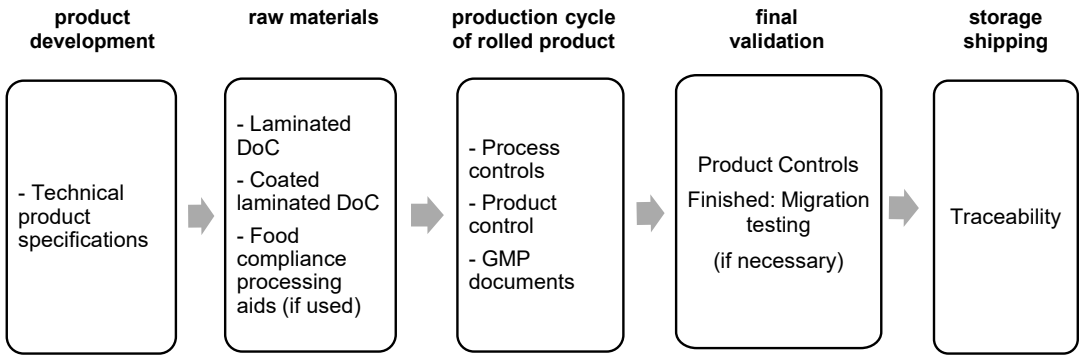

Figure B1.3 FINISHED PRODUCTS IN ALUMINIUM AS IT IS OR COATED: production work steps and correlation with the SD for the DoC

B1.1.4. Industrial processes

The flow charts and detailed descriptions of the production phases of the products are described in points B1.1.3 and B7.1.3 in the document *Rapporto ISTISAN* 23/4 Rev. (8).

Producers of rolled aluminium products and its alloys intended for contact with food are required to comply with Regulation (EC) 2023/2006 as amended and must therefore implement a Quality Management System (QMS) (of the type, but not necessarily, ISO 9001) such as to ensure, in particular, process control and traceability.

B1.1.4.1. Product development and raw material purchase

On the base of the requirements deriving from the end use of the product to be manufactured, the technical product specification is defined and consequently the production cycle is developed taking into account the regulations in force for materials and articles in contact with foodstuffs (Food Contact Materials, FCMs).

All the parameters are then defined in order to guarantee the control of production processes and product quality.

The documentation provided by the producers of the raw materials (e.g. technical data sheets, declaration of composition, declarations of compliance) is requested and evaluated in relation to

the usage specifications, defined by the end customer, where available, and/or by foreseeable usage indications.

It is good practice implement for a supplier qualification process, as provided in the document *Rapporto ISTISAN* 23/4 Rev. (8) in paragraphs B1.2.1.2.

B1.1.4.2. Production

For each process/product, the conditions that allow adequate control of the manufacturing process must be identified through the definition of a series of critical parameters (e.g. process temperature, pressure, etc.) by means of which product control is guaranteed.

Adequate quality controls shell be carried out on the product, in order to verify its conformity to the reference specification.

Traceability must be guaranteed for the whole production process.

B1.1.4.3. Final product approval

The product is approved on the basis of verification of its conformity to the specification.

Depending on the results of the checks provided by the specification, the final validation of the product is carried out.

In addition, all the appropriate checks required by the reference law must be carried out on the finished product to demonstrate the compliance of the packaging with the final use for which it is intended. Only after all checks, including quality checks, will the material be made available for shipment.

Note. All checks carried out on the finished product can be carried out internally or entrusted to an external laboratory (e.g. migration tests, where applicable). Alternatively, where applicable, theoretical calculations which are able to demonstrate the conformity of the material are allowed. Also, for tis ones, however, it is necessary to have appropriate documentation, which must be part of the SD, to be shown in case of request by the competent authorities.
Regarding the tests reports carried out by external laboratories, in accordance with the law, the documentation must be available to be presented to the competent authorities in the SD, while any provision of the SD or part of it to customers will be the result of a commercial agreement.

B1.1.4.4. Storage

Storage activities are also managed to maintain product traceability. Consequently, an appropriate type of packaging of the material and the related identification labelling must also be defined.

It must always be possible to trace the quality status of the products in stock through the appropriate codes and operating procedures/instructions.

B1.1.4.5. Shipment

The activities related to shipment involve the qualification of the companies that transport the product from the manufacturer to the end user. Carriers must also be selected on the basis of their ability to meet the quality requirements set by the companies in order to maintain the compliance of the transported product with the reference standards.

Transport documents are not necessarily part of the documentation required by the legislation on FMCs, but they are part of other legislative obligations. However, transport documents may also include relevant documentation, such as declarations of compliance with technical specifications, test reports, etc., if not otherwise shipped to the customer.

Therefore, if a correlation with compliance documents is available in the transport documentation, this could facilitate traceability paths.

B1.2. Supporting documentation

B1.2.1. Introduction

The purpose of this section is to clarify the requirements in relation to the SD required by Regulation (EC) 1935/2004 as amended concerning materials and articles intended to come into contact with foodstuffs.

Specific documentation elements applicable to the operator's position in the supply chain are identified.

The documents which constitute the SD should be periodically reviewed in order to take into account potential changes in the composition of formulations, changes in materials and production processes, regulatory updates, changes in suppliers or technological state of the art.

The documents which constitute the SD can also be made available and consulted through the use of databases or digital systems.

The SD may concern a family of products: for example, the recordings of the controls carried out on a particular finished product are also recognized for products of the same type that have, compared to those of the material under test, not critical morphological different characteristics (e.g. different thicknesses) and/or usage (e.g. time, temperature).

B1.2.2. SD for manufacturers of aluminium rolled products and thin foil

In the production of aluminium rolled products and thin foil, the only work steps of the production process that are relevant for food-contact compliance are the chemical composition of the alloy and the possible pre-lubrication of the strips with the use of technological process aid (pre-lubrication oil). The following paragraphs describe the SD relating to the above-mentioned phases.

B1.2.2.1. Raw materials

The SD should contain at least the following information:

- Radioactivity control recording for metal coming from suppliers;
- Declaration of composition of suppliers for raw materials such as rolling slabs and/or rolling coils, according to UNI EN 602 (11) as considered in DM 76/2007;
- Traceability.

In the case of pre-lubrication, the SD should also contain:

- DoC to direct contact with foodstaff of the technological process aid (pre-lubrication oil), as prescribed by Article 4, paragraph 2 of DM 76/2007 and also in compliance with the Regulation (EC) 1935/2004 as amended;
- Traceability of the production batch of the technological process aid (pre-lubrication oil.

It is also good practice to receive the DoC with respect to the documentation required in the documents of the *Food and Drug Administration* (12, 13), which is not mandatory in any case.

It is a further element of good practice to receive from the supplier of the technological process aid (pre-lubrication oil) the declaration of the absence of potentially allergenic substances listed in Annex III bis of Directive 2003/89/EC.

B1.2.2.2. Production cycle

Foundry (Cast House)
- Chemical composition (in compliance with Ministerial Decree 76/2007) reported in the DoC of the specific batch[11] accompanying the finished goods.
- Traceability.

Pre-lubrication possible
- Traceability of the production batch of the technological process aid (pre-lubrication oil).

Regulation (EC) 2023/2006 as amended, requires the storage, in the SD or in documents related to it, of the amounts of technological aid applied on the laminate expressed in mg/m^2.

B1.2.3. SD manufacturers of thin foil of transformed aluminium (painted and/or lacquered)

The SD can concern a single product or a group of products with similar compositional characteristics and coming from the same process.

B1.2.3.1. Raw materials

The SD should contain the documents proving compliance with the requirements of the DM 21/03/1973 as amended (articles 5, 6, 9, 9 bis, 9ter, 10, 11, 12) in relation to the following information:
- product technical data sheets (document containing the characteristics of the product in relation to the expected quality and specific use);
- information on composition;
- information on the toxicological characteristics of the product and (if available) of the breakdown products under foreseeable conditions of use, when known;
- adequate information on substances under restriction in foodstuffs and, where appropriate, compositional criteria in accordance with existing directives;
- where appropriate, information on assessments carried out for the verification of migration of substances with the Specific Migration Limit (SML), obtained by means of tests, mathematical models, calculations or appropriate scientific argumentation;
- supplier's DoC that includes references to national legislation, where applicable and/or information to support the risk assessment;
- in the case of products with particular intended uses, information that has been used to assess and support suitability for such uses.

B1.2.3.2. Production cycle

Regarding the raw materials from which we start, the SD should contain the documents proving compliance with the requirements of the DM 21/03/1973 as amended (articles 5, 6, 9, 9 bis, 9 ter, 10, 11, 12) in relation to the following information:

[11] An orientation for the batch DoC is in the UNI EN10204 standard (14)

- documentation relating to the product development phase;
- traceability of the semifinished rolled product;
- traceability of raw materials (paints, inks);
- recording by production batch of the process parameters that have an influence on the final characteristics of the product;
- recording of specific controls on the product controls (e.g., adhesion, possible sterilization, etc.);
- recordings of migration tests, total and/or specific migration tests for the side in direct contact with the food in accordance with the DM 21/03/1973 as amended (the frequency of such tests is defined in the company's GMP documentation);
- specifications of finished products (document containing the characteristics of the product in relation to the expected quality);
- Information to support the risk assessment.

B1.2.4. SD for manufacturers of finished products in aluminium as it is or coated

The SD can concern a single product or a group of products with similar compositional characteristics and coming from the same process.

B1.2.4.1. Raw materials

The SD should contain the following information:
- product technical data sheets (document containing the characteristics of the product in
- relation to the expected quality and specific use);
- information on composition;
- information on the toxicological characteristics of the product and (if available) of the breakdown products under foreseeable conditions of use, when known;
- adequate information on substances under restriction in foodstuffs and, where appropriate, compositional criteria in accordance with existing directives;
- where appropriate, information on assessments carried out for the verification of migration of substances with SML, obtained by means of tests, mathematical models, calculations or appropriate scientific argumentation;
- a statement of the supplier's composition, including references to national legislation, where applicable, and/or information to support the risk assessment;
- in the case of products with particular intended uses, information that has been used to assess and support the suitability for such uses.

B1.2.4.2. Production cycle

The SD should contain the following information:
- traceability of the semifinished rolled product coated as it is or coated;
- traceability of the production batch of the technological process aid in case of is used any pre-lubrication and recording of the quantity applied on, expressed in mg/m^2;
- if the DoC of the suppliers of coated laminates does not indicate details about its conditions of end use, the producer is requested to carry out total and specific migration tests for the side in direct contact with the food according to the DM 21/03/1973 as amended. The frequency of the aforementioned tests shell be defined in the company's GMP documentation;
- documentation relating to the checks carried out on the finished product in order to control the fixed technical specifications (e.g., paint integrity after drawing, etc.).

B1.3. Points of correspondence between DdC and SD

The SD contains some specific elements that are mentioned directly by the DdC, namely:
– product description;
– limitations of use;
– applicable legislation.

B1.4. SD topics not necessarily covered by GMP documentation

Some topics supporting the compliance of products in contact with food may not necessarily be managed within the GMP system of the company organization.

For example, the company, during the product development, may have elaborated indicative documentation useful for the evaluation of the products and consider not necessary periodically review such a document, managing this activity inside the GMP system.

All this does not imply the lack of such documentation or the absence of compliance work but only the unsystematic execution of some activities. The documentation will be in any case traceable and linkable to the goods to which it refers.

Annex B1.

Sheets for supporting documentation of aluminium food contact materials

Regulatory references

Regulation (EC) 1935/2004 as amended
Regulation (EC) 2023/2006 as amended (where applicable)
Regulation (EC) 625/2017
DPR 777/1982
DL.vo 108/1992
DM 76/2007
DL.vo 29/2017
Note of the Ministry of Health no. 32249, 11/10/2011

To harmonize the sheets of all the supply chains, the nine points contained in Annex IV of Regulation (EU) 10/2011 as amended have been used, although this Regulation is not directly applicable to the supply chain of aluminium.

Sheet B1.a Economic operator issuing the DdC

INDICATION	DESCRIPTION
Requirement 1	Identity and address of the economic operator issuing the DoC
Supporting documentation	Company and/or functional organization chart and/or delegation and/or management procedures and/or documentation deriving from the company policy establishing responsibilities
Present guideline	A1.3.2.2
DM 76/2007	art. 8
Regulation (EC) 1935/2004 as amended	art. 16.2 art. 2.2, paragraph d
Notes	If the economic operator issuing the DoC is the same as the economic operator producing or importing, requirements 1 and 2 may coincide To identify the responsibilities referred to this requirement, reference is made to art. 2 paragraph d of Regulation (EC) 1935/2004 as amended

Sheet B1.b Economic operator who produces or imports the good

INDICATION	DESCRIPTION
Requirement 2	Identity and address of the economic operator producing or importing: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished product *tick the relevant item*
Supporting documentation	Documentation proving the identity and address of the economic operator producing or importing raw materials/substances, intermediate/semi-finished products or finished products (e.g. specifications, transport documents, supply contracts, etc.)
Present guideline	A1.3.2.2
DM 76/2007	art. 8
Regulation (EC) 1935/2004 as amended	art. 16.2 art. 2.2, paragraph d
Notes	If the economic operator issuing the DoC is the same as the economic operator producing or importing, requirements 1 and 2 may coincide To identify the responsibilities referred to in this requirement, reference is made to art. 2, paragraph d of Regulation (EC) 1935/2004 as amended

Sheet B1.c Identity of the asset

INDICATION	DESCRIPTION
Requirement 3	Identity of the asset cui si riferisce la DdC: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished product *tick the relevant item*
Supporting documentation	Documentation for the identification of the asset (e.g. type of material/object, batch numbers, catalogue numbers, code numbers, etc.)
Present guideline	A1.3.2.2
DM 76/2007	art. 1
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	Traceability documents, etc., can also be useful

Sheet B1.d Functional barrier

INDICATION	DESCRIPTION
Requirement 4	Information on any functional barrier
Supporting documentation	Not applicable
This guideline	Not applicable
DM 76/2007	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	This requirement does not apply

Sheet B1.e Compliance with EU regulations/national legislation

INDICATION	DESCRIPTION
Requirement 5	Declaration of compliance with EU regulations and/or national legislation where applicable
Supporting documentation	Supporting documentation: – the results of analysis of the chemical composition of the alloy used – the supplier's certificate/analysis – supplier declarations
Present guideline	from B1.2.2 to B1.2.4
DM 76/2007	art. 8 paragraph 2 art. 4 paragraph 1 annex I and II
Regulation (EC) 1935/2004 as amended	art. 3 art. 16.2
Notes	-

Sheet B1.f Restricted substances/materials

INDICATION	DESCRIPTION
Requirement 6	Adequate information about the substances and/or materials used and/or degradation products for which restrictions are in place
Supporting documentation	DoC of the processing aid supplier
Present guideline	B1.2.2.1 B1.2.3.1 from B1.2.4.1 to B1.2.4.2
DM 76/2007	art. 4, paragraph 2 (use of appropriate processing aid)
Regulation (EC) 1935/2004 as amended	art.16.2
Notes	e.g. pre-lubrication oil used as a processing aid

Sheet B1.g Restricted substances/materials in foodstuffs

INDICATION	DESCRIPTION
Requirement 7	Adequate information on substances and materials used that are restricted in foodstuffs
Supporting documentation	Not applicable
Present guideline	Not applicable
DM 76/2007	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	This requirement does not apply

Sheet B1.h Directions for use

INDICATION	DESCRIPTION
Requirement 8	Indications regarding the use of FCMs: ❑ types of food products with which it is intended to come into contact ❑ duration, treatment temperature and storage in contact with food ❑ contact test conditions (simulant, duration, temperature) ❑ contact surface area to volume ratio for determining the compliance of the FCMs ❑ other restrictions of use *tick the relevant items*
Supporting documentation	Documentation proving compliance checks for the declared uses (e.g., notes on declarations, labels, or other documents sent to the customer)
Present guideline	see notes
DM 76/2007	art. 5 art. 6
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	Since DM 76/2007 already provides for conditions of use and labelling, it is not necessary to prepare a specific paragraph on this requirement, but reference is made to articles 5 and 6 of the aforementioned decree.

Sheet B1.i Date of declaration

INDICATION	DESCRIPTION
Requirement 9	Date of declaration
Supporting documentation	-
Present guideline	A1.3.2.2
DM 76/2007	art.8
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	-

B2. PAPER AND BOARD: PRODUCTION

B2.1. Characterization of the sector

B2.1.1. Field of application of the guideline

Present guideline on Supporting Documentation (SD) for the Declaration of Compliance (DoC) applies to all companies that produce paper and cardboard (not yet processed or printed) from virgin fibre or paper to be recycled until the development of sheet and it's setting up in reels or sheets.

B2.1.2. Applicable legislation

European legislation

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

Italian legislation

- DPR 777/1982 - Decree of the President of the Republic No. 777/1982 on implementation of the Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs as amended.
- DL.vo 108/1992 - Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- DL.vo 29/2017 - Legislative Decree No. 29/2017 on sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food.
- DM 21/03/1973 - Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, for contact with foodstuffs or substances for personal use as amended.

B2.1.3. Relationships between GMP, SD, DoC

In the production of paper and cardboard there are various activities that can intervene on the compliance of the material in contact with food and that refer to GMP standard (Good Manufacturing Practice). In this context, SD and DoC are also part of the system.

Figure B2.1 below illustrates the flow of activities and documents relating to the production of paper and cardboard. This does not deal with subsequent processes, such as transformation processes and printing, which are the subject of another chapter (*see* B3) of this guideline. For a more in-depth description, however, see chapter B2.2.

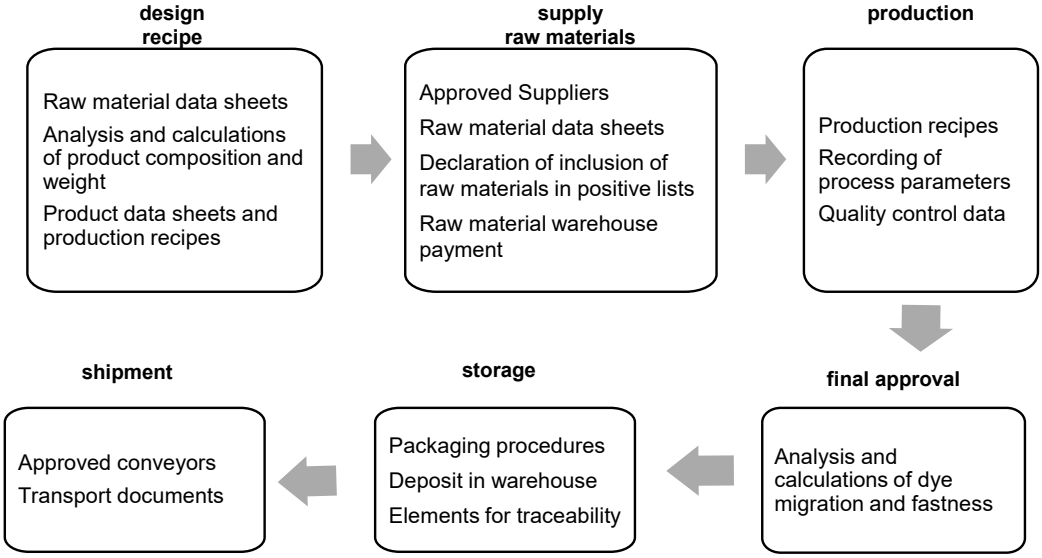

Figure B2.1 UNPRINTED AND UNPROCESSED PAPER AND CARDBOARD: production phases and correlation with SD and DoC

B2.1.4. Paper and cardboard production process

The steps of the production process summarized in the flow diagram in Figure B2.1 are described below and then the SD, the correspondence points between Doc, SD and GMP as well as the topics of the SD not covered by the GMP system are analysed in detail.

B2.1.4.1. Design and recipe

The company develops its products according to market demand, selecting raw materials and technologies suitable for achieving the set goal. The product is often accompanied by a technical sheet that represents its main performance characteristics.

Part of the development activities is dedicated to verifying the regulatory requirements to be complied with relating to the characteristics, composition and weight of the product, also depending on the type of food with which the material is intended to come into contact, the nature of the fibrous materials and the characteristics of the fillers, auxiliary substances and processing aid (e.g. technical data sheets or declaration of composition provided by the producers of these materials), which must be included in the positive lists of the DM 21/03/1973 as amended. In this regard, it should be noted that fibrous materials (cellulous, wood pulp and paper to be recycled) do not have to be accompanied by a declaration of compliance under current legislation.

The characteristics of the incoming substances and the parameters of the production process to be subjected to quality control are then defined in compliance with the provisions of Regulation (EC) 2023/2006 and subsequent amendments. The work is completed with the definition of the production recipe, containing the qualitative and quantitative indications of the substances and raw materials to be used in production.

B2.1.4.2. Procurement of raw materials

The process of acquiring raw materials (i.e., fibrous materials, filler substances, auxiliary substances and processing aids) involves the approval of suppliers who are able to supply the substances necessary for the production of the material under development and to meet the required technical legislative and quality specifications.

Each starting substance is identified by a single technical specification that possible suppliers must always meet. The company verifies the correspondence between the specifications provided by the supplier (technical sheets) and the required specifications and, if so, approves the supplier's raw material. This process is applied to every raw material and every supplier. The supplier shall accompany, where appropriate, its product with technical documentation, declarations of inclusion in the positive lists of the DM 21/03/1973 as amended, analysis reports, etc. Upon entry into the factory, the raw materials are subjected to an acceptance, verification and storage procedure.

B2.1.4.3. Production

In compliance with the provisions of Regulation (EC) 2023/2006 as amended., for each process/product the conditions must be identified that allow adequate control of the production process through the definition of a series of critical process parameters (i.e. that allow the control of compliance with the production recipe and through these carry out a control of the product. The recording of critical process parameters is part of the SD.

Adequate quality controls are carried out on the product, either in-line or after production, to verify its adherence to the reference specification.

B2.1.4.4. Final approval

In this phase, in relation to the specific sector of use for which the product has been developed (e.g. contact or not with food subjected to migration tests), the company carries out analyses and calculations to verify compliance with the applicable legislative requirements and the expected technical characteristics (weight, composition, solidity, etc.).

All the checks made on the finished product can be carried out internally or entrusted to an external laboratory.

Reference documentation from external laboratories will also be an integral part of the SD available in the company for the competent authorities

Analyses and calculations can be carried out both on the finished material and on products produced from it.

B2.1.4.5. Storage

Traceability starts with the mother reel and continues until the distribution of the product to the end user. The paper and cardboard manufacturer is therefore responsible for initiating traceability for the part of its competence. Warehouse activities are therefore managed to ensure their traceability and keep products intended for contact with food identified. Consequently, the

appropriate types of packaging of the material and the related identification markings must also be defined.

It must always be possible to trace the quality status of the products in stock through the appropriate codes and operating procedures/instructions.

The material that has shown discrepancies in production must be identified and separated.

B2.1.4.6. Shipment

The preparatory activities for shipment require the approval of the suppliers who transport the product from the paper and cardboard manufacturer to the converter. Carriers must also be selected on the basis of their ability to meet the quality requirements set by the companies in order to maintain the compliance of the transported product with the reference standard.

Transport documents are not necessarily part of the documentation required by the legislation on or materials and articles in contact with foodstuffs (Food Contact Materials, FCMs), but they are part of other legislative obligations. However, transport documents may also include relevant documentation, such as declarations of compliance, if not otherwise shipped to the customer. Therefore, if a correlation with compliance documents is available in the transport documentation, this could facilitate traceability paths.

B2.2. Supporting documentation

B2.2.1. Introduction

This section presents the basic points of the SD regarding paper and cardboard intended to come into contact with foodstuffs.

The documents that make up the SD should be reviewed periodically to reflect potential changes in the composition of recipes, changes in materials and production processes, regulatory updates, changes in suppliers or adaptations to technical progress.

The documents that make up the SD can also be made available and consulted through the use of databases or computer systems.

The SD may concern a family of products: for example, the records of the controls carried out on a particular finished product are also recognized for products of the same type that have, compared to those of the material under test, less critical morphological characteristics (e.g. different thicknesses) and use (e.g. time, temperature).

B2.2.2. SD for paper and board manufacturers

Manufacturers of paper and cardboard intended for contact with foodstuffs are required to comply with Regulation (EC) 2023/2006 as amended and must therefore implement a Quality Management System (QMS) (such as, but not necessarily, ISO 9001) that guarantees in particular the control of activities, processes and traceability. These requirements also apply to paper and board imported into the EU.

The SD can concern a single product or a group of products with similar compositional characteristics and coming from the same process, even using worst case techniques in order to simplify its management.

Not all the documents indicated below must necessarily always be present in the collection of the SD, but only the documents that, on a case-by-case basis, are deemed necessary to support and justify the evaluations that allow the issuance of the DoC.

B2.2.2.1. Composition of paper and cardboard

The SD should contain at least:
- description of the product (e.g., paper, cardboard, cardboard, etc.);
- product specification (document containing the characteristics of the product in relation to the expected quality and in particular the indication whether it is suitable for food for which migration tests are required or whether multilayered);
- information on composition and weight.

B2.2.2.2. Collecting relevant information from suppliers

The SD should contain at least:
- identification of the raw material;
- information on the technical quality of the raw material;
- supplier's declaration of inclusion of raw materials in the positive lists including references to national legislation, where applicable.

B2.2.2.3. Manufacturing, storage and shipment documentation

The SD should contain at least:
- information on the evaluation of critical process, storage and shipment parameters or that may have an influence on product compliance;
- record of production, storage and shipment parameters that may affect product compliance;
- record of quality controls that may affect product compliance;
- tracking, inventory and shipment record.

B2.2.2.4. Composition assessment documentation

The SD should contain at least:
- information on the assessments carried out to verify the compliance of the composition and possible limitations on contact with only foods not subject to migration tests;
- risk assessment, e.g. for substances not intentionally added.

B2.2.2.5. Documentation on the evaluation of substances subject to migration

The SD should contain at least:
- information on the assessments carried out for the verification of migration, obtained by means of tests, mathematical models, calculations or appropriate scientific argumentation.
- migration tests are carried out for lead, provided for by DM 21/03/1973 as amended for the determination of the purity requirements of paper and cardboard and for certain substances, if used in the production process, for which transfer limits are provided as a condition for their inclusion in the positive lists of DM 21/03/1973 as amended.

B2.3. Points of correspondence between DoC and SD

The SD contains some specific elements that are cited directly by the DoC.

The DoC confirms to the next actor in the supply chain that the compliance work has been carried out, indicating if necessary, what further activities should be carried out by the user.

As regard the SD prepared by paper and board producers, the reference documents for the DoC are at least:

- product description;
- possible limitation to contact with food for which no migration tests are provided;
- applicable legislation.

B2.4. Points of correspondence between GMP and SD

For paper and cardboard manufacturers, some documents included in the documentation of the GMP system are listed and are also used in the SD:

- specifications of finished products;
- raw materials specifications;
- information on analysis and composition or migration calculations if these are managed in the company's QMS or GMP.

B2.5. SD topics not necessarily covered by GMP documentation

Some topics supporting the compliance of products in contact with food may not necessarily be managed within the GMP system of a given company organization.

For example, the company may have produced during the development phase an indicative documentation useful for the evaluation of products and consider it unnecessary for this documentation to be produced periodically and managed in the GMP system.

Below is a non-exhaustive list of these documents:

- results of analysis and migration calculations (if not managed in the company's QMS or GMP);
- evaluations concerning NIAS (Non-Intentionally Added Substances);
- evaluations of the composition of paper and cardboard.

All this does not imply the lack of such documentation or the absence of compliance work but only the unsystematic execution of some activities. The documentation will in any case be traceable and traceable to the asset to which it refers.

Annex B2

Sheets for supporting documentation of paper and cardboard food contact materials: production

Regulatory references

Regulation (EC) 1935/2004 as amended
Regulation (EC) 2023/2006 as amended (where applicable)
Regulation (EC) 625/2017
DM 21/03/1973 as amended
DPR 777/1982
DL.vo 108/1992
DL.vo 29/2017
Note of the Ministry of Health no. 32249, 11/10/2011

To harmonize the sheets of all the supply chains, the nine points contained in Annex IV of Regulation (EU) 10/2011 as amended have been used, although this Regulation is not directly applicable to the supply chain of paper and cardboard.

Sheet B2.a Economic operator issuing the compliance declaration

INDICATION	DESCRIPTION
Requirement 1	Identity and address of the economic operator issuing the DoC
Supporting documentation	Company and/or functional organization chart and/or delegation and/or management procedures and/or documentation deriving from the company policy establishing responsibilities
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art.6
Regulation (EC) 1935/2004 as amended	art 2.2, paragraph d art 16.2
Notes	If the economic operator issuing the DoC is the same as the economic operator producing or importing, requirements 1 and 2 may coincide. To identify the responsibilities referred to this requirement, reference is made to art. 2 paragraph d of Regulation (EC) 1935/2004 as amended

Sheet B2.b Economic operator who produces or imports the good

INDICATION	DESCRIPTION
Requirement 2	Identity and address of the economic operator producing or importing: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished products *tick the relevant item*
Supporting documentation	Documentation proving the identity and address of the economic operator who produces or imports raw materials, intermediate/semi-finished products, finished products (e.g. specifications, transport documents, supply contracts, etc.)
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6 art.8, paragraph c
Regulation (EC) 1935/2004 as amended	art 16.2
Notes	Paper and cardboard that has not yet been processed are to be considered intermediate products, except in cases where they are directly used without further processing, in which case they are to be considered finished products. If the economic operator issuing the DoC is the same as the economic operator producing or importing, requirements 1 and 2 may coincide.

Sheet B2.c Identity of the asset

INDICATION	DESCRIPTION
Requirement 3	Identity of the asset to which the DdC refers: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished products *tick the relevant item*
Supporting documentation	Documentation for the identification of the asset (e.g. type of material/object, batch numbers, catalogue numbers, code numbers, etc.)
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	Paper and cardboard that has not yet been processed are to be considered intermediate products, except in cases where they are directly used without further processing, in which case they are to be considered finished products. Traceability documents can also be useful.

Sheet B2.d Functional barrier

INDICATION	DESCRIPTION
Requirement 4	Information on the possible functional barrier
Supporting documentation	Not applicable
Present guideline	Not applicable
DM 21/03/1973 as amended	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	This requirement is not applicable

Sheet B2.e Compliance with EU regulations/national legislation

INDICATION	DESCRIPTION
Requirement 5	Declaration of the European regulations and/or national legislation where applicable
Supporting documentation	Supporting documentation: – use of substances present in Annex. Section II of the DM 21/03/1973 as amended (e.g. declarations of inclusion in the positive lists) – production recipes and GMP system – analysis results and/or calculations on the material/object produced
Present guideline	from B2.1.4.1 to B2.1.4.4 B2.2.1.2 B2.2.1.5
DM 21/03/1973 as amended	art.6 art 27 27 bis (where applicable) art 28
Regulation (EC) 1935/2004 as amended	art. 3 art. 16.2
Notes	-

Sheet B2.f Substances/materials subject to restriction and/or compositional requirements

INDICATION	DESCRIPTION
Requirement 6	Adequate information about the composition and the substances and/or materials used and/or degradation products for which restrictions are in place
Supporting documentation	Supporting documentation: – compliance with composition and purity requirements – assessment of any reaction and degradation products of the substances
Present guideline	B2.1.4.2 from B2.2.1.1 to B2.2.1.5
DM 21/03/1973 as amended	art.6 art. 27 art. 27 bis (where applicable) art. 28 annex II section 4
Regulation (EC) 1935/2004 as amended	art.3 art.16.2
Notes	-

Sheet B2.g Restricted substances/materials in foodstuffs

INDICATION	DESCRIPTION
Requirement 7	Adequate information on substances and materials used that are restricted in foodstuffs
Supporting documentation	Not applicable
Present guideline	Not applicable
DM 21/03/1973 as amended	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	This requirement does not apply

Sheet B2.h Directions for use

INDICATION	DESCRIPTION
Requirement 8	Indications on the use of FCMs: ❑ types of food products with which it is intended to come into contact ❑ duration, treatment temperature and storage in contact with food ❑ contact test conditions (simulant, duration, temperature) ❑ contact surface to volume ratio for determining FCMs compliance ❑ restrictions on use *tick the relevant items*
Supporting documentation	Documentation proving compliance checks with the declared uses (e.g. analysis reports, production recipes, etc.)
Present guideline	B2.2.1.1 B2.2.1.3 B2.2.1.5
DM 21/03/1973 as amended	art. 8 b
Regulation (EC) 1935/2004 as amended	art.15 art 16.2
Notes	Tests on durability, treatment temperature, storage and the ratio between contact surface and volume are normally carried out on the finished FCMs and not on paper and cardboard as they are.

Sheet B2.2.i Date of declaration

INDICATION	DESCRIPTION
Requirement 9	Date of declaration
Supporting documentation	-
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art.6
Regulation (EC) 1935/2004 as amended	art.16.2
Notes	-

B3. PAPER AND BOARD: CONVERTING

B3.1. Characterization of the sector

B3.1.1. Field of application of the guideline

Present guideline on Supporting Documentation (SD) for the Declaration of Compliance (DoC) applies to all companies that produce paper and cardboard packaging (cases, sacks, bags, containers, corrugated cardboard products). The production cycle includes the transformation of paper and cardboard, used alone or in combination with other materials, for packaging intended to contain food products. For non-cellulosic materials but possibly present in the final packaging, reference must be made, where existing, to the guidelines of the specific material (plastic films, paper, aluminium, etc.).

B3.1.2. Applicable legislation

European legislation

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

Italian legislation

- DPR 777/1982 - Decree of the President of the Republic No. 777/1982 on implementation of the Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs as amended.
- DL.vo 108/1992 - Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- DL.vo 29/2017 - Legislative Decree No. 29/2017 on sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food.
- DM 21/03/1973 - Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, for contact with foodstuffs or substances for personal use as amended.

B3.1.3. Relationships between GMP, SD, DoC

In the production of paper and cardboard packaging, there are several activities that can intervene on the compliance of the material in contact with food and that refer to Good Manufacturing Practice (GMP) standards. Supporting Documents (SD) and Compliance Declarations (CD) are also part of the system in this context.

Figure B3.1 illustrates the flow of activities and documents relating to the production of paper and cardboard packaging. In this context, the previous phases such as the paper production processes, which are the subject of another chapter (*see* B2) of this guideline, are not covered. For a more in-depth description, however, see the chapter B3.2.

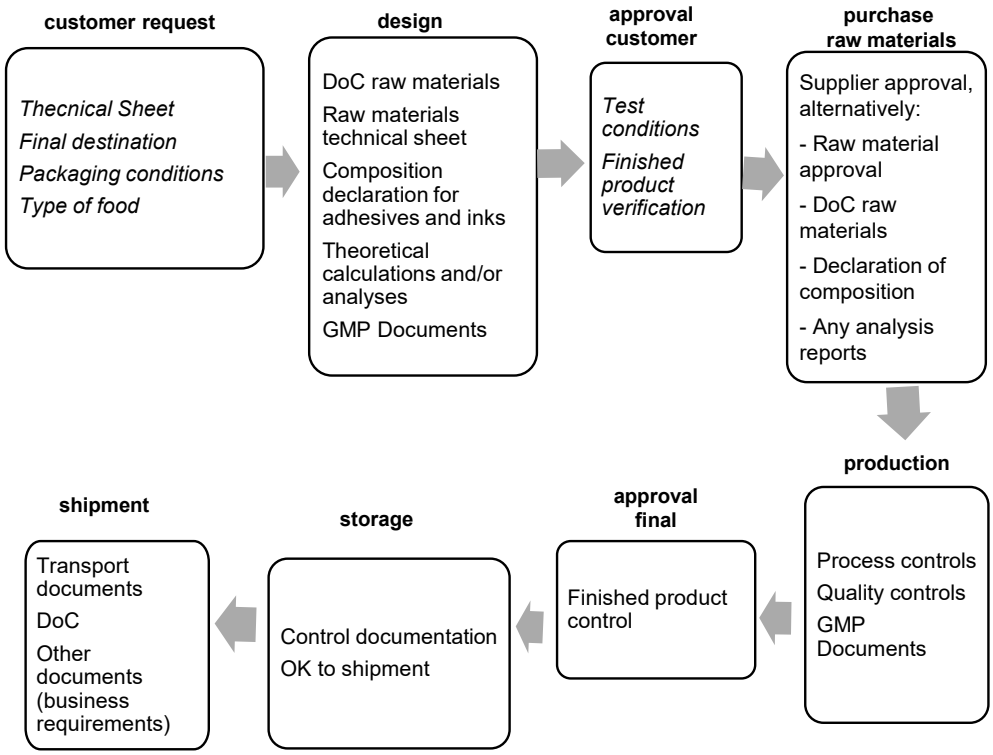

Figure B3.1 PAPER AND CARDBOARD:
production phases and correlation with SD for the DoC
(non-mandatory actions are in italics, even if usually present)

B3.1.4. Paper and cardboard packaging production process

The steps of the production process summarized in the flowchart are described below and then the SD, the correspondence points between DoC, SD and GMP standards as well as the topics of SD not covered by the GMP system are analysed in detail.

B3.1.4.1. Order/customer request

This phase of the production process generally requires collaboration between the customer and the packaging manufacturer. The two parties should in fact exchange the information necessary to ensure that the packaging to be made is suitable for the food it will have to contain.

Therefore, the characterizing aspects of the food to be packaged should be disclosed, in particular its nature, the packaging methods, the duration and type of storage in the warehouse of the packaged product and everything useful to ensure that the packaging is compliant and safe for the product to be packaged.

Although the issue of specific documentation is not required by law at this stage, it is desirable that the necessary information is available to allow the design of suitable packaging or the optimal adaptation of an already available packaging (in italics in the diagram in Figure B3.1).

B3.1.4.2. Design

In the design phase, the company will have to identify the characteristics that the packaging must have to be suitable for coming into contact with the food. Therefore, starting from the information obtained from the collaboration with the customer or from his own design objective, he will be able to choose which materials to use and which legislative obligations the finished packaging will have to meet.

B3.1.4.2.1. Raw materials

The choice of raw materials to be used to make paper, cardboard or corrugated cardboard packaging intended for contact with food, must be made by verifying that the raw materials comply with the provisions of the DM 21/03/1973 as amended, that they meet the requirements set out in Regulation (EC) 1935/2004 as amended, that the supplier has a GMP system in place in accordance with the provisions of Regulation (EC) 2023/2006 as amended.

The supplier of paper or cardboard used as starting materials must issue its own DoC to the packaging manufacturer. The latter, in addition to certifying the compliance of the material with the legal requirements, constitutes an indispensable part of the SD for the transformer which must be kept available to the competent authority upon request.

With regard to other raw materials used such as adhesives, inks and printing varnishes, in the absence of specific legislation, they should be accompanied by adequate information[12] attesting to their characteristics and allowing the compliance of the packaging to be produced in contact with food to be assessed.

This information must also be part of the SD that the packaging manufacturer must have.

B3.1.4.2.2. Control of production conditions

During the production process of the packaging, it is necessary to carry out process controls to ensure compliance with the regulatory provisions provided for by the legislation, in particular regarding the qualitative and technical characteristics of the product.

The operations of this phase will therefore be necessary for the definition of the technical parameters of the process and product (production sheet) to be maintained and controlled to ensure compliance with the specifications of the finished product during industrial production.

Laboratory analyses can also be carried out on the finished product to ensure that the packaging complies with the provisions of the legislation on materials and articles in contact with food (Food Contact Materials, FCMs), and to draw up the relevant DoC. Alternatively, compliance can be verified with mathematical calculations or screening analyses. The test results are also part of the SD that the packaging manufacturer must keep available.

[12] For the meaning of "adequate information", refer to the DG Sanco Guideline 2013 (10) which, even if not directly applicable, constitutes an authoritative guideline.

B3.1.4.2.3. GMP documentation

Throughout the production process, the requirements of Regulation (EC) 2023/2006 and subsequent amendments must be complied with. Information on the necessary requirements can be found in the documents *Rapporto ISTISAN* 23/4 Rev. (8) and *Rapporto ISTISAN* 13/14 (4)[13] to which reference is made for the relevant documentation.

B3.1.4.3. Product approval by the customer

Once the customer has received the packaging intended to contain the food, he should carry out the appropriate technical checks and compliance of the packaging and food product with the legislation on FCMs. Once the checks have been carried out, it would be desirable that feedback be provided to the packaging manufacturer to confirm or not the suitability of the packaging for the specific food for which it was designed.

B3.1.4.4. Purchase raw materials

When the customer has confirmed the approval of the packaging and has therefore issued the purchase order, the converter must start its production cycle with the procurement of raw materials.

The converter is required to use only approved starting materials, i.e. for which it has, through the supplier's information and/or through checks and verifications carried out during the design phase, all the data necessary to ensure the compliance of the packaging produced with the legal requirements, including restrictions due to the conditions of use.

There can be many ways of selecting materials and/or suppliers, but in any case, it is necessary for the company to have the necessary documentation to demonstrate how the starting materials were chosen. The approval of the supplier and materials is a legislative requirement clearly expressed in art. 5, paragraph 2, of Regulation (EC) 2023/2006 as amended. For more information, please refer to chapter A3.2 in the document *Rapporto ISTISAN* 23/4 Rev. (8).

B3.1.4.4.1. Supplier approval

One of the possible criteria for choosing a raw material is to approve a supplier through a pre-established, organized and documented process that may also include supply specifications. The relevant documentation, including procedures, technical specifications and supply specifications will form part of the SD.

You should also ensure that the following requirements are met:

- issuance of a DoC in accordance with the provisions of the relevant legislation (for raw materials that provide for it);
- provision of adequate information for raw materials not regulated by specific legislation;
- application by the supplier of a GMP system as required by Regulation (EC) 2023/2006 as amended (where applicable).

As an alternative to supplier approval, a raw material can be approved (*see* chapter B3.2.12 in the document *Rapporto ISTISAN* 23/4 Rev.) (8).

All this information and documentation must be part of the SD to be kept in the company.

[13] The doument *Rapporto ISTISAN* 13/14) (4) has since been published as *Rapporto ISTISAN* 24/36

B3.1.4.4.2. Other documents

Before putting a raw material into production, it may be necessary to perform other control analyses in-house or in external laboratories. Where this evidence is necessary to establish compliance with food contact, the relevant analysis reports and technical arguments will form part of the SD and must be available from the company and available to the competent authorities upon request.

B3.1.4.5. Production

Producers of paper, cardboard or corrugated cardboard packaging intended to come into contact with food must comply with the provisions of Regulation (EC) 2023/2006 as amended. Therefore, they must implement a Quality Assurance System (QAS) and a Quality Control System (QCS), in order to keep production activities and processes under control and their traceability must be guaranteed through all phases. It will therefore be necessary to establish the control and verification points that will have to be monitored to ensure the compliance of the product intended to come into contact with food. Please refer the document *Rapporto ISTISAN* 23/4 Rev. (8), in particular to the chapter B3.2.2.

B3.1.4.5.1. Production sheet

At the time of production, operators should have a production sheet that provides the necessary indications to produce material that complies with specifications and legal requirements.

B3.1.4.5.2. Process controls, quality controls on the product

On the basis of the indications given in the production sheets, the process and quality control plan should also be established, i.e. the list of checks to be carried out to ensure that the machine parameters are correctly set and respected and that the product meets technical specifications (e.g. ink adhesion to prevent counter-printing phenomena, set off) that also ensure compliance with the legislation on FCMs. The control plan and the records made will be part of the SD available to the competent authority upon request.

B3.1.4.6. Final approval

B3.1.4.6.1. Controls on the finished product

The finished product must meet the requirements of the reference law on materials in contact with food. All the checks made on the finished product can be carried out internally or entrusted to an external laboratory. The reference documentation will be an integral part of the SD available in the company for the competent authorities. Any provision of SD to customers, which is not mandatory, will be the result of a possible commercial agreement.

B3.1.4.7. Storage

The material deemed suitable according to the company's procedures will be placed in storage establishing the storage and packaging conditions (possibly agreed with the customer).

The material will be appropriately identified to allow its correlation with the SD relating to the production order.

B3.1.4.8. Shipment

B3.1.4.8.1. Transport documents

Transport documents are not necessarily part of the documentation required by the legislation on FMCs, but they are part of other legislative obligations.

However, transport documents may also include relevant and/or useful documentation (e.g. compliance statements, test reports, etc.) if not sent to the customer in any other way. Therefore, if a correlation with compliance documents is available in the transport documentation, this could facilitate traceability paths.

B3.2. Supporting documentation

B3.2.1. Introduction

This Section presents the key points of the SD concerning the production of paper packaging and cardboard intended to come into contact with foodstuffs.

Specific documentation elements applicable to the operator's position in the supply chain are identified.

The documents that make up the SD should be reviewed periodically if there are changes in materials and production processes, regulatory updates, changes in suppliers or adaptations to technical progress.

The documents that make up the SD can also be made available and consulted through the use of databases or computer systems.

SD may concern a family of products: for example, the records of the checks carried out on a particular finished product are also recognized for products of the same type that have, compared to those of the material under test, less critical morphological characteristics (e.g. different thicknesses) and use (e.g. time, temperature).

B3.2.2. SD for paper and cardboard packaging manufacturers

Producers of paper and cardboard packaging intended for contact with food are required to comply with Regulation (EC) 2023/2006 as amended and additions and have therefore implemented a Quality Management System (QMS) that guarantees in particular the control of activities, processes and traceability. These requirements also apply to paper and board imported into the EU.

SD can concern a single product or a group of products with similar compositional characteristics and coming from the same process, even employing worst case techniques in order to simplify management.

Below is an indicative list of useful documents, underlining that not all of them must necessarily always be present in the collection of SD, but only the documents that, on a case-by-case basis, are deemed necessary to support and justify the evaluations that allow the DoC to be issued.

B3.2.2.1. Composition of paper and cardboard packaging

The SD sheet should contain at least:

- description of the product (e.g., paper, cardboard, cardboard, etc.);
- trade name of the product(s) (if any);

- product specification (document containing the characteristics of the product in relation to the expected quality);
- technical information on the raw materials used;
- information on composition and weight.

B3.2.2.2. Collection of relevant information from suppliers

B3.2.2.2.1. For paper or cardboard

The SD should contain at least:
- identification of the raw material/material;
- information on the technical quality of the raw material/material;
- DoC, including compliance with positive lists in accordance with the provisions of national reference legislation;
- purity requirements: information that may be necessary to ensure compliance with specific provisions of the applicable legislation, with particular reference to the intended use, if there are limitations (e.g., use of recycled paper).

B3.2.2.2.2. For non-regulated materials (inks, adhesives, etc.)

The SD should contain at least:
- product identification;
- adequate information (e.g., compositional declaration) for substances subject to migration limits, restrictions of use, or that are formed during the process for which a risk assessment must be carried out to comply with the compliance requirements of Article 3 of Regulation (EC) 1935/2004 as amended;
- information on the technical quality of the product.

B3.2.2.3. Composition assessment documentation

The producer of paper and cardboard packaging must carry out an assessment of the composition of the material in order to support and formalise the decision to consider the product subject to the SD suitable for contact with food on the basis of:
- information on the assessments carried out to verify the compliance of the composition and possible limitations on contact with only foods not subject to migration tests;
- risk assessment, e.g. for substances not intentionally added.

B3.2.2.4. Documentation on the evaluation of substances subject to migration verification

The SD should contain at least:
- information on the assessments carried out for the verification of migration, obtained by means of tests, mathematical models, calculations or appropriate scientific argumentation;
- migration tests are carried out for lead, provided for by DM 21/03/1973 as amended, for the determination of the purity requirements of paper and cardboard and for certain substances, if used in the production process, for which transfer limits are provided as a condition for their inclusion in the positive lists of DM 21/03/1973 as amended.

B3.2.2.5. Documentation on particular uses mentioned in the DoC

In the case of products with particular intended uses, (e.g., only for foods for which there are no migration tests in Ministerial Decree 220/1993 (15) the SD will contain information that has been used to assess and support the suitability for such uses.

B3.3. Points of correspondence between DoC and SD

SD contains some specific elements that are mentioned directly by the DoC.

The DoC confirms to the next actor in the supply chain that the compliance work has been carried out, indicating if any, what further activities need to be carried out by the user.

As regards the SD prepared by producers of paper and cardboard packaging, including corrugated cardboard, the reference documents for the DoC are at least:

- product description;
- where appropriate, information that has been used to assess and support suitability for particular uses mentioned in the DoC, e.g. limitation to contact with food for which no migration evidence is required;
- applicable legislation.

B3.4. Points of correspondence between GMP and SD

For manufacturers of paper and cardboard packaging, some documents included in the GMP documentation are listed and are also used in the SD:

- specifications of finished products;
- raw materials specifications;
- information on analysis and composition or migration calculations if these are managed in the company's Quality System or GMP.

B3.5. SD topics not necessarily covered by GMP documentation

Some topics supporting compliance of paper and cardboard packaging intended for contact with food may not necessarily be managed within the GMP system of a given business organization.

For example, the company may have produced guidance documentation useful for product evaluation during development, but considers it unnecessary for this documentation to be produced periodically and managed in the GMP system.

Below is a non-exhaustive list of these documents:

- results of analysis and migration calculations (if not managed in the company's Quality System or GMP);
- evaluations concerning NIAS (Non-Intentionally Added Substances);
- evaluations of the composition of paper and cardboard.

All this does not imply the lack of such documentation or the absence of compliance work but only the unsystematic execution of some activities. The documentation will in any case be traceable and traceable to the asset to which it refers.

Annex B3

Sheets for supporting documentation of paper and cardboard food contact materials: converting

Regulatory references

Regulation (EC) 1935/2004 as amended
Regulation (EC) 2023/2006 as amended (where applicable)
Regulation (EC) 625/2017
DM 21/03/1973 as amended
DPR 777/1982
DL.vo 108/1992
DL.vo 29/2017
Note of the Ministry of Health no. 32249, 11/10/2011

To harmonize the sheets of all the supply chains, the nine points contained in Annex IV of Regulation (EU) 10/2011 as amended have been used, although this Regulation is not directly applicable to the supply chain of paper and cardboard.

Sheet B3.a Economic operator issuing the compliance declaration

INDICATION	DESCRIPTION
Requirement 1	Identity and address of the economic operator issuing the D0C
Supporting documentation	Company and/or functional organization chart and/or delegation and/or management procedures and/or documentation deriving from the company policy establishing responsibilities
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art.6
Regulation (EC) 1935/2004 as amended	art 2.2, paragraph d art 16.2
Notes	If the economic operator issuing the DoC is the same as the economic operator producing or importing, requirements 1 and 2 may coincide. To identify the responsibilities referred to this requirement, reference is made to art. 2, paragraph d of Regulation (EC) 1935/2004 as amended

Sheet B3.b Economic operator who produces or imports the good

INDICATION	DESCRIPTION
Requirement 2	Identity and address of the economic operator producing or importing: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished products *tick the relevant item*
Supporting documentation	Documentation proving the identity and address of the economic operator producing or importing raw materials, intermediate/semi-finished products, finished products (e.g. specifications, transport documents, supply contracts, etc.)
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art 6 art.8, paragraph c
Regulation (EC) 1935/2004 as amended	art 16.2
Notes	If the economic operator issuing the DoC is the same as the Economic Operator producing or importing, requirements 1 and 2 may coincide

Sheet B3.c Identity of the asset

INDICATION	DESCRIPTION
Requirement 3	Identity of the asset to which the DoC refers: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished products *tick the relevant item*
Supporting documentation	Documentation for the identification of the asset (e.g. type of material/object, batch numbers, catalogue numbers, code numbers, etc.)
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art 6
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	Traceability documents can also be useful

Sheet B3.d Functional barrier

INDICATION	DESCRIPTION
Requirement 4	Information on the possible functional barrier
Supporting documentation	Not applicable
Present guideline	Not applicable
DM 21/03/1973 as amended	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	This requirement does not apply

Sheet B3.e Compliance with EU regulations/national legislation

INDICATION	DESCRIPTION
Requirement 5	DoC with European regulations and/or national legislation where applicable
Supporting documentation	Supporting documentation: – DoC certifying the use of raw materials in compliance with the DM 21/03/1973 as amended – analysis results and/or calculations on the finished packaging
Present guideline	from B3.1.4.2 to B3.1.4.6
DM 21/03/1973 as amended	art.6 art. 27 art. 27 bis, (where applicable) art. 28
Regulation (EC) 1935/2004 as amended	art. 3 art. 16.2
Notes	-

Sheet B3.f Substances/materials subject to restriction and/or compositional requirements

INDICATION	DESCRIPTION
Requirement 6	Adequate information about the composition and the substances and/or materials used and/or degradation products for which restrictions are in place
Supporting documentation	Supporting documentation: – compliance with composition and purity requirements – assessment of any reaction and degradation products of the substances.
Present guideline	B3.1.4.2 from B3.2.2.1 to B3.2.2.5
DM 21/03/1973 as amended	art. 6 art. 27 art. 27 bis (where applicable) art. 28 annex II section 4
Regulation (EC) 1935/2004 as amended	art.3 art.16.2
Notes	-

Sheet B3.g Restricted substances/materials in foodstuffs

INDICATION	DESCRIPTION
Requirement 7	Adequate information on substances and materials used that are restricted in foodstuffs
Supporting documentation	Not applicable
Present guideline	Not applicable
DM 21/03/1973 as amended	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	This requirement does not apply

Sheet B3.h Directions for use

INDICATION	DESCRIPTION
Requirement 8	Indications on the use of FCMs: ❑ types of food products with which it is intended to come into contact ❑ duration, treatment temperature and storage in contact with food ❑ contact test conditions (simulant, duration, temperature) ❑ contact surface to volume ratio for determining FCMs compliance ❑ restrictions on use *tick the relevant items*
Supporting documentation	Documentation proving compliance checks with the declared uses (e.g. analysis reports, production recipes, etc.)
Present guideline	B3.2.2.2 B3.2.2.3 B3.2.2.5
DM 21/03/1973 as amended	art. 8 b
Regulation (EC) 1935/2004 as amended	art. 15 art 16.2
Notes	Tests on durability, treatment temperature, storage and the ratio between contact surface and volume are normally carried out on the finished FCMs and not on paper and cardboard as they are

Sheet B3.i Date of declaration

INDICATION	DESCRIPTION
Requirement 9	Date of declaration
Supporting documentation	-
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art.6
Regulation (EC) 1935/2004 as amended	art.16.2
Notes	-

B4. FLEXIBLE PACKAGING

B4.1. Characterization of the sector

B4.1.1. Field of application of the guideline

The present guideline on Supporting Documentation (SD) for the Declaration of Compliance (DoC) applies to all companies that produce flexible packaging regardless of the materials they are made of. For the starting raw materials, reference should be made to the guidelines for the specific material (plastic films, paper, aluminium etc.), where available. The flexible packaging chain includes paper, plastic film, regenerated cellulose, and aluminium foil used either individually or in combination, for primary and/or secondary packaging intended for contact with food products.

This definition specifically excludes stretch and heat shrink films used for secondary packaging of palletised products, shopping bags, supermarkets self-service bags, sealable neutral bags and big bags for transporting loose products. Polyvinyl Chloride (PVC) films and other polymers sold for domestic use are also excluded, as is aluminium foil sold directly to the consumers.

The paper or cardboard based polylaminates for packaging liquid products do not fall under the definition of flexible packaging.

B4.1.2. Applicable legislation

European legislation

- Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/CEE and 89/109/CEE as amended.
- Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as amended.
- Regulation (EU) 2017/625 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- Regulation (EU) 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.
- Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food as amended.

Italian legislation

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

- DL.vo 108/1992 - Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- DL.vo 29/2017 - Legislative Decree No. 29/2017 on sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food.
- DM 21/03/1973 - Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, for contact with foodstuffs or substances for personal use as amended.

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[14].

B4.1.3. Relationships between GMP, SD, DoC

The present guideline analyses the content and correlation between the SD and the DoC in relation to Regulation (EC) 2023/2006 as amended, and more generally with respect to the production phases of flexible packaging intended for contact with food.

Figure B4.1 below summarizes, for example, the flow of activities and documents relating to the production of flexible packaging intended to come into contact with food products. For a more in-depth description, however, see the chapter B4.2.

B4.1.4. Flexible packaging manufacturing process

The steps of the production process summarized in the flowchart in Figure B4.1 are briefly described below and then the SD and the points of correspondence between DoC, SD and Good Manufacturing Practice (GMP) standards are analysed in detail.

B4.1.4.1. Introduction

The organization of companies in the flexible packaging sector is an integrated process that includes all phases from the customer's request to the design, the production up to the shipment of products to the end customer. The system operates within the framework of a overall management system of the entire process.

Therefore, not all the evidence relating to the documentation supporting compliance is found in a single folder or file of the production order, but in any case, within the management system there will be a procedure that allows the necessary connections to be made to trace the reference documents to be shown to the competent authorities on request.

This document is therefore organized by describing the process in its phases, and for each phase the SD of product compliance is described.

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

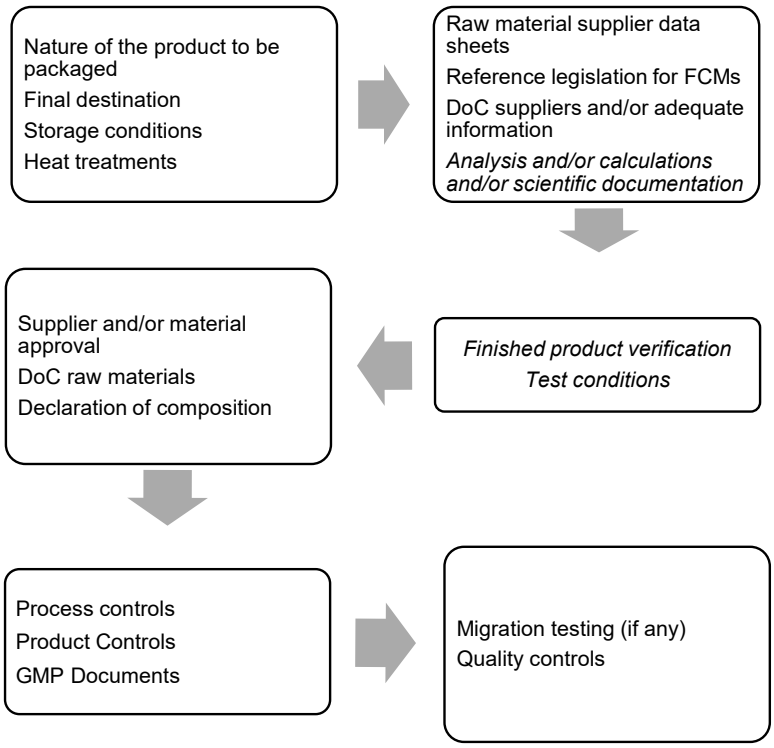

Figure B4.1. FLEXIBLE PACKAGING:
Industrial process flow diagram for correlation with SD for DoC
(non-mandatory items in italics)

B4.1.4.2. Order/customer request

In the flexible packaging sector, generally, each new type of packaging originates from a specific request of a customer who need to package a food product to be placed on the market.

The flexible packaging manufacturer (converter) can pursue two paths to achieve the required result: design a new packaging or adapt an existing product to the customer's needs.

In both cases, it is useful to have the appropriate information available from the design phase in order to verify that the packaging that will be produced complies with the requirements of the reference legislation for materials in contact with food as well as meets the customer's technical requirements (food preservation, shelf life, etc.). See in this regard what is described in the corresponding chapter B4 in the document *Rapporto ISTISAN* 23/7 Rev. (8).

B4.1.4.2.1. Reference documents

In order to properly design flexible packaging in compliance with customer requirements, the following information should be known and available, even if it is not required by law:

- the nature of the product to be packaged, if possible, specifying the product or group of products with reference to the food categories outlined by Regulation (EU) 10/2011 as amended;
- the final destination (e.g., surface/volume ratio, physical state, etc.);
- the shelf life of the product to be packaged;
- the techniques for filling, closing and storing the final package;

- the thermal preservation processes to which the packaging will be subjected together with its contents.

B4.1.4.3. Design

Once the converter has the right information, it is possible to start with the design of the new packaging by selecting the necessary raw materials, the appropriate production technologies and the most suitable process conditions.

During the design phase, all information must be verified to ensure legislative and performance compliance. In the event that the converter develops a product in accordance with a use compliance design, the produced material produced must:

- respond to the performance for the intended end use;
- comply with the current legislation for materials and articles in contact with food (Food Contact Materials, FCMs).

To this end, it must be produced with raw materials that, after verification, guarantee, at all phases of the process, compliance with the intended use of the object and the legislative requirements regarding food contact (*see* B4.2.1.2 in the document *Rapporto ISTISAN* 23/4 Rev.) (8).

It will therefore be necessary to receive from your suppliers the DoC for the starting materials regulated by legislation (e.g. plastic films, paper, aluminium foil) and adequate information (Declaration of Composition) for other raw materials (e.g. inks, adhesives).

Once the packaging manufacturer, having collected the necessary information (DoC and/or composition declarations), they can verify the compliance of their product with the legal requirements.

The legislation in force allows the suitability of the finished product to be ascertained, under the specified conditions of use, through laboratory analysis or theoretical calculations in accordance with Regulation (EU) 10/2011 as amended.

The DoC and adequate supplier information, analysis reports and/or theoretical calculations must be part of the reference documents to be made available to the competent authorities upon request. All these documents become a part of the SD for the *converter*.

For the documentation necessary to demonstrate compliance with Regulation (EC) 2023/2006 as amended, please refer the document *Rapporto ISTISAN* 23/4 Rev. (8), par. B4.2.1.2. The relevant documents must be available to the competent authority.

B4.1.4.4. Process and product controls

During the production of the packaging, the process control parameters must be defined to ensure that the product complies with the legal, technical and quality specifications established for the ongoing project.

The appropriate controls required by the reference legislation must be carried out on the finished product (e.g., overall and/or specific migration tests, limits of dual use additives, etc.). Alternatively, calculations must be made to demonstrate compliance with the intended end use of the product. This information will be included in the SD.

B4.1.4.5. Product approval by the food industry

The food industry that receives a new material from a flexible packaging manufacturer for the first time is required to verify that the product meets the technical and legislative requirements for which it was designed. It would be desirable for the converter to receive an indication from

the customer of the controls carried out during the approval of the new packaging with appropriate indications on all points that may affect the food safety of the packaging.

B4.1.4.6. Purchase raw materials

Once the order has been received from the customer, the first production phase begins, which is the procurement of raw materials. The raw materials acquisition process involves the approval of one or more suppliers able to supply the necessary raw materials for the production of the material under development and to meet the required technical and quality specifications.

Each specific raw material is identified by a unique technical specification that possible suppliers must always meet. The converter punctually verifies the supplier's ability to meet the technical specification of the raw material and approves the raw material. This process is applied to each raw material and each supplier. The supplier provides the product with technical documentation and/or compliance/composition declarations and/or analysis reports, as required.

The methods for selection and approval of materials and/or suppliers may be different, but in any case, it is necessary to have the necessary documentation within the company demonstrating how the starting materials were chosen. The approval of suppliers and materials is a legislative requirement expressed in art. 5, paragraph 2, of Regulation (EC) 2023/2006 as amended. See in this regard what is described in the document *Rapporto ISTISAN* 23/4 Rev. (8) (chapters A3.2 e B4.2.1.2)

It is good practice for the starting materials to come from qualified suppliers. Qualification means a pre-established, organized and documented process that may also include supply specifications. In addition, it is advisable to check, also through periodic inspections, the quality assurance system of suppliers of starting materials or subcontractors to ensure that it complies with the requirements expressed by Regulation (EC) 2023/2006 as amended, where applicable.

As an alternative to supplier approval, it is also possible to approve a specific suitable material to ensure compliance with the flexible packaging that will be produced.

The DoC of the suppliers of those materials regulated by law will be part of the corporate SD while for other non-regulated raw materials (inks, adhesives, paints, etc.), the *converter* must have, as SD, adequate information given by the suppliers.

B4.1.4.7. Production

For each process/product, the conditions that allow for adequate control of the production process must be identified through the definition of a series of critical parameters (e.g. process temperature, pressures, etc.) and through these a product control must be performed. Adequate quality controls are then carried out on the product to verify its compliance to the reference specification.

Manufacturers of flexible packaging intended for contact with food are required to comply with Regulation (EC) 2023/2006 as amended and, therefore, they have implemented a management system that guarantees in particular the control of activities, processes and traceability. SD can concern a single product or a group of products with similar compositional characteristics and coming from the same process, even employing worst case techniques.

The production phase must be carefully analysed and monitored, as this is the stage in which the raw materials are treated and modified to form a semi-finished product that will then result in the finished product. Therefore, to operate under a GMP system, it is necessary to establish in advance the control and verification points that must be monitored to ensure the compliance of the product intended to come into contact with food. See in this regard the document *Rapporto ISTISAN* 23/7 Rev. (8) to the chapter B4.

At the time of production (printing, lamination, cutting, etc.), operators must have adequate information that provides all the information the production of the required material in compliance with the specifications.

In particular, for the different phases of production, the following information must be available:

- *Printing and lamination*
  - raw materials to be used with their technical specifications (e.g., type, thickness, band, etc.);
  - inks and adhesives to be used (e.g., series, viscosity, any additives, etc.);
  - machine condition.
- *Cutting and/or packaging*
  - the operator must receive the necessary information so that at the end of the corresponding process phase a product that complies with the specifications is obtained;
  - an appropriate SD, certifying the information given in production, must be available to the competent authorities who request it.

B4.1.4.7.1. Process and production controls

The production process must be appropriately approved and monitored. Based on the evidence from the application of Regulation (EC) 2023/2006 as amended, to the production process (*see* chapters A3 and B4.2 in the document *Rapporto ISTISAN* 23/4 Rev.), the manufacturer will identify the critical points of the process and any necessary controls to be carried out.

The documentation relating to the controls will be part of the SD of the flexible packaging manufacturers and will be available within the company, for the reference authorities.

B4.1.4.8. Final approval and storage

The appropriate controls required by the reference legislation must be carried out on the finished product (e.g. migration tests, dual use additives, etc.) to demonstrate compliance with the intended end use. Only after all the controls, including quality checks, will the material be made available for shipment. The reference documentation must be present within the company for the competent authorities.

It should be specified that it is not prescribed for all orders to be verified by performing all the tests, as it is possible consider periodic testing as sufficient, provided that for different production batches of the same specification, produced at different times, the same process conditions are maintained and the same raw materials are used, and that in the meantime the legislative requirements have not changed.

Note. All controls performed on the finished product can be carried out internally or entrusted to an external laboratory (e.g. migration tests). Alternatively, theoretical calculations that can attest to the conformity of the material are allowed, where possible. However, for the latter as well, appropriate documentation must be available and must be part of the supporting documentation to be shown upon request by the competent authorities.
In the case of test reports carried out in external laboratories, in accordance with the law, the document must be presented to the authorities in SD, while any provision to customers will be the subject to a commercial agreement.
When the material is stored, it must be uniquely identified in order to correlate it with all the control documentation relating to the production order. All technical documents (test reports, calculations, etc.) must be easily available in case of request by the competent authorities, even if they will not necessarily be archived all together.

B4.1.4.8.1. Packaging conditions

The packaging conditions can be established in agreement with the customer or can be chosen according to internal procedures. In any case, particular attention must be paid to ensure that the packaging guarantees the safety of the finished product by avoiding risks that could deteriorate the material (e.g. external contamination) and make it no longer suitable for contact with food. With regard to compliance with Regulation (EC) 2023/2006 and subsequent amendments and additions, please refer to the document *Rapporto ISTISAN* 23/7 Rev. (8), chapters B4.2.2.3 and B4.2.2.4.

B4.1.4.9. Shipment

B4.1.4.9.1. Transport documents

Once the material has been recognized as compliant with the FCMs requirements, it will be prepared for shipment.

Transport documents are not necessarily part of the documentation required by the legislation on FMCs, but they are part of other legislative obligations. However, transport documents may also include relevant and/or useful documentation (the material, the recipient customer, quantities, test reports or declarations of compliance, etc.) if not otherwise send to the customer. Therefore, if a correlation with compliance documents is available in the transport documentation, this could facilitate traceability paths.

All these documents must be filed and kept within the company according to the provisions of the relevant legislation. All operations must also be carried out in compliance with Regulation (EC) 1935/2004 as amended, which requires the traceability of the material in all the different phases within the company.

B4.1.4.9.2. Declaration of compliance

When a product is shipped to the customer, it must necessarily be accompanied either by a DoC certifying compliance with all the legislative requirements provided for (*see* art. 6 of the DM 21/03/1973 as amended and art. 16 Regulation (EC) 1935/2004 as amended), or in any case the product must be related to a DoC (e.g. by means of supply specifications or contract). The contents of the document are defined in the relevant laws (e.g. Annex IV of Regulation (EU) 10/2011 and subsequent amendments and additions in the case of plastics). Subject to compliance with applicable provisions, agreed membership models may be used (*see* Part C of this guideline).

Please note that the DoC does not necessarily have to be accompanied by test reports or other SD, but this documentation must still be present within the company and provide to the authorities upon request.

B4.2. Supporting documentation

B4.2.1. Introduction

The purpose of this section is to clarify the requirements in relation to SD required by Regulation (EC) 1935/2004 as amended concerning materials and articles intended to come into contact with foodstuffs and in particular by Regulation (EU) 10/2011 as amended concerning plastic materials and articles intended to come into contact with foodstuffs.

Specific documentation elements applicable to the operator’s position in the supply chain are identified.

The documents that make up the SD should be reviewed periodically whenever there are changes in materials and production processes, regulatory updates, changes in suppliers or adaptations to technical progress.

The documents that make up the SD can also be made available and consulted through the use of databases or computer systems.

SD may concern a family of products: for example, the records of the checks carried out on a particular finished product are also recognized for products of the same type that compared to the test material have less critical morphological characteristics (e.g. different thicknesses) and use (e.g. time, temperature).

B4.2.2. SD for flexible packaging manufacturers

Manufacturers of flexible packaging intended for contact with food are required to comply with Regulation (EC) 2023/2006 as amended therefore, they must implement a quality management system that guarantees control over activities, processes and traceability.

SD can concern a single product or a group of products with similar compositional characteristics and coming from the same process, even employing worst case techniques.

Below is an indicative list of useful documents, underlining that not all of them must necessarily always be present in the collection of SD, but only the documents that, on a case-by-case basis, are deemed necessary to support and justify the evaluations that allow the DoC to be issued.

B4.2.2.1. Composition of flexible packaging

The SD must contain at least:

- product description (e.g., PET/ink-adhesive/Al/adhesive/PE);
- trade name of the product(s) (if any);
- product specification (document containing the characteristics of the product in relation to the expected quality);
- technical information on the employed raw materials used;
- if used, any information on substances used behind a barrier (e.g. for multilayer plastic materials and articles: non-Carcinogenic, Mutagenic or toxic for Reproduction (CMR)[15] and not in nanoform, limit of detection not >0.01 mg/kg).

B4.2.2.2. Collection of relevant information from Suppliers

B4.2.2.2.1. For regulated materials (plastic films, paper, aluminium)

The SD should contain at least the following information:

- identification of the raw material/material;
- DoC in accordance with the provisions of the relevant legislation;
- any adequate information on potential non-listed substances (e.g., for plastic films, a risk assessment must be carried out for non-listed substances and for NIAS (Non-Intentionally Added Substances), according to art. 19 of Regulation (EU) 10/2011 as amended;
- purity requirements: information that may be necessary to ensure compliance with specific provisions of the applicable legislation, with particular reference to substances also subject to restrictions in foodstuffs.

[15] *see* Regulation (EU) 10/2011 as amended art. 13 and art.14

B4.2.2.2.2. For non-regulated materials (inks, adhesives, paints, etc.)

The SD should contain at least the following information:

- product identification;
- adequate information (e.g., declaration of composition) for substances subject to migration limits, dual use, and restrictions of use);
- any adequate information on possible NIAS present or that may be formed during the production process;
- information on the technical quality of the product.

B4.2.2.3. Composition assessment documentation

The converter must carry out an assessment of the composition of the material in order to support and formalise the decision to consider the product covered by SD suitable for contact with food on the basis of:

- information on the assessments carried out to verify the compliance of the composition of plastics and any restrictions (QM/QMA[16], etc.).
- risk assessment carried out for non-listed substances and NIAS, according to art. 19 of Regulation (EU) 10/2011 as amended used in plastics.

B4.2.2.4. Documentation on the evaluation of substances subject to SML

Specific Migration testing (SML) and Overall Migration testing are not always mandatory for flexible packaging manufacturers; in any case, the manufacturer of flexible packaging may carry out guidance checks to ensure that substances with SML do not exceed the limits set under certain conditions, if indicated in the DoC.

The SD will then contain any information on the assessments carried out for the verification of the migration of substances with SML, obtained by means of tests, mathematical models, calculations or appropriate scientific argumentation (in accordance with the screening methods for the verification of the suitability of plastics for the production of materials and articles intended for contact with food), e.g. to assess compliance under foreseeable conditions of use.

B4.2.2.5. Documentation on particular uses mentioned in the DoC

In the case of products with particular intended uses (e.g., for prolonged use at room temperature or use behind a barrier), the SD will contain information that has been used to assess and support suitability for such uses.

B4.3. Points of correspondence between DoC and SD

SD contains some specific elements that are mentioned directly by the DoC.

The DoC confirms to the next actor in the supply chain that the compliance work has been carried out, indicating if any, what further activities need to be carried out by the user.

As regards the SD prepared by flexible packaging manufacturers, the reference documents for the DoC are at least:

[16] From Regulation (EU) 10/2001: QM/QMA = residual content for food contact surface area (QMA)

- product description;
- migration tests in accordance with the provisions of Regulation (EU) 10/2011 as amended (Overall Migration and/or SML). Alternatively, mathematical calculations and/or screening tests may be valid;
- possible risk assessment of unlisted substances and NIAS, according to art. 19 of Regulation (EU) 10/2011 as amended.
- if necessary, information that has been used to assess and support suitability for particular uses mentioned in the DoC.

Note. For multilayer flexible packaging made of plastic material only, Regulation (EU) 10/2011 as amended applies in full, while for multilayer multi-material flexible packaging the regulation is applicable only to plastic layers and only as regards the composition, which must comply with Regulation (EU) 10/2011 as amended. In both cases, however, the requirements of Regulation (EC) 1935/2004 as amended (Articles 3 and 16) remain valid, as well as the national provisions of DM 21/03/1973 as amended.

B4.4. SD topics not necessarily covered by GMP documentation

Some topics supporting the compliance of flexible food contact packaging may not necessarily be addressed within the GMP system of a given business organization.

For example, the company may have produced a guideline documentation during the development phase to support the evaluation of products, but may consider it unnecessary for this documentation to be produced periodically and managed in the GMP system.

Below is a non-exhaustive list of these documents:

- results of overall migration tests and/or SML (if not already managed in the company's GMP system);
- application of mathematical models for migration screening;
- evaluations concerning any NIAS;
- evaluation of the use of any functional barrier;
- technical documentation on applications and recommended conditions of use.

This does not imply the lack of such documentation or the absence of compliance work, but only that certain activities are not performed systematically. Nevertheless, the documentation must be traceable and traceable to the asset to which it refers.

Annex B4

Sheets for supporting documentation of plastic food contact materials: flexible packaging

Regulatory references

Regulation (EC) 1935/2004 as amended
Regulation (EC) 2023/2006 as amended (where applicable)
Regulation (EU) 10/2011 as amended
Regulation 1895/2005/EC
Regulation (EC) 625/2017
DM 21/03/1973 as amended
DPR 777/1982
DL.vo 108/1992
DL.vo 29/2017
Note of the Ministry of Health no. 32249, 11/10/2011
Note of the Ministry of Health no. 15844, 12/5/2011
Guideline "Union Guidance on Regulation (EU) n. 10/2011 on plastic materials and articles intended to coming into contact with food as regards information in the supply chain" below indicated as DG Sanco 2013.

To harmonize the sheets of all the supply chains, the nine points contained in Annex IV of Regulation (EU) 10/2011 as amended have been used, although this Regulation is not directly applicable to the supply chain of flexible packaging.

Sheet B4.a Economic operator issuing the compliance declaration

INDICATION	DESCRIPTION
Requirement 1	Identity and address of the economic operator issuing the DoC
Supporting documentation	Company and/or functional organization chart and/or delegation and/or management procedures and/or documentation deriving from the company policy establishing responsibilities
Present guideline	A1.3.2.2
DG Sanco 2013	4.3.1 (only for multi-material plywood) 4.4
Regulation (EU) 10/2011 as amended	art. 15.2 Annex IV.1
DM 21/03/1973 as amended	art.6 art. 8, paragraph c
Regulation (EC) 1935/2004 as amended	art.2.2, paragraph d art.16
Notes	If the economic operator issuing the DoC is the same economic operator that produces or imports, requirements 1 and 2 may coincide. To identify the responsibilities referred to this requirement, reference is made to art. 2, paragraph d of Regulation (EC) 1935/2004 as amended

Sheet B4.b Economic operator who produces or imports the good

INDICATION	DESCRIPTION
Requirement 2	Identity and address of the economic operator producing or importing: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished product *tick the relevant item*
Supporting documentation	Documentation proving the identity and address of the economic operator producing or importing raw materials/substances, intermediate/semi-finished products or finished products (e.g. specifications, transport documents, supply contracts, etc.)
Present guideline	A1.3.2.2
DG Sanco 2013	4.3.1 4.4
Regulation (EU) 10/2011 as amended	art. 15.2, Annex IV.1
DM 21/03/1973 as amended	art. 6 art. 8, paragraph c
Regulation (EC) 1935/2004 as amended	art. 2.2, paragraph d art. 16
Notes	If the economic operator issuing the DoC is the same as the economic operator producing or importing, requirements 1 and 2 may coincide. To identify the responsibilities referred to in this requirement, reference is made to art. 2, paragraph d of Regulation (EC) 1935/2004 as amended

Sheet B4.c Identity of the asset

INDICATION	DESCRIPTION
Requirement 3	Identity of the asset to which the DdC refers: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ Finished Products *tick the relevant item*
Supporting documentation	Documentation for the identification of the asset (e.g. type of material/object, batch number, catalogue number, code number, etc.)
Present guideline	A1.3.2.2
DG Sanco 2013	4.3.1 4.4
Regulation (EU) 10/2011 as amended	art. 15, Annex IV
DM 21/03/1973 as amended	art.6
Regulation (EC) 1935/2004 as amended	art.16
Notes	Descriptions such as PP/ink/Adhesive/PE, PET/ink/Adhesive/AL/Adhesive/PE, Ink/AL/Adhesive/PE are used. Traceability documents, etc., can also be useful.

Sheet B4.d Functional barrier

INDICATION	DESCRIPTION
Requirement 4	Information on any functional barriers ❑ semi-finished products ❑ finished products *tick the relevant item*
Supporting documentation	*Semi finished products* – documentation on investigations (documentary and/or analytical) to verify that the substances present are not CMR and/or in nanoform *Finished products* with a functional barrier – evidence on the absence of substances classified as CMR or nanoform – analytical tests or other scientific evidence demonstrating that under the intended conditions of use, the migration of unauthorised substances is not detectable with a detection limit of 0,01 mg/kg
Present guideline	B4.2.1.3 B4.2.1.7
DG Sanco 2013	4.3.1.9 4.4.9
Regulation (EU) 10/2011 as amended	art. 13 and 14 Annex IV.9
DM 21/03/1973 as amended	art.5
Regulation (EC) 1935/2004 as amended	art.3
Notes	See note in paragraph B4.3 in this guideline

Sheet B4.e Compliance with Regulations

INDICATION	DESCRIPTION
Requirement 5	Declaration of compliance with EU Regulations and/or national legislation where applicable
Supporting documentation	Relevant to Regulation (EU) 10/2011 as amended, for: *Semi finished products* Supporting documentation: – use of substances listed in Annexes I and II – risk assessment according to the criteria set out in art. 19 for substances used in the production process, and not listed in Annexes I and II – risk assessment according to the criteria set out in art. 19 for substances not intentionally added that may be formed during production. *Finished products* Supporting documentation: – use of substances listed in Annexes I and II – risk assessment according to the criteria set out in art. 19 for substances used in the production process, and not listed in Annexes I and II – risk assessment according to the criteria set out in art. 19 for substances not intentionally added that may be formed during production – compliance with the overall migration limit. Further information can be provided with reference to the test conditions adopted or to the identification number of these conditions in Table 3 – Annex V
Present guideline	from B 4.2.1.3 to B 4.2.1.7
DG Sanco 2013	4.3.1.5 4.4.5
Regulation (EU) 10/2011 as amended	art. 15 art. 19 Annex IV.5
DM 21/03/1973 as amended	art. 6
Regulation (EC) 1935/2004 as amended	art. 3 art. 16
Notes	See note in paragraph B4.3 in this guideline

Sheet B4.f Restricted substances/materials

INDICATION	DESCRIPTION
Requirement 6	Adequate information on the substances and/or materials used and/or degradation products for which restrictions are in place
Supporting documentation	Supporting documentation: – identification of restricted substances in accordance with Regulation (EU) 10/2011 as amended (Unique Substance Identification Number, EEC Reference number for packaging materials, CAS-Chemical Abstracts Service number, chemical name) or national legislation or confirmation that no restricted substances are used. – information available on compliance with the restrictions applicable to the substances used (SML, SML T, QM) accompanied by the test conditions, the simulants used. The documents may be analysis reports and/or mathematical calculations and/or screening analyses and/or other appropriate scientific documentation
Present guideline	from B4.2.1.4 to B4.2.1.6
DG Sanco 2013	4.3.1 4.4
Regulation (EU) 10/2011 as amended	art. 9 art. 15 Annex IV
DM 21/03/1973 as amended	art.9.2
Regulation (EC) 1935/2004 as amended	art.16
Notes	*see* note to paragraph B4.3 in this guideline

Sheet B4.g Restricted substances/materials in foodstuffs

INDICATION	DESCRIPTION
Requirement 7	Adequate information on restricted substances and materials used in foodstuffs
Supporting documentation	Supporting documentation: – identification of substances used and also subject to restrictions in food products as reported in Regulation (EC) 1333/2008 and 1334/2008 and adequate information in accordance with the legislative requirement
Present guideline	B4.2.1.4
DG Sanco 2013	4.3.1.7 4.4.7
Regulation (EU) 10/2011 as amended	art. 11.3 art. 15 Annex IV.7
DM 21/03/1973 as amended	-
Regulation (EC) 1935/2004 as amended	art.16
Notes	*see* Note of the Ministry of Health DGSAN.VI/ 15844-P-12/05/2011

Sheet B4.h Directions for use

INDICATION	DESCRIPTION
Requirement 8	Indications for the use of FCMs: ❑ types of food products with which it is intended to come into contact ❑ duration, treatment temperature and storage in contact with food ❑ contact test conditions (simulant, duration, temperature) ❑ contact surface to volume ratio for determining FCMs compliance ❑ other restrictions of use *tick the relevant items*
Supporting documentation	Documentation proving compliance checks with the declared uses: – DoC of raw materials and/or – adequate information for inks or adhesives and/or – screening analysis reports and/or – migration tests and/or mathematical calculations and/or other scientific evidence
Present guideline	B4.2.1.7
DG Sanco 2013	4.3.1 4.4
Regulation (EU) 10/2011 as amended	art. 15 Annex IV
DM 21/03/1973 as amended	-
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	*see* Note of the Ministry of Health DGSAN.VI/ 15844-P-12/05/2011

Sheet B4.i Date of declaration

INDICATION	DESCRIPTION
Requirement 9	Date of declaration
Supporting documentation	-
Present guideline	A1.3.2.2
DG Sanco 2013	4.3.1 4.4
Regulation (EU) 10/2011 as amended	art. 15 Annex IV.4
DM 21/03/1973 as amended	art. 6
Regulation (EC) 1935/2004 as amended	art. 16
Notes	The declaration remains valid as long as there are no substantial changes in the composition and/or production process of the material or such as to involve the modification of its essential requirements for compliance purposes, or as long as the legislative references cited therein do not undergo changes or updates such as to require the issuance of a new DoC

B5. WOOD OR WOOD FIBRE

B5.1. Characterization of the sector

B5.1.1. Field of application of the guideline

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

B5.1.2. Applicable legislation

European legislation

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

Italian legislation

- DPR 777/1982 - Decree of the President of the Republic No. 777/1982 on implementation of the Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs as amended.
- DL.vo 108/1992 - Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- DL.vo 29/2017 - Legislative Decree No. 29/2017 on sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food.

B5.1.3. Relationships between GMP, SD, DoC

Present guideline analyses the content and correlation between the SD and the DoC in relation to the GMP (Good Manufacturing Practice) system in relation to the production phases of

packaging of wood, and/or wood fibre, and/or plywood and cutting boards, logs and stumps of wood intended for contact with food.

Figure B5.1 schematically represents, for example purposes, the correlation flows between activities and documents relating to the various phases of product development and implementation. The diagram illustrates for example purposes the flow of activities and documents related to the production of wooden packaging.

For a more in-depth description, however, see the chapter B5.2.

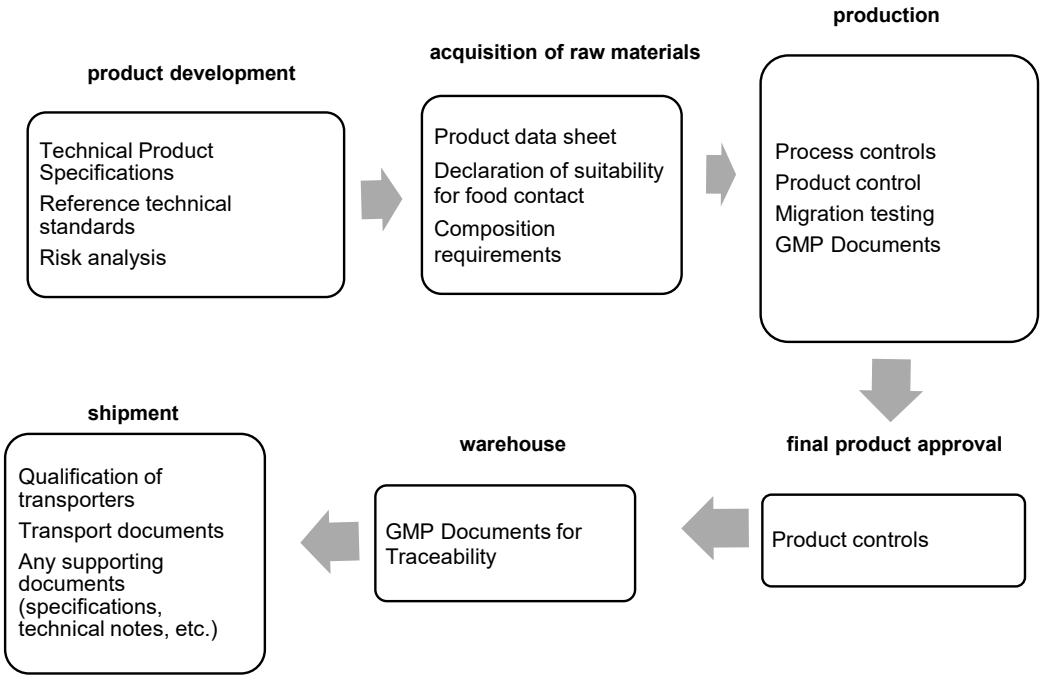

Figure B5.1. WOODEN PACKAGING:
production phases and correlation with SD for DoC

B5.1.4. Industrial processes

The flow diagrams and detailed descriptions of the production phases of the products are described in the points B5.1.3.1. e B5.1.3.2. in the document *Rapporto ISTISAN* 23/4 Rev. (8).

Producers of wood packaging intended for contact with food are required to comply with Regulation (EC) 2023/2006 and subsequent amendments and additions and must therefore implement a quality management system such as to ensure, in particular, process control and traceability.

For further information on wooden packaging in contact with food, please refer to the document Rapporto *ISTISAN* 15/38 (16).

B5.1.4.1. Product development and raw materials procurement

Based on the needs deriving from the end use of the product to be made, the technical specification of the product is defined, and the production cycle is developed taking into account the regulations in force for materials and articles in contact with foodstuffs (Food Contact Materials, FCMs).

All the parameters necessary for the control of production processes and product quality control are then defined.

The documentation provided by the manufacturers of raw materials (e.g. technical data sheets, composition declarations, compliance declarations, etc.) is requested and evaluated in relation to the specifications of use defined by the end customer, where available, and/or by the foreseeable directions for use.

It is good practice to provide for a supplier qualification process, as provided in the document *Rapporto ISTISAN* 23/4 Rev. (8) in par. B5.2.1.2.

B5.1.4.2. Production

For each process/product, the conditions that allow adequate control of the production process must be identified through the definition of a series of critical parameters (e.g. presence of moulds, control of residues from preservative treatments, etc.) by means of which product control is guaranteed. Adequate quality controls are carried out on the product, which verify its adherence to the reference specification.

Traceability must be guaranteed for the entire production process.

B5.1.4.3. Final product approval

The product is approved on the basis of verification of its compliance with the specification. Depending on the results of the tests envisaged by the specification, the final evaluation of the product is carried out.

B5.1.4.4. Storage

Warehouse activities are also managed to maintain product traceability.
Consequently, the appropriate types of packaging of the material and the related identification markings must also be defined. It must always be possible to trace the quality status of the products in stock through the appropriate codes and operating procedures/instructions.

B5.1.4.5. Shipment

The activities related to shipment provide for the approval of the companies that transport the product from the manufacturer to the end user. It is also important to work in synergy with carriers, so that they are able to meet the quality requirements set by companies in order to maintain compliance of the transported product with the reference standards.

Transport documents are not necessarily part of the documentation required by the legislation on FMCs, but they are part of other legislative obligations. However, transport documents may also include relevant and/or useful documentation (e.g. DoC, test reports, etc.) if not otherwise shipped to the customer. Therefore, if a correlation with compliance documents is available in the transport documentation, this could facilitate traceability paths.

B5.2. Supporting documentation

B5.2.1. Introduction

It is good practice, as well as a requirement that can be inferred from Regulation (EC) 2023/2006 as amended that, in the face of a placing on the market of wooden packaging intended

for contact with food, declared compliant with applicable laws, there is an in-house SD including both evidence of the correct implementation and implementation of the GMP system (documentation from suppliers, process checks, etc.) and the results of any tests, analyses and other scientific evidence or arguments. In fact, this allows the producer to demonstrate full compliance with art. 3 of Regulation (EC) 1935/2004 as amended.

The following paragraphs identify the elements of SD that apply to the operator's position in the supply chain.

The documents that make up the SD should be reviewed periodically to reflect potential changes in materials and production processes, regulatory updates, supplier changes, or adaptations to technical progress.

The documents that make up the SD can also be made available and consulted through the use of databases or computer systems.

It is not possible to establish in advance which and how many tests and related SDs should be, since the processes and treatments may vary over time and from company to company, but indicatively at least what is reported in the following paragraphs should be present/considered.

SD may concern a family of products: for example, the records of the checks carried out on a particular finished product are also recognized for products of the same type that have, compared to those of the material under test, less critical morphological characteristics (e.g. different thicknesses) and use (e.g. time, temperature).

B5.2.2. SD for producers of fruit and vegetable packaging made of wood, and/or wood fibre, and/or plywood

In the production of wooden packaging, the relevant phases of the production process, for the purposes of food compliance, are the acceptance phase of raw materials and the phase of permanence in the warehouse of the finished product, with the aim of verifying, for example, the absence of mould and periodically checking the absence of residues from preservative treatments. The following paragraphs describe the SD relating to the aforementioned phases.

B5.2.2.1. Raw materials

The SD should contain at least the following information:

- Product data sheets (document containing the characteristics of the product in relation to the expected quality and specific use).
- Appropriate information on restricted substances in foodstuffs and, where appropriate, compositional criteria in accordance with existing directives.
- DoC of the materials/objects received and used for the production of fruit and vegetable packaging (e.g., bottoms, wire, cantons, etc.). In the absence of the DoC, the manufacturer assumes responsibility for selecting materials/objects that guarantee the suitability of the box for contact with food.
- Analysis of Pentachlorophenol (PCP) level. This parameter could be considered both as an internal control, to qualify suppliers and for sample checks on supplies. In such a case, the "absence" of PCP can reasonably be guaranteed if the analytical method applied for the determination of PCP (and its corresponding salts and esters) demonstrates a limit of detection of 0.02 mg/kg.
- Absence of creosote, creosote oils, naphthalene and anthracene oils, tar acids and oils and in any case of the substances or groups of substances referred to in point 31 of Regulation

(EC) 1907/2006 as amended. Even this parameter, which must in any case be respected by law, could be considered both to qualify suppliers and for sample checks on supplies. A DoC of the supply will be part of the Supporting documentation.

- Analysis of the metal content. This parameter, which is also required by environmental laws for some metals, could also be adopted both as an internal control, to qualify suppliers, and for sample checks on supplies.
- Glue. Depending on the position in the supply chain, the following will be available in the support SD:
  - panel manufacturer or importer: indication of the type of glue used, evidence on formaldehyde migration, if not delegated to the next step;
  - producer of wood packaging: DoC regarding the migration of formaldehyde, issued by the manufacturer or importer of panels, or indication of the type of glue used; evidence on formaldehyde migration, if not carried out in the previous step. It should be noted that the control of compliance with this parameter does not necessarily have to be carried out for each batch, but, once the specifications on the starting materials have been established and the production process has been validated for compliance with formaldehyde migration levels, compliance can be guaranteed by maintaining the process parameters within the GMP system. In this case, adequate documentation must be prepared in this regard.[17]
- Inks. Since the inks are not intended to come into contact with the food, adequate documentation of the GMP system will be prepared to demonstrate how this parameter is controlled. Annex I of Regulation (EC) 2023/2006 as amended and supplemented will be taken into account for the preparation of the documentation of the GMP system.
- Elements to support the traceability/selection of starting materials:
  - list of qualified suppliers or list of approved supplies;
  - supplier qualification criteria or supply approval criteria. This documentation should already be part of the GMP system documentation required by Regulation (EC) 2023/2006 as amended.

B5.2.2.2. Production cycle/finished product

The SD should contain at least the following information:

- traceability of fruit and vegetable packaging;
- documentation relating to the product development phase;
- specifications of finished products (document containing the characteristics of the product in relation to the expected quality);
- information to support the risk assessment;
- analysis of Pentachlorophenol (PCP) levels (if not already available);
- absence of creosote, creosote oils (if not already available);
- analysis of the metal content (if not already available);

[17] From a regulatory point of view, there is currently no limit for the migration of formaldehyde from wooden objects, however a useful reference may be the SML of 15 mg/kg food, established for the migration of formaldehyde from plastics (Regulation (EU) 10/2011 as amended). In any case, in the conformity assessments, it must be taken into account that fruit and vegetables are made up of solid foods, and therefore the simulation with liquids, even if analytically more practicable, will be more severe than the real situation.

- use of other substances or treatments for the wooden box or its constituent parts, falls under the responsibility of the manufacturer. Such use or treatment must therefore be governed by Regulation (EC) 2023/2006 as amended and supplemented and the finished product must meet the general requirements of Article 3 of Regulation (EC) 1935/2004 as amended. In this case, the manufacturer must produce and maintain adequate documentation to support the compliance of the wooden box or packaging;
- evidence on formaldehyde migration, if not carried out in the previous step by the manufacturer or importer of panels and/or plywood.

B5.2.3. SD for manufacturers of cutting boards, stumps and wood logs

In the production of cutting boards, stumps and wooden blocks, the relevant phases of the production process, for the purposes of food compliance, are the acceptance phase of raw materials and the phase of permanence in the warehouse of the finished product, with the aim of verifying, for example, the absence of mould, periodically checking the absence of residues from preservative treatments. The SD relating to the aforementioned phases is described in the following paragraphs.

B5.2.3.1. Raw materials

The SD should contain at least the following information:

- Product data sheets (document containing the characteristics of the product in relation to the expected quality and specific use).
- Appropriate information on restricted substances in foodstuffs and, where appropriate, compositional criteria in accordance with existing directives.
- DoC of the materials/objects received and used for the production of cutting boards, stumps and stumps (e.g., pre-assembled, oils, glues, etc.). In the absence of the DC, the manufacturer assumes responsibility for selecting materials/objects that guarantee the suitability of the box for contact with food.
- Analysis of Pentachlorophenol (PCP) levels. This parameter could be considered both as an internal control, to qualify suppliers and for sample checks on supplies. In such a case, the "absence" of PCP can reasonably be guaranteed if the analytical method applied for the determination of PCP (and its corresponding salts and esters) demonstrates a limit of detection of 0.02 mg/kg.
- Absence of creosote, creosote oils, naphthalene and anthracene oils, tar acids and oils and in any case of the substances or groups of substances referred to in point 31 of EC Regulation 1907/2006 as amended. Even this parameter, which must in any case be respected by law, could be considered both to qualify suppliers and for sample checks on supplies. A DoC of the supply will constitute SD.
- Analysis of the metal content. This parameter, moreover for some metals, also required by environmental laws, could also be adopted both as an internal control, to qualify suppliers, and for sample checks on supplies.
- Glue. Depending on the position in the supply chain, the SD will provide:
  - manufacturer or importer of pre-assemblies: indication of the type of glue used, evidence on formaldehyde migration, if not delegated to the next step;

  - manufacturer of cutting boards, stumps and blocks: DoC relating to the migration of formaldehyde issued by the manufacturer or importer of pre-assemblies or indication of the type of glue used; evidence on the migration of formaldehyde, if not carried out in the previous step [18].
- Elements to support the traceability/selection of starting materials:
  - list of qualified suppliers or list of approved supplies;
  - supplier qualification criteria or supply approval criteria. This documentation should already be part of the documentation on Good Manufacturing Practices (GMP) required by Regulation (EC) 2023/2006 as amended.

B5.2.3.2. Production cycle/finished product

The SD should contain the following information:

- traceability of cutting boards, stumps and stumps;
- documentation relating to the product development phase;
- specifications of finished products (document containing the characteristics of the product in relation to the expected quality);
- Information to support the risk assessment
- analysis of Pentachlorophenol (PCP) levels;
- absence of creosote, creosote oils;
- analysis of the metal content;
- use of other substances or treatments on cutting boards, stumps and stumps or their constituent parts falls under the responsibility of the manufacturer. Such use or treatment must therefore be governed by Regulation (EC) 2023/2006 as amended, and the finished product must meet the general requirements of Article 3 of Regulation (EC) 1935/2004 as amended. In this case, the manufacturer must produce and maintain adequate documentation to support the compliance of cutting boards, stumps and stumps
- evidence on formaldehyde migration, if not carried out in the previous step by the manufacturer or importer of pre-assemblies.

B5.3. Points of correspondence between DoC and SD

SD contains some specific elements that are mentioned directly by the DoC.

The DoC confirms to the next actor in the supply chain that the compliance work has been carried out, indicating if any, what further activities need to be carried out by the user.

As regards the SD prepared by the producers of wood packaging, the reference documents for the DoC are at least:

- product description;
- possibly information that has been used to assess and support suitability for particular uses mentioned in the DoC.

[18] From a regulatory point of view, there is currently no limit for the migration of formaldehyde from wooden objects, however a useful reference may be the LMS of 15 mg/kg food established for the migration of formaldehyde from plastics (Regulation (EU) 10/2011 and subsequent amendments) (*see also Rapporto ISTISAN* 23/4 Rev.).

B5.4 SD topics not necessarily covered by GMP documentation

Some topics supporting compliance of wood food contact packaging may not necessarily be addressed within the GMP system of a given business organization.

For example, the company may have produced during the development phase an indicative documentation useful for the evaluation of products, but considers it unnecessary for this documentation to be produced periodically and managed in the GMP system (e.g. use of glues, particular substances, etc.).

All this does not imply the lack of such documentation or the absence of compliance work but only the unsystematic execution of some activities. The documentation will in any case be traceable and traceable to the asset to which it refers.

Annex B5

Sheets for supporting documentation of wood or wood-based food contact materials

Regulatory references

Regulation (EC) 1935/2004 as amended
Regulation (EC) 2023/2006 as amended (where applicable)
Regulation (EC) 625/2017
DPR 777/1982
DL.vo 108/1992
DL.vo 29/2017
Note of the Ministry of Health no. 32249, 11/10/2011

To harmonize the sheets of all the supply chains, the nine points contained in Annex IV of Regulation (EU) 10/2011 as amended have been used, although this Regulation is not directly applicable to the supply chain of wood.

Sheet B5.a Economic operator issuing the compliance declaration

INDICATION	DESCRIPTION
Requirement 1	Identity and address of the economic operator issuing the DoC
Supporting documentation	Company and/or functional organization chart and/or delegation and/or management procedures and/or documentation deriving from the company policy establishing responsibilities
Present guideline	A1.3.2.2
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 16.2 art. 2.2, paragraph d
Notes	If the Economic Operator issuing the DoC is the same as the Economic Operator producing or importing, requirements 1 and 2 may may coincide

Sheet B5.b Economic operator who produces or imports the good

INDICATION	DESCRIPTION
Requirement 2	Identity and address of the economic operator producing or importing: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished product *tick the relevant item*
Supporting documentation	Documentation proving the identity and address of the economic operator producing or importing raw materials/substances, intermediates/semi-finished products or finished products (e.g. specifications, transport documents, supply contracts, etc.)
Present guideline	A1.3.2.2
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 16.2 art. 2.2, paragraph d
Notes	If the Economic Operator issuing the DoC is the same as the Economic Operator producing or importing, requirements 1 and 2 may may coincide

Sheet B5.c Identity of the asset

INDICATION	DESCRIPTION
Requirement 3	Identity: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished product *tick the relevant item*
Supporting documentation	Documentation for the identification of the asset (e.g. type of material/object, batch numbers, catalogue numbers, code numbers, etc.)
Present guideline	A1.3.2.2
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	Traceability documents can also be useful

Sheet B5.d Functional barrier

INDICATION	DESCRIPTION
Requirement 4	Information on the possible functional barrier
Supporting documentation	Not applicable
Present guideline	Not applicable
DL.vo 108/1992	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	This requirement does not apply

Sheet B5.e Compliance with EU regulations/national legislation

INDICATION	DESCRIPTION
Requirement 5	Declaration of compliance with EU Regulations and/or national legislation where applicable
Supporting documentation	Documentation proving the compliance of the materials/objects used (e.g. declarations of manufacturers of semi-finished products/panels/wire, specific checks, etc.)
Present guideline	B5.1.4.3 B5.2.2.1 B5.2.2.2 B5.2.3.1 B5.2.3.2
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 3 art. 16.2
Notes	-

Sheet B5.f Restricted substances/materials

INDICATION	DESCRIPTION
Requirement 6	Adequate information about the substances and/or materials used and/or degradation products for which restrictions are in place
Supporting documentation	Not applicable
Present guideline	Not applicable
DL.vo 108/1992	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	This requirement does not apply

Sheet B5.g Restricted substances/materials in foodstuffs

INDICATION	DESCRIPTION
Requirement 7	Adequate information on substances and materials used that are restricted in foodstuffs
Supporting documentation	Not applicable
Present guideline	B5.2.2.1 B5.2.3.1
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	-

Sheet B5.h Directions for use

INDICATION	DESCRIPTION
Requirement 8	Indications for the use of FCMs: ❑ types of food products with which it is intended to come into contact ❑ duration, treatment temperature and storage in contact with food ❑ contact test conditions (simulant, duration, temperature) ❑ contact surface to volume ratio for determining FCMs compliance ❑ restrictions on use *tick the relevant items*
Supporting documentation	Documentation proving compliance checks with the declared uses (e.g. composition declaration, analysis reports, etc.)
Present guideline	B5.2.2.2 B5.2.3.2
DL.vo 108/1992	-
Regulation (EC) 1935/2004 as amended	art. 15
Notes	-

Sheet B5.i Date of declaration

INDICATION	DESCRIPTION
Requirement 9	Date of declaration
Supporting documentation	-
Present guideline	A1.3.2.2
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	-

B6a. PLASTICS. POLYMER PRODUCTION AND MASTERBATCH

B6a.1. Characterization of the sector

B6a.1.1. Field of application of this guideline

Present guideline on Supporting Documentation (SD) for the Declaration of Compliance (DoC) is applicable to all companies operating in the production chain of polymers and masterbatch for plastic packaging intended for contact with food.

Starting substances for the production of polymers (additives, catalysts, monomers, etc.) are excluded from the scope of application of Regulation (EC) 2023/2006 as amended. In this case, the producer of a starting substance, who must still emit a DoC, should have the corresponding SD obviously commensurate with his role.

The scope of this guideline excludes recycled plastics regulated by Regulation (EU) 2022/1616 concerning materials and articles made of recycled plastic intended to come into contact with food, which repeals Regulation (EC) 282/2008.

B6a.1.2. Applicable legislation

European legislation

- Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/CEE and 89/109/CEE as amended.
- Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as amended.
- Regulation (EU) 2017/625 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- Regulation (EU) 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.
- Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food as amended.
- Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs.
- Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs.

Italian legislation

- DPR 777/1982 - Decree of the President of the Republic No. 777/1982 on implementation of the Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs as amended.
- DL.vo 108/1992 - Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- DL.vo 29/2017 - Legislative Decree No. 29/2017 on sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food.
- DM 21/03/1973 - Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, for contact with foodstuffs or substances for personal use as amended.

B6a.1.3. Relationships between GMP, SD, DoC

Present guideline analyses the content and correlation between SD and DoC in relation to the GMP (Good Manufacturing Practice) system with respect to the production phases of plastics and *masterbatch* intended for contact with food.

Figure B6a below summarizes, by way of example, the flow of activities and documents relating to the production of plastics (in granules or other physical forms) and masterbatch intended for food applications. For a more in-depth description, however, see the chapter B6a.2.

B6a.1.4. Industrial process: production of plastics- *masterbatch*

The steps of the production process summarized in the flowchart in Figure B6a.1 are described below, and then the SD, the points of correspondence between DoC, SD, and GMP standards, as well as the topics of SDs not covered by the GMP system are analysed in detail.

B6a.1.4.1. Market demand/product development

Based on market needs, the company develops/modifies a product/"product portfolio" that meets the technical requirements of the applications. In general, we do not develop specific products for customers, but we tend to develop products dedicated to satisfying the needs expressed by the different applications identified on the market. In this case, a specific technical sheet is prepared that contains the physical-mechanical characteristics of the product.

In the event that applications are intended for contact with food, part of the development activities is focused on verifying the compliance of the product with current laws.

We proceed to request and evaluate the documentation (e.g. technical sheets, declaration of composition or compliance), provided by the producers of raw materials.

Theoretical calculations and/or analyses are also carried out to ascertain suitability for contact with food.

All the parameters necessary for the control of the production processes and the characteristics to be subjected to quality control are then defined.

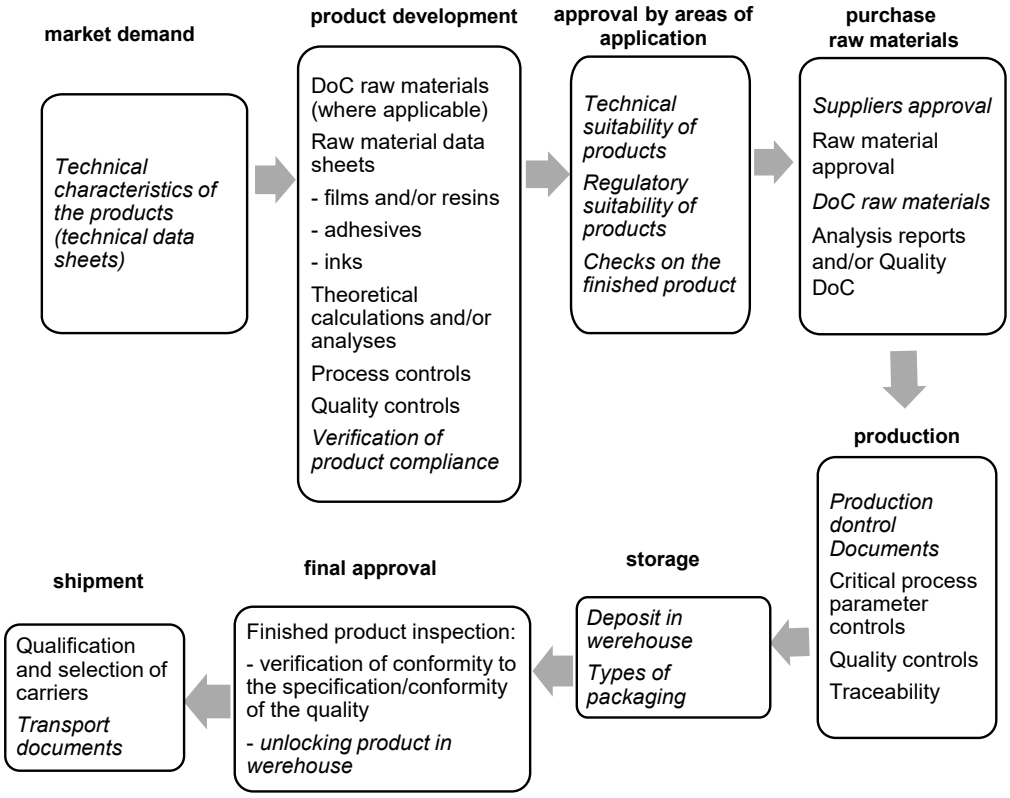

Figure B6a.1. PLASTICS AND MASTERBATCH:
production phases and correlation with the SD for the DoC
(in italics the phases managed by the Quality Management System)

B6a.1.4.2. Approval by areas of application

In relation to the specific sector of use and the final application for which the product has been developed, orientation tests are carried out to verify the satisfaction of the expected technical characteristics, and more generally of the regulatory suitability.

Analyses can be carried out both on the finished product (plastic material) and on products produced from it.

B6a.1.4.3. Purchase raw materials

The raw materials acquisition process (procurement) involves the approval of one or more suppliers able to supply the raw materials necessary for the production of the material under development and to meet the required technical and quality specifications.

A particular raw material is identified by a single technical specification that possible suppliers must always meet. The company shall promptly verify the supplier's ability to satisfy the specific raw material and shall approve the raw material of a specific supplier. This process is applied to every raw material and every supplier. The supplier accompanies its product with technical documentation, compliance/composition declarations, analysis reports.

B6a.1.4.4. Production

For each process/product, the conditions that allow adequate control of the production process must be identified through the definition of a series of critical parameters (e.g. process temperature, pressure, etc.) and through these to carry out a product control. Adequate quality controls are carried out on the product, which verify its adherence to the reference specification. Traceability must be guaranteed for the entire production process.

B6a.1.4.5. Storage

Warehouse activities are managed to maintain product traceability. Consequently, the appropriate types of packaging of the material and the related identification markings must also be defined.

It must always be possible to trace the quality status of the products in stock through the appropriate codes and operating procedures/instructions.

B6a.1.4.6. Final product approval

The product is approved on the basis of verification of its compliance with the specification. Depending on the results of the tests envisaged by the specification, the quality level of the product is defined. After this phase, the product is made available for marketing.

B6a.1.4.7. Shipment

The preparatory activities for shipment provide for the approval of the companies that transport the product from the manufacturer to the end user. Carriers must also be selected on the basis of their ability to meet the quality requirements set by the companies in order to maintain the compliance of the transported product with the reference standards.

Transport documents are not necessarily part of the documentation required by the legislation on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs), but they are part of other legislative obligations. However, transport documents may also include relevant and/or useful documentation (e.g. DoC, test reports, etc.) if not otherwise shipped to the customer. Therefore, if a correlation with compliance documents is available in the transport documentation, this could facilitate traceability paths.

B6a.2. Supporting documentation (for substances/plastics/masterbatch)

B6a.2.1. Introduction

The purpose of this section is to clarify the requirements in relation to SD required by Regulation (EC) 1935/2004 as amended concerning materials and articles intended to come into contact with foodstuffs and in particular by Regulation (EU) 10/2011 as amended concerning plastic materials and articles intended to come into contact with foodstuffs.

Specific documentation elements applicable to the operator’s position in the supply chain are identified.

The documents that make up the SD should be reviewed periodically to reflect potential changes in the composition of formulations, changes in materials and production processes, regulatory updates, changes in suppliers or adaptations to technical progress.

The documents that make up the SD can also be made available and available for consultation through the use of databases or computer systems. SD may concern a family of products: for example, the records of the checks carried out on a particular finished product are also recognized for products of the same type that have, compared to those of the material under test, less critical compositional characteristics (e.g. different thicknesses) and use (e.g. time, temperature).

B6a.2.2. SD for manufacturers of monomers, starting substances, authorised additives under Regulation (EU) 10/2011, and for manufacturers of other substances authorised by other regulations

B6a.2.2.1. Sector: Manufacturers of starting substances

Manufacturers of substances (monomers, starting substances, authorised additives, including for example PPAs and dyes) for use in plastics intended to come into contact with foodstuffs, although not required to comply with Regulation (EC) 2023/2006 as amended, have preferably implemented a quality management system (es. ISO 9001) that guarantees in particular the control of activities, of processes and traceability. These requirements also apply to substances imported into the EU.

The SD should contain at least the following information:

- product identification (chemical name, trade name, etc.);
- product specification (document containing the characteristics of the product in relation to the expected quality, e.g. fineness, density, physical condition, etc.);
- purity requirements: information necessary to ensure compliance with specific provisions of the applicable legislation, with particular reference to substances also subject to restrictions in foodstuffs;
- adequate information on chemical reactivity and possible degradation products and processes of the substance (e.g. oxidation products, hydrolysis, etc.):
- information on the toxicological characteristics of the substance/product and available information on the toxicological characteristics of the decomposition products under foreseeable conditions of use, when known;
- information on the presence and quantity of substances for which genotoxicity cannot be excluded, as required by the XV update of Regulation 10/2011 as amended. Annex IV;
- any limitations of use (if applicable) (e.g. degradation of an additive at specified process temperatures) and any information on the stability of the product.

B6a.2.3. SD for manufacturers of plastics and masterbatch (as intermediates)

Producers of plastics and masterbatch intended for contact with food are required to comply with Regulation (EC) 2023/2006 as amended and additions and have therefore implemented a quality management system (e.g. but not necessarily ISO 9001) that guarantees in particular the control of activities, processes and traceability aimed at compliance with the applicable requirements of Regulation (EC) 1935/2004 as amended, in particular of Regulation (EU) 10/2011 as amended. These requirements also apply to plastics and masterbatch imported into the EU.

SD can concern a single product or a group of products with similar compositional characteristics and coming from the same process, even employing worst case techniques.

Not all the documents indicated below must necessarily always be present in the collection of SD, but only the documents that, on a case-by-case basis, are necessary to support and justify the evaluations that allow the issue of the DoC.

B6a.2.3.1. Composition of plastics/masterbatch

The SD should contain at least the following information:

- product description (e.g. LDPE (Low Density PolyEthylene), PP (polypropylene), master containing additives, etc.);
- trade name of the product(s);
- product specification (document containing the characteristics of the product in relation to the expected quality e.g. Melt Flow Index, density, etc.);
- about the composition.

B6a.2.3.2. Collecting relevant information from suppliers

B6a.2.3.2.1. For substances authorised in Regulation (EU) 10/2011 (e.g. monomers, additives, PPA[19] , etc.)

The SD should contain at least the following information:

- identification of the product(s);
- DoC as described in Regulation (EU) 10/2011 as amended including any restrictions on use and any information on the technical quality of the product;
- appropriate information on restricted substances in foodstuffs and, where appropriate, purity criteria in accordance with existing Directives.

B6a.2.3.2.2. For substances not authorised in Regulation (EU) 10/2011 (e.g. PPA, catalysts, dyes, solvents, etc.)

The SD should contain at least the following information:

- identification of the product(s);
- DoC of the supplier that includes references to national legislations, when applicable;
- information on the technical quality of the product.

B6a.2.3.3. Composition assessment documentation

The manufacturer must carry out an assessment of the composition of the material in order to support and formalise the decision to consider the product covered by SD suitable for contact with food on the basis of:

- information on assessments carried out to verify compliance with plastics/masterbatch composition and any restrictions (QM/QMA,[20] etc.);
- risk assessment of unlisted substances (e.g. Non Intentionally Added Substances, NIAS) according to art. 19 of Regulation (EU) 10/2011 as amended.

[19] Polymerisation Production aids

[20] Regulation (EU) 10/2001: QM/QMA = residual content per food contact surface area (QMA)

B6a.2.3.4. Documentation on the evaluation of substances subject to SML

Specific migration (SML) and overall migration (OM) tests are not mandatory for producers of plastics in granule/masterbatch form and the like; in any case, the plastics/masterbatch producer may carry out guidance checks to ensure that substances with SML do not exceed the limits set under certain conditions, if indicated in the DoC.

The SD should contain at least:

- any information on the assessments carried out for the verification of the migration of substances with SML, obtained by means of tests, mathematical models, calculations or appropriate scientific argumentation (in accordance with the screening methods for the verification of the suitability of plastics for the production of FCMs), e.g. to assess compliance under foreseeable conditions of use.

B6a.2.3.5. Documentation on particular uses mentioned in the DoC

In the case of products with particular intended uses, (e.g. substances to be used behind a barrier, products suitable for use in microwave ovens) the SD should contain at least, if available:

- information used to assess and support suitability for such uses.

B6a.3. Points of correspondence between DoC and SD

SD contains some specific elements that are mentioned directly by the DC.

The DoC confirms to the next actor in the supply chain that the compliance work has been carried out, indicating if any, what further activities need to be carried out by the user.

The reference documents for the DoC are at least:

SD prepared by the manufacturers of substances (monomers, starting substances, additives, PPAs)

- product identification (chemical name, trade name, etc.);
- purity requirements: information that may be necessary to ensure compliance with specific provisions of the applicable legislation, with particular reference to substances also subject to restrictions in foodstuffs;
- any limitations of use (e.g. use not recommended for contact with fatty foods) in the DoC must be justified in the SD.

SD prepared by manufacturers of plastics and masterbatch

- product identification (chemical name, trade name: e.g. LDPE, PP, master containing additives, etc.);
- compliance declarations issued by raw materials suppliers;
- risk assessment of non-listed substances, according to art. 19 of Regulation (EU) 10/2011 as amended;
- if necessary, information on the migration of substances with SML;
- any limitations of use and any information on the stability of the product;
- information that has been used to assess and support suitability for particular intended use, listed in DoC.

B6a.4. Points of correspondence between GMP and SD

The requirements of Regulation (EC) 2023/2006 as amended do not apply to producers of starting substances (monomers, additives, PPA, etc.) (*see* relevant articles of the Regulation EC) 2023/2006 as amended and in the document *Rapporto ISTISAN* 23/4 Rev.) (8).

For plastics and masterbatch manufacturers, some documents included in the GMP documentation are listed and are also part of the SD.

- specifications of finished products (document containing the characteristics of the product in relation to the expected quality);
- raw materials specifications;
- information on migration tests, if these are managed in the company's Quality System or GMP, otherwise they will be part of the SD relating to the specific compliance work for the product or group of products (*see* par. B6a.5).

B6a.5. SD topics not necessarily covered by GMP documentation

Some topics supporting the compliance of food contact products may not necessarily be covered within the GMP system.

For example, the company may have produced during the development phase a guideline documentation useful for the evaluation of products but considers it unnecessary for this documentation to be produced periodically and managed in the GMP system.

Below is a non-exhaustive list of these documents:

- results of overall migration tests (if not already managed in the company's Quality System or GMP);
- results of specific migration tests (if not already managed in the company's Quality System or GMP);
- application of mathematical models for migration screening;
- evaluations concerning NIAS;
- plastics composition assessments and masterbatches;
- technical documentation on applications and recommended conditions of use.

This does not imply the lack of such documentation, or the absence of compliance work, but only the unsystematic execution of this activity. The documentation will in any case be traceable and unequivocally attributable to the asset to which it refers.

Annex B6a

Sheets for supporting documentation of plastic manufacturers food contact materials: polymers and masterbatch

Regulatory references

Regulation (EC) 1935/2004 as amended
Regulation (EC) 2023/2006 as amended (where applicable)
Regulation (EC) 625/2017
Regulation (EU) 10/2011 as amended
Regulation (EC) 1895/2005
DM 21/03/1973 as amended
DPR 777/1982
DL.vo 108/1992
DL.vo 29/2017
Note of the Ministry of Health no. 32249, 11/10/2011
Guideline "Union Guidance on Regulation (EU) n. 10/2011 on plastic materials and articles intended to coming into contact with food as regard information in the supply chain" hereinafter referred to as DG Sanco 2013.

To harmonize the sheets of all the supply chains, the nine points contained in Annex IV of Regulation (EU) 10/2011 as amended have been used.

Sheet B6a.a Economic operator issuing the compliance declaration

INDICATION	DESCRIPTION
Requirement 1	Identity and address of the economic operator issuing the DoC
Supporting documentation	Company and/or functional organization chart and/or delegation and/or management procedures and/or documentation deriving from the company policy establishing responsibilities
Present guideline	A1.3.2.2
DG Sanco 2013	4.3.1.1
Regulation (EU) 10/2011 as amended	art. 15.2 Annex IV.1
DM 21/03/1973 as amended	art. 6 art. 8, paragraph c
Regulation (EC) 1935/2004 as amended	art. 16.1 art. 2, paragraph d
Notes	If the Economic Operator issuing the DoC is the same Economic Operator that produces or imports, requirements 1 and 2 may coincide. To identify the responsibilities referred to this requirement, reference is made to Article 2, paragraph d Regulation (EC) 1935/2004 as amended

Sheet B6a.b Economic operator who produces or imports the good

INDICATION	DESCRIPTION
Requirement 2	Identity and address of the economic operator producing or importing: ❑ raw materials/substances ❑ Intermediates/semi-finished products (polymers/masterbatch) ❑ finished products* *tick the relevant item*
Supporting documentation	Documentation including the identity and address of the economic operator producing or importing the starting substances/materials or polymers/ masterbatch as intermediates (e.g. specifications, transport documents, supply contracts, etc.)
Present guideline	A1.3.2.2
DG Sanco 2013	4.3.1.2
Regulation (EU) 10/2011 as amended	art. 15.2 Annex IV.2
DM 21/03/1973 as amended	art. 6 art. 8, paragraph c
Regulation (EC) 1935/2004 as amended	art. 16.1 art. 2.2, paragraph d
Notes	If the Economic Operator issuing the DoC is the same as the Economic Operator producing or importing, requirements 1 and 2 may coincide.

* the B6a supply chain produces/imports only starting substances/materials or polymers/masterbatch as intermediates

Sheet B6a.c Identity of the asset

INDICATION	DESCRIPTION
Requirement 3	Identity of the asset to which the DdC refers: ❑ starting substances/materials ❑ intermediates/semi-finished products (polymers/ masterbatch) ❑ finished products* *tick the relevant item*
Supporting documentation	Documentation for the identification of starting substances/materials or polymers/ masterbatch as intermediates (e.g. lot, catalogue, code numbers, etc.)
Present guideline	A1.3.2.2
DG Sanco 2013	4.2.1 – A3, B3, C3 4.3.1.3
Regulation (EU) 10/2011 as amended	art. 15 Annex IV.3
DM 21/03/1973 as amended	art. 6
Regulation (EC) 1935/2004 as amended	art. 16.1
Notes	Traceability documents, etc., can also be useful.

* B6a supply chain only produces/imports starting substances/materials or polymers/masterbatch as intermediates

Sheet B6a.d Functional barrier

INDICATION	DESCRIPTION
Requirement 4	Information on the possible functional barrier
Supporting documentation	Not applicable
Present guideline	Not applicable
DG Sanco 2013	Not applicable
Regulation (EU) 10/2011 as amended	Not applicable
DM 21/03/1973 as amended	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	This requirement does not apply plastics in primary form (e.g. granules) and masterbatch.

Sheet B6a.e Compliance with EU regulations/national legislation

INDICATION	DESCRIPTION
Requirement 5	Declaration of compliance with EU Regulations and/or national legislation where applicable
Supporting documentation	Relevant to Regulation (EU) 10/2011 and subsequent amendments for: ***Authorised and listed substances*** Supporting documentation: – use of substances listed in Annexes I and II – evaluation of technical quality and evaluation of impurities according to art.19 ***Substances not listed but authorized (art. 6, c.1, 2, 4b, 5)*** Documentation on: – national authorisations (appropriate supplier's declaration),or – risk assessment according to the criteria set out in art. 19 for substances used in the production process, and not listed in Annexes I and II ***Substances not listed but authorised (Article 6 par., 3)*** Documentation on: – applicability of the derogation referred to in art. 6 paragraph 3 (suitable declaration of suitability of the supplier) ***Intermediates (polymers/masterbatch)*** Supporting documentation: – use of substances listed in Annexes I and II – risk assessment according to the criteria set out in art. 19 for substances used in the production process, and not listed in Annexes I and II – risk assessment according to the criteria set out in art. 19 for substances not intentionally added that may be formed during production.
Present guideline	B6a.1.4.6; B6a.2.2; B6a.2.3
DG Sanco 2013	4.2.1A; 4.2.1B; 4.3.1
Regulation (EU) 10/2011 as amended	art. 15; art. 19; Annex IV.5
DM 21/03/1973 as amended	-
Regulation (EC) 1935/2004 as amended	art. 3; art. 16.1
Notes	-

Sheet B6a.f Restricted substances/materials

INDICATION	DESCRIPTION
Requirement 6	Adequate information about the substances and/or materials used and/or degradation products for which restrictions are in place
Supporting documentation	Supporting documentation: – identification of restricted substances in accordance with Regulation (EU) 10/2011 as amended (unique substance identification number, EEC reference number for packaging materials, CAS number, chemical name), or national legislation or confirmation that no restricted substances are used. – identification and quantities of substances restricted in Annex II or for which genotoxicity has not been excluded and which originate from intentional use during a production step and which can be expected to migrate from the final material in quantities exceeding 0.00015 mg/kg food or food simulated. – available information on compliance with restrictions on the substances used (e.g. based on mathematical models)
Present guideline	B6a.2.3.3
DG Sanco 2013	4.2.1.A 6 4.2.1.B 6 4.3.1.6
Regulation (EU) 10/2011 as amended	art. 9 art. 15 Annex IV.6
DM 21/03/1973 as amended	art. 9.2
Regulation (EC) 1935/2004 as amended	art. 16.1
Notes	Specific and overall migration tests are not mandatory for producers of plastics such as granules/masterbatch and the like; in any case, the plastics/masterbatch manufacturer may carry out guidance checks to ensure that substances with SML do not exceed the limits set under certain conditions, if indicated in the DoC.

Sheet B6a.g Restricted substances/materials in foodstuffs

INDICATION	DESCRIPTION
Requirement 7	Adequate information on substances and materials used that are restricted in foodstuffs
Supporting documentation	Supporting documentation: – identification of substances used and also subject to restrictions in foodstuffs as reported in Regulations (EC) 1333/2008 and 1334/2008 – compliance with any criteria and purity requirements
Present guideline	B6a.2.3.2
DG Sanco 2013	4.2.1.A 7 4.2.1.B 7 4.3.1.7
Regulation (EU) 10/2011 as amended	art. 11.3 art. 15 Annex IV.7
DM 21/03/1973 as amended	-
Regulation (EC) 1935/2004 as amended	art. 16.1
Note	-

Sheet B6a.h Directions for use

INDICATION	DESCRIPTION
Requirement 8	Indications for the use of FCMs: ❑ types of food products with which it is intended to come into contact ❑ duration, treatment temperature and storage in contact with food ❑ contact test conditions (simulant, duration, temperature) ❑ contact surface to volume ratio for determining FCMs compliance ❑ other restrictions of use *tick the relevant items*
Supporting documentation	Relevant to Regulation (EU) 10/2011 as amended, for: ***Authorised and listed substances and non-listed but authorised substances (art. 6, c.1, 2, 3, 4b, 5)*** Documentation on: – information used to establish any restrictions or specifications of use in addition to the specifications of use in column 10 of Annex I ***Intermediates (polymers/masterbatch)*** Documentation on: – information used to establish any restrictions or specifications of use in addition to the specifications of use in column 10 of Annex I ***Unlisted substances contained in polymers/masterbatch intended for use only behind a functional barrier*** Documentation on: – evidence (documentary and/or analytical) that the substance is not CMR and/or in nanoform – checks on compliance with the limit referred to in Articles 13 and 14 ***Intermediate materials (polymers/masterbatch) intended to be used only below a functional barrier*** Documentation on: – evidence (documentary and/or analytical) that the unlisted substances present in the material are not CMR and/or nanoform
Present guideline	da B6a.2.3.3 a B6a.2.3.5
DG Sanco 2013	4.2.1 A.8 4.2.1 C9 4.2.1B.8 4.3.1.8 4.3.1.9
Regulation (EU) 10/2011 as amended	art.13 - art.15 Annex IV.8 Annex IV.9
DM 21/03/1973 as amended	art. 5 art. 8.b
Regulation (EC) 1935/2004 as amended	art. 3 art. 15 art. 16.1
Notes	-

Sheet B6a.i Date of declaration

INDICATION	DESCRIPTION
Requirement 9	Date of declaration
Supporting documentation	-
Present guideline	A1.3.2.2
DG Sanco 2013	4.3.1. point 4
Regulation (EU) 10/2011 as amended	art. 15 Annex IV.4
DM 21/03/1973 as amended	art. 6
Regulation (EC) 1935/2004 as amended	art. 16.1
Notes	-

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

B6b.1. Characterization of the sector

B6b.1.1. Field of application of the guideline

Present guideline on Supporting Documentation (SD) for the Declaration of Compliance (DoC) is applicable to all companies operating in the plastics processing chain for the production of semi-finished products and plastic packaging intended for contact with food pursuant to art. 1 of Regulation (EU) 10/2011 as amended.

B6b.1.2. Applicable legislation

European legislation

- Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/CEE and 89/109/CEE as amended.
- Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as amended.
- Regulation (EU) 2017/625 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- Regulation (EU) 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.
- Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food as amended.
- Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs.
- Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs.

Italian legislation

- DPR 777/1982 - Decree of the President of the Republic No. 777/1982 on implementation of the Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs as amended.
- DL.vo 108/1992 - Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- DL.vo 29/2017 - Legislative Decree No. 29/2017 on sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food.
- DM 21/03/1973 - Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, for contact with foodstuffs or substances for personal use as amended.

B6b.1.3. Relationships between GMP, SD, DoC

Present guideline lists the criteria for the preparation of SD for Good Manufacturing Practice (GMP) and DoC for the plastics processing industry.

The categories of products considered are:

- rigid and flexible semi-finished products intended for the production of finished packaging;
- rigid and flexible packaging for the food industry and for the distribution system;
- rigid and flexible packaging intended for the final consumer through the distribution system.

This document analyses the correlation between the production activities and the contents of the SD, the DoC in relation to GMP and more generally with respect to the production phases of packaging and semi-finished products in plastics corresponding to the types indicated above.

Figure B6b.1 schematizes the flow of activities and documents relating to the production of packaging and semi-finished products in plastic materials intended for contact with food. For a more detailed description, however, see chapter B6b.2.

B6b.1.4. Industrial process: production of semi-finished products and packaging in plastic materials

The steps of the production process summarized in the flowchart are described below and then the Supporting Documentation, the points of correspondence between DoC, SD and GMP standards as well as the topics of SD not covered by the GMP system are analysed in detail.

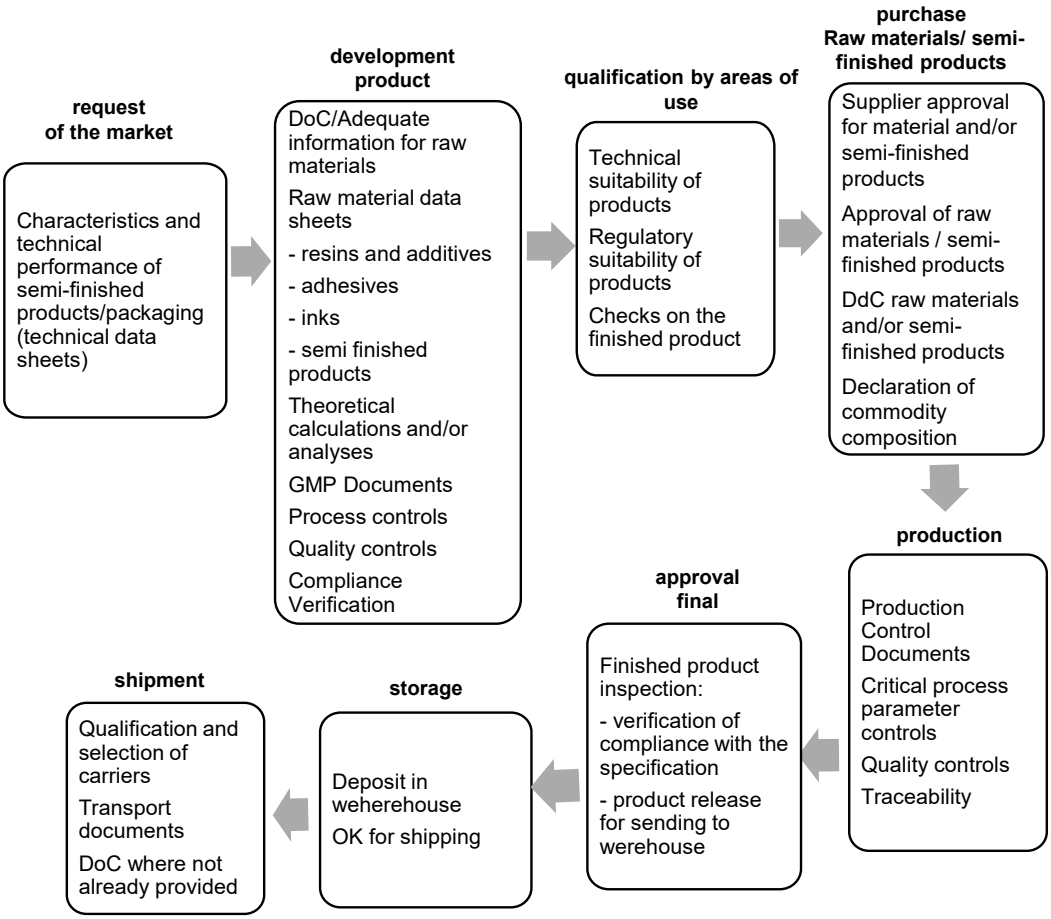

Figure B6b1. PROCESSING (PRODUCTION OF SEMI-FINISHED PRODUCTS AND PACKAGING): production phases and correlation with SD for DoC

B6b.1.4.1. Market demand and product development

Based on market needs, the company develops and/or modifies a product and/or a "product portfolio" capable of meeting the technical and legislative requirements deriving from the applications. In general, products are not developed specifically for individual customers, but rather to meet the needs expressed by the different applications identified in the market. In such cases, a specific technical sheet is prepared that contains the physical-mechanical characteristics and performance of the product.

In specific cases, it is necessary to acquire specific information from the customer on the type of food that will be placed in the packaging, as well as filling times and temperatures, life cycles and storage conditions.

Documentation (e.g. technical sheets, DoC or composition) provided by the producers of the raw materials is then requested and evaluated.

All the necessary parameters necessary for the control of production processes and the characteristics/performance to be subjected to quality control are defined.

B6b.1.4.2. Approval by the sector of use

In relation to the specific sector of use and the final application for which the product has been developed (semi-finished product or packaging), the expected technical characteristics and, more generally, regulatory suitability must be met.

In this regard, analyses and/or evaluations required according to the intended use must be carried out on the finished packaging. The starting raw materials must be accompanied by the DoC or composition specification

B6b.1.4.3. Purchase of raw materials and semi-finished products

The process of acquiring raw materials and semi-finished products involves the qualification of one or more suppliers capable of supplying the suitable raw materials/semi-finished products suitable for the production of the products under development and meeting the required technical and quality specifications.

A particular raw material or semi-finished product is identified by a technical specification that suppliers must always meet. The company shall promptly verify the supplier's ability to comply with the technical specifications and shall approve the raw material/semi-finished product from that specific supplier. This process is applied to each raw material/semi-finished product and each supplier. The supplier shall accompany its raw material/semi-finished product with technical documentation and declarations of compliance/composition.

B6b.1.4.4. Production

For each product, conditions must be identified that allow adequate control of the production process through the definition of a series of critical parameters which in turn enable product control.

Adequate quality controls are carried out on the product to verify its compliance to the reference specification.

Traceability must be guaranteed throughout the entire production process.

At the time of production, operators must have access to a technical sheet that provides all the information that must be used to produce the semi-finished product or packaging in compliance.

In particular, for the different production technologies, the following information must be available:

- raw materials or semi-finished products to be used, with their technical specifications;
- technical parameters to be respected according to the adopted transformation technologies;
- for printing machines, all the parameters that determine the quality of the product must be indicated.

All parameters must be reported on specific production sheets that must be part of the GMP documentation. If any of them are necessary to establish the SD, they must be organized to be made available to the competent authorities.

B6b.1.4.5. Final product approval

All the controls required by the relevant legislation must be carried out on the semi-finished packaging to demonstrate its compliance with the use for which it is intended.

Only after all the checks, including quality checks, can the stocking be decided. The SD must be present within the company (or at predefined third-party facilities) and must be readily available to the competent authorities.

For packaging, where mathematical calculations or modelling estimates are used, in accordance with the provisions of Regulation (EU) 10/2011 as amended, as an alternative to migration tests, these must be disclosed and justified with the SD.

The suitability assessment also provides for the performance of a risk assessment of non-listed substances (e.g. NIAS, Non-Intentionally Added Substances) in accordance with the provisions of Article 19 of Regulation (EU) 10/2011 as amended. This examination must be carried out in accordance with internationally recognised scientific principles of risk assessment.

B6b.1.4.6. Storage

Warehouse activities are managed to maintain product traceability. Consequently, the appropriate types of product packaging and the related identification markings must also be defined.

It must always be possible to trace the quality status of the products in stock through the appropriate coding system and operating procedures/instructions to ensure traceability.

B6b.1.4.7. Shipment

The preparatory activities for shipment provide for the approval of the companies that transport the product from the manufacturer to the end user. Carriers must also be selected on the basis of their ability to meet the quality requirements set by the companies in order to maintain the compliance of the transported product with the reference standards.

Transport documents are not necessarily part of the documentation required by the legislation on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs), but they fall under other legislative obligations. However, transport documents may also include relevant and/or useful documentation (e.g. compliance statements, data sheets, etc.) if not otherwise sent to the customer. Therefore, if a correlation with compliance documents is available in the transport documentation, this could facilitate traceability paths.

B6b.2. Supporting documentation

B6b.2.1. Introduction

This section clarifies the requirements for SD required by Regulation (EC) 1935/2004 as amended and specified by Regulation (EU) 10/2011 as amended and by DM 21/03/1973 as amended concerning plastic materials and articles intended to come into contact with foodstuffs.

The elements of the specific documentation applicable to the position of the operator (plastics processing industry) within the supply chain are identified.

The documents that make up the SD should be periodically reviewed to reflect changes in the composition of formulations, changes in materials and production processes, regulatory updates, changes in suppliers or adaptations to technical progress.

The documents that make up the SD can also be made available and accessible through the use of databases or IT systems

SD may cover a family of products: for example, the records of the checks carried out on a particular finished product are also recognized for products of the same type that have, compared to those of the material under test, less critical morphological characteristics (e.g., different thicknesses) and use (e.g., time, temperature).

B6b.2.2. SD for semi-finished and packaging manufacturers

Producers of semi-finished products and packaging intended for contact with food are required to comply with Regulation (EC) 2023/2006 as amended, they have therefore implemented a quality management system (e.g., but not necessarily ISO 9001) that guarantees in particular the control of activities, processes and traceability aimed at compliance with the applicable requirements of Regulation (EC) 1935/2004 as amended.

Not all the documents indicated below must necessarily always be present in the collection of SD, but only the documents that, on a case-by-case basis, are necessary to support and justify the evaluations that allow the issuance of the DoC.

B6b.2.2.1. Sector: Manufacturers of semi-finished products

B6b.2.2.1.1. Composition of semi-finished products

The SD should contain at least the following information:

- product description (e.g. LDPE-Low Density PolyEthylene sheet; preforms in PET, Poly Ethilene Terephatlate, etc.);
- trade name of the product(s);
- product specification (document containing the characteristics of the product in relation to the expected quality e.g. Melt Flow Index, density, etc.);
- information on the composition.

B6b.2.2.1.2. Collecting relevant information from suppliers

With reference to Regulation (EU) 10/2011 as amended, the SD should contain at least the following information:

Authorised substances

- identification of the product(s);
- DoC as described in Regulation (EU) 10/2011 as amended, including any restrictions on use and any information on the technical quality of the product;
- adequate information for non-listed substances with reference to the provisions of art. 19 of Regulation (EU) 10/2011 as amended;
- appropriate information on restricted substances in foodstuffs and, where appropriate, purity criteria in accordance with existing directives.

Non-authorized substances (dyes, solvents, etc.)

- identification of the product(s);
- DoC of the supplier that includes references to national legislation;
- adequate information with reference to the provisions of art. 19 of Regulation (EU) 10/2011 as amended;
- information on the technical quality of the product.

Non-plastic intermediates (inks, adhesives, coatings)

- identification of the product(s);
- adequate information on substances for which Regulation (EU) 10/2011 as amended provides for restrictions or notification of use (e.g. substances with Specific Migration Limit (SML), dual-use additives).

B6b.2.2.1.3. Documentation on the evaluation of substances subject to SML

The SD should contain at least the following information:

- information on the presence of restricted substances;
- any information on assessments carried out for the verification of migration of substances with SMLs, obtained by means of tests, mathematical models, calculations or appropriate scientific argumentation (in accordance with screening methods for the verification of the suitability of plastics for the production of materials and articles intended for contact with food), e.g. to assess compliance under foreseeable conditions of use.

Note. Specific and overall migration tests are not mandatory for manufacturers of semi-finished products/plastic intermediates; in any case, the producer of semi-finished products/plastic intermediate products may carry out guidance checks to ensure that substances with SML do not exceed the limits set under certain conditions, if indicated in the DoC.

B6b.2.2.1.4. Documentation on particular uses mentioned in the DoC

The SD should contain at least the following information:

- in the case of products with particular intended uses (e.g. semi-finished products to be used behind a functional barrier) information that has been used to assess and support suitability for such uses.

B6b.2.2.2. Industry: Packaging Manufacturers

B6b.2.2.2.1. Composition of packaging

The SD should contain at least the following information:

- product description (e.g. PP film, Polypropylene);
- trade name of the product(s);
- product specification (document containing the characteristics of the product in relation to the expected quality e.g. Melt Flow Index, density, etc.);
- information on the composition (including the presence of adhesives, coatings or inks);
- information on substances used behind a functional barrier (e.g. non-CMR, Carcinogenic, Mutagenic or toxic for Reproduction, and not in nanoform, detection limit not > 0.01 mg/kg).

B6b.2.2.2.2. Collecting relevant information from suppliers

With reference to Regulation (EU) 10/2011 as amended, the SD should contain at least the following information:

- *Authorised substances*
  - identification of the product(s);
  - DoC including any restrictions on use and any information on the technical quality of the product;
  - adequate information for non-listed substances with reference to the provisions of art. 19;
  - adequate information on restricted substances in foodstuffs and, where appropriate, purity criteria in accordance with existing directives.

– *Non-authorized substances (PPAs[21], catalysts, dyes, solvents, etc.)*
  - identification of the product(s);
  - DoC of the provider including references to national legislation, where applicable;
  - adequate information with reference to the provisions of Article 19;
  - information on the technical quality of the product.
– *Non-plastic intermediates (inks, adhesives, coatings)*
  - product identification;
  - adequate information on substances for which Regulation (EU) 10/2011 as amended provides for restrictions or notification of use (e.g. substances with SML, dual-use additives, etc.).

Note. Specific and overall migration testing is not always mandatory for plastic packaging manufacturers; in any case, the manufacturer of plastic packaging may carry out guidance checks to ensure that substances with SML do not exceed the limits set under certain conditions, if indicated in the DoC.

B6b.2.2.2.3. Composition Assessment Documentation

The SD should contain at least the following information:

– the manufacturer must carry out an assessment of the composition of the material in order to support and formalize the decision to consider the product subject to the SD suitable for contact with food on the basis of:
  - information on the assessments carried out to verify the compliance of the composition of plastics and any restrictions (QM/QMA, [22]etc.);
  - risk assessment of non-listed substances (e.g. NIAS) according to art. 19 of Regulation (EU) 10/2011 as amended.

B6b.2.2.2.4. Documentation on the evaluation of substances subject to SML

The SD should contain at least the following information:
– information on the presence of restricted substances;
– any information on assessments carried out for the verification of the migration of substances with SML, obtained by means of tests, mathematical models, calculations or appropriate scientific argumentation (in accordance with screening methods for the verification of the suitability of plastics for the production of materials and articles intended for contact with food), e.g. to assess compliance under foreseeable conditions of use.

[21] Polymerisation Production Aids
[22] Regulation (EU) 10/2001: QM/QMA = residual content per food contact surface area (QMA)

B6b.2.2.2.5 Documentation on particular uses mentioned in the DoC

The SD should contain at least the following information:

- in the case of products with particular intended uses, (e.g. for prolonged use at room temperature or use behind a functional barrier) information that has been used to assess and support suitability for such uses.

B6b.3. Points of correspondence between DoC and SD

SD contains some specific elements that are mentioned directly by the DoC.

As regards SD prepared by producers of semi-finished products and packaging of plastics, the reference documents for the DoC are:

- product description;
- DoC/composition issued by the supplier of the raw material;
- migration tests, mathematical calculations, screening tests (for packaging/finished products);
- risk assessment of non-listed substances, according to Article 19 of Regulation (EU) 10/2011 as amended;
- if necessary, information on the migration of substances with SML;
- any limitations of use and any information on the stability of the product;
- information used to assess and support suitability for particular uses mentioned in the DoC.

B6b.4. Points of correspondence between GMP and SD

For manufacturers of semi-finished products and packaging of plastics, some documents included in the GMP documentation are listed and are also used in SD.

- specifications of the raw materials used
- product specifications and performance (semi-finished products and packaging)
- information about migration trials that are managed in the company's quality system or by the GMP system.

The GMP documentation must provide evidence that the company has in place a SD management system that is used to determine compliance.

B6b.5. SD topics not necessarily covered by GMP documentation

Some topics supporting the compliance of semi-finished products and packaging intended for contact with food may not necessarily be managed within the GMP system.

For example, during the development phase the company may have produced a guideline documentation useful for the evaluation of products, but may consider it unnecessary for this documentation to be produced periodically and managed in the GMP system.

Below is a non-exhaustive list of these documents:

- overall migration test results (if not already managed in the company's quality system, or GMP);

- results of specific migration tests (if not already managed in the company quality system or, GMP);
- application of mathematical models for the evaluation of migrations;
- evaluations concerning NIAS;
- technical documentation on end uses and recommended conditions of use.

This does not imply the lack of such documentation, or the absence of compliance work, but only the unsystematic execution of this activity. The documentation will in any case be traceable and unequivocally attributable to the asset to which it refers.

Annex B6b

Sheets for supporting documentation of plastic food contact materials. Plastics-processing: semi-finished products and packaging

Regulatory references

Regulation (EC) 1935/2004 as amended
Regulation (EC) 2023/2006 as amended (where applicable)
Regulation (EC) 625/2017
Regulation (EU) 10/2011 as amended
Regulation (EC) 1895/2005
DM 21/03/79 as amended
DPR 777/1982
DL.vo 108/1992
DL.vo 29/2017
Note of the Ministry of Health no. 32249, 11/10/2011
Guideline "Union Guidance on Regulation (EU) n. 10/2011 on plastic materials and articles intended to coming into contact with food as regard SD information in the supply chain" hereinafter referred to as DG Sanco 2013.

To harmonize the sheets of all the supply chains, the nine points contained in Annex IV of Regulation (EU) 10/2011 as amended have been used.

Sheet B6b.a Economic operator issuing the compliance declaration

INDICATION	DESCRIPTION
Requirement 1	Identity and address of the Economic operator issuing the DoC on: ❑ intermediates/semi-finished products ❑ packaging *tick the relevant item*
Supporting documentation	Company and/or functional organization chart and/or delegation and/or management procedures and/or documentation deriving from the company policy establishing responsibilities
Present guideline	A1.3.2.2
DG Sanco 2013	4.3.1.1 4.4.1
Regulation (EU) 10/2011 as amended	art. 15.2 Annex IV.1
DM 21/03/1973 as amended	art. 6 art. 8, paragraph c
Regulation (EC) 1935/2004 as amended	art. 16. 1 art. 2, paragraph d
Notes	If the economic operator issuing the DoC is the same economic operator that produces or imports, requirements 1 and 2 may coincide. To identify the responsibilities referred to this Requirements, please refer to Article 2 paragraph, d Regulation (EC) 1935/2004 as amended.

Sheet B6b.b Economic operator who produces or imports the good

INDICATION	DESCRIPTION
Requirement 2	Identity and address of the economic operator producing or importing: ❑ intermediates/semi-finished products ❑ packaging *tick the relevant item*
Supporting documentation	Supporting documentation: identity and address of the economic operator producing or importing semi-finished / intermediate or finished products (e.g. specifications, transport documents, supply contracts, etc.)
Present guideline	A1.3.2.2
DG Sanco 2013	4.3.1.2 4.4.2
Regulation (EU) 10/2011 as amended	art. 15.2 Annex IV.2
DM 21/03/1973 as amended	art. 6 art.8, paragraph c
Regulation (EC) 1935/2004 as amended	art. 16. 1 art. 2.2, paragraph d
Notes	If the economic operator issuing the DoC is the same as the economic operator producing or importing, requirements 1 and 2 may coincide. To identify the responsibilities referred to in this Requirements, please refer to Article 2 paragraph d of Regulation (EC) 1935/2004 as amended.

Sheet B6b.c Identità del bene

INDICATION	DESCRIPTION
Requirement 3	Identity of the asset to which the DoC refers: ❑ intermediates/semi-finished products ❑ packaging *tick the relevant item*
Supporting documentation	Documentation for the identification of the asset (e.g. type of material/object, batch numbers, catalogue numbers, code numbers, etc.)
Present guideline	A1.3.2.2
DG Sanco 2013	4.3.1.3 4.4.3
Regulation (EU) 10/2011 as amended	art. 15 Annex IV.3
DM 21/03/1973 as amended	art. 6
Regulation (EC) 1935/2004 as amended	art. 16.1
Notes	It could be indicated, for example, “PP sheet, PET bottle, HDPE bottle” etc. Traceability documents, etc., can also be useful.

Sheet B6b.d Functional barrier

INDICATION	DESCRIPTION
Requirement 4	Information on the possible Functional barrier on: ❑ intermediates/semi-finished products ❑ packaging *tick the relevant item*
Supporting documentation	*Intermediates/semi-finished products* – documentation on investigations (documentary and/or analytical) to verify that the substances present are not CMR and/or in nanoform *Packaging* (with functional barrier) - evidence on the absence of substances classified as CMR or nanoform - analytical tests or other scientific evidence demonstrating that under the intended conditions of use, the migration of unauthorised substances is undetectable with a detection limit of 0.01 mg/kg
Present guideline	B6b.2.2.1.4 B6b 2.2.2.4
DG Sanco 2013	4.3.1.9 4.4.9
Regulation (EU) 10/2011 as amended	art. 13 art. 14 Annex IV.9
DM 21/03/1973 as amended	art. 5
Regulation (EC) 1935/2004 as amended	art. 3
Notes	Plastics intended for use behind a functional barrier must be provided with the information given in section 9, chapter 4.3.1, of the European guideline

Sheet B6b.e Compliance with EU regulations/national legislation

INDICATION	DESCRIPTION
Requirement 5	Declaration of compliance with EU regulations and/or national legislation where applicable on: ❑ intermediates/semi-finished products ❑ packaging *tick the relevant item*
Supporting documentation	*With regards to Regulation (EU) 10/2011 as amended* ***Intermediates/semi-finished products*** Supporting documentation: – use of substances listed in Annexes I and II – risk assessment according to the criteria set out in art. 19 for substances used in the production process, and not listed in Annexes I and II or adequate information so that such compliance can be verified by the downstream user – risk assessment according to the criteria set out in art. 19 for unintentionally added substances that may be formed during production or adequate information for such compliance to be verified by the downstream user ***Packaging*** Supporting documentation: – the use of substances listed in Annexes I and II – the risk assessment according to the criteria referred to in art. 19 for substances used in the production process, and not listed in Annexes I and II or adequate information so that such compliance can be verified by the downstream user – the risk assessment according to the criteria referred to in art. 19 for unintentionally added substances that may be formed during production or adequate information for such compliance to be verified by the downstream user – compliance with the overall migration limit. Further information can be provided with reference to the test conditions adopted or to the identification number of these conditions in Table 3 – Annex V
Present guideline	B6b.2.2.1 B6b.2.2.2
DG Sanco 2013	4.3.1.5 4.4.5
Regulation (EU) 10/2011 as amended	art. 15 art. 19 Annex IV.5
DM 21/03/1973 as amended	art. 9.2
Regulation (EC) 1935/2004 as amended	art.3 e art. t. 16.1
Notes	-

Sheet B6b.f Restricted substances/materials

INDICATION	DESCRIPTION
Requirement 6	Adequate information about degradation substances and/or materials and/or products for which restrictions are in place on: ❑ intermediates/semi-finished products ❑ packaging *tick the relevant item*
Supporting documentation	Relevant to Regulation (EU) 10/2011 as amended or national legislation for: ***Intermediates/semi-finished products*** Supporting documentation: – identification of restricted substances (unique substance identification number, EEC reference number for packaging materials, Chemical Abstracts Service (CAS) number, chemical name ***Packaging*** Supporting documentation: – identification of restricted substances (unique substance identification number, EEC reference number for packaging materials, CAS number, chemical name) – available information on compliance with restrictions applicable to the substances used (LMS, LMS T, QM) (e.g. based on analyses, calculations or mathematical models)
Present guideline	B6b.2.2.1.3 B6b.2.2.2.3
DG Sanco 2013	4.3.1.6 4.4.6
Regulation (EU) 10/2011 as amended	art. 9 art. 15 Annex IV.6
DM 21/03/1973 as amended	art. 9.2
Regulation (EC) 1935/2004 as amended	art. 16.1
Notes	Overall and specific migration tests are not mandatory for producers of semi-finished products, in any case orientation checks can be carried out to ascertain that substances with SML do not exceed the limits set under certain conditions, if indicated in the DoC.

Sheet B6b.g Restricted substances/materials in foodstuffs

INDICATION	DESCRIPTION
Requirement 7	Appropriate information on substances and materials used that are restricted in foodstuffs on: ❑ intermediates/semi-finished products ❑ packaging *tick the relevant item*
Supporting documentation	Supporting documentation: – identification of substances used also subject to restrictions in food products as reported in Regulations (EC) 1333/2008 and 1334/2008. – compliance with any criteria and purity requirements
Present guideline	B6b.2.2.1.2; B6b.2.2.2.2
DG Sanco 2013	4.3.1.7; 4.4.7
Regulation (EU) 10/2011 as amended	art. 11.3; art. 15 Annex IV.7
DM 21/03/1973 as amended	-
Regulation (EC) 1935/2004 as amended	art. 16.1
Notes	-

Sheet B6b.h Directions for use

INDICATION	DESCRIPTION
Requirement 8	Indications for the use of FCMs: ❑ intermediates/semi-finished products ❑ packaging Also specify: ❑ types of food products with which it is intended to come into contact ❑ duration, treatment temperature and storage in contact with food ❑ contact test conditions (simulant, duration, temperature) ❑ contact surface to volume ratio for determining FCMs compliance ❑ other restrictions or information related to use *tick the relevant items*
Supporting documentation	Documentation proving compliance checks with the declared uses: – DoC of raw materials and/or – adequate information for inks or adhesives and/or – screening analysis reports and/or – migration tests and/or mathematical calculations and/or other scientific evidence
Present guideline	B6b.2.2.1.2 - 2.2.1.4 B6b.2.2.2.2 - 2.2.2.5
DG Sanco 2013	4.3.1.8; 4.4.8
Regulation (EU) 10/2011 as amended	art. 13-15 Annex IV.8; Annex IV.9
DM 21/03/1973 as amended	art. 5; art. 8.b
Regulation (EC) 1935/2004 as amended	art. 3, art. 15 e art. 16.1
Notes	-

Sheet B6b.i Date of declaration

INDICATION	DESCRIPTION
Requirement 9	Date of declaration on: ❑ intermediates/semi-finished products ❑ packaging *tick the relevant item*
Supporting documentation	-
Present guideline	A1.3.2.2
DG Sanco 2013	4.3.1.4 4.4.4
Regulation (EU) 10/2011 as amended	art. 15 Annex IV.4
DM 21/03/1973 as amended	art. 6
Regulation (EC) 1935/2004 as amended	art. 16.1
Notes	-

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

B7.1. Characterization of the sector

B7.1.1. Field of application of the guideline

This guideline on Supporting Documentation (SD) for the Declaration of Compliance (DoC) applies 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 as referred to in Article 1 of Regulation (EC) 1935/2004 as amended

The main items that are covered by this guideline are:

- 3-piece cans and aerosol cans with electro welded bod;
- 2-piece cans;
- lids for 2-piece cans and 3-piece cans;
- caps;
- crown closures.

Thin foils and laminates for aluminium bowls are treated in chapter B1 of this guideline.

B7.1.2. Applicable legislation

European legislation

- Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/CEE and 89/109/CEE as amended.
- Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as amended.
- Regulation (EU) 2017/625 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- Regulation (EU) 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food. (Application areas: Paints for boxes and lids, Seals for capsules.)
- Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food as amended. (Application field: Seals for capsules and crown caps.)

Italian legislation

- DPR 777/1982 - Decree of the President of the Republic No. 777/1982 on implementation of the Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs as amended.
- DL.vo 108/1992 - Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- DL.vo 29/2017 - Legislative Decree No. 29/2017 on sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food.
- DM 21/03/1973 - Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, for contact with foodstuffs or substances for personal use as amended. (Application areas: Paints for boxes and lids, seals for capsules, additives for paints and plastics.)
- Decree No. 405/1984 updated by Decree of 13rd July 1995 on the determining the composition of tinplate welded with tin-lead alloy and other methods; migration limits for Sn, Fe and Pb; sampling methods and processes for overall organic migration test; some technical requirement, as amended. (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 overall organic migration test. (Field of Application: tin-free steel).

In addition, for clarification on the application of regulatory provisions in this sector, useful references are the following Circulars of the Ministry of Health:

- Note of the Ministry of Health DGSAN.VI/ 15844-P-12/05/2011: EU Regulation no. 10/2011 concerning plastic materials and articles intended to come into contact with foodstuffs;
- Ministerial Circular DGSAN.VI/12174-P-23/4/2010: Indications regarding controls on tinplate and chrome-plated materials and objects.

B7.1.3. Relationships between GMP, SD, DoC

Present guideline analyses the content and correlation between SD and DoC and DoC themselves with reference to Good Manufacturing Practice (GMP) relating to the production phases of metal and alloy products, bare or coated, intended for contact with food.

Figure B7.1 below represents, for example, the correlation flows between activities and documents relating to the various phases of product development and implementation. For a more in-depth description, however, see the chapter B7.2.

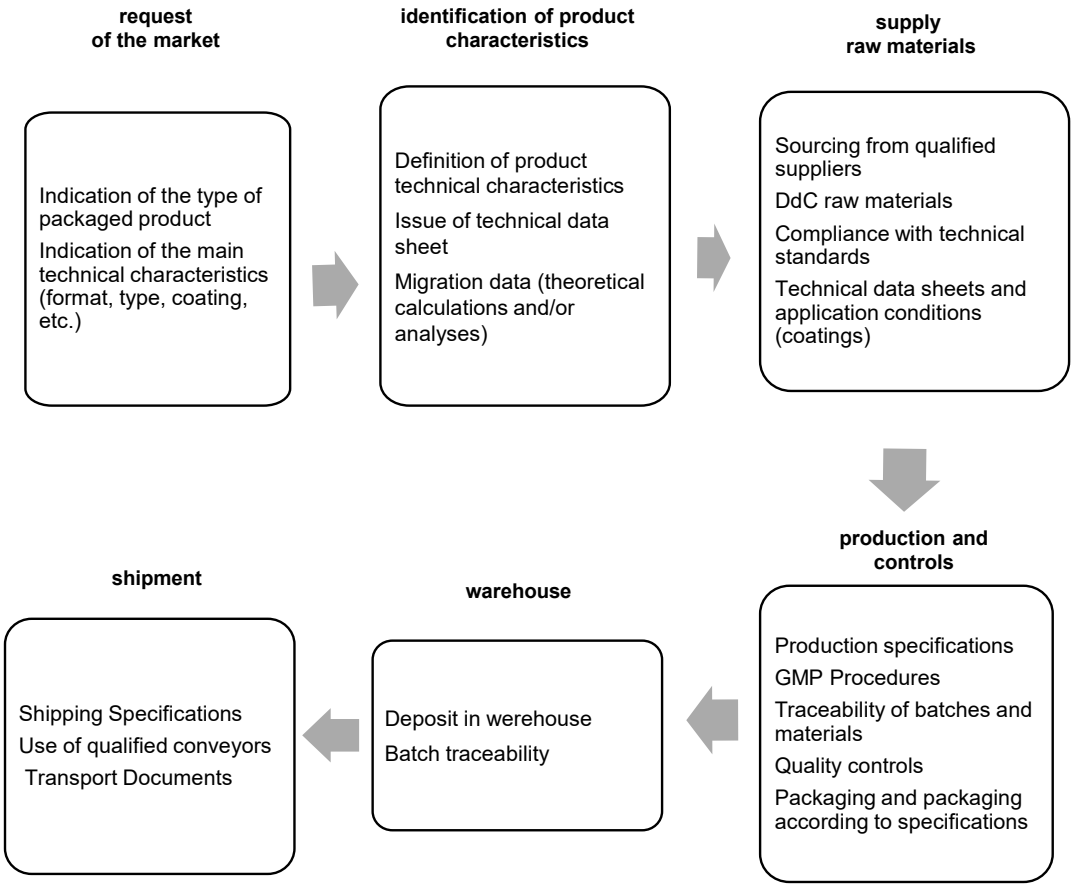

Figure B7.1. COATED AND NOT-COATED METAL AND METAL ALLOY PACKAGING: production phases and correlation with SD for DoC

B7.1.4. Industrial production processes for coated and not-coated metal and metal alloy packaging

The flow diagrams and detailed descriptions of the production phases of the products are described in sections B7.1.3 in the document *Rapporto ISTISAN* 23/4 Rev. (8).

Manufacturers of metals intended for contact with food are required to comply with Regulation (EC) 2023/2006 as amended and additions and must therefore implement a quality management system (es. ISO 9001 or other) such as to ensure, in particular, process control and traceability.

B7.1.4.1. Definition of product specifications and purchase raw materials

On the basis of the needs deriving from the end use of the product to be made, the technical specification of the product is defined, and the production cycle is developed taking into account the regulations in force for materials and articles in contact with foodstuffs (Food Contact Materials, FCMs). All the parameters necessary for the control of production processes and product quality control are then defined.

The documentation provided by the manufacturers of raw materials (e.g. technical data sheets, compliance declarations, etc.) is requested and evaluated in relation to the specifications of use, defined by the end customer, where available, and/or by the foreseeable directions for use.

It is good practice to provide for a supplier qualification process, as required by the document *Rapporto ISTISAN* 23/4 Rev. (8) to paragraph B7.2.1.2.

B7.1.4.2. Production

For each process/product, the conditions that allow adequate control of the production process must be identified through the definition of a series of control parameters (e.g. firing temperature, paints, dimensional parameters, etc.) by means of which both the compliance of the product with respect to technical specifications and food contact is ensured.

Traceability must be guaranteed for the entire production process.

B7.1.4.3. Product Control

The product is checked during the various processing phases. Adequate quality controls are carried out on the product, which verify both its adherence to the reference specification and some technological tests that confirm its suitability with respect to the established use.

Depending on the results of the tests expected during the production process, the compliance of the product with the technical specifications is confirmed without the need for a final evaluation test.

B7.1.4.4. Storage

Warehouse activities are also managed to maintain product traceability.

Consequently, the appropriate types of packaging of the material and the related identification markings must also be defined. It must always be possible to trace the quality status of the products in stock through the appropriate codes and operating procedures/instructions.

B7.1.4.5. Shipment

The activities related to shipment involve the approval of the companies that transport the product from the manufacturer to the end user. Carriers must also be selected on the basis of their ability to meet the quality requirements set by companies in order to maintain the compliance of the transported product with the reference standards.

Transport documents are not necessarily part of the documentation required by the legislation on FMCs, but they are part of other legislative obligations. However, transport documents may also include relevant and/or useful documentation (e.g. compliance statements, test reports, etc.) if not otherwise shipped to the customer. Therefore, if a correlation with compliance documents is available in the transport documentation, this could facilitate traceability paths.

B7.2. Supporting documentation

B7.2.1. Introduction

The purpose of this section is to clarify the requirements in relation to SD required by Regulation (EC) 1935/2004 as amended concerning materials and articles intended to come into contact with foodstuffs.

The elements of the specific documentation applicable to the operator's position in the supply chain are identified, it being understood that the packaging producer is legally obliged to:

- transmit their DoC downstream;
- request upstream all the declarations and the SD necessary to draw up their own DoC;
- to keep the SD complex in the company available to the competent authorities.

The documents that make up the SD should be reviewed periodically to reflect potential changes in the composition of formulations, changes in materials and production processes, regulatory updates, changes in suppliers or adaptations to technical progress.

The documents that make up the SD can also be made available and consulted through the use of databases or computer systems

SD may concern a family of products: for example, the records of the checks carried out on a particular finished product are also recognized for products of the same type that have, compared to those of the material under test, less critical morphological characteristics (e.g. different thicknesses) and use (e.g. time, temperature).

B7.2.2. SD for manufacturers of metal laminates

In the production of rolled products, the relevant aspects of the production process, for the purposes of food compliance, are the chemical composition of the alloy and lubrication with the use of technological adjuvants.

The SD should contain at least the following information:

- identification and description of the product (passivation, thickness, hardness, tin covering, etc.);
- DoC of suppliers of starting laminates to DM 18/02/1984[23] as emended;
- DoC of suppliers of starting laminates to DM 243/1988[24];
- elements for complete traceability of the material;
- DoC of suppliers to Regulation (EC) 1935/2004 as amended.

B7.2.3. SD for painted metal laminates and/or finished components

The SD should contain at least the following information:

- identification and description of the product and materials used (laminate, paints, technical specifications, etc.);
- elements for the complete traceability of materials;
- DoC of coating suppliers to DM 21/03/1973 as amended;
- Adequate information and/or DoC of paint suppliers;
- DoC of suppliers to Regulation (EC) 1895/2005;
- DoC to DM 18/02/1984[24] updated with DM 405/1995 of suppliers;
- DoC to DM 243/1988[24] of suppliers;
- DoC of supplies to Regulation (EC) 1935/2004 as amended

SD can concern a single product or a group of products with similar compositional characteristics and coming from the same process, even employing worst case techniques to group the products.

[23] Alternatively, there could be compliance with the European standards UNI EN 10202 (17), UNI EN 10333 (18), UNI EN 610 (19) which, as they are more restrictive, imply compliance with the Italian decrees on Tinplate and Chrome Plate, which should in any case be in reference.

B7.2.4. SD for finished products of bare or coated metal

The SD should contain at least the following information:

- *Metal laminates*
  - product identification and description (passivation, thickness, hardness, Sn coverage, technical specifications, etc.);
  - DoC of suppliers of laminated products to DM 18/02/1984[24] as amended;
  - DoC of suppliers of laminated products to DM 243/1988[24];
  - DoC of suppliers to the Regulation (EC) 1935/2004 as amended;
  - elements for complete material traceability;
- *Coatings used in direct contact with the product*
  - DoC of paint suppliers to Regulation (EC) 1935/2004 as amended;
  - DoC of paint suppliers to DM 21/03/1973 as amended;
  - DoC of paint suppliers to Regulation (EC) 1895/2005;
  - elements for complete material traceability;
  - technical data sheets;
- *Gaskets for capsules and crown caps*
  - DoC of the gasket supplier to Regulation (EU) 10/2011 as amended.

In addition, in all cases of finished products, the SD should contain information on overall and/or specific migration values (obtained from the supplier and/or theoretical calculations and/or migration tests performed by third-party laboratories). In the presence of GMP documentation on the maintenance of the process parameters that guarantee the compliance of the product with the regulations applicable to the sector (see above), the migration data is considered valid until the applied coating products are changed.

B7.3 Points of correspondence between DoC and SD

SD contains some specific elements that are mentioned directly by the DoC.

The DoC confirms to the next actor in the supply chain that the compliance work has been carried out, indicating if any, what further activities need to be carried out by the user.

As regards the SD prepared by manufacturers of metal and metal alloy packaging, coated and not-coated, the reference documents for the DoC are at least:

- product description;
- migration tests in accordance with the applicable provisions (Overall and/or Specific). Alternatively, mathematical calculations and/or screening tests may be valid;
- any information on the risk assessment of unlisted substances and NIAS (Non-Intentionally Added Substances);
- possibly, information that has been used to assess and support suitability for particular uses mentioned in the DdC.

Note. For coatings on metals, the national decrees on Tinplate and Chrome Plate mentioned above are taken into account. In both cases, however, the requirements of Regulation (EC) 1935/2004 as amended and amended (art. 3, art. 16) remain valid, as well as the national provisions of DM 21/3/73 as amended and additions and Regulation (EU) 10/2011 as amended as clarified by the Circular of the Ministry of Health DGSAN.VI/ 15844-P-12/05/2011

B7.4. Points of correspondence between GMP and SD

Some elements that are already part of the documentation of the GMP system of the production cycle can also be included in the Supporting documentation, for example:

- elements for the traceability of the laminate;
- elements for the traceability of paints;
- recording of defined product controls (e.g. dimensional checks, technological tests, visual checks, etc.);
- recording of process controls (e.g. firing temperatures of painting ovens);
- product specifications and performance.

The GMP documentation must provide evidence that the company has in place a SD management system that is used to determine compliance.

B7.5. SD topics not necessarily covered by GMP documentation

Some topics supporting compliance of coated and not-coated metal and metal alloy packaging intended for food contact may not necessarily be addressed within the GMP system of a given business organization. For example, the company may have produced during the development phase a guideline documentation useful for the evaluation of products but considers it unnecessary for this documentation to be produced periodically and managed in the GMP system. Below is a non-exhaustive list of these documents:

- results of overall and/or specific migration tests (if not already managed in the company quality system or GMP);
- application of mathematical models for migration screening;
- evaluations concerning any NIAS;
- evaluation of the use of a possible functional barrier;
- technical documentation on applications and recommended conditions of use.

All this does not imply the lack of such documentation or the absence of compliance work but only the unsystematic execution of some activities. The documentation will in any case be traceable and traceable to the asset to which it refers.

Annex B7

Sheets for supporting documentation of metals and metal alloys, coated and not-coated food contact materials

Regulatory references

Regulation (EC) 1935/2004 as amended
Regulation (EC) 1895/2005
Regulation (EC) 2023/2006 as amended
Regulation (EU) 10/2011 as amended
DM 21/03/1973 as amended
DM 18/02/1984 updated with D 405/1995
D 243/1988
DM 338/1998
DPR 777/1982
DL.vo 108/1992
DL.vo 29/2017
Note of the Ministry of Health no. 15844, 12/05/2011
Note of the Ministry of Health no. 12174, 23/4/2010
Note of the Ministry of Health no. 32249, 11/10/2011

To harmonize the sheets of all the supply chains, the nine points contained in Annex IV of Regulation (EU) 10/2011 as amended have been used, although this Regulation is not directly applicable to the supply chain of coated or not-coated metal and metal alloy.

Sheet B7.a Economic operator issuing the compliance declaration

INDICATION	DESCRIPTION
Requirement 1	Identity and address of the economic operator issuing the DoC
Supporting documentation	Company and/or functional organization chart and/or delegation and/or management procedures and/or documentation deriving from the company policy establishing responsibilities
Present guideline	A1.3.2.2
DM 18/02/1984 as amended	art. 1
DM 243/1988	art. 1
DM 21/03/1973 as amended	art. 6 art. 8, paragraph c
Regulation (EC) 1935/2004 as amended	art. 16.2 art. 2, paragraph d
Notes	If the economic operator issuing the DoC is the same as the economic operator producing or importing, requirements 1 and 2 may coincide. To identify the responsibilities referred to this Requirements, please refer to art. 2 paragraph d of Regulation (EC) 1935/2004 as amended.

Sheet B7.b Economic operator who produces or imports the good

INDICATION	DESCRIPTION
Requirement 2	Identity and address of the economic operator producing or importing: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished products *tick the relevant item*
Supporting documentation	Supporting documentation: identity and address of the economic operator producing or importing raw materials/substances, semi-finished products/intermediates or finished products (e.g. specifications, transport documents, supply contracts, etc.)
Present guideline	A1.3.2.2
DM 18/02/1984 as amended	art. 1
DM 243/1988	art.1
DM 21/03/1973 as amended	art. 6 art. 8, paragraph c
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	If the economic operator issuing the DoC is the same as the economic operator producing or importing, requirements 1 and 2 may coincide

Sheet B7.c Identity of the asset

INDICATION	DESCRIPTION
Requirement 3	Identity of the asset to which the DdC refers: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished products *tick the relevant item*
Supporting documentation	Documentation for the identification of the asset (e.g. type of material/object, batch numbers, catalogue numbers, code numbers, etc.)
Present guideline	A1.3.2.2
DM 18/02/1984 as amended	art. 1
DM 243/1988	art. 1
DM 21/03/1973 as amended	art. 6
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	Traceability documents, etc., can also be useful.

Sheet B7.d Functional barrier

INDICATION	DESCRIPTION
Requirement 4	Information on any functional barrier
Supporting documentation	Not applicable
Present guideline	Not applicable
DM 18/02/1984 as amended	Not applicable
DM 243/1988	Not applicable
DM 21/03/1973 as amended	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	This requirement does not apply

Sheet B7.e Compliance with EU regulations/national legislation

INDICATION	DESCRIPTION
Requirement 5	Declaration of compliance with EU Regulations and/or national Legislation where applicable
Supporting documentation	Supporting documentation: – use of raw materials formulated with substances listed in Annex I of DM 18/2/1984, or in Annex I of DM 243/1988, or in Annex II of DM 21/03/1973 as amended, or in Annexes I and II of Regulation (EU) 10/2011 as amended for the gaskets of caps and crown caps – compliance with the overall migration limit (when applicable) supported by analytical tests and/or mathematical calculations and/or screening analyses – risk assessment for substances used in the production process, and covered by the scope of application of art.10 of the DM 21/03/1973 as amended and/or according to the criteria set out in art. 19 of Regulation (EU) 10/2011 as amended – risk assessment for substances not intentionally added that may be formed during production and covered by the scope of application of art.10 of the DM 21/03/1973 as amended and/or according to the criteria set out in art. 19 of Regulation (EU) 10/2011 as amended
Present guideline	B7.2.2 e B7.2.3 (for intermediates/semi-finished products) B7.2.4 (for finished products)
DM 18/02/1984 as amended	art. 1
DM 243/1988	art. 1
DM 21/03/1973 as amended	art. 3 art. 6
Regulation (EU) 10/2011 as amended	art. 19 (for cap gaskets and crown caps)
Regulation (EC) 1935/2004 as amended	art. 3 art. 16.2
Notes	Note from the Ministry of Health no. 15844, 12/05/2011 Note from the Ministry of Health no. 32249, 11/10/2011 Note from the Ministry of Health no. 12174, 23/4/2010

Sheet B7.f Restricted substances/materials

INDICATION	DESCRIPTION
Requirement 6	Adequate information about the substances and/or materials used and/or degradation products for which restrictions are in place
Supporting documentation	Supporting documentation: – identification of restricted substances in accordance with the provisions of Regulation (EC) 1895/2005, DM 21/03/1973 as amended, Ministerial Decree 18/2/1984 and by DM 243/1988, by Regulation (EU) 10/2011 as amended for gaskets of capsules and crown caps, or confirmation that no restricted substances are used. – available information on compliance with the restrictions applicable to the substances used (SML, SML T, QM) together with the test conditions and simulants used. Documents can be analysis reports and/or mathematical calculations and/or screening analyses.
Present guideline	B7.2.2 - B7.2.3 (for intermediates/semi-finished products) B7.2.4 (for finished products)
DM 18/02/1984 as amended	Annex I e II
DM 243/1988	Annex I e II
DM 21/03/1973 as amended	art. 9.4, art. 9.4bis, Annex II
Regulation (EU) 10/2011 as amended	art. 9, art. 15, Annex IV
Regulation (EC) 1935/2004 as amended	art.16.2
Notes	Note from the Ministry of Health no. 15844, 12/05/2011 Note from the Ministry of Health no. 32249, 11/10/2011 Note from the Ministry of Health no. 12174, 23/4/2010

Sheet B7.g Restricted substances/materials in foodstuffs

INDICATION	DESCRIPTION
Requirement 7	Adequate information on restricted substances and materials used in foodstuffs
Supporting documentation	Supporting documentation: – identification of substances used also subject to restrictions in food products as reported in Regulations (EC) 1333/2008 and 1334/2008. – compliance with any criteria and purity requirements
Present guideline	B7.2.2 e B7.2.3 (for intermediates/semi-finished products) B7.2.4 (for finished products)
DM 18/02/1984 as amended	art. 1
DM 243/1988	art. 1
DM 21/03/1973 as amended	art.9, art. 9 bis
Regulation (EU) 10/2011 as amended	art. 11.3, art. 15, Annex IV.7
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	Note from the Ministry of Health no. 15844, 12/05/2011 Note from the Ministry of Health no. 32249, 11/10/2011 Note from the Ministry of Health no. 12174, 23/4/2010

Sheet B7.h Directions for use

INDICATION	DESCRIPTION
Requirement 8	Information on the use of FCMs: ❑ intermediates/semi-finished products ❑ packaging *tick the relevant item* Indications for the use of FCMs: ❑ types of food products with which it is intended to come into contact ❑ duration, treatment temperature and storage in contact with food ❑ contact test conditions (simulant, duration, temperature) ❑ ratio of contact surface area to volume for determining compliance of FCMs ❑ other restrictions or information related to the use *tick the relevant items*
Supporting documentation	Documentation on: – information used to establish any restrictions or specifications of use in addition to the specifications of use in the applicable national legislations and/or in column 10 of Annex I to Regulation (EU) 10/2011 as amended where applicable (e.g. composition statements, analysis reports, migration tests, etc.) – documentation proving compliance checks with the declared uses (e.g. analysis reports, migration tests, etc.)
Present guideline	B7.2.2 e B7.2.3 (for intermediates/semi-finished products) B7.2.4 (for finished products)
DM 21/03/1973 as amended	art. 8. b
Regulation (EU) 10/2011 as amended	art. 14; art. 15; Annex IV.8; Annex IV.9
Regulation (EC) 1935/2004 as amended	art. 15 art. 16.2
Notes	Note from the Ministry of Health no. 15844, 12/05/2011 Note from the Ministry of Health no. 32249, 11/10/2011 Note from the Ministry of Health no. 12174, 23/4/2010

Sheet B7.i Date of declaration

INDICATION	DESCRIPTION
Requirement 9	Date of declaration
Supporting documentation	
Present guideline	A1.3.2.2
DM 18/02/1984 as amended	art. 1
DM 243/1988	art. 1
DM 21/03/1973 as amended	art. 6
Regulation (EU) 10/2011 as amended	art. 15 Annex IV.4
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	-

B8. CORK: CORK STOPPERS

B8.1. Characterization of the sector

B8.1.1. Field of application of the guideline

Present guideline on Supporting Documentation (SD) for the Declaration of Compliance (DoC) is applicable to companies that producing the following products intended to come into contact with food as defined in paragraph. B8.1.1. in the document *Rapporto ISTISAN* 23/4 Rev. (8) this is, corks or parts of corks or any other material or articles for corks in which the main component is manufactured cork which, in the state of finished products, 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[24]. Exclusion from the application of this guideline does not automatically imply exclusion from the Regulation (EC) 2023/2006 as amended.

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.

B8.1.2. Applicable legislation

European legislation

- Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/CEE and 89/109/CEE as amended.
- Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as amended.
- Regulation (EU) 2017/625 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food as amended.

[24] The definition coincides with the definition in the Appendix of the "Resolution ResAP(2004)2 on cork stoppers and other materials and articles made of cork intended to come into contact with food".

Italian legislation

- DPR 777/1982 - Decree of the President of the Republic No. 777/1982 on implementation of the Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs as amended.
- DL.vo 108/1992 - Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- DL.vo 29/2017 - Legislative Decree No. 29/2017 on sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food.
- DM 21/03/1973 - Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, for contact with foodstuffs or substances for personal use as amended (for the parts relating to article 9.4).

B8.1.3. Relationships between GMP, SD, DoC

Present guideline analyses the content and correlation between the SD and the DoC, and the DoC themselves with reference to the Good Manufacturing Practice (GMP) standards relating to the production phases of cork stoppers intended for contact with food.

Figure B8.1 below illustrates, for example, the flow of correlation between activities and documents relating to the various phases of product development and implementation. For a more detailed description, however, see chapter B8.2.

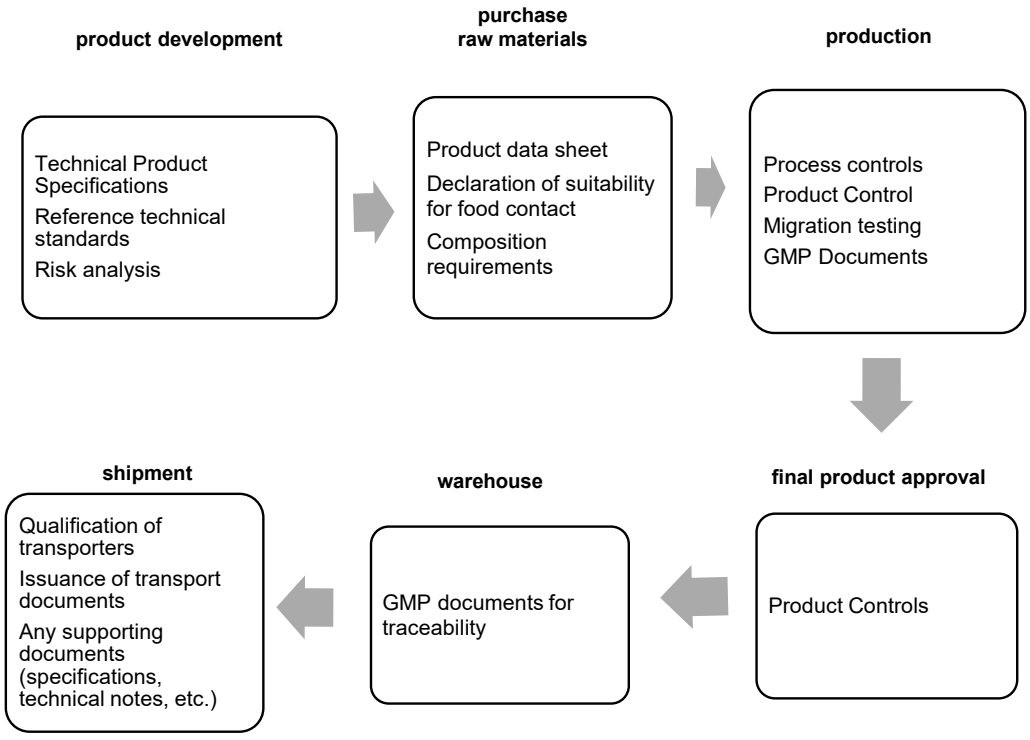

Figure B8.1. CORK STOPPERS:
production phases and correlation with SD for DoC

B8.1.4. Industrial processes for the production of cork stoppers

The flow diagrams and detailed descriptions of the production phases of the products are described in points B8.1.3. in the document *Rapporto ISTISAN* 23/4 Rev. (8).

Manufacturers of cork stoppers intended for contact with food are required to comply with Regulation (EC) 2023/2006 as amended and must therefore implement a Quality Management System (QMS) such as to ensure, in particular, process control and traceability. This system does not necessarily have to be according to ISO 9001.

B8.1.4.1. Product development and procurement of raw materials

Based on the needs deriving from the final use of the product to be made, the technical specification of the product is defined, and the production cycle is developed taking into account the regulations in force for materials and articles in contact with foodstuffs (Food Contact Materials, FCMs). All the parameters necessary for the control of production processes and product quality control are then defined. The documentation provided by the manufacturers of raw materials (e.g. technical data sheets, composition declaration, compliance declarations) is requested and evaluated in relation to the specifications of use, defined by the end customer, where available, and/or by the foreseeable directions for use.

It is good practice to provide for a supplier qualification process, as provided in the document *Rapporto ISTISAN* 23/4 Rev. (8) in par. B8.2.1.2.

B8.1.4.2. Production

For each process/product, the conditions that allow adequate control of the production process must be identified through the definition of a series of critical parameters by means of which product control is guaranteed. Adequate quality controls are carried out on the product, which verify its adherence to the reference specification. Traceability must be guaranteed for the entire production process.

B8.1.4.3. Final product approval

The product is approved on the basis of verification of its compliance with the specification. Depending on the results of the tests envisaged by the specification, the final evaluation of the product is carried out.

B8.1.4.4. Storage

Warehouse activities are also managed to maintain product traceability.

Consequently, the appropriate types of packaging of the material and the related identification markings must also be defined. It must always be possible to trace the quality status of the products in stock through the appropriate codes and operating procedures/instructions.

B8.1.4.5. Shipment

Shipment can take place with their own vehicles or through transporters who are selected on the basis of their ability to meet the quality requirements set by the companies, in order to maintain the compliance of the transported product with the reference standards.

Transport documents are not necessarily part of the documentation required by the legislation on FMCs, but they are part of other legislative obligations. However, transport documents may also include relevant and/or useful documentation (e.g. DoC, test reports, etc.) if not otherwise

shipped to the customer. Therefore, if a correlation with compliance documents is available in the transport documentation, this could facilitate traceability paths.

B8.2. Supporting documentation

B8.2.1. Introduction

It is good practice, as well as a requirement that can be deduced from Regulation (EC) 2023/2006 as amended that, in the face of a placing on the market of cork stoppers intended for contact with food, declared compliant with applicable laws, there is *an in-house* SD including both evidence of the correct implementation and implementation of GMP (documentation from suppliers, process verifications, etc.) and the results of any tests, analyses and other scientific evidence or arguments. In fact, this allows the producer to demonstrate full compliance with art. 3 of Regulation (EC) 1935/2004 as amended.

Specific documentation elements applicable to the operator's position in the supply chain are identified.

The documents that make up the SD should be reviewed periodically to reflect potential changes in materials and production processes, regulatory updates, supplier changes, or adaptations to technical progress.

The documents that make up the SD can also be made available and consulted through the use of databases or computer systems

It is not possible to establish in advance which and how many tests and related supporting documentation should be, since processes and treatments may vary over time and from company to company, but indicatively at least what is reported in the following paragraphs should be present/considered.

SD may concern a family of products: for example, the records of the checks carried out on a particular finished product are also recognized for products of the same type that have, compared to those of the material under test, less critical morphological characteristics (e.g. different thicknesses) and use (e.g. time, temperature).

B8.2.2. SD for cork stopper production

In the production of cork stoppers, the relevant phases of the production process, for the purposes of food compliance, are all those related to the controls and phases following the chemical treatments of the corks in which it is required that the absence of residues from treatments must be periodically checked. The following paragraphs describe the SD relating to the aforementioned phases.

B8.2.2.1. Raw materials

The SD should contain at least the following information:

- Product data sheets (document containing the characteristics of the product in relation to the expected quality and specific use).
- Appropriate information on restricted substances in foodstuffs and, where appropriate, compositional criteria in accordance with existing directives.

- DoC of the materials/objects received and used for the production of the cork stopper (e.g., washers, granulates, agglomerated cork cylinders, etc.). In the absence of the DoC, the manufacturer assumes responsibility for selecting materials/objects that guarantee the suitability of the cork for contact with food.
- Glue. Depending on the position in the supply chain, the SD will be available in the:
  - manufacturer or importer of caps, washers, agglomerated caps with or without washers: indication of the type of glue used, evidence on the migration of substances of toxicological interest;
  - manufacturer of caps, washers, agglomerated caps with or without washers: DoC to the migration of substances of toxicological interest released by the manufacturer or importer of caps, washers, agglomerated caps with or without washers, or indication of the type of glue used; evidence on the migration of substances of toxicological interest, if not carried out in the previous step. It should be noted that the control of compliance with this parameter does not necessarily have to be carried out for each batch, but, once the specifications on the starting materials have been established and the production process has been validated for the purpose of compliance with migration levels, compliance can be guaranteed by maintaining the process parameters within the GMP system. In this case, adequate documentation must be prepared in this regard.
- Inks. Since the inks are not intended to come into contact with food, appropriate GMP documentation will be prepared to demonstrate how this parameter is controlled. Annex I of Regulation (EC) 2023/2006 as amended and supplemented will be taken into account for the preparation of GMP documentation.
- Lubricants. Products and mixtures used for the lubrication of corks, including silicones, must comply with applicable food contact laws and specific regulations for the wine industry.
- Elements to support the traceability/selection of starting materials:
  - list of qualified suppliers or list of approved supplies;
  - supplier qualification criteria or supply approval criteria. This documentation should already be part of the GMP documentation required by Regulation (EC) 2023/2006 as amended.

B8.2.2.2. Production cycle/finished product

The SD should contain the following information:
- traceability of the cork;
- documentation relating to the product development phase;
- specifications of finished products – product technical sheet (document containing the characteristics of the product in relation to the expected quality);
- information to support the risk assessment;
- evidence on the migration of substances of toxicological interest, if not carried out in the previous step by the manufacturer or importer of caps, washers, agglomerated caps with or without washers.

The use of other substances or treatments for the cork stopper or its constituent parts falls under the responsibility of the manufacturer. Such use or treatment must therefore be governed by Regulation (EC) 2023/2006 as amended and the finished product must meet the general requirements of article 3 of Regulation (EC) 1935/2004 as amended. In this case, the manufacturer must produce and maintain adequate SD of the compliance of the cork stopper.

B8.3. Points of correspondence between DoC and SD

SD contains some specific elements that are mentioned directly by the DoC.

The DoC confirms to the next actor in the supply chain that the *compliance work* has been carried out, indicating if any, what further activities need to be carried out by the user.

As regards the SD prepared by the manufacturers of corks or their components, the reference documents for the DoC are at least:

- product description;
- possibly information that has been used to assess and support suitability for particular uses mentioned in the DoC.

B8.4. SD topics not necessarily covered by GMP documentation

Some topics supporting compliance of cork stoppers or their components intended for food contact may not necessarily be addressed within the GMP system of a given business organization.

For example, the company may have produced during the development phase an indicative documentation useful for the evaluation of the products but considers it unnecessary that this documentation be produced periodically and managed in the GMP system (e.g. use of glues, particular substances, etc.).

All this does not imply the lack of such documentation or the absence of compliance work but only the unsystematic execution of some activities. The documentation will in any case be traceable and traceable to the asset to which it refers.

Annex B8

Sheets for supporting documentation of cork stoppers

Regulatory references

Regulation (EC) 1935/2004 as amended
Regulation (EC) 2023/2006 as amended (where applicable)
Regulation (EC) 625/2017
DPR 777/1982
DL.vo 108/1992
DL.vo 29/2017
Note of the Ministry of Health no. 32249, 11/10/2011

To harmonize the sheets of all the supply chains, the nine points contained in Annex IV of Regulation (EU) 10/2011 as amended have been used, although this Regulation is not directly applicable to the supply chain of cork.

Sheet B8.a Economic operator issuing the compliance declaration

INDICATION	DESCRIPTION
Requirement 1	Identity and address of the economic operator issuing the DoC
Supporting documentation	Company and/or functional organization chart and/or delegation and/or management procedures and/or documentation deriving from the company policy establishing responsibilities
Present guideline	A1.3.2.2
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 16.2 art. 2.2, paragraph d
Notes	If the economic operator issuing the DoC is the same as the economic operator producing or importing, requirements 1 and 2 may coincide

Sheet B8.b Economic operator who produces or imports the good

INDICATION	DESCRIPTION
Requirement 2	Identity and address of the economic operator producing or importing: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished product *tick the relevant item*
Supporting documentation	Documentation proving the identity and address of the economic operator producing or importing raw materials/substances, intermediates/semi-finished products or finished products (e.g. specifications, transport documents, supply contracts, etc.)
Present guideline	A1.3.2.2
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 16.2 art. 2.2, paragraph d
Notes	If the economic operator issuing the DoC is the same as the economic operator producing or importing, requirements 1 and 2 may coincide

Sheet B8.c Identity of the asset

INDICATION	DESCRIPTION
Requirement 3	Identity of the asset to which the DdC refers: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished product *tick the relevant item*
Supporting documentation	Documentation for the identification of the asset (e.g. type of material/object, batch numbers, catalogue numbers, code numbers, etc.)
Present guideline	A1.3.2.2
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	Traceability documents can also be useful

Sheet B8.d Functional barrier

INDICATION	DESCRIPTION
Requirement 4	Information on the possible functional barrier
Supporting documentation	Not applicable
Present guideline	Not applicable
DL.vo 108/1992	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	This requirement does not apply

Sheet B8.e Compliance with EU regulations/national legislation

INDICATION	DESCRIPTION
Requirement 5	Declaration of compliance with EU Regulations and/or national legislation where applicable
Supporting documentation	Documentation proving the compliance of the materials/objects used (e.g. declarations of manufacturers of semi-finished products/panels/wire, specific checks, etc.)
Present guideline	B8.1.4.3 B8.2.2.1 and B8.2.2.2
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 3 art. 16.2
Notes	-

Sheet B8.f Restricted substances/materials

INDICATION	DESCRIPTION
Requirement 6	Adequate information about the substances and/or materials used and/or degradation products for which restrictions are in place
Supporting documentation	Not applicable
Present guideline	Not applicable
DL.vo 108/1992	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	This requirement is not applicable

Sheet B8.g Restricted substances/materials in foodstuffs

INDICATION	DESCRIPTION
Requirement 7	Adequate information on substances and materials used that are restricted in foodstuffs
Supporting documentation	Not applicable
Present guideline	B8.1.4.3 B8.2.2.1 B8.2.2.2
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	-

Sheet B8.h Directions for use

INDICATION	DESCRIPTION
Requirement 8	Indications for the use of FCMs: ❑ types of food products with which it is intended to come into contact ❑ duration, treatment temperature and storage in contact with food ❑ contact test conditions (simulant, duration, temperature) ❑ ratio of contact surface area to volume for determining compliance of FCMs ❑ restrictions on use *tick the relevant items*
Supporting documentation	Documentation proving compliance checks with the declared uses (e.g. composition declaration, analysis reports, etc.)
Present guideline	B8.2.2.2
DL.vo 108/1992	-
Regulation (EC) 1935/2004 as amended	art. 15
Notes	-

Sheet B8.i Date of declaration

INDICATION	DESCRIPTION
Requirement 9	Date of declaration
Supporting documentation	-
Present guideline	A1.3.2.2
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	-

B9. GLASS

B9.1. Characterization of the sector

B9.1.1. Field of application of the guideline

Present guideline on Supporting Documentation (SD) for the Declaration of Compliance (DoC) 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, either first by pressing and then by blowing the molten glass in two different moulds (so called press and blow process), or by blow and blow.

B9.1.2. Applicable legislation

European legislation

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

Italian legislation

- DPR 777/1982 - Decree of the President of the Republic No. 777/1982 on implementation of the Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs as amended.
- DL.vo 108/1992 - Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- DL.vo 29/2017 - Legislative Decree No. 29/2017 on sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food.
- DM 21/03/1973 - Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, for contact with foodstuffs or substances for personal use as amended.

B9.1.3. Phases of the production process: premises, flow scheme and description

In this guideline, the term "Company" is adopted to indicate the company as a whole, while the term "Glassworks" is used as a synonym for "plant" or "production site".

Present guideline takes up the scheme proposed in chapter B9 in the document *Rapporto ISTISAN* 23/4 Rev. (8), to which reference is made for the description of the glass production cycle. This document indicates the types of the various SD, useful and necessary to demonstrate the existence of the Requirements (R) to which the DoC refers.

For the glass industry, which produces glass containers, the requirements that are implicitly declared at the time of issuing the DoC are:

- R1: Overall Migration (DM 21/03/1973 as amended);
- R2: Specific migration (DM 21/03/1973 as amended);
- R3: Traceability/Traceability (art. 17 Regulation (EC) 1935/2004 as amended).

With regard to each of these, the glass companies shall keep and make available to the competent authority the relevant SD.

The documents that make up SD may be periodically revised to reflect potential changes in materials and production processes, regulatory updates, supplier changes or adaptations to technical progress.

The documents that make up the SD can also be made available and consulted through the use of databases or computer systems

SDs are distinguished by type according to the following nomenclature, which will be used in this chapter:

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

For each processing phase and each activity (8), the SD is associated with the Good Manufacturing Practice (GMP) standards relating to the work phase considered and at the same time is related to the Requirement (R) whose compliance is declared through the DoC.

B9.1.3.1. Flow diagram and brief description

The production chain of glass containers intended to come into contact with food can be divided into three main areas:

- Hot Zone (*Hot-End*)
  consisting of the sub-processes: Batch preparation, Melting, Forming and Annealing;
- Cold Zone (*Cold-End*)
  consisting of the sub-processes: Product Control, Packaging/Palletizing;
- Storage and shipment Zone.

The flow diagram in Figure B9.1 shows the production phases of a glass container and the controls applied by the glass industry that guarantee compliance with the suitability for food contact.

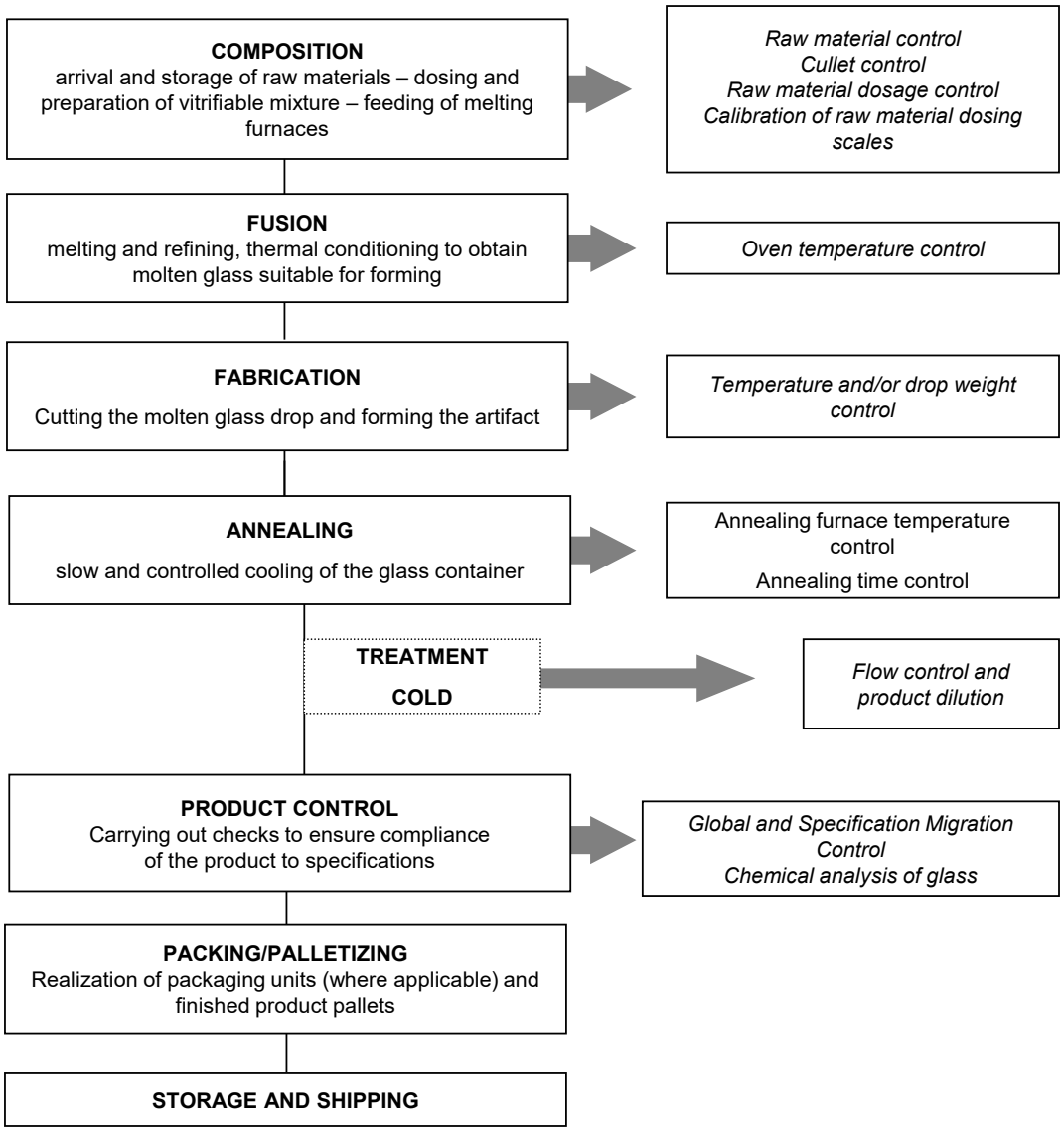

Figure B9.1. GLASS: production phases and correlation with SD for DoC
(in italics the controls directly linked to compliance with suitability for food contact)

B9.1.4. Hot Zone

B9.1.4.1. Batch preparation

Composition is the first sub-process encountered in the Hot Zone and concerns the reception and storage of raw materials and the preparation of the vitrifiable mixture.

Natural or synthetic raw materials (silica sand, sodium carbonate, calcium carbonate, dolomite, etc.) and cullet are suitably dosed, mixed and humidified in order to obtain the vitrifiable mixture (batch).

All natural and synthetic raw materials are of external origin, while cullet can derive from internal recycling of production rejects (so called internal cullet) and/or external separate collection and treatment of container glass waste (so called external cullet).

Natural and synthetic raw materials are normally stored in silos. The cullet is usually stored in heaps outside the plant and loaded into the dosing plant by means of a tractor loader.

The *batch*, i.e. the quantity of mixture transferred simultaneously to the furnace, with a total weight of between 500 and 2,000 kg, is sent directly to the melting furnace through a system of conveyor belts and loaded into the furnace by means of mechanical chargers.

B9.1.4.1.1. Controls

The raw materials are subjected to an acceptance process that essentially involves verifying their compliance with the required contractual requirements (product specification) and chemical-physical characterization according to the company's control procedures. The acceptance process is governed by internal company procedures.

The controls applied below:

- *Raw materials* (silica sand, sodium carbonate, calcium carbonate, dolomite, etc.)
  The purpose of the control is to ensure that the incoming raw materials correspond to what was ordered at the time of purchase (technical specification) and that they are fully discharged into the appropriate silos or destination areas in order to avoid possible contamination and mixing with other raw materials of different kinds.
  The control makes it possible to verify the compliance of raw materials with the chemical-physical specifications established by the companies and to reject non-compliant materials. In the event of problems encountered on production, it is possible to trace the causes attributable to the quality of the material supplied. Normally, in this phase, documentary and visual checks are carried out for all incoming loads. Humidity and particle size are then checked and chemical analyses are carried out on the samples taken according to internal control procedures.

- *Cullet*
  The purpose of the check is to ascertain that the incoming cullet complies with the specifications agreed with the suppliers in order to reject the non-compliant cullet. In the event of problems encountered on production, it is possible to trace the causes attributable to the quality of the material supplied.
  In particular, documentary and visual checks are carried out for all incoming loads in order to verify that the cullet complies with the requirements of the supply specifications. In accordance with the provisions of internal control procedures, chemical analyses are carried out on the samples taken.
  For both types of raw materials, it is possible to summarize the control procedure as follows:
  a) Upon arrival of the truck, raw material or cullet, at glassworks, the reception staff performs:
     - the registration in the entry form of the relevant data: date and time of entry; vehicle license plate and data of the haulier; type of cullet or raw material; supplier data; details of the transport document;
     - the entry checks required by the procedure, concerning in particular the visual verification of the material and its compliance with the requirements set out in the specifications.
     - the acceptance or refusal of the supply.
  b) At the end of the unloading operations, the operator in charge will return the countersigned transport document.

c) According to internal procedures, the Company will carry out the analytical controls required in relation to the raw materials and/or cullet collected, with particular attention to pollutants and impurities (ceramics, glass ceramics, pyrex, magnetic and non-magnetic metals, organic substances, stones, refractories and high-melting point substances, iron oxides, etc.).

- *Dosages of raw materials*
  The purpose of the control is to verify the dosage of raw materials through the use of calibrated scales, based on the composition of the glass to be obtained from the production process and after appropriate stoichiometric calculation.

- *Calibration of scales for dosing raw materials*
  The periodic check of the scales serves both to ensure the correctness of the dosages, in order to avoid inhomogeneity and variations in the chemical composition, and consequently in the physical properties of the glass, and to maintain the workability of the glass constant.
  The checks, carried out by personnel of the Company or a third party, involve the following operations:
  a) emptying and cleaning of scales;
  b) verification of the accuracy of the indication of "zero";
  c) positioning of the test weights on the scale until a load equal to the working weight (full scale of the balance) is reached;
  d) checking the accuracy of the indication;
  e) removal of the test weights and rechecking of the "zero" indication with possible recalibration;
  f) scale linearity check with specific checks.

B9.1.4.1.2. SD and verified requirements

For each of the controls described above, specific Registration Forms (RF) are prepared where all sensitive information relating to raw materials, their dosage and calibration of the balances are collected. These modules represent the SD necessary to verify the implementation of the GMP regulation and are reported in the procedures of each individual company.

Through the control of raw materials and scales, as well as the definition of specific tolerances, it is also possible to monitor and manage compliance with the following requirements prescribed by the DM 21/03/1973 as amended:

R1 = *Overall Migration* for type A, B, C Glass Containers.

R2 = *Migration Specific* for type C glass containers (for short and repeated contacts).

B9.1.4.2. Melting

The melting and refining process consists of a complex sequence of chemical-physical reactions that take place at high temperatures to transform the vitrifiable mixture into glass.

The temperature is a function of the chemical formulation of the glass and is between 1450 and 1550°C.

Before exiting the furnace, the molten glass is subjected to a refinement process that aims to make the molten glass homogeneous and bubble-free.

Melting and refining take place inside the melting furnace made of refractory material.

The plant is active 24 hours a day and is controlled by monitors and process computers that allow to constantly check the operating parameters.

At the exit of the melting furnace, the conditioning phase follows, which consists of the controlled cooling of the glass mass up to the so called gob temperature, normally between 1000 and 1350°C.

B9.1.4.2.1. Controls

- *Oven temperature*
  The control has the purpose of continuously verifying the temperature of the furnace through instrumental monitoring.

B9.1.4.2.2. SD and verified requirements

The melting process has no direct influence on the suitability of a container to come into contact with food and consequently there are no SD suitable for implementing Regulation (EC) 2023/2006 as amended. This process is mentioned only for the purpose of connecting with the document *Rapporto ISTISAN* 23/4 Rev. (8) as gross or sudden changes in the manufacturing parameters can be indicators of an anomaly in the composition. The company's internal procedures indicate the methods of detection, recording (RF) and intervention (O or WP).

B9.1.4.3. Fabrication

Glass containers intended to come into contact with food are produced with automatic machines capable of producing a high number of pieces per minute.

A distinction should be made between the manufacturing process of containers, understood as packaging (bottles and vases), and the manufacturing process of household items (goblets, glasses, cups, tumblers and plates).

For both manufacturing processes, the first phase is represented by the cutting of the molten glass drop, technically called gob or parison, which must have a well-defined shape, weight and temperature. The temperature of the glass gob is a function of the weight of the container and must also be adjusted according to the type of container you want to obtain from the process.

B9.1.4.3.1. Controls

- *Temperature of the glass in the gob formation phase*
  The purpose of the check is to verify that the temperature of the molten glass gob complies with the specification.
- *Gob weight*
  The purpose of the check is to verify that the weight of the drop remains within the tolerances required for the specific item and for the entire production batch.

B9.1.4.3.2. SD and verified requirements

The manufacturing process has no direct influence on the suitability of a container intended to come into contact with food and consequently there are no Support Documentation (SD) suitable for implementing Regulation (EC) 2023/2006 as amended. This process is mentioned only for the purpose of connecting with the document *Rapporto ISTISAN* 23/4 Rev. as gross or sudden changes in the manufacturing parameters can be indicators of an anomaly in the composition. The company's internal procedures indicate the methods of detection, recording (RF) and intervention (O or WP).

B9.1.4.4. Annealing

The rapid cooling of the outer surface of the container during the forming process creates tensions in the glass mass that induce mechanical brittleness in the glass part.

To eliminate these tensions, the glass container passes through the annealing furnace, where it is brought to a temperature of 550°C and then cooled very slowly to avoid creating new stresses.

B9.1.4.4.1. Controls

- *Temperature of the annealing furnace*
  The purpose of the check is to ensure that the temperatures of the annealing furnace are kept within the tolerances required for the specific container.
- *Annealing time*
  The purpose of the check is to ensure that the annealing time is sufficient to minimize the residual stresses present inside the container.

B9.1.4.4.2. Supporting documentation and verified requirements

The annealing process has no influence on the suitability of a container to come into contact with food and consequently there are no SD suitable for implementing Regulation (EC) 2023/2006 as amended. This process is mentioned only for the purpose of connecting with the document *Rapporto ISTISAN* 23/4 Rev. (8).

B9.1.5. Cold Zone

B9.1.5.1. Product control

Product control is the first sub-process encountered in the Cold Zone and concerns the manual and/or automatic quality control of all containers leaving the annealing furnace. The container's compliance with the predefined specifications is verified. Containers that are considered not compliant are automatically removed from the packaging line and are recycled in the same production process as internal cullet for remelting.

Physical and mechanical controls, continuous and/or on a statistical basis, are carried out with dedicated instrumentation, in order to obtain the quality level of the finished product that meets the needs of the target market of the product.

B9.1.5.1.1. Controls according to DM 21/03/1973

The legislation on materials and articles in contact with food requires the following migration controls for glass containers:

- *Overall migration*
  - For glass articles belonging to *Category A* (borosilicate and sodium-calcium, colourless or coloured glass) in any contact condition, including sterilisation, a test at 120 °C for 30 minutes with distilled water is envisaged, followed by evaporation of the aqueous solvent in a previously calibrated capsule and gravimetric determination of the residue.
  - For glass articles belonging to *Category B* (sodium-lime glass, also opaque) to be used in contact conditions not exceeding 80°C, a contact test with distilled water at 80°C for 2 hours is required, subsequent evaporation of the aqueous solvent in a previously calibrated capsule and gravimetric determination of the residue.

- For glass articles belonging to *Category C* (lead glass) intended for short and repeated contact, there are 3 contact tests at 40°C with distilled water and gravimetric determination of the residue after the third attack.

– *Specific migration for Category C glass*
  - Specific migration of lead after 3 contact tests with 3% acetic acid at 40°C for 24 hours each and determination of lead on the simulant from the third attack.

B9.1.5.1.2. Other analytical and process controls

In addition to the mandatory controls required by the Italian legislation on materials and articles in contact with food, the glassworks can also carry out further analytical checks, to verify that the glass obtained from the production process complies with certain technical specifications (e.g. environmental requirements, customer specifications, compliance with technical standards on specific migration, etc.) and with mandatory standards present in some European countries, listed below:

– *Verification of the limits for specific migration according to ISO 7086 for soda lime glass (categories A and B)*
  For sodium-lime glass (categories A and B), the ISO 7086-1:2019 standard provides for the determination of lead and cadmium on acetic extracts from a test conducted in acetic acid at 22±2°C for 24 h on 4 containers. Such control is not binding.

– *Verification of the limits for specific migration according to ISO 6486 for ceramic, glass-ceramic and tableware*
  For ceramic, glass-ceramic and glassware referred to as *dinner ware* (articles for serving food on the table, including plates) and glassware referred to as *flatware* (with a depth of less than 25 mm), it is possible to control the specific migration of lead and cadmium by applying ISO 6486:2019 (*Ceramic ware, glass ceramic ware and glass dinnerware in contact with food – Release of lead and cadmium part 1 Test method and 2 Permissible limits*). Such control is not binding.

– *Verification of limits for specific migration according to German legislation*
  BfR Recommendations on Food Contact Materials: DIN EN 1388-2 e DIN51031-DIN51032.
  For food contact packaging, it is necessary to control the specific migration of lead and cadmium, including in the mouth contact area, after contact with a 4% acetic acid solution at 22°C for 24 hours. These migrations have limit values.

– *Verification of the limits for specific migration according to the German standard DIN 51031-51032 for decorated articles*
  For decorated articles, it is possible to control the specific migration of lead and cadmium by applying the German standard DIN 51031-51032:1986 (*Determination of release of lead and cadmium from silicate surfaced article intended for use in contact with fooSDtuff*), which provides for the determination of these metals from glass, ceramic and glass-ceramic articles both inside the articles themselves (*flatware* and holloware, without distinction), and in the area of the "drinking rim", i.e. the area in contact with the mouth at 20 mm from the edge. Such control is not binding.

- *Verification of limits for specific migration according to French legislation*
  DGCCRF MCDA sheet n°2(V01-01/05/2016) *Suitability for food contact of inorganic materials (excluding metals and alloys) intended to come into contact with foodstuffs. Glass - crystal - ceramic - glass-ceramic glazed objects*
  For glass, crystal, ceramic and glass-ceramic glazed articles according to French legislation, it is necessary to control the migration of lead, cadmium and chromium (VI) after a first contact with 4% acetic acid at 22°C for 24 hours and the migration of aluminium, cobalt and arsenic at the third attack under the same conditions. These migrations have limit values.

- *Verification of limits for specific migration according to Dutch legislation*
  Regulation of the Minister for Public Health, Welfare and Sport of 14 March 2014, laying down the Commodities Act Regulation on packaging and consumer articles coming into contact with foodstuffs (Commodities Act (Packaging and Consumer Articles) Regulation [Warenwetregeling verpakkingen en gebruiksartikelen])
  For all packaging in contact with food products, it is necessary to control not only the overall migration but also the specific migration of antimony, arsenic, barium, boron, cadmium, cerium, chromium, fluorine, cobalt, lithium, lead, manganese, nickel, rubidium and zirconium after contact with 3% acetic acid at 22°C for 24 hours. These migrations have limit values.

- *Cold treatment control*
  The cold treatment is aimed at optimizing the sliding of the containers on the filling lines and is carried out by applying specific products on the external surface of the article. The following checks are carried out, which are not of a binding nature:
  - adjustment and tuning of the equipment;
  - product flow control;
  - product dilution control.

Additional regulations may be present in other European and non-European countries, however it is believed that the verification of those above allows almost all situations to be covered. Please refer to Part C for further information on the sector.

B9.1.5.1.3. SD and verified requirements

To carry out each of the checks described above (B9.1.5.1.1. and B9.1.5.1.2) specific Registration Forms (RF) and Operating or Work Procedure (O or WP) are prepared:

- *Overall migration for Category A, B, C glass and specific migration for lead glass (Category C)*
  The sampling methods and the frequency of controls are defined by specific internal company procedures (MP or O). The checks are normally carried out by an external laboratory accredited according to the UNI EN ISO 17025 standard (e.g. Glass Experimental Station). Each company must have analysis reports to demonstrate compliance with current legislation (MR).

- *Specific migration according to ISO 7086:2019 for soda lime glass (Categories A and B), specific migration according to DIN 51031/1986 and 51032/1986, specific migration according to ISO 6486/2019*
  The sampling methods and frequency of controls are defined by specific internal company procedures (MP or O). The checks are normally carried out by an external laboratory

accredited according to the UNI EN ISO 17025 standard (e.g. Glass Experimental Station) and the analysis reports are kept by the Company (RF).

– *Chemical analysis of glass*
Each company provides for controls, with an expiry date defined internally on the basis of specific internal company procedures (MP or O), of the composition of the glass. These checks can be carried out either internally or by an external laboratory (e.g. Glass Experimental Station). Each company will have an Analysis Report issued by an external laboratory or an Internal Analysis Report (RF).

– *Cold treatment*
Each company will have operating procedures (O or WP) to be made available to personnel in relation to the adjustment and tuning of equipment, control of product flow and control of product dilution. For the latter, the company will also have an RF.

B9.1.5.2. Packaging/palletizing, storage and shipment

The packaging, generally the 'pallet', has the task of protecting the product during storage and transport. For household items, there is normally primary packaging (basket or trunk of 4/6 pieces) which is placed in a secondary packaging consisting of a American or master box.

To meet the requirement of traceability of the container intended for food contact, glass companies adopt the practice of clearly labelling and identifying the individual sales unit to the customer.

Properly labelled packaging is stored in warehouses organised by sectors, so that the required item can be immediately located.

B9.1.5.2.1. Controls

Through all the control systems of the finished product, it is possible to monitor and manage compliance with the Requirement defined as "R3" or "Traceability and tracking":

– *Storage of the products in the warehouse*
Every company must have a procedure available that authorizes the storage of finished products. The authorization for the storage of finished products and their shipment to customers takes place after all the checks required by the control procedure have been carried out to ascertain the final suitability for the use for which the finished products are intended.
For any products that are not suitable for internal controls or coming from returns due to non-compliance detected by customers, a procedure must be in place that allows identification and prevents shipment. Any finished products returned by customers because they are non-compliant must be stored in a predefined area and clearly identified.
The environmental and storage conditions of the warehouse area must be such as to preserve the suitability of the containers for the use for which they are intended.

– *Shipment of the finished product*
Each company provides controls and records relating to the shipment of finished products to customers.

B9.1.5.2.2. SD and verified requirements

– *Storage of the products in the warehouse*
Each company has Operational (O or WP) and Registration Forms (RF) available for the storage of finished products.

- *Shipment of the finished product*
  Each company has Operational (O or WP) and Registration Forms (RF)available for the shipment of the finished product. Transport documents are issued for finished goods.

B9.2. Supporting documentation

B9.2.1 Introduction

The documents that make up the SD should be reviewed periodically to reflect potential changes in the batch formulation or chemical composition, changes in materials and production processes, regulatory updates, changes in suppliers, or adaptations to technical progress.

The documents that make up the SD can also be made available and consulted through the use of databases or computer systems.

SD may concern a family of products: for example, the records of the checks carried out on a particular finished product are also recognized for products of the same type that present, compared to those of the material under test, less critical morphological and use characteristics (e.g. time, temperature).

B9.3. Points of correspondence between DoC and SD

SD contains some specific elements that are mentioned directly by the DoC, namely:
- product description;
- applicable legislation.

B9.4. SD topics not necessarily covered by GMP documentation

Some topics supporting the compliance of products in contact with food may not necessarily be managed within the GMP system of a given company organization.

For example, the company may have produced during the product development phase an indicative documentation useful for the evaluation of products and consider it unnecessary for this documentation to be produced periodically and managed in the GMP system.

All this does not imply the lack of such documentation or the absence of compliance work but only the unsystematic execution of some activities. The documentation will in any case be traceable and traceable to the asset to which it refers.

Annex B9

Sheets for supporting documentation of glass food contact materials

Regulatory references

Regulation (EC) 1935/2004 as amended
Regulation (EC) 2023/2006 as amended (where applicable)
Regulation (EC) 625/2017
DM 21/03/1973 as amended
DPR 777/1982
DL.vo 108/1992
DL.vo 29/2017
Note of the Ministry of Health no. 32249, 11/10/2011

To harmonize the sheets of all the supply chains, the nine points contained in Annex IV of Regulation (EU) 10/2011 as amended have been used, although this Regulation is not directly applicable to the supply chain of glass.

Sheet B9.a Economic operator issuing the compliance declaration

INDICATION	DESCRIPTION
Requirement 1	Identity and address of the economic operator issuing the DoC
Supporting documentation	Company and/or functional organization chart and/or delegation and/or management procedures and/or documentation deriving from the company policy establishing responsibilities
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6 art. 8, paragraph c
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	If the economic operator issuing the DoC is the same as the economic operator producing or importing, requirements 1 and 2 may coincide. To identify the responsibilities referred to this Requirements, please refer to art. 2 paragraph d) of Regulation (EC) 1935/2004 as amended

Sheet B9.b Economic operator who produces or imports the good

INDICATION	DESCRIPTION
Requirement 2	Identity and address of the economic operator producing or importing: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished products *tick the relevant item*
Supporting documentation	Documentation proving the identity and address of the economic operator producing or importing raw materials/substances, intermediates/semi-finished products or finished products. (e.g. specifications, transport document, supply contracts, etc.)
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6 art. 8, paragraph c
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	If the economic operator issuing the DoC, it is the same as the economic operator producing or importing, requirements 1 and 2 may coincide. To identify the responsibilities referred to in this Requirements, please refer to art. 2 paragraph d) of Regulation (EC) 1935/2004 as amended

Sheet B9.c Identity of the asset

INDICATION	DESCRIPTION
Requirement 3	Identity of the asset to which the DoC refers: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished products *tick the relevant item*
Supporting documentation	Documentation for the identification of the asset (e.g. type of material/object, batch numbers, catalogue numbers, code numbers, etc.)
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6 art. 35
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	Traceability documents can also be useful

Sheet B9.d Functional barrier

INDICATION	DESCRIPTION
Requirement 4	Information on the possible functional barrier
Supporting documentation	Not applicable
Present guideline	Not applicable
DM 21/03/1973 as amended	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	This requirement does not apply

Sheet B9.e Compliance with EU regulations/national legislation

INDICATION	DESCRIPTION
Requirement 5	Declaration of compliance with EU Regulations and/or national legislation where applicable
Supporting documentation	Supporting documentation: – category of glass used, in relation to its composition; – verification of limits for overall migration; – verification of the limits for specific migration and subsequent amendments for lead glass (Category C)
Present guideline	B9.1.5.1.1 B9.1.5.1.3
DM 21/03/1973 as amended	art. 6 art. 34 art. 3 Annex II sez 5
Regulation (EC) 1935/2004 as amended	art. 16.2 art. 3
Notes	For references to useful technical standards, even if not mandatory, see par. B9.1.5.1.2 of this guideline

Sheet B9.f Restricted substances/materials

INDICATION	DESCRIPTION
Requirement 6	Adequate information about the substances and/or materials used and/or degradation products for which restrictions are in place
Supporting documentation	Documentation proving the verification of the limits for specific migration according to DM 21/03/1973 as amended lead glass (Category C)
Present guideline	B9.1.5.1.1
DM 21/03/1973 as amended	All II sez. 5
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	For useful references, even if not mandatory, see par. B9.1.5.1.2 of this guideline

Sheet B9.g Restricted substances/materials in foodstuffs

INDICATION	DESCRIPTION
Requirement7	Adequate information on substances and materials used that are restricted in foodstuffs
Supporting documentation	Not applicable
Present guideline	Not applicable
DM 21/03/1973 as amended	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	This requirement is not applicable

Sheet B9.h Directions for use

INDICATION	DESCRIPTION
Requirement 8	Indications relating to the use of FCMs: ❑ types of food products with which it is intended to come into contact ❑ duration, treatment temperature and storage in contact with food ❑ contact test conditions (simulant, duration, temperature) ❑ ratio of contact surface area to volume for determining compliance of FCMs ❑ restrictions on use *tick the relevant items*
Supporting documentation	Documentation proving compliance checks with the declared uses (e.g., composition statements, analysis reports, migration tests, etc.)
Present guideline	B9.1.5.1.1 B9.1.5.1.3
DM 21/03/1973 as amended	art. 35 - All II sez 5 art.8b
Regulation (EC) 1935/2004 as amended	art. 16.2 art. 15
Notes	For references to useful technical standards, even if not mandatory, see par. B9.1.5.1.2 of this guideline

Sheet B9.i Date of declaration

INDICATION	DESCRIPTION
Requirement 9	Date of declaration
Supporting documentation	-
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	-

B10. COATING

B10.1. Characterization of the sector

B10.1.1. Field of application of the guideline

Present guideline on Supporting Documentation (SD) for the Declaration of Compliance (DoC) applies to all companies that produce coating products for metal and aluminium packaging intended to come into contact with foodstuffs.

B10.1.2. Applicable legislation

European legislation

- Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/CEE and 89/109/CEE as amended.
- Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as amended.
- Regulation (EU) 2017/625 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- Regulation (EU) 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food (It applies to paints for boxes and lids, seals for capsules).

Italian legislation

- DPR 777/1982 - Decree of the President of the Republic No. 777/1982 on implementation of the Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs as amended.
- DL.vo 108/1992 - Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- DL.vo 29/2017 - Legislative Decree No. 29/2017 on sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food.
- DM 21/03/1973 - Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, for contact with foodstuffs or substances for personal use as amended.

Currently, there is no specific legislation at European level that regulates coatings for metal and aluminium intended to come into contact with foodstuffs. Therefore, at EU level, coatings

fall, like all materials intended for use in contact with food, under the general EU regulations mentioned above.

Coatings for metal and aluminium also refer to Regulation (EU) 10/2011 as amended exclusively with regard to additives contained in the single list of authorised substances as reported in DM 21/03/1973 as amended and in particular in Annex II, section I - part b "Additives for plastics" last replaced by the entry into force of Annex I of Regulation (EU) 10/2011 as amended.

Important clarifications relating to coatings can be found in the EU document "Union Guidance on Regulation (EU) N.10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain" published by DG Sanco in 2013 (hereinafter referred to in the text as DG Sanco 2013) (10).

For the applicability at Italian level of the DM 21/03/1973 as amended to the sector, a useful reference is also the Note of the Ministry of Health no. 15844, 12/05/2011.

B10.1.3. Relationships between GMP, SD and appropriate information

Present guideline analyses the content and correlation between SD and Appropriate Information (AI), as defined by Regulation (EU) 10/2011 as amended and by the DG Sanco 2013 Guideline, as well as between the AI themselves with reference to the GMP (Good Manufacturing Practice) system relating to the production phases of coatings for metal and aluminium packaging.

Figure B10.1 represents, for example, the correlation flows between activities and documents relating to the various phases of product development and implementation.

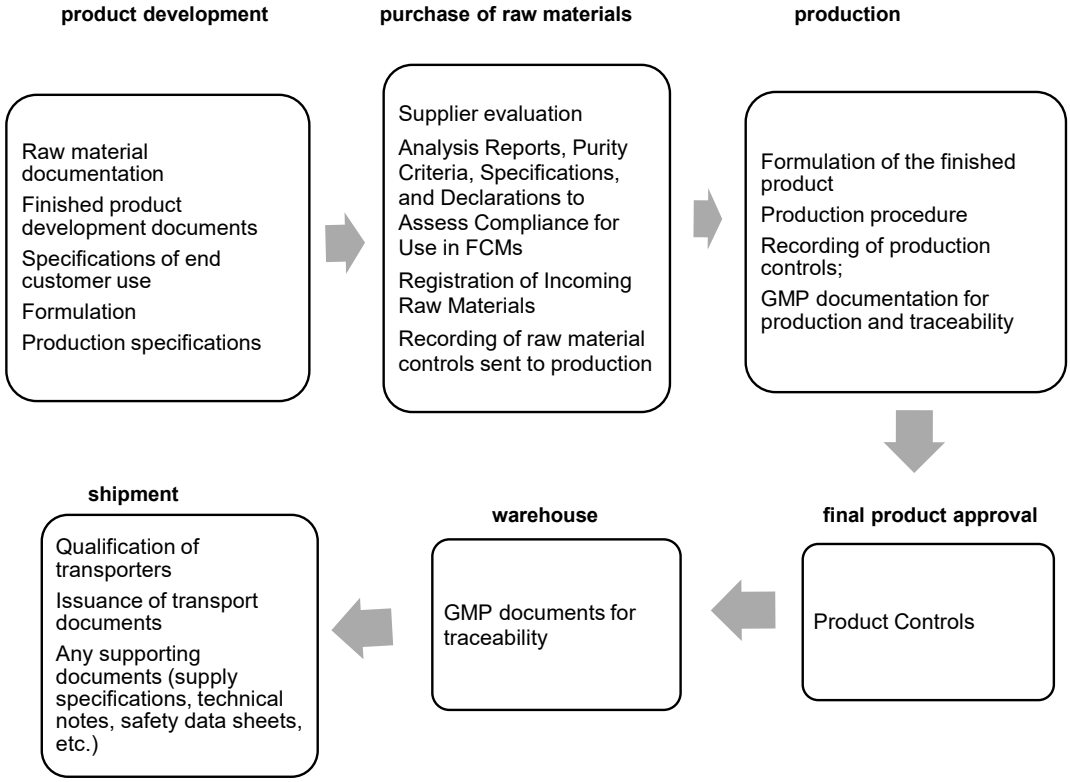

Figure B10.1. COATING PRODUCTS ON METALS (coatings): production phases and correlation with SD for DoC

For a more detailed description, however, see chapter B10.2. It is important to note that AI can be emitted as early as the product development process, as you already have all the necessary information. SD is developed during all industrial processes from product development to shipment of the finished product.

B10.1.4. Industrial processes

The flow diagrams and the detailed description of the production phases are described in point B10.1.5 in the document *Rapporto ISTISAN* 23/4 Rev. (8).

Manufacturers of coatings for metal packaging for food must implement, organize and maintain a quality assurance system capable of ensuring the achievement of the objectives set out in Regulation (EC) 2023/2006 as amended, such as to guarantee, in particular, process control and traceability.

B10.1.4.1. Product development

Based on market needs, the coating manufacturer develops a product that meets the technical requirements arising from the applications. Based on the final use of the product to be made, the technical specification is defined, and the production cycle is developed taking into account the regulations in force for materials and articles in contact with foodstuffs (Food Contact Materials, FCMs).

All the parameters necessary for the control of production processes and product quality control are then defined.

For each raw material, technical specifications are agreed between the supplier and the coating manufacturer. The documentation provided by the manufacturers of raw materials (e.g. technical data sheets, composition declaration, compliance declarations, adequate information) is requested and evaluated in relation to the specifications of use, defined by the end customer, where available, and/or by the foreseeable directions for use.

B10.1.4.2. Purchase of raw materials

The raw materials acquisition process involves the approval of suppliers who are able to supply the raw materials necessary for the production of the material under development and to meet the required technical and quality specifications taking into account the final application in FCMs.

It is good practice to provide for a supplier qualification process, as provided for in chapter B10.2 in the document *Rapporto ISTISAN* 23/4 Rev. (8).

Each raw material is identified by a technical specification, containing technical information and information regarding the suitability for use in FCMs, which possible suppliers must always meet. The company shall verify the correspondence between the specifications provided by the supplier and the required technical specifications and, if so, approve the supplier's raw material. This process is applied to every raw material and every supplier. The supplier shall accompany, where appropriate, its product with technical documentation, adequate information, compliance/composition statements, analysis reports. Upon entering the factory, raw materials are subjected to an acceptance, verification and storage procedure.

For each raw material, is requested – or is ensured to be present in the technical documentation – a DoC in accordance with the national and international legislation in force. Sector guidelines are also considered for guidance (*see* Part C of this document)

For the selection criteria for raw materials and their identification, please refer to par. B10.2.1.2 "Production" in the document *Rapporto ISTISAN* 23/4 Rev. (8).

B10.1.4.3. Production

For each production batch, a document relating to it is issued, which provides details about the raw materials, the quantities to be used, the equipment to be used, the manufacturing methods and the laboratory controls to be carried out in the various phases of the production process.

Only raw materials that have passed quality control can be used in the quantities and proportions necessary to obtain the required product quality.

The equipment used must be suitable for producing the required product and kept in good operating condition, clean and, where necessary, maintained and/or calibrated.

For each phase of the production process, records of the activities carried out must be maintained, to ensure the traceability of the finished product.

Refer to paragraphs: B10.2.1.2. "Production", B10.2.2.1 "Management of raw materials warehouse ", B10.2.2.2 "Production controls" in the document *Rapporto ISTISAN* 23/4 Rev. (8).

B10.1.4.4. Final product approval

Before final approval, the product undergoes a series of quality checks during production. Operating instructions and procedures describe how controls are to be carried out (standard or internal methods) and to ensure traceability. The data resulting from quality control operations are appropriately recorded, often in computerized tables or databases.

After final approval, the product is made available for marketing.

Refer to par. B10.2.2.3 "Quality control of the finished products" in the document *Rapporto ISTISAN* 23/4 Rev. (8).

B10.1.4.5. Storage

Each product is identified by a specific trade name, a reference number and a specific *batch* number, the packaging is selected in such a way as to maintain the characteristics of the coating and protect it from external agents during transport and storage.

Warehouse activities, such as:

- the transfer of the finished product to the warehouse,
- picking and shipment operations,
- the selection of carriers and the checks to be carried out on the means of transport, are managed to ensure product traceability (operating instructions and procedures).

Refer to par. B10.2.2.4. "Management of finished products warehouse" in the document *Rapporto ISTISAN* 23/4 Rev. (8).

B10.1.4.6. Shipment

Carriers are selected on the basis of their ability to meet the quality requirements set by the companies, in order to maintain the compliance of the transported product with the reference standards.

Transport documents are not necessarily part of the documentation required by the legislation on FMC, but they are part of other legislative obligations. However, transport documents may also include relevant and/or useful documentation (e.g. technical data sheets, composition statements, test reports, etc.) if not sent to the customer in any other way. Therefore, if a correlation with compliance documents is available in the transport documentation, this could facilitate traceability paths.

Refer to par. B10.2.2.5 "Distribution, shipment and delivery" in the document *Rapporto ISTISAN* 23/4 Rev. (8).

B10.2. Supporting documentation

B10.2.1. Introduction

The purpose of this section is to clarify the requirements in relation to SD regarding materials and articles intended to come into contact with foodstuffs (*see* general part).

Specific documentation elements applicable to the operator's position in the supply chain are identified.

The documents that make up the SD should be reviewed periodically to reflect potential changes in the composition of formulations, changes in materials and production processes, regulatory updates, changes in suppliers or adaptations to technical progress.

SD may concern a family of products: for example, the records of the controls carried out on a particular finished product are also recognized for products of the same type that have, compared to those of the material under test, less critical morphological characteristics (e.g. different thicknesses) and use (e.g. time, temperature).

The documents that make up the SD can also be made available and consulted through the use of databases or computer systems.

Since a risk assessment is required, it is good practice that this is carried out in collaboration with the customer, in order to verify that all the processes involved in the manufacture of the final article guarantee compliance with Article 3 of Regulation (EC) 1935/2004 as amended. In fact, in the application phase, a whole series of parameters are not part of the possibilities of direct control by the coating manufacturer, and situations of non-compliance with the requirements of European and national legislation regarding materials and articles in direct contact with food may therefore occur.

In this sense, it is therefore very important that an exchange of information takes place between the coating manufacturer and the user in order to prevent the production technique or post-production treatments (forming) from affecting the compliance of the final article.

Joint risk assessment may be part of trade agreements between the parties.

B10.2.2. SD for raw materials producers

The raw materials used in the production of coatings can be divided into 2 categories as far as SD is concerned:

- basic substances;
- mixtures and/or polymers.

Both types of raw materials are purchased from an external supplier and the SD for the two categories is listed below.

B10.2.2.1. Raw materials: basic substances

Although they are not required to comply with Regulation (EC) 2023/2006 as amended, suppliers of basic substances used in the formulation of coatings for metal and aluminium intended for contact with food, as an indispensable basis for the qualification of suppliers, should have implemented a quality management system (ISO 9001 or similar) that guarantees in particular the control of activities, of processes and traceability. These requirements also apply to substances imported into the European Union (EU).

Producers of basic substances are not subject to the rules on the DoC for plastics at EU level, but it is recommended to share Adequate Information with coating manufacturers (*see* DG Sanco 2013 par. 4.2.2) (10).

The SD for basic substances used in the production of coatings should at least contain the following information, with regard to substances with restrictions in Regulation (EU) 10/2011 as amended:

- Product identification (chemical name, trade name, etc.) and supplier;
- Technical specifications of the product (document that contains the characteristics that identify the qualitative status of the product);
- Chemical identity of the substance (CAS number, Chemical Abstract Service, FCMs number[25], chemical name, in case of dual use additive E or FL number[26], etc.);
- Purity/titre requirements: information that may be necessary to ensure compliance with specific provisions of the applicable legislation;
- If available information on possible products and processes of degradation of the substance (e.g. oxidation products, hydrolysis, etc.);
- When known, information on the toxicity of the substance and, if available, of the breakdown products under foreseeable conditions of use;
- Any information on the stability of the product (if available) and the consequent limitations of use (if known, e.g. degradation of an additive at specified process temperatures);
- Any other information that allows the user of the substance to carry out the risk assessment in accordance with the principles of Article 19 of Regulation (EU) 10/2011 as amended according to the conditions of use (*see* DG Sanco 2013 par. 4.2.2 paragraph 8) (10).

B10.2.2.2. Raw materials: mixtures and/or polymers

Although they are not required to comply with Regulation (EC) 2023/2006 as amended, suppliers of basic substances used in the formulation of coatings for metal and aluminium intended for contact with food as an indispensable basis for the qualification of suppliers should have implemented a quality management system (ISO 9001 or similar,) that guarantees in particular the control of activities, of processes and traceability. These requirements also apply to blends and polymers imported into the EU.

Manufacturers of mixtures and/or polymers for the formulation of coatings are not subject to the DoC Regulations for plastics at EU level, but the sharing of appropriate information with coating manufacturers is recommended. These requirements also apply to blends and polymers imported into the EU.

The SD should contain at least the following information:

- Product identification;
- Technical specifications of the product (document that contains the characteristics that identify the qualitative status of the product);
- Adequate supplier information regarding mixtures and/or polymers to Regulation (EC) 1935/2004 as amended including references to applicable European and national legislation, including any restrictions on use;
- Chemical identity of the substances/mixtures contained (CAS number, FCM number, chemical name, etc.);
- Information regarding the presence of dual use substances (E or FL numbers) listed in Regulations (EC) 1333/2008 and Regulations (EC) 1334/2008;
- Purity requirements: information that may be necessary to ensure compliance with specific provisions of the applicable legislation;

[25] From the Regulation (EU) 10/200: FCM substance No = the unique identification number of the substance Food Contact Material.

[26] In the case of dual-use additives, the E number for food additives or the FL number for flavourings must also be indicated.

– If available information on possible products and processes of degradation of the substance (e.g. oxidation products, hydrolysis, etc.);
– Toxicological information on the product and, if available, of the breakdown products under foreseeable conditions of use, when known;
– Any information on the stability of the product (if available) and the consequent limitations of use (if known) (e.g. degradation of an additive at specified process temperatures);
– Any other information that allows the coating user to carry out the risk assessment in accordance with the principles of Article 19 of Regulation (EU) 10/2011 as amended according to the conditions of use (*see* DG Sanco 2013 par. 4.2.2 paragraph 8) (10).

B10.2.3. SD for production cycle/finished products

The SD for production cycle and finished products should at least contain the following information:

1. *Coating formulation*
   – Product description (trade name and chemical description);
   – Information on the composition/list of ingredients and their quantities.
2. *Collection of relevant information from raw materials suppliers and evaluation of the composition for the purpose of demonstrating compliance of use in FCMs*
   – Identification of raw materials: chemical composition of the product;
   – Adequate supplier information on compliance with Regulation (EC) 1935/2004 as amended including references to applicable European and national legislation, including any restrictions on use;
   – Any analyses and/or calculations to assess compliance with restrictions in the case of substances subject to restrictions in national and European legislation;
   – Confirmation that a risk assessment has been carried out in relation to the presence of NIAS (Non-Intentionally Added Substances) or relevant information is reported to enable the regulatory compliance verification to be completed. The level of detail and in-depth analysis can be assessed with the logic called "case by case".[27]
3. *Information on the production cycle*
   – Records of production parameters;
   – Recording of quality control in production and finished products;
   – Specifications of finished products;
   – Traceability documents;
   – If you notice the use and all the information relating to the composition and destination of the final product, as well as the production process in which the coating is used. There may also be migration assessments of substances with SML (Specific Migration Limit), obtained by means of tests, mathematical models or calculations in accordance with screening methods. For example, the documentation available in the form of analysis reports, or mathematical modelling, or supplier declarations, might be as follows:
     - overall and specific migration test results, if applicable and if known end-use;
     - results of migration simulations, using mathematical models and calculations in accordance with the provisions of Regulation (EU) 10/2011 as amended;[28]

[27] Concept introduced for plastic FCMs in DG Sanco 2013 par. 4.3.2 point 8 (10).
[28] It should be noted, however, that, for the applicable parts derived from the DM 21/03/1973 as amended as amended, the legislative reference in force continues to be the Decree of 22 July 1998, no. 338 of the Ministry of Health which transposes Directive 97/48/EC.

- mathematical calculations of total transfer, i.e. assuming a complete migration of substances from the *coating* to the food;
- if one of the three points has already been verified by another player in the supply chain (upstream or downstream), the relative declaration.

Not all the documents indicated need necessarily be present in the SD collection for a certain material or process, but only the documents deemed necessary to support and justify the assessments that allow the Appropriate Information to be issued (Composition Statement).

B10.3. Matching points between the appropriate information and SD

It is recommended that the manufacturer provide all Appropriate Information (AI) (DG Sanco 2013 par. 4.2.2.) (10) also through the issuance of the DoC.

The coating manufacturer has the necessary information to ensure the compliance of the coating product applied with the provisions of DM 21/03/1973 as amended and verifies compliance with the applicable Overall and Specific Migration Limits, to comply with the provisions of Article 3 of Regulation (EC) 1935/2004 as amended. The coating manufacturer also has information on any dual use additives undertakes to communicate their presence within the AI or in the DoC.

The SD contains some specific elements relevant to the emission of AI such as:

- product identification;
- information on the presence of substances listed in restricted national and EU legislation; information on the presence of substances listed in the provisional list of additives used in plastics;
- information on the presence of dual-use substances.

B10.4. Points of correspondence between GMP and SD

For coating manufacturers, some documents included in the GMP documentation are listed that are also used in SDs:

- raw materials specifications (supplier declarations);
- specifications of finished products;
- production specifications (operating instructions and procedures);
- information on migration analysis (if provided for in the company's Quality System or GMP);
- recording production parameters;
- registration of quality controls for finished products.

B10.5. SD topics not necessarily covered by GMP documentation

Some topics supporting the compliance of food contact products may not necessarily be addressed within the GMP system of a given business organization.

For example, the company may have produced during the development phase an indicative documentation useful for the evaluation of products, but considers it unnecessary for this documentation to be produced periodically and managed in the GMP system (e.g. use of particular substances, etc.).

All this does not imply the lack of such documentation or the absence of compliance work but only the unsystematic execution of some activities. The documentation will in any case be traceable and traceable to the asset to which it refers.

Annex B10

Sheets for supporting documentation of coated metal products (coating) food contact materials

Regulatory references

Regulation (EC) 1935/2004 as amended
Regulation (EC) 2023/2006 as amended (where applicable)
Regulation (EC) 625/2017
Regulation (EU) 10/2011 as amended
DPR 777/1982
DL.vo 108/1992
DM 21/03/1973 as amended
DL.vo 29/2017
Guideline "Union Guidance on Regulation (EU) n. 10/2011 on plastic materials and articles intended to coming into contact with food as regards information in the supply chain" hereinafter referred to as DG Sanco 2013.
Note of the Ministry of Health no. 32249, 11/10/2011

To harmonize the sheets of all the supply chains, the nine points contained in Annex IV of Regulation (EU) 10/2011 as amended have been used, although this Regulation is not directly applicable to the supply chain of coating products on metals (coatings)

Sheet B10.a Economic Operator Issuing the Appropriate Information (AI)

INDICATION	DESCRIPTION
Requirement 1	Identity and address of the economic operator issuing the appropriate information (declaration of composition)
Supporting documentation	Company and/or functional organization chart and/or delegation and/or management procedures and/or documentation deriving from the company policy establishing responsibilities
Present guideline	A1.3.2.2
DG Sanco 2013	4.3.2.1
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 2.2 paragraph d art. 16.2
Note	If the economic operator issuing the appropriate information (composition declaration) is the same as the economic operator producing or importing the articles in question, requirements 1 and 2 may be the same. To identify the responsibilities referred to this Requirements, please refer to Article 2 paragraph d of Regulation (EC) 1935/2004 as amended

Sheet B10.b Economic operator who produces or imports the good

INDICATION	DESCRIPTION
Requirement 2	Identity and address of the economic operator producing or importing: ❑ raw materials/basic substances ❑ intermediates/semi-finished products ❑ finished products *tick the relevant item*
Supporting documentation	Documentation proving the identity and address of the economic operator producing or importing intermediate/semi-finished or finished products (e.g. specifications, transport documents, supply contracts, etc.)
Present guideline	A1.3.2.2
DG Sanco 2013	4.2.2.2 4.3.2.2
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 2 paragraph d art. 16.2
Note	Coatings in their form of production and delivery to the customer are to be considered, from the point of view of the *coating manufacturer*, as FINISHED PRODUCTS. If, on the other hand, we look at printed packaging as a finished product, within the supply chain coatings are instead to be considered SEMI-FINISHED products. If the economic operator issuing the Adequate Information (declaration of composition) is the same as the economic operator producing or importing, requirements 1 and 2 may coincide. To identify the responsibilities referred to in this Requirements, please refer to art. 2 paragraph d of Regulation (EC) 1935/2004 as amended

Sheet B10.c Identity of the asset

INDICATION	DESCRIPTION
Requirement 3	Identity of the asset to which the Adequate Information refers: ❑ raw materials/basic substances ❑ intermediates/semi-finished products ❑ finished products *tick the relevant item*
Supporting documentation	Coating identification documentation: – Product description (trade name and chemical nature) – information on composition/list of ingredients and their quantities – technical sheet
Present guideline	A1.3.2.2
DG Sanco 2013	4.2.2.3 4.3.2.3
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 16.2
Note	*Coatings* in their form of production and delivery to the customer are to be considered, from the point of view of the *coating manufacturer*, as FINISHED PRODUCTS If, on the other hand, we look at printed packaging as a finished product, within the supply chain the coatings are instead to be considered SEMI-FINISHED Traceability documents, etc., can also be useful.

Sheet B10.d Functional barrier

INDICATION	DESCRIPTION
Requirement 4	Information on the possible functional barrier
Supporting documentation	Not applicable
Present guideline	Not applicable
DG Sanco 2013	Not applicable (4.3.2.9)
DL.vo 108/1992	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Note	This requirement is not applicable

Sheet B10.e Compliance with EU regulations/national legislation

INDICATION	DESCRIPTION
Requirement 5	Declaration of compliance with EU Regulations and/or national legislation where applicable
Supporting documentation	*With reference to the Regulation (EU) 10/2011 as amended* ***Authorised and listed substances*** Supporting documentation: – use of substances listed in Annexes I and II ***Substances not listed but authorized (art. 6 paragraph 3)*** Supporting documentation: – applicability of the derogation referred to in Article 6, paragraph 3 – risk assessment in accordance with Regulation (EC) 1935/2004 as amended and information to support risk assessment in accordance with art. 19 of Regulation (EU) 10/2011 as amended which must be carried out by users according to the conditions of use ***Intermediates and semi-finished products*** Supporting documentation: – use of substances listed in Annexes I and II – risk assessment according to the criteria set out in art. 19 for substances used in the production process, and for substances not listed in Annexes I and II – risk assessment according to the criteria set out in art. 19 for substances not intentionally added that may be formed during production
Present guideline	B10.2.2.1 B10.2.2.2 B10.2.2.3
DG Sanco 2013	4.2.2.5 4.2.2.8 4.3.2
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 3 art. 16.2
Note	-

Sheet B10.f Restricted substances/materials

INDICATION	DESCRIPTION
Requirement 6	Adequate information about the substances and/or materials used and/or degradation products for which restrictions are in place
Supporting documentation	Supporting documentation: – the identification of restricted substances in accordance with Regulation (EU) 10/2011 as amended by national legislation or confirms that no restricted substances are used (unique substance identification number, EEC reference number for packaging materials, CAS (Chemical Abstracts Service) number, chemical name – the available information on compliance with the restrictions applicable to the substances used (LMS, LMS T, QM) together with the test conditions, the simulants used. The documents may be analysis reports and/or mathematical calculations and/or screening analyses and/or other appropriate scientific documentation
Present guideline	B10.2.2.1 B10.2.2.2
DG Sanco 2013	4.2.2.6 4.2.2.8 4.3.2.6 4.3.2.8
DL.vo 108/1992	art.5
Regulation (EC) 1935/2004 as amended	art.16.2
Note	-

Sheet B10.g Restricted substances/materials in foodstuffs

INDICATION	DESCRIPTION
Requirement 7	Adequate information on substances and materials used that are restricted in foodstuffs
Supporting documentation	Supporting documentation: – identification of substances used and also subject to restrictions in foodstuffs as reported in Regulations (EC) 1333/2008 and 1334/2008 – compliance with any criteria and purity requirements
Present guideline	B 10.2.2.1 B10.2.2.2
DG Sanco 2013	4.2.2.3 4.3.2.7
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art.16.2
Note	-

Sheet B10.h Directions for use

INDICATION	DESCRIPTION
Requirement 8	Indications for the use of FCMs: ❑ types of food products with which it is intended to come into contact ❑ duration, treatment temperature and storage in contact with food ❑ contact test conditions (simulant, duration, temperature) ❑ ratio of contact surface area to volume for determining compliance of FCMs ❑ other Restrictions of Use *tick the relevant items*
Supporting documentation	*With reference to the Regulation (EU) 10/2011 as amended* ***Authorised and listed substances or substances not authorised but listed (Article 6, paragraph 3)*** Supporting documentation*:* – analyses and evaluations aimed at indicating the type of food, the storage time and temperature – risk assessment in accordance with art. 19 and/or information to help the downstream user in the risk assessment work according to the conditions of use ***Intermediates/semi-finished products*** Supporting documentation*:* – analyses and evaluations aimed at indicating the type of food, the storage time and temperature – risk assessment in accordance with art. 19 and/or information to help the downstream user in the risk assessment work according to the conditions of use
Present guideline	B 10.2.2.1 B 10.2.2.2 B 10.2.2.3
DG Sanco 2013	4.2.2.8 4.3.2.8
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 16.2 art. 15
Note	-

Sheet B10.i Date of declaration

INDICATION	DESCRIPTION
Requirement 9	Date of declaration
Supporting documentation	-
Present guideline	A1.3.2.2
DG Sanco 2013	4.2.2.4 4.3.2.4
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 16.2
Note	

B11. ADHESIVES AND SEALANTS

B11.1. Characterization of the sector

B11.1.1. Field of application of the guideline

Present guideline on Supporting Documentation (SD) for the Declaration of Compliance (DoC) applies to all companies manufacturing adhesives and sealants used in the production of food-contact packaging.

B11.1.2. Applicable legislation

European legislation

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

Italian legislation

- DPR 777/1982 - Decree of the 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 as amended.
- DL.vo 108/1992 - 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.
- DL.vo 29/2017 - Italian Legislative Decree No. 29 of 10th February 2017 on Sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food.
- Ministerial Decree of 21st March 1973 on hygiene requirements of packages, containers and tools destined to come into contact with food or substances for personal use and following changes and integrations.

Currently, there is no specific legislation, either at European or national level, regulating adhesives and sealants intended for use in materials and articles in contact with food. Therefore, adhesives and sealants, like all materials intended for use in contact with food, fall under the general regulations mentioned above.

Other useful references to assess the compliance of an adhesive/sealant with Regulation (EC) 1935/2004 as amended can be found in specific national and/or European regulations for other materials, such as Regulation (EU) 10/2011 concerning plastic materials and articles intended to come into contact with foodstuffs and subsequent amendments and additions.

Important clarifications relating to adhesives and sealants are also present in the EU document "Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain" published by DG Sanco in 2013 (hereinafter referred to as DG Sanco 2013) (10).

B11.1.3. Relationships between GMP, SD and appropriate information

Present guideline analyses the content and correlation between SD and Appropriate Information (AI), as defined by Regulation (EU) 10/2011 as amended and DG Sanco 2013, as well as the AI themselves with reference to the Good Manufacturing Practice (GMP) standards relating to the production phases of adhesives and sealants used in the production of packaging intended for contact with food.

Figure B11.1 represents, for example, the correlation flows between activities and documents relating to the various phases of product development and implementation. For a more in-depth description, however, see chapter B11.2.

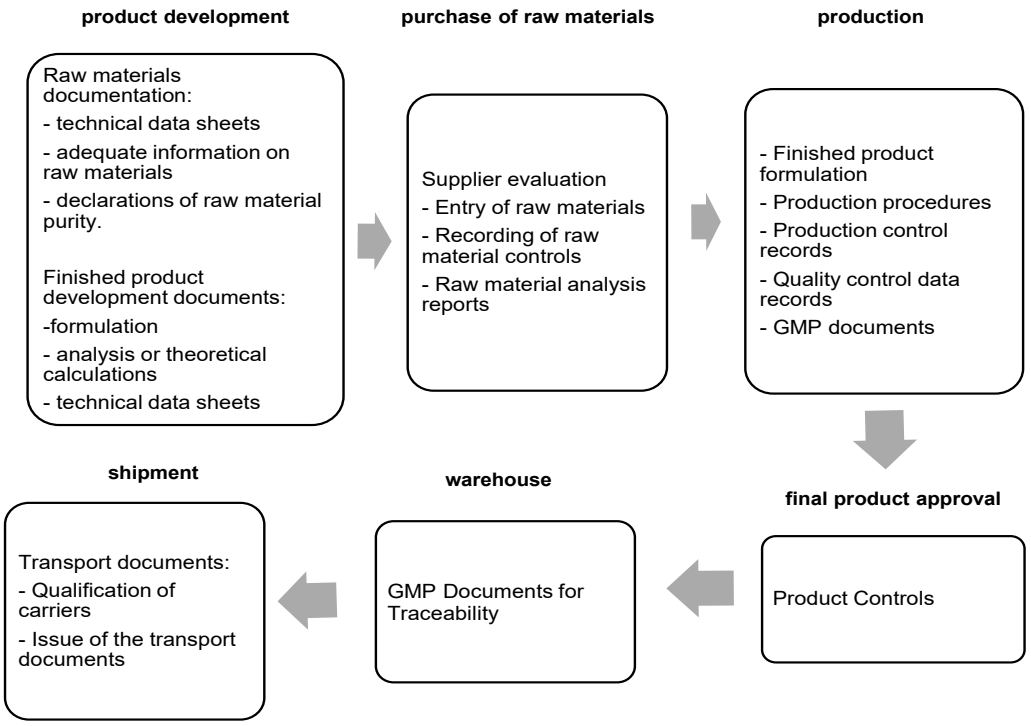

Figure B11.1. ADHESIVES AND SEALANTS: production phases and correlation with SD for DoC

It is important to note that AI can be emitted as early as the product development process, as you already have all the necessary information. SD is developed during all industrial processes from product development to shipment of the finished product.

B11.1.4. Industrial processes

The flow diagram and the detailed description of the production phases of the products are described in points B11.1.4.1. and B11.1.4.2. in the document *Rapporto ISTISAN* 23/4 Rev. (8).

Manufacturers of adhesives and sealants used in the production of packaging intended for contact with food must implement, organize and maintain a Quality Management and Assurance System capable of ensuring that the requirements of Regulation (EC) 2023/2006 as amended are met, such as to guarantee, in particular, process control and traceability.

B11.1.4.1. Product development

Based on the needs arising from the market, the adhesive/sealant manufacturer develops a product that meets the technical requirements of different applications. Based on the final use of the product to be made, the technical specification of the product is defined and the production cycle is developed, taking into account the regulations in force for materials and articles in contact with foodstuffs (Food Contact Materials, FCMs).

All the parameters necessary for the control of production processes and product quality control are then defined.

The documentation provided by the manufacturers of raw materials (e.g. technical data sheets, declaration of composition, DoC, AI) is requested and evaluated in relation to the specifications of use, defined by the end customer, where available, and/or by the foreseeable Directions for use.

B11.1.4.2. Purchase of raw materials

The raw materials acquisition process involves the approval of suppliers who are able to supply the raw materials necessary for the production of the material under development and to meet the required technical and quality specifications taking into account the final application in FCMs.

It is good practice to provide for a supplier qualification process, as provided for in paragraph B11.2.1.2. in the document *Rapporto ISTISAN* 23/4 Rev. (8).

Each raw material is identified by a technical specification, containing technical information and information regarding the suitability for use in FCMs, which possible suppliers must always meet. The company shall verify the correspondence between the specifications provided by the supplier and the required technical specifications and, if so, approve the supplier's raw material. This process is applied to every raw material and every supplier. The supplier shall accompany, where appropriate, its product with technical documentation, adequate information, compliance/composition statements, analysis reports. Upon entering the factory, raw materials are subjected to an acceptance, verification and storage procedure.

B11.1.4.3. Production

For each product, the conditions must be identified that allow adequate control of the production process through the definition of a series of critical parameters (e.g. formulation, production procedure, etc.) by means of which product control is guaranteed.

For each production batch, a document relating to it is issued, which provides details about the raw materials, the quantities to be used, the equipment to be used, the manufacturing methods and the laboratory controls to be carried out in the various phases of the production process (*see* the document *Rapporto ISTISAN* 23/4 Rev. par. B11.2.1.2. Production) (8).

For each phase of the production process, records of the activities carried out must be maintained, to ensure the traceability of the finished product.

Adequate quality controls are carried out on the product, which verify its adherence to the reference specification.

The traceability required for FCMs must be guaranteed for the entire production process.

B11.1.4.4. Final product approval

The product is approved on the basis of verification of its compliance with the technical specification. Depending on the results of the tests envisaged by the specification, the final evaluation of the product is carried out. After this phase, the product is made available for marketing.

B11.1.4.5. Storage

Each product is identified by a trade name, a reference number and a batch number. The packaging is selected in such a way as to maintain the quality characteristics of adhesives and sealants over time and protect them from external agents during transport and storage.

All warehouse activities are managed to maintain product traceability.

It must always be possible to trace the quality status of the products in stock through the appropriate codes and operating procedures/instructions.

B11.1.4.6. Shipment

The activities related to shipment provide for the approval of the companies that transport the product from the manufacturer to the end user. Carriers must also be selected on the basis of their ability to meet the quality and FCMs compliance requirements set by the companies in order to maintain the compliance of the transported product with the reference standards.

Transport documents are not necessarily part of the documentation required by the legislation on FMC, but they are part of other legislative obligations. However, transport documents may also include relevant and/or useful documentation (e.g. data sheets, composition statements, test reports, etc.) if not otherwise shipped to the customer. Therefore, if a correlation with compliance documents is available in the transport documentation, this could facilitate traceability paths.

B11.2. Supporting documentation

B11.2.1. Introduction

The purpose of this section is to clarify the requirements relating to SD in the case of adhesives and sealants used in multilayer laminates, consisting exclusively of plastic layers as provided for in Regulation (EU) 10/2011 as amended concerning plastic materials and articles intended to come into contact with foodstuffs.

In addition, this section is also intended to clarify the requirements relating to SD regarding the general use of adhesives and sealants in materials and articles intended to come into contact with foodstuffs. In fact, even if a detailed guideline is not available for other materials that are not harmonized at Community level and/or regulated only at national legislation, it seems appropriate that the SD in such cases should contain the same type of information.

Specific documentation elements applicable to the operator’s position in the supply chain are identified.

The documents that make up the SD should be reviewed periodically to reflect potential changes in the composition of formulations, changes in raw materials and production processes, regulatory updates, changes in suppliers or adaptations to technical progress.

The documents that make up the SD can also be made available and consulted through the use of databases or computer systems.

SD may concern a family of products: for example, the records of the checks carried out on a particular finished product are also recognized for products of the same type that have, compared to those of the material under test, less critical morphological characteristics (e.g. different thicknesses) and use (e.g. time, temperature).

B11.2.2. SD for raw materials producers

The raw materials used in the production of adhesives and sealants can be divided into two categories:

- basic substances;
- mixtures and/or polymers.

Both types of raw materials are purchased from an external supplier and the SD for the two categories is listed below.

B11.2.2.1. Raw materials: basic substances

Although they are not required to comply with Regulation (EC) 2023/2006 as amended, suppliers of basic substances should have implemented a Quality Management System (such as, but not necessarily, ISO 9001) that guarantees in particular the control of activities, processes and traceability. These requirements also apply to substances imported into the EU.

Producers of basic substances are not subject to the rules on the DoC for plastics at EU level, but it is recommended to share Adequate Information with manufacturers of adhesives and sealants used in materials and articles in contact with food (*see* DG Sanco 2013 Guideline, par.4.2.2)

The SD for basic substances used in the production of adhesives and sealants for materials and articles of plastics or other materials[29] should at least contain the following information, with regard to substances with restrictions in Regulation (EU) 10/2011 as amended:

- Identification of the raw material (chemical name, trade name, etc.) and the supplier (trader);
- Technical specifications of the product (document that contains the characteristics that identify the qualitative status of the product);
- Chemical identity of the substance (CAS number, Chemical Abstract Service, FCM number[30], chemical name, in case of dual use additive E or FL number[31], etc.);
- Confirmation, if the substance is authorised by Regulation (EU) 10/2011 as amended by other specific national legislation;
- Purity/titre requirements: information that may be necessary to ensure compliance with specific provisions of the applicable legislation;
- If information is available on possible products and processes of degradation of the substance (e.g. oxidation products, hydrolysis):
- When known, information on the toxicity of the substance and, if available, of the breakdown products under foreseeable conditions of use;

[29] Not covered by Regulation (EU) 10/2011 as amended but subject to national legislation

[30] From the Regulation (EU) 10/200: FCM substance No = the unique identification number of the substance Food Contact Material.

[31] In the case of dual-use additives, the E number for food additives or the FL number for flavourings must also be indicated.

- Any information on product stability (if available) and the resulting limitations of use (if known) (e.g. degradation of an additive at specified process temperatures);
- Any other information that allows the user of the substance to carry out the risk assessment according to the conditions of use (in accordance with the principles of Article 19 of Regulation (EU) 10/2011 as amended or national rules).

B11.2.2.2. Raw materials: mixtures and/or polymers

Suppliers of mixtures and/or polymers used in the formulation of adhesives/sealants for metal and aluminium intended for contact with food as an indispensable basis for the qualification of suppliers should have implemented a quality management system (such as, but not necessarily, ISO 9001) that guarantees in particular the control of activities, processes and traceability. These requirements also apply to blends and polymers imported into the European Union (EU).

Manufacturers of mixtures or polymers used for the formulation of adhesives/sealants are not subject to the EU regulations on the DoC for plastics, but it is recommended to share Appropriate Information with manufacturers of adhesives and sealants used in materials and articles in contact with food (*see* DG Sanco 2013 par.4.2.2) (10). These requirements also apply to blends and/or polymers imported into the EU.

The SD for mixtures and/or polymers used in the production of adhesives and sealants for plastic or other materials and articles (not covered by Regulation (EU) 10/2011 as amended, but subject to national rules) should at least contain the following information, relating to substances restricted by Regulation (EU) 10/2011 as amended:

- Identification of the raw material (trade name, etc.) and the supplier (trader);
- Technical specifications of the product (document that contains the characteristics that identify the qualitative status of the product);
- Adequate supplier information regarding mixtures and/or polymers to Regulation (EC) 1935/2004 as amended including references to applicable European and national legislation, including any restrictions on use;
- Chemical identity of the substances/mixtures contained (CAS number, FCM number, chemical name, if any);
- Information regarding the presence of *dual use substances* (E or FL numbers) listed in Regulations (UE) 1333/2008 and 1334/2008;
- Purity requirements: information that may be necessary to ensure compliance with specific provisions of the applicable legislation;
- If available, information on possible products and degradation processes of mixtures and/or polymers (e.g. oxidation products, hydrolysis);
- Toxicological information on the product and, if available, of the breakdown products under foreseeable conditions of use, when known;
- Any information on the stability of the product (if available) and the consequent limitations of use (if known) (e.g. degradation of an additive at specified process temperatures);
- Any other information that allows the user of mixtures or polymers to carry out a risk assessment based on the conditions of use (in accordance with the principles of Article 19 of Regulation (EU) 10/2011 as amended or national regulations) (*see* DG Sanco 2013 par. 4.3.2 point 8) (10).

B11.2.3. SD by production cycle/finished products

The SD for production cycle and finished products should contain at least the following information:

– *Adhesive/sealant formulation*
  - product description (trade name and chemical description);
  - formulation: list of raw materials and their quantities.

– *Collection of relevant information from raw materials suppliers and evaluation of the composition for the purpose of demonstrating compliance of use in FCMs*
  - identification of raw materials: chemical composition of the product;
  - AI on the compliance of raw materials with Regulation (EC) 1935/2004 as amended, including references to applicable European and national legislation, including any restrictions on use;
  - any analyses and/or calculations to assess compliance with restrictions in the case of substances subject to restrictions in national and European legislation;
  - confirmation that a risk assessment has been carried out in relation to the presence of NIAS (Non-Intentionally Added Substances) or relevant information is reported to enable the regulatory compliance verification to be completed. The level of detail and depth can be evaluated with the logic called "case by case".[32]

– *Information relating to the production cycle:*
  - records of production parameters;
  - quality control records of finished products;
  - specifications of finished products;
  - traceability documents;
  - if note, the use and all the information relating to the composition and destination of the final product, as well as the production process in which the adhesive/sealant is used, it is also possible to carry out evaluations on the migration of substances with SML, obtained by means of tests, mathematical models or calculations in accordance with the screening methods. For example, the documentation available in the form of analysis reports, or mathematical modelling, or supplier declarations, might be as follows:
    - Overall and specific migration test results, if applicable and if the end use is known;
    - Results of migration simulations, using mathematical models and calculations in accordance with the provisions of Regulation (EU) 10/2011 as amended;
    - Mathematical calculations of total transfer, i.e. assuming a complete migration of the substances contained in the adhesive into the food;
    - If one of the three points has already been verified by another player in the supply chain (upstream or downstream), the relevant declaration.

Not all the documents indicated need necessarily be present in SD collection for a certain material or process, but only those documents deemed necessary to support and justify the assessments that allow the appropriate information to be issued.

B11.3. Matching points between the appropriate information and SD

It is recommended that the manufacturer of adhesives and sealants provide Appropiate Information (AI) (DG Sanco Guideline 2013 par. 4.2.2.).

SD contains some specific elements related to AI, namely:

– Product identification;

[32] Concept introduced for plastic FCMs in DG Sanco 2013 par. 4.3.2 point 8 (10).

- Information on the presence of substances listed in national and European legislation and related restrictions (Regulation (EU) 10/2011 as amended, DM 21/03/1973 as amended);
- For products used in plastic packaging, risk assessment of substances used intentionally but not listed, according to art. 19 of Regulation (EU) 10/2011 as amended;
- For products used in plastic packaging, risk assessment of any decomposition and reaction products, according to Article 19 of Regulation (EU) 10/2011 as amended;
- Information on the presence of dual-use substances.

B11.4. Points of correspondence between GMP and SD

For manufacturers of adhesives and sealants, some documents included in the GMP documentation are listed that are also used in SD:

- specifications of finished products;
- raw materials specifications;
- information on analysis and composition or migration calculations, if these are managed in the company's Quality System or GMP;
- records of production parameters;
- quality control records of finished products.

B11.5. SD topics not necessarily covered by GMP documentation

Some topics supporting the compliance of products in contact with food may not necessarily be managed within the GMP system of a given company organization.

For example, the company may have produced during the development phase an indicative documentation useful for the evaluation of products, but considers it unnecessary for this documentation to be produced periodically and managed in the GMP system (e.g. use of particular substances, etc.).

Below is a non-exhaustive list of these documents:

- Results of analysis and migration calculations (if not already managed in the company's Quality System or GMP);
- Evaluations concerning NIAS;
- Evaluation of the composition of adhesives and sealants.

All this does not imply the lack of such documentation or the absence of *compliance work*, but only the unsystematic execution of some activities. The documentation will in any case be traceable and traceable to the asset to which it refers.

Annex B11

Sheets for supporting documentation of adhesives and sealants food contact materials

Regulatory references

Regulation (EC) 1935/2004 as amended
Regulation (EC) 2023/2006 as amended (where applicable)
Regulation (EC) 625/2017
DPR 777/1982
DL.vo 108/1992
DL.vo 29/2017
Guideline "Union Guidance on Regulation (EU) n. 10/2011 on plastic materials and articles intended to coming into contact with food as regard information in the supply chain" hereinafter referred to as DG Sanco 2013
Note of the Ministry of Health no. 32249, 11/10/2011

To harmonize the sheets of all the supply chains, the nine points contained in Annex IV of Regulation (EU) 10/2011 as amended have been used, although this Regulation is not directly applicable to the supply chain of adhesives and sealants.

Sheet B11.a Economic Operator Issuing the Appropriate Information (AI)

INDICATION	DESCRIPTION
Requirement 1	Identity and address of the economic operator issuing the Adequate Information (declaration of composition)
Supporting documentation	Company and/or functional organization chart and/or delegation and/or management procedures and/or documentation deriving from the company policy establishing responsibilities
Present guideline	A1.3.2.2
DG Sanco 2013	4.3.2.1
DL.vo 108/1992	art.5
Regulation (EC) 1935/2004 as amended	art. 2.2 art. 16.2
Notes	If the economic operator issuing the Adequate Information is the same as the economic operator producing or importing, requirements 1 and 2 may coincide To identify the responsibilities referred to this Requirements, please refer to art. 2 paragraph d of Regulation (EC) 1935/2004 as amended

Sheet B11.b Economic operator who produces or imports the good

INDICATION	DESCRIPTION
Requirement 2	Identity and address of the economic operator producing or importing: ❑ raw materials/basic substances ❑ intermediates/semi-finished products ❑ finished products *tick the relevant item*
Supporting documentation	Documentation proving the identity and address of the economic operator producing or importing raw materials/substances, intermediate/semi-finished products or finished products (e.g. specifications, transport documents, supply contracts, etc.).
Present guideline	A1.3.2.2
DG Sanco 2013	4.2.2.2 4.3.2.2
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 2, paragraph d art. 16.2
Notes	Adhesives and sealants in their form of production and delivery to the customer are to be considered, from the point of view of the manufacturer of adhesives and sealants, as FINISHED PRODUCTS. If, on the other hand, we look at the finished product packaging, within the supply chain, adhesives and sealants are to be considered SEMI-FINISHED. If the economic operator issuing the Adequate Information is the same as the economic operator producing or importing, requirements 1 and 2 may coincide To identify the responsibilities referred to in this Requirements, please refer to art. 2, paragraph d of Regulation (EC) 1935/2004 as amended

Sheet B11.c Identity of the asset

INDICATION	DESCRIPTION
Requirement 3	Identity of the asset to which the Adequate Information refers: ❑ raw materials/basic substances ❑ intermediates/semi-finished products ❑ Finished Products *tick the relevant item*
Supporting documentation	Documentation proving the identification of the adhesive (trade name and chemical nature) Technical sheet Formulation: Identification of raw materials and intermediates (trade name associated with chemical nature)
Present guideline	A1.3.2.2
DG Sanco 2013	4.2.2.3 4.3.2.3
DL.vo 108/1992	art.5
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	Adhesives and sealants in their form of production and delivery to the customer are to be considered, from the point of view of the manufacturer of adhesives and sealants, as FINISHED PRODUCTS If, on the other hand, we look at the finished product packaging, within the supply chain, adhesives and sealants are to be considered SEMI-FINISHED Traceability documents, etc., can also be useful.

Sheet B11.d Functional barrier

INDICATION	DESCRIPTION
Requirement 4	Information on the possible functional barrier
Supporting documentation	Not applicable
Present guideline	Not applicable
DG Sanco 2013	Not applicable (4.3.2.9)
DL.vo 108/1992	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	This requirement does not apply

Sheet B11.e Compliance with EU regulations/national legislation

INDICATION	DESCRIPTION
Requirement 5	Declaration of compliance with EU Regulations and/or national legislation where applicable
Supporting documentation	*Relevant to Regulation (EU) 10/2011 as amended for:* ***Authorised and listed basic substances*** Supporting documentation: – use of substances listed in Annexes I and II ***Basic substances not listed but authorised (Article 6, paragraph 3)*** Supporting documentation: – documentation on the applicability of the derogation referred to in Article 6, paragraph 3 – risk assessment in accordance with Regulation (EC) 1935/2004 as amended and information to support risk assessment in accordance with art. 19 which must be carried out by users according to the conditions of use ***Mixtures and/or polymers: Intermediates and semi-finished products*** Supporting documentation: – use of substances listed in Annexes I and II – risk assessment according to the criteria set out in art. 19 for substances used in the production process, and not listed in Annexes I and II – risk assessment according to the criteria set out in art. 19 for substances not intentionally added that may be formed during production
Present guideline	da B11.2.2.1 a B11.2.2.3
DG Sanco 2013	4.2.2.5 4.2.2.8 4.3.2.5 4.3.2.8
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 3 art. 16.2
Notes	In the case of applications on matrices other than plastic materials or flexible films, it is necessary to verify the congruity with existing national legislation (e.g. for paper and cardboard, in Italy it is necessary to consider the DM 21/03/1973 as amended)

Sheet B11.f Restricted substances/materials

INDICATION	DESCRIPTION
Requirement 6	Adequate information about the substances and/or materials used and/or degradation products for which restrictions are in place
Supporting documentation	Supporting documentation: – presence of substances subject to specific restrictions in Annex I and II of Regulation (EU) 10/2011 as amended (Unique Substance Identification No., EEC Reference No. for packaging materials, CAS - Chemical Abstracts Service number, chemical name – presence of substances listed with restrictions in national legislation (DM 21/03/1973 as amended) – risk assessment in accordance with art. 19 for substances not listed in Regulation (EU) 10/2011 as amended and/or in national legislation or information to help the downstream user in the risk assessment work. – identification of substances that may be formed during production.
Present guideline	B11.2.2.1 B11.2.2.2
DG Sanco 2013	4.3.2.6 4.3.2.8
DL.vo 108/1992	art.5
Regulation (EC) 1935/2004 as amended	art.16.2
Notes	In the case of applications on matrices other than plastic materials or flexible films, it is necessary to verify the congruity with existing national legislation (e.g. for paper and cardboard, in Italy it is necessary to consider the DM 21/03/1973 as amended).

Sheet B 11.g Restricted substances/materials in foodstuffs

INDICATION	DESCRIPTION
Requirement 7	Adequate information on substances and materials used that are restricted in foodstuffs
Supporting documentation	Supporting documentation: – identification of substances used and also subject to restrictions in food products as reported in Regulations (EC) 1333/2008 and 1334/2008. – compliance with any criteria and purity requirements.
Present guideline	B11.2.2.1 B11.2.2.2
DG Sanco 2013	4.2.2.3 4.3.2.7
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	-

Sheet B11.h Directions for use

INDICATION	DESCRIPTION
Requirement 8	Indications for the use of FCMs: ❑ types of food products with which it is intended to come into contact ❑ duration, treatment temperature and storage in contact with food ❑ contact test conditions (simulant, duration, temperature) ❑ ratio of contact surface area to volume for determining compliance of FCMs ❑ restrictions on Use *tick the relevant items*
Supporting documentation	*With reference to the Regulation (EU) 10/2011 as amended* ***Authorised and listed substances and Substances not listed but authorised (art. 6, paragraph 3)*** Supporting documentation: – analyses and evaluations aimed at indicating the type of food, the treatment, the time and temperature of storage with the food – risk assessment in accordance with art. 19 and/or information to help the downstream user in the risk assessment work according to the conditions of use ***Intermediates/semi-finished products*** Supporting documentation: – analyses and evaluations aimed at indicating the type of food, the treatment, the time and temperature of storage with the food. – risk assessment in accordance with art. 19 and/or information to help the downstream user in the risk assessment work based on the conditions of use. – evaluation of whether the use can only be below functional barrier. In the case: Identification of substances not listed in Annex I. – assessment of the presence of CMR and nanoform substances
Present guideline	B11.2.2.2 B11.2.2.3
DG Sanco 2013	4.2.2.8, 4.3.2.8
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 15, art. 16.2
Notes	-

Sheet B11.i. Date of declaration

INDICATION	DESCRIPTION
Requirement 9	Date of declaration
Supporting documentation	-
Present guideline	A1.3.2.2
DG Sanco 2013	4.2.2.4, 4.3.2.4
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	-

B12. PRINTING INKS

B12.1. Characterization of the sector

B12.1.1. Field of application of the guideline

Present guideline on the Supporting Documentation (SD) for the Declaration of Compliance (DoC) applies to all companies manufacturing printing inks and auxiliaries intended for the external printing of food packaging, hereinafter referred to as printing inks.

B12.1.2. Applicable legislation

European legislation

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

Italian legislation

- DPR 777/1982 - Decree of the President of the Republic No. 777/1982 on implementation of the Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs as amended.
- DL.vo 108/1992 - Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- DL.vo 29/2017 - Legislative Decree No. 29/2017 on sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food.

Currently, only general provisions exist, as there is no specific legislation, either at European or national level, regulating printing inks intended for printing on food packaging.

Therefore, printing inks, like all materials intended for use in contact with food, under the general regulations mentioned above. Other useful references for assessing the compliance of an printing ink with Regulation (EC) 1935/2004 as amended can be found in specific national and/or European legislation for other materials, such as:

- DM 21/03/1973 - Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, for contact with foodstuffs or substances for personal use as amended.

- Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food as amended.

Important clarifications relating to adhesives and sealants are also present in the EU document "Union Guidance on Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain" published by DG Sanco in 2013 (hereinafter in the text cited as DG Sanco 2013) (10).

B12.1.3. Relationships between GMP, SD and adequate information

In this guideline the content and correlation between SD and Adequate Information (AI), as defined by Regulation (EU) 10/2011 as amended and by the DG Sanco 2013 Guideline, as well as the AI themselves with reference to the Good Manufacturing Practice (GMP) standards relating to the production phases of printing inks intended for the external printing of food packaging, are analysed.

Figure B12 below represents, for illustrative purposes, the correlation flows between activities and documents relating to the various phases of product development and implementation. For a more detailed description, however, see chapter B12.2.

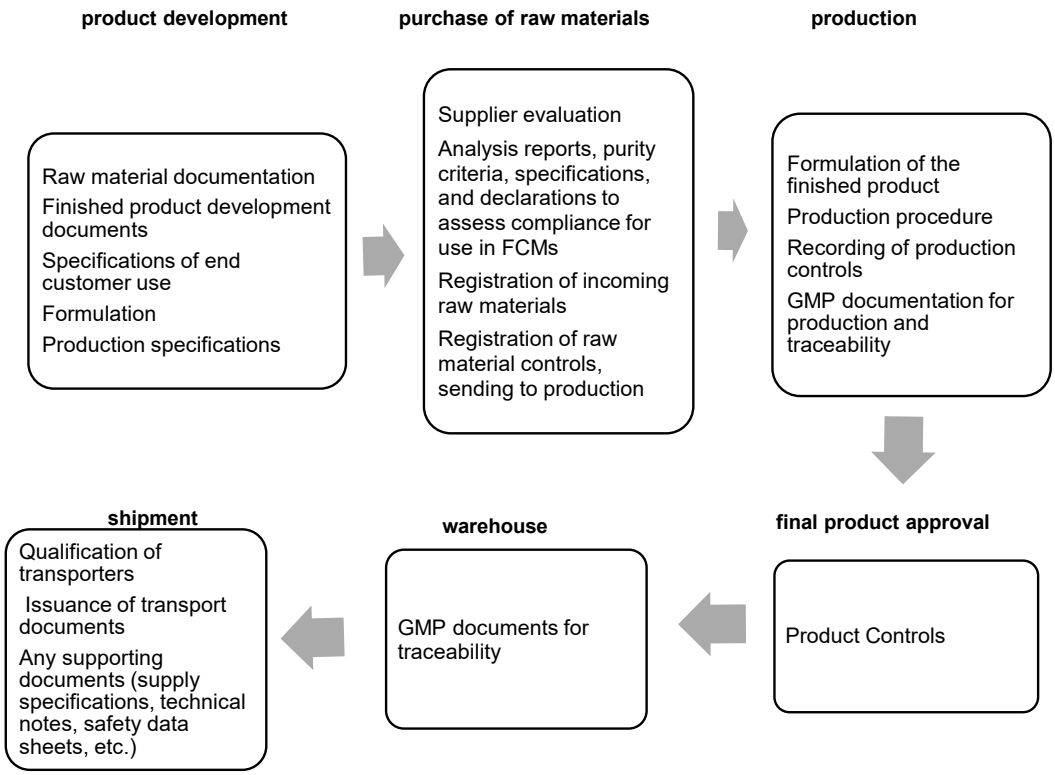

Figure B12. PRINTING INKS:
production phases and correlation with SD for DoC

B12.1.4. Industrial processes

The flow diagrams and the detailed description of the production phases are described in points B12.1.3 and B12.1.4 in the document *Rapporto ISTISAN* 23/4 Rev. (8). Manufacturers of printing inks intended for the external printing of food packaging must implement, organize and maintain a quality assurance system capable of ensuring the achievement of the objectives set out in Regulation (EC) 2023/2006 as amended, such as to guarantee, in particular, process control and traceability.

B12.1.4.1. Product development

Based on the needs arising from the market, the printing ink manufacturer develops a product that meets the technical requirements arising from the applications. Based on the final use of the product to be made, the technical specification is defined and the production cycle is developed taking into account the regulations in force for materials and articles in contact with foodstuffs (Food Contact Materials, FCMs).

All the parameters necessary for the control of production processes and product quality control are then defined.

For each raw material, specifications are agreed between the supplier and the manufacturer of printing inks. The documentation provided by the manufacturers of raw materials (e.g. technical data sheets, declaration of composition, DoC, AI) is requested and evaluated in relation to the specifications of use, defined by the end customer, where available, and/or by the foreseeable directions for use.

B12.1.4.2. Purchase of raw materials

The raw materials acquisition process includes the approval of suppliers who are able to supply the raw materials necessary for the production of the material under development and to meet the required technical and quality specifications taking into account the final application in FCMs.

It is good practice to provide for a supplier qualification process, as provided for in par. B12.2.1.2 in the document *Rapporto ISTISAN* 23/4 Rev. (8).

Each raw material is identified by a technical specification, containing technical information and information regarding suitability for use in FCMs, which potential suppliers must always meet. The company verifies the correspondence between the specifications provided by the supplier and the required technical specifications and, if so, the supplier's raw material is approved. This process is applied to every raw material and every supplier. The supplier shall accompany, where appropriate, its product with technical documentation, adequate information, compliance/composition statements, analysis reports. Upon entering the plant, raw materials are subjected to an acceptance, verification and storage procedure.

B12.1.4.3. Production

For each production batch, a document relating to it is issued, which provides details about the raw materials, the quantities to be used, the equipment to be used, the manufacturing methods and the laboratory controls to be carried out in the various phases of the production process.

Only raw materials that have passed quality control can be used in the quantities and proportions necessary to obtain the required product quality.

The equipment used must be suitable for producing the required product and kept in good operating condition, clean and, where necessary, maintained and/or calibrated.

For each phase of the production process, records of the activities carried out must be maintained, to ensure the traceability of the finished product.

Refer to the following paragraphs: B12.2.1.2. “Production”, B12.2.2.1 “Management of raw materials warehouses”, B12.2.2.2 “Production controls” in the document *Rapporto ISTISAN* 23/4 Rev. (8).

B12.1.4.4. Final product approval

During production, the ink is qualitatively checked at different stages before final approval. Operating instructions and procedures describe how controls are to be carried out (standard or internal methods) and to ensure their traceability. The data resulting from quality control operations are appropriately recorded.

After final approval, the product is made available for marketing.

Refer to par. B12.2.2.3 “Quality control of the finished products” in the document *Rapporto ISTISAN* 23/4 Rev. (8).

B12.1.4.5. Storage

Each product is identified by a trade name, a reference number and a batch number. The packaging is selected in such a way as to maintain the quality characteristics of the printing inks over time and protect them from external agents during transport and storage.

Warehouse activities, such as:

- the transfer of the finished product to the warehouse,
- picking and shipment operations,
- the selection of transporters and the checks to be carried out on the means of transport

are managed in such a way as to guarantee the traceability of the product (operating instructions and procedures).

Refer to par. B12.2.2.4. “Management of finished products warehouse” in the document *Rapporto ISTISAN* 23/4 (8).

B12.1.4.6. Shipment

Carriers are selected on the basis of their characteristics as well as their ability to meet the quality requirements set by the companies, in order to maintain the compliance of the transported product with the reference standards.

Transport documents are not necessarily part of the documentation required by the legislation on FMC, but they are part of other legislative obligations. However, transport documents may also include relevant and/or useful documentation (e.g. technical data sheets, composition statements, test reports, etc.) if not sent to the customer in any other way. Therefore, if a correlation with compliance documents is available in the transport documentation, this could facilitate traceability paths.

Reference is made to par. in par. B12.2.2.5. “Distribution, shipment and delivery” in the document *Rapporto ISTISAN* 23/4 Rev. (8).

B12.2. Supporting documentation

B12.2.1. Introduction

The purpose of this section is to clarify the requirements relating to SD regarding materials and articles intended to come into contact with foodstuffs.

Specific documentation elements applicable to the operator's position in the supply chain are identified.

The documents that make up the SD should be reviewed periodically to reflect any changes in the composition of formulations, changes in raw materials and production processes, regulatory updates, changes in suppliers or adaptations to technical progress.

The documents that make up the SD can also be made available and consulted through the use of databases or computer systems.

SD may concern a family of products: for example, the records of the checks carried out on a particular finished product are also recognized for products of the same type that have, compared to those of the material under test, less critical morphological characteristics (e.g. different quantities) and use (e.g. time, temperature).

B12.2.2. SD for raw materials producers

The raw materials used in the production of printing inks can be divided into 2 categories as far as SD is concerned:

- basic substances;
- mixtures and/or polymers.

Both types of raw materials can be purchased from an external supplier; the SD for the two categories is listed below.

B12.2.2.1. Raw materials: basic substances

Although they are not required to comply with Regulation (EC) 2023/2006 as amended, suppliers of basic substances used in the formulation of printing inks intended for the external printing of food packaging as an indispensable basis for the qualification of suppliers should have implemented a quality management system (such as, but not necessarily ISO 9001) that guarantees in particular the control of activities, of processes and traceability. These requirements also apply to substances imported into the European Union (EU).

Manufacturers of basic substances are not subject to the rules on the DoC for plastics at EU level, but it is recommended that they share Adequate Information with the manufacturers of printing inks (*see* DG Sanco 2013 par. 4.2.2) (10).

The SD for basic substances used in the production of printing inks should at least contain the following information, relating to substances with restrictions in Regulation (EU) 10/2011 as amended (*see* DG Sanco 2013 par. 4.2.2) (10):

- Identification of the product (chemical name, trade name, etc.) and supplier;
- Technical specifications of the product (document that contains the characteristics that identify the qualitative status of the product);
- Chemical identity of the substance (CAS number, Chemical Abstract Service, FCM number, chemical name, in the case of dual use additive, E or FL number;
- Purity/titre requirements: information that may be necessary to ensure compliance with specific provisions of the applicable legislation;
- If available, information on possible products and processes of degradation of the substance (e.g. oxidation products, hydrolysis);
- When known, information on the toxicity of the substance and, if available, of the breakdown products under foreseeable conditions of use;
- Any information on product stability (if available) and the resulting limitations of use (if known) (e.g. degradation of an additive at specified process temperatures);

- Identification of NIAS (Non-Intentionally Added Substances), both through the supplier and through targeted analyses (where necessary);
- Any other information that allows the user of the substance to carry out the risk assessment in accordance with Article 19 of Regulation (EU) 10/2011 as amended and supplemented according to the conditions of use.

It is good practice that the risk assessment is carried out in collaboration with the customer, in order to verify that all the industrial printing, converting and post-production processes involved in the manufacture of the final article guarantee compliance with art. 3 Regulation (EC) 1935/2004 as amended. In fact, in the application phase, a series of parameters are not within the scope of direct control by the ink manufacturer, and situations of non-compliance with the requirements of European and national legislation regarding materials and articles in direct contact with food could therefore occur.

In this context, it is therefore very important that an exchange of information takes place between the ink manufacturer and the end user in order to prevent the production technique or post-production treatments (embossing, etc.) from affecting the compliance of the final article.

In the case of applications on matrices other than plastic materials or flexible films, it is necessary to verify the congruity with existing national regulations (e.g. for paper and cardboard, in Italy it is necessary to consider the DM 21/03/1973 as amended).

The joint risk assessment may be part of the commercial agreements between the parties.

B12.2.2.2. Raw materials: mixtures and/or polymers

Although they are not required to comply with Regulation (EC) 2023/2006 as amended, suppliers of mixtures or polymers used in the formulation of printing inks intended for the external printing of food packaging, as an indispensable basis for the qualification of suppliers, should have implemented a quality management system (ISO 9001 or similar) that guarantees in particular the control of activities, of processes and traceability. These requirements also apply to substances imported into the European Union (EU).

Manufacturers of blends and/or polymers for printing inks are not subject to the DoC rules for plastics at EU level, but it is recommended that they share appropriate information with the manufacturers of printing inks. These requirements also apply to blends and/or polymers imported into the EU.

The SD for mixtures and/or polymers used in the production of printing inks should at least contain the following information:

- Product identification;
- Technical specifications of the product (document that contains the characteristics that identify the qualitative status of the product);
- Adequate supplier information regarding mixtures and/or polymers to Regulation (EC) 1935/2004 as amended including references to applicable European and national legislations, including any restrictions on use
- Chemical identity of the substances/mixtures contained (CAS number, FCM number if any, chemical name, etc.)
- Information regarding the presence of dual use substances (E or FL numbers) listed in Regulations 1333/2008 and 1334/2008;
- Purity requirements: information that may be necessary to ensure compliance with specific provisions of the applicable legislation;
- If available, information on possible products and degradation processes of mixtures and/or polymers (e.g. oxidation products, hydrolysis, etc.);
- Toxicological information on the product and, if available, of any decomposition products under foreseeable conditions of use, when known;

– Any information on the stability of the product (if available) and the consequent limitations of use (if known) (e.g. degradation of an additive at specified process temperatures);
– Identification of NIAS, both through the supplier and through targeted analyses (where necessary);
– Information that allows the user of printing inks to carry out the risk assessment in accordance with Article 19 of Regulation (EU) 10/2011 as amended according to the conditions of use (*see* DG Sanco 2013 par 4.2.2 paragraph 8) (10).

B12.2.2.3. SD for printing ink/finished products production cycle

The SD per production cycle/finished products should at least contain the following information:

– *Printing ink formulation*
  - Product description (trade name and chemical description);
  - Information on the composition/list of ingredients and their quantities.

– *Collection of relevant information from raw materials suppliers and evaluation of the composition for the purpose of demonstrating compliance of use in FCMs*
  - Identification of raw materials: chemical composition of the product;
  - Adequate information from raw materials suppliers on compliance with Regulation (EC) 1935/2004 as amended, including references to applicable European and national legislation, including any restrictions on use.
  - Any analyses and/or calculations to assess compliance with restrictions in the case of substances subject to the restrictions in national and European legislation.
  - Confirmation that a risk assessment has been carried out in relation to the presence of any NIAS or relevant information is reported[33] to allow the regulatory compliance check to be completed. The level of detail and depth can be assessed with the logic called "case by case".[34]

– *Information on the production cycle*
  - Records of production parameters
  - Recording of quality control in production and finished products
  - Specifications of finished products
  - Traceability documents
  - If known, the use and all information relating to the composition and destination of the ink, as well as the production process in which it is to be used. Where possible, NIAS migration assessments that may develop or form during the manufacturing process shall also be carried out with SML, obtained by means of tests, mathematical models or calculations in accordance with screening methods. For example, the documentation available on the migration of these substances in the form of analysis reports, or mathematical modelling, or supplier declarations, could be as follows:
    ▪ overall and specific migration test results, if applicable and if known end-use;
    ▪ results of migration simulations, using mathematical models and calculations in accordance with the provisions of Regulation (EU) 10/2011 as amended;
    ▪ mathematical calculations of total transfer, i.e. assuming a complete migration of the substances contained in the printing ink into the food;

[33] *see* DG Sanco 2013 point 4.4 par. 5c (10).
[34] Concept introduced for plastics in DG Sanco 2013 p. 23 (10).

- if one of the three points has already been verified by another player in the supply chain (upstream or downstream), the relative declaration.

Not all the documents indicated need to be present in the SD collection for a certain material or process, but only those documents deemed necessary to support and justify the assessments that allow the Appropriate Information to be issued (Composition Statement).

B12.3. Matching points between appropriate information and SD

It is recommended that the printing ink manufacturer provide Appropriate Information (AI) (DG Sanco 2013 par. 4.2.2.) (10).

For printing inks intended for food packaging, the manufacturer issues a "composition declaration" which contains the information that the customer needs to verify the compliance of the finished packaging with the provisions of Regulation (EU) 10/2011 and subsequent amendments, where applicable, and, more generally, to verify compliance with Article 3 of Regulation (EC) 1935/2004 as amended. The Composition Declaration also indicates the so-called dual use substances, i.e. for both industrial use and as food additives, in order to allow even in these cases, the verification of the compliance of the finished object with the concentration limits of the same.

SD contains some specific elements that are mentioned directly from the Composition Declaration, namely:

- Product identification;
- Information on the presence of substances listed in national and EU legislation relating to restrictions (e.g. Regulation (EU) 10/2011 and subsequent amendments)[35];
- Information on the presence of substances listed in the provisional list of additives used in plastics;
- Information on the presence of dual use substances.

B12.4. Points of correspondence between GMP and SD

For printing ink manufacturers, some documents included in the GMP documentation are listed and are also used in SD:

- Specifications of raw materials ((supplier declarations and, if necessary, further specific analyses);
- Specifications of finished products with any further checks;
- Production specifications (operating instructions and procedures);
- Information on migration analysis (if provided for in the company's Quality System or GMP);
- Recording production parameters;
- Registration of quality controls for finished products.

[35] Any citation of the Swiss Ordinance 817.023.21 does not constitute a legislative obligation.

B12.5. SD topics not necessarily covered by GMP documentation

Some topics supporting the compliance of products in contact with food may not necessarily be managed within the GMP system of a given company organization

For example, the company may have produced guidance documentation useful for compliance assessment during the design phase of a new product, but considers it unnecessary for this documentation to be produced periodically and managed in the GMP system.

Below is a non-exhaustive example list of these documents:

- construction materials of production equipment;
- auxiliaries used for the maintenance of production equipment (lubricants, glides);
- operating parameters of the production machines indicated by the manufacturer;
- additional measures to prevent contamination of printing ink during the production process.

All this does not imply the lack of such documentation or the absence of compliance work, but only the unsystematic execution of some activities. The documentation will in any case be traceable and traceable to the asset to which it refers.

Annex B12

Sheets for supporting documentation of printing inks food contact materials

Regulatory references

Regulation (EC) 1935/2004 as amended
Regulation (EC) 2023/2006 as amended (where applicable)
Regulation (EC) 625/2017
DPR 777/1982
DL.vo 108/1992
DL.vo 29/2017
Guideline "Union Guidance on Regulation (EU) n. 10/2011 on plastic materials and articles intended to coming into contact with food as regard information in the supply chain" hereinafter referred to as DG Sanco 2013
Note of the Ministry of Health no. 32249, 11/10/2011
Note of the Ministry of Health no. 15844, 12/05/2011

To harmonize the sheets of all the supply chains, the nine points contained in Annex IV of Regulation (EU) 10/2011 as amended have been used, although this Regulation is not directly applicable to the supply chain of printing ink for FCMs.

Sheet B12.a Economic Operator Issuing the Appropriate Information (AI)

INDICATION	DESCRIPTION
Requirement 1	Identity and address of the economic operator issuing the appropriate information (declaration of composition)
Supporting documentation	Company and/or functional organization chart and/or delegation and/or management procedures and/or documentation deriving from the company policy establishing responsibilities
Present guideline	A1.3.2.2
DG Sanco 2013	4.3.2.1
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 2.2, paragraph d art. 16.2
Notes	If the economic operator issuing the appropriate information (composition declaration) is the same as the economic operator producing or importing the inks in question, requirements 1 and 2 may be the same. To identify the responsibilities referred to this Requirements, please refer to Article 2 paragraph d of Regulation (EC) 1935/2004 as amended

Sheet B12.b Economic operator who produces or imports the good

INDICATION	DESCRIPTION
Requirement 2	Identity and address of the economic operator producing or importing: ❑ raw materials/basic substances ❑ intermediates/semi-finished products ❑ finished products *tick the relevant item*
Supporting documentation	Documentation proving the identity and address of the economic operator producing or importing intermediate/semi-finished or finished products (e.g. specifications, transport documents, supply contracts, etc.)
Present guideline	A1.3.2.2
DG Sanco 2013	4.2.2.2 4.3.2.2
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 2 paragraph d art. 16.2
Notes	Printing inks in their form of production and delivery to the customer are to be considered, from the point of view of the ink manufacturer, as FINISHED PRODUCTS. If, on the other hand, we look at printed packaging as a finished product, within the supply chain printing inks are to be considered INTERMEDIATE PRODUCTS If the economic operator issuing the appropriate information (composition declaration) is the same as the economic operator producing or importing, requirements 1 and 2 may coincide To identify the responsibilities referred to in this Requirements, please refer to art. 2 paragraph d of Regulation (EC) 1935/2004 as amended

Sheet B12.c Identity of the asset

INDICATION	DESCRIPTION
Requirement 3	Identity of the asset to which the Adequate Information refers: ❑ raw materials/basic substances ❑ intermediates/semi-finished products ❑ finished products *tick the relevant item*
Supporting documentation	Ink identification documentation: – description of the product (trade name and chemical nature); – information on the composition/list of ingredients, and their quantities. – technical sheet
Present guideline	da B12.1.4.1 a B12.1.4.3
DG Sanco 2013	4.2.2.3 4.3.2.3
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	Printing inks in their form of production and delivery to the customer are to be considered, from the point of view of the ink manufacturer, as FINISHED PRODUCTS If, on the other hand, we look at printed packaging as a finished product, within the supply chain printing inks are to be considered INTERMEDIATE PRODUCTS Traceability documents, etc., can also be useful.

Sheet B12.d Functional barrier

INDICATION	DESCRIPTION
Requirement 4	Information on the possible functional barrier
Supporting documentation	Not applicable
Present guideline	Not applicable
DG Sanco 2013	Not applicable (4.3.2.9)
DL.vo 108/1992	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	This requirement is not applicable

Sheet B12.e Compliance with EU regulations/national legislation

INDICATION	DESCRIPTION
Requirement 5	Declaration of compliance with EU Regulations and/or national legislation where applicable
Supporting documentation	*With reference to Regulation (EU) 10/2011 as amended* ***Authorised and listed substances*** Supporting documentation: – use of substances listed in Annexes I and II ***Substances not listed but authorized (art. 6, paragraph 3)*** Supporting documentation: – applicability of the derogation referred to in Article 6, paragraph 3 – risk assessment in accordance with Regulation (EC) 1935/2004 as amended according to the criteria set out in art. 19 ***Intermediates and semi-finished products*** Supporting documentation: – use of substances listed in Annexes I and II – risk assessment according to the criteria set out in art. 19 for substances used in the production process, and not listed in Annexes I and II – risk assessment according to the criteria set out in art. 19 for substances not intentionally added that may be formed during production
Present guideline	B12.2.2.1 - B12.2.2.3
DG Sanco 2013	4.2.2.5 4.2.2.8 4.3.2
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 3 art. 16.2
Notes	*see* text in B 12.2.1 of these guidelines on information sharing

Sheet B12.f Restricted substances/materials

INDICATION	DESCRIPTION
Requirement 6	Adequate information about the substances and/or materials used and/or degradation products for which restrictions are in place
Supporting documentation	Supporting documentation: – Identification of restricted substances and subsequent amendments and additions in accordance with Regulation (EU) 10/2011 or national legislation or confirmation that restricted substances are not used (unique substance identification number, EEC reference number for packaging materials, CAS-Chemical Abstracts Service number, chemical name) – Information that may be available on compliance with the restrictions applicable to the substances used (SML, SML T, QM) together with the test conditions, the simulants used. The documents may be analysis reports and/or mathematical calculations and/or screening analyses and/or other appropriate scientific argument
Present guideline	B12.2.2.1 B12.2.2.2
DG Sanco 2013	4.2.2.6 4.3.2.6 4.3.2.8
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art.16.2
Notes	-

Sheet B12.g Restricted substances/materials in foodstuffs

INDICATION	DESCRIPTION
Requirement 7	Adequate information on substances and materials used that are restricted in foodstuffs
Supporting documentation	Documentation proving the identification of substances used, including those subject to restrictions in foodstuffs, as reported in Regulations (EC) 1333/2008 and 1334/2008
Present guideline	B 12.2.2.1 B12.2.2.2
DG Sanco 2013	4.2.2.3 4.3.2.7
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	-

Sheet B12.h Directions for use

INDICATION	DESCRIPTION
Requirement 8	Information on the use of FCMs: ❑ duration, treatment temperature and storage in contact with food ❑ contact test conditions (simulant, duration, temperature) ❑ restrictions on use *tick the relevant items*
Supporting documentation	*With reference to Regulation (EU) 10/2011 as amended* ***Authorised and listed substances and non-listed but authorised substances (Article 6, paragraph 3)*** Supporting documentation*:* – analyses and evaluations aimed at indicating the type of food, storage time and temperature, if specified in the DoC – risk assessment in accordance with art. 19 and/or information to help the downstream user in the risk assessment work according to the conditions of use ***Intermediates/semi-finished products*** Supporting documentation*:* – analyses and evaluations aimed at indicating the type of food, storage time and temperature. – risk assessment in accordance with art. 19 and/or information to help the downstream user in the risk assessment work according to the conditions of use – evaluation of whether the use can only be below functional barrier. In the case: Identification of substances not listed in Annex I. – assessment of the possible presence of substances classified as CMR and in nanoform
Present guideline	B12.2.2.1 - B12.2.2.3
DG Sanco 2013	4.2.2.8 4.3.2.8
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 15 art. 16.2
Notes	-

Sheet B12.i Date of declaration

INDICATION	DESCRIPTION
Requirement 9	Date of declaration
Supporting documentation	-
Present guideline	A1.3.2.2
DG Sanco 2013	4.2.2.4 4.3.2.4
DL.vo 108/1992	art. 5
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	-

B13. COATED METAL ARTICLES INTENDED FOR COOKING

B13.1. Characterization of the sector

B13.1.1. Field of application of the guideline

Present guideline on the Supporting Documentation (SD) for the Declaration of Compliance (DoC) applies to companies that produce articles consisting of a metal base, with a non-stick coating of various kinds, intended for contact and cooking of food for repeated use.

The main articles covered by this guideline are:

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

Articles such as baking trays referred to in chapter B7. "Metals and metal alloys coated or not-coated" and the paint products referred to in the dedicated chapter B10. "Coating".

B13.1.2. Applicable legislation

European legislation

- Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/CEE and 89/109/CEE as amended.
- Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as amended.
- Regulation (EU) 2017/625 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.
- Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food as amended (Applicable for test conditions only)
- Regulation (EU) 2018/213 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials as amended.

Italian legislation

- DPR 777/1982 - Decree of the President of the Republic No. 777/1982 on implementation of the Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs as amended.
- DL.vo 108/1992 - Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- DL.vo 29/2017 - Legislative Decree No. 29/2017 on sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food

The following references may also be useful:

- DM 21/03/1973 - Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, for contact with foodstuffs or substances for personal use as amended.
- Note of the Ministry of Health DGSAN.VI/ 15844-P-12/05/2011: EU Regulation no. 10/2011 concerning plastic materials and articles intended to come into contact with foodstuffs.
- Note of the Ministry of Health DGSAN.VI/ 32249-P-11/10/2011: Declaration of compliance of materials and articles intended to come into contact with food products.

B13.1.3. Relationships between GMP, SD, DoC

This guideline analyses the content and correlation between SD and DoC and DoC themselves with reference to Good Manufacturing Practice (GMP) standards relating to the production phases of objects consisting of a metal base, with non-stick coating of various kinds, intended for contact and cooking of food for repeated use.

Figure B13.1 below represents, for example, the correlation flows between activities and documents relating to the various phases of product development and implementation. For a more detailed description, however, see chapter B13.2.

The flow diagrams and the detailed description of the production phases of the products are described in points B13.1.3 in the document *Rapporto ISTISAN* 23/4 Rev. (8).

Producers of metals intended for contact with food are required to comply with Regulation (EC) 2023/2006 and subsequent amendments and additions and must therefore implement a quality management system (es. ISO 9001) such as to ensure, in particular, process control and traceability.

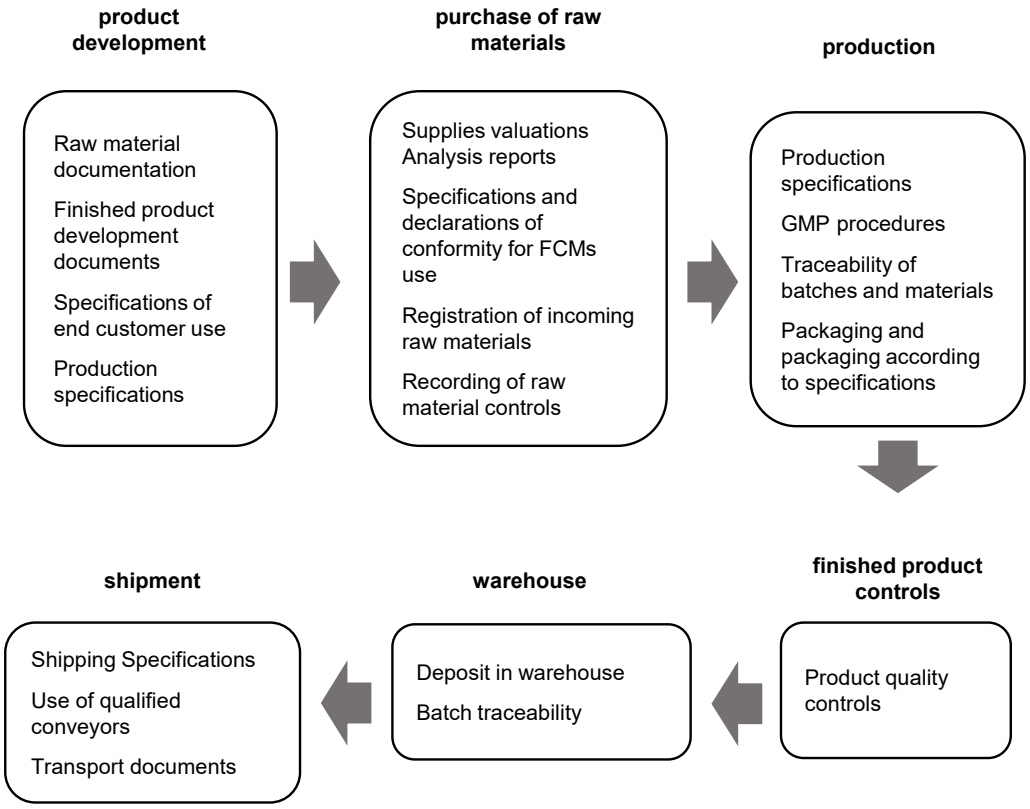

Figure 13.1.1 COATED METAL ARTICLES INTENDED FOR COOKING: production phases and correlation with SD for DoC

B13.1.3.1. Product development and purchasing raw materials

On the basis of the needs deriving from the end use of the product to be made, the technical specification of the product is defined and the production cycle is developed taking into account the regulations in force for materials and articles in contact with foodstuffs (Food Contact Materials, FCMs).

All the parameters necessary for the control of production processes and product quality control are then defined.

The documentation provided by the manufacturers of raw materials (e.g. technical data sheets, compliance declarations, etc.) is requested and evaluated in relation to the specifications of use, defined by the end customer, where available, and/or by the foreseeable Directions for use.

It is good practice to provide for a supplier qualification process, as required in the document *Rapporto ISTISAN* 23/4 Rev. (8) in paragraphs B13.2.1.2.

B13.1.3.2. Production

For each process/product, the conditions that allow adequate control of the production process must be identified through the definition of a series of control parameters (e.g. temperature, cooking curves, dimensional parameters, etc.) by means of which both the compliance of the product with respect to technical specifications and food contact is ensured.

Traceability must be guaranteed for the entire production process.

B13.1.3.3. Product control

The product is checked during the various processing phases. Adequate quality controls are carried out on the product, which verify both its adherence to the reference specification and some technological tests that confirm its suitability with respect to the established use.

Depending on the results of the tests expected during the production process, the technical characteristics of the product are confirmed to the technical specifications without the need for a final evaluation test.

B13.1.3.4. Storage

Warehouse activities are also managed to maintain product traceability.

Consequently, the appropriate types of packaging of the material and the related identification markings must also be defined. It must always be possible to trace the quality status of the products in stock through the appropriate codes and operating procedures/instructions.

B13.1.3.5. Shipment

The activities related to shipment provide for the suitability of the companies that transport the product from the manufacturer to the end user. Carriers must also be selected on the basis of their ability to meet the quality requirements set by companies in order to maintain the compliance of the transported product with the reference standards.

Transport documents are not necessarily part of the documentation required by the legislation on FMC, but they are part of other legislative obligations. However, transport documents may also include relevant and/or useful documentation (e.g. compliance declarations, etc.) if not sent to the customer in another way. Therefore, if a correlation with compliance documents is available in the transport documentation, this could facilitate traceability paths.

B13.2. Supporting documentation

B13.2.1. Introduction

The purpose of this section is to clarify the requirements in relation to SD required by Regulation (EC) 1935/2004 as amended concerning materials and articles intended to come into contact with foodstuffs.

Specific documentation elements applicable to the operator’s position in the supply chain are identified.

The documents that make up the SD should be reviewed periodically to reflect potential changes in the composition of formulations, changes in materials and production processes, regulatory updates, changes in suppliers, or adaptations to technical progress.

The documents that make up the SD can also be made available and consulted through the use of databases or computer systems.

SD may concern a family of products: for example, the records of the checks carried out on a particular finished product are also recognized for products of the same type that have, compared to those of the material under test, less critical morphological characteristics (e.g. different thicknesses) and use (e.g. time, temperature).

B13.2.2. SD for cooking articles from non-stick coated raw material

In the production of cooking articles from non-stick coated raw material, the relevant aspects of the production process, for the purposes of food compliance, verified technical characteristics of the product through controls on the production process.

The SD should contain at least the following information:

- Identification and description of the product (non-stick coated raw material, technical specifications, etc.);
- Elements for complete material traceability;
- DoC of the suppliers of the coated material to the DM 21/03/1973 as amended;
- DoC of suppliers to Regulation (EC) 1895/2005 on the restriction of the use of certain epoxy derivatives in materials and articles intended to come into contact with food;
- DoC of suppliers to Regulation (EU) 2018/213 on the use of bisphenol A in paints and coatings intended to come into contact with food and amending Regulation (EU) 10/2011 as amended as regards the use of this substance in plastic materials intended to come into contact with food.

B13.2.3. SD for cooking items in non-stick coated metal on inner surface with spray technology

In the production of non-stick coated metal baking items with spray technology, the relevant aspects of the production process, for the purposes of food compliance, are the composition and correct application of the coating material.

The SD should contain at least the following information:

- Identification and description of the product and materials used (metal raw material, paints, technical specifications, etc.);
- Elements for the complete traceability of materials;
- Declaration of suitability for use for the manufacture of articles compliant with food contact (suppliers declare compliance with food contact only of the coating provided that it is used with an adequate technological process);
- Adequate information;
- DoC of suppliers to Regulation 1895/2005/EEC;
- DoC of suppliers to Regulation (EC) 1935/2004 as amended.

SD can concern a single product or a group of products with similar compositional characteristics and coming from the same process, even employing *worst case* techniques to group the products.

B13.2.4. SD for metal items coated with non-stick on inner surface with roller technology

In the production of non-stick coated metal baking items with roller technology, the relevant aspects of the production process, for the purposes of food compliance, are the composition and correct application of the coating material.

The SD should contain at least the following information:

- identification and description of the product and materials used (metal raw material, paints, technical specifications, etc.);
- elements for the complete traceability of materials;

- declaration of suitability for use for the manufacture of food-safe articles;
- DoC of suppliers to Regulation 1895/2005/EEC;
- DoC of suppliers to Regulation (EC) 1935/2004 as amended.

SD may concern a single product or a group of products with similar compositional characteristics and coming from the same process, even employing worst-case techniques to group the products.

In addition, in all cases of finished products, the SD should contain information on overall and/or specific migration values (obtained from the FCMs manufacturer and/or theoretical calculations and/or migration tests performed by third-party laboratories). If there is documentation from the GMP system on the maintenance of the process parameters that ensure the compliance of the product with the regulations applicable to the industry (*see* above), the migration data is considered valid until the applied coating materials are changed.

This statement is valid from the date shown in the header and will be promptly replaced if there are changes in the production/formulation of the material or if the legislative references of this statement are modified and updated.

B13.3. Points of correspondence between DoC and SD

SD contains some specific elements that are mentioned directly by the DoC.

The DoC confirms to the next actor in the supply chain that the compliance work has been carried out, indicating, if necessary, what further activities should be carried out by the user.

As regards the SD prepared by manufacturers of articles consisting of a metal base, with a non-stick coating of various kinds, intended for contact and cooking of food for repeated use, the reference documents for the DoC are at least:

- Product identification and description;
- Migration tests in accordance with applicable (overall and/or specific) provisions. Alternatively, mathematical calculations and/or screening tests may be valid;
- Any information on the risk assessment of unlisted substances and NIAS (Non-Intentionally Added Substances);
- Possibly, information that has been used to assess and support suitability for particular uses mentioned in the DoC.

B13.4. Points of correspondence between GMP and SD

Some elements that are already part of the GMP documentation of the production cycle can also be included in the Supporting documentation, for example:

- elements for the traceability of metal raw material;
- elements for the traceability of paints;
- recording of defined product controls (e.g. quality controls, technological tests, visual controls, etc.);
- recording of process controls (e.g. firing temperatures of painting ovens);
- product specifications and performance.

The GMP documentation must provide evidence that the company has in place a SD management system that is used to determine compliance.

B13.5. SD topics not necessarily covered by GMP documentation

Some topics supporting compliance of coated metal items intended for cooking that are suitable for food contact may not necessarily be addressed within the GMP system of a given business organization.

For example, the company may have created during the product development phase an indicative documentation useful for the evaluation of the items, but considers it unnecessary for this documentation to be produced periodically and managed in the GMP system.

Below is a non-exhaustive list of these documents:

- results of overall and/or specific migration tests carried out in order to assess risks related to any process drifts;
- application of mathematical models for migration screening;
- evaluations concerning any NIAS;
- technical documentation on applications and recommended conditions of use.

All this does not imply the lack of such documentation or the absence of compliance work but only the unsystematic execution of some activities. The documentation will in any case be traceable and traceable to the asset to which it refers.

Annex B13

Sheets for supporting documentation of coated metal articles intended for cooking

Regulatory references

Regulation (EC) 1935/2004 as amended
Regulation (EC) 2023/2006 as amended
Regulation (EC) 625/2017
Regulation (EC) 1895/2005
Regulation (EC) 2018/2013
Regulation (EC) 10/2011 as amended.
DPR 777/1982
DL.vo 108/1992
DL.vo 29/2017
DM 21/03/1973 as amended

To harmonize the sheets of all the supply chains, the nine points contained in Annex IV of Regulation (EU) 10/2011 as amended have been used, although this Regulation is not directly applicable to the supply chain of coated metal articles intended for cooking

Sheet B13.a Economic operator issuing the compliance declaration

INDICATION	DESCRIPTION
Requirement 1	Identity and address of the economic operator issuing the declaration of compliance
Supporting documentation	Company and/or functional organization chart and/or delegation and/or management procedures and/or documentation deriving from the company policy establishing responsibilities
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6, art.8, paragraph c
Regulation (EC) 1935/2004 as amended	art. 16.2 art. 2, paragraph d
Notes	If the economic operator issuing the declaration of compliance is the same as the economic operator producing or importing, requirements 1 and 2 may coincide. To identify the responsibilities referred to this Requirements, please refer to art. 2 paragraph d of Regulation (EC) 1935/2004 as amended

Sheet B13.b Economic operator who produces or imports the good

INDICATION	DESCRIPTION
Requirement 2	Identity and address of the economic operator producing or importing: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished products *tick the relevant item*
Supporting documentation	Supporting documentation: identity and address of the economic operator producing or importing raw materials/substances, semi-finished products/intermediates or finished products (e.g. specifications, transport documents, supply contracts, etc.)
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6 art. 8, paragraph c
Regulation (EC) 1935/2004 as amended	art.16.2
Notes	If the economic operator issuing the declaration of compliance is the same as the economic operator producing or importing, requirements 1 and 2 may coincide

Sheet B13.c Identity of the asset

INDICATION	DESCRIPTION
Requirement 3	Identity of the asset to which the compliance statement refers: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished products *tick the relevant item*
Supporting documentation	Documentation for the identification of the asset (e.g. type of material/object, batch numbers, catalogue numbers, code numbers, etc.)
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	Traceability documents, etc., can also be useful.

Sheet B13.2.d Functional barrier

INDICATION	DESCRIPTION
Requirement 4	Information on any functional barrier
Supporting documentation	Not applicable
Present guideline	Not applicable
DM 21/03/1973 as amended	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	-

Sheet B13.e Compliance with EU regulations/national legislation

INDICATION	DESCRIPTION
Requirement 5	Declaration of compliance with EU Regulations and/or national Legislation where applicable
Supporting documentation	Supporting documentation: – the use of raw materials formulated with substances listed in Annex. II of the DM 21/03/1973 as amended, or in Annexes I and II of Regulation (EU) No. 10/2011 as amended. – compliance with the overall migration limit (when applicable) supported by analytical tests and/or mathematical calculations and/or screening analyses – the risk assessment for substances used in the production process and covered by the scope of application of Article 10 of the DM 21/03/1973 as amended, and/or according to the criteria set out in Article 19 of Regulation 10/2011 as amended. – the risk assessment for substances not intentionally added that may be formed during production and covered by the scope of application of Article 10 of the DM 21/03/1973 as amended and/or according to the criteria set out in Article 19 of Regulation 10/2011 as amended.
Present guideline	B13.2.2 (for articles for cooking from non-stick coated raw material) B13.2.3 (for non-stick coated metal cooking items on the inner surface with spray technology) B13.2.4 (for non-stick coated metal baking items on the inner surface with roller technology)
DM 21/03/1973 as amended	art. 10
Regulation (EU) 10/11 as amended	art. 19
Regulation (EC) 1935/2004 as amended	art. 3 art. 16.2
Notes	Regulation (EU) 10/2011 as amended is applied in this sector only for positive lists and test methods

Sheet B13.f Restricted substances/materials

INDICATION	DESCRIPTION
Requirement 6	Adequate information about the substances and/or materials used and/or degradation products for which restrictions are in place
Supporting documentation	Supporting documentation: – the identification of restricted substances in accordance with the provisions of Regulation 1895/2005, DM 21/03/1973 as amended, Regulation (EU) 10/2011 as amended or confirmation that no restricted substances are used. – the available information on compliance with the restrictions applicable to the substances used (SML, SML T, QM) together with the test conditions and simulants used. Documents can be analysis reports and/or mathematical calculations and/or screening analyses.
Present guideline	B13.2.2 (for articles for cooking from non-stick coated raw material) B13.2.3 (for non-stick coated metal cooking items on the inner surface with spray technology) B13.2.4 (for non-stick coated metal cooking items on the inner surface with roller technology)
DM 21/03/1973 as amended	art. 9.4 e 9.4bis, Annex II
Regulation (EU) 10/2011 as amended	art. 9, art.15, Annex IV
Regulation (EC) 1935/2004 as amended	art.16.2
Notes	-

Sheet B13.g Restricted substances/materials in foodstuffs

INDICATION	DESCRIPTION
Requirement 7	Adequate information on restricted substances and materials used in foodstuffs
Supporting documentation	Supporting documentation: – the identification of substances used, including those subject to restrictions in foodstuffs, as reported in Regulations (EC) 1333/2008 and 1334/2008. – compliance with any criteria and purity requirements
Present guideline	B13.2.2 (for articles for cooking from non-stick coated raw material) B13.2.3 (for non-stick coated metal cooking items on the inner surface with spray technology) B13.2.4 (for non-stick coated metal cooking items on the inner surface with roller technology)
DM 21/03/1973 as amended	art. 9, 9 bis
Regulation (EU) 10/2011 as amended	art. 11.3, art. 15, Annex IV.7
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	-

Sheet B13.h Directions for use

INDICATION	DESCRIPTION
Requirement 8	Information on the use of FCMs: ❑ intermediates/semi-finished products ❑ packaging *tick the relevant item* Information on the use of FCMs: ❑ types of food products with which it is intended to come into contact ❑ duration, treatment temperature and storage in contact with food ❑ contact test conditions (simulant, duration, temperature) ❑ ratio of contact surface area to volume for determining compliance of FCMs ❑ other restrictions or information related to the use *tick the relevant items*
Supporting documentation	Documentation on: – information used to establish any restrictions or specifications of use in addition to the specifications of use in the applicable national legislations and/or in column 10 of Annex I of Regulation (EU) 10/2011 as amended where applicable (e.g. composition statements, analysis reports, migration tests, etc.) – documentation proving compliance checks with the declared uses (e.g. analysis reports, migration tests, etc.)
Present guideline	B13.2.2 (for articles for cooking from non-stick coated raw material) B13.2.3 (for non-stick coated metal cooking items on the inner surface with spray technology) B13.2.4 (for non-stick coated metal cooking items on the inner surface with roller technology)
DM 21/03/1973 as amended	art. 8. b
Regulation (EU) 10/2011 as amended	art. 14, art. 15 Annex IV.8, Annex IV.9
Regulation (EC) 1935/2004 as amended	art. 16.2 art. 15
Notes	-

Sheet B13.i Date of declaration

INDICATION	DESCRIPTION
Requirement 9	Date of declaration
Supporting documentation	-
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6
Regulation (EU) 10/2011 as amended	art. 15 Annex IV.4
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	-

B14a. RUBBER. PRODUCTION OF ELASTOMERS, COMPOUNDS AND MASTERBATCH

B14a.1. Characterization of the sector

B14a.1.1. Field of application of guideline

The present guideline on Supporting Documentation (SD) for the Declaration of Compliance (DoC) applies to all companies operating in the production chain of elastomers, compounds and masterbatch for the production of rubber articles intended for contact with foodstuffs referred to in Article 1 of Regulation (EC) 1935/2004 as amended.

Starting substances for the production of elastomers (additives, catalysts, monomers, etc.) are excluded from the scope of Regulation (EC) 2023/2006 as amended. In this case, the producer of a starting substance, who must still emit a DoC, should have the corresponding SD obviously commensurate with his role.

B14a.1.2. Applicable legislation

European legislation

- Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/CEE and 89/109/CEE as amended.
- Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as amended.
- Regulation (EU) 2017/625 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- Commission Directive 93/11/EEC concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers.

Italian legislation

- DPR 777/1982 - Decree of the President of the Republic No. 777/1982 on implementation of the Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs as amended.
- DL.vo 108/1992 - Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- DL.vo 29/2017 - Legislative Decree No. 29/2017 on sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food.

– DM 21/03/1973 - Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, for contact with foodstuffs or substances for personal use as amended.

B14a.1.3. Relationships between GMP, SD, DoC

The content and correlation between SD and DoC in relation to Good Manufacturing Practice (GMP) standards with respect to the production phases of elastomers, rubber compounds and masterbatch for the production of rubber articles intended for contact with food are analysed.

Figure B14a. below summarizes, by way of example, the flow of activities and documents relating to the production of elastomers, rubber compounds and masterbatch for food applications. For a more detailed description, however, see chapter B14a.2.

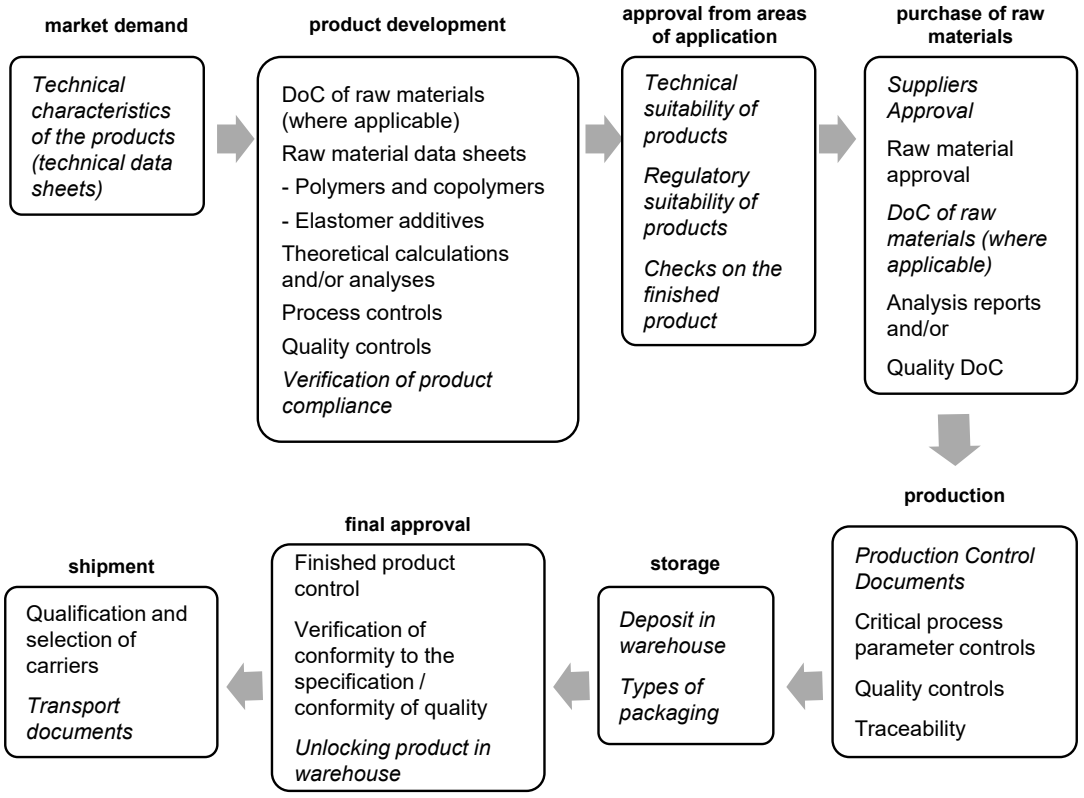

Figure B14a.1. PRODUCTION OF ELASTOMERS, RUBBER COMPOUNDS AND MASTERBATCH: production phases and correlation with SD for DoC (in italics the phases managed by the Quality Management System)

B14a.1.4. Industrial process: production of elastomers, rubber compounds – rubber masterbatch

The steps of the production process summarized in the flowchart of Figure B14a.1 are described below and then the SD are analysed in detail, the points of correspondence between DoC, SD and GMP standards as well as the topics of the SD not covered by the GMP standards.

B14a.1.4.1. Market demand/product development

Based on market needs, the company develops/modifies a product/"product portfolio" that meets the technical requirements of the applications. It is possible to develop both specific products for customers and products dedicated to satisfying the needs expressed by the different applications identified on the market. In this case, a specific technical sheet is prepared that contains the physical-mechanical characteristics of the product.

In the event that applications are intended for contact with food, part of the development activities is focused on verifying the compliance of the product with current laws.

The documentation (e.g. technical data sheets, declaration of composition or compliance) provided by the producers of the raw materials is requested and evaluated.

Theoretical and/or analytical evaluations are also carried out, such as overall and specific migration and organoleptic tests, to ascertain suitability for contact with food.

All the parameters necessary for the control of the production processes and the characteristics to be subjected to quality control are then defined.

B14a.1.4.2. Approval by sector of use

In relation to the specific sector of use and the final application for which the product has been developed, orientation tests are carried out to verify the satisfaction of the expected technical characteristics, and more generally of the regulatory suitability.

Analyses can be carried out both on the elastomer, on the vulcanized compound, and on products produced from it.

B14a.1.4.3. Purchase of raw materials

The raw materials acquisition process (procurement) involves the approval of one or more suppliers able to supply the raw materials necessary for the production of the material under development and to meet the required technical and quality specifications.

A particular raw material is identified by a single technical specification that possible suppliers must always meet. The company shall promptly verify the supplier's ability to meet the specification of the raw material and shall approve the raw material of a specific supplier. This process is applied to every raw material and every supplier. The supplier shall accompany its product with technical documentation, declarations of compliance with the standards referred to in point B14a.1.2 (where applicable), composition, analysis reports.

B14a.1.4.4. Production

For each process/product, the conditions that allow adequate control of the production process must be identified through the definition of a series of critical parameters (e.g. polymerization conditions, mixing cycle, process temperature, cross-linking conditions, possible post-curing) and through these to carry out a product control. Adequate quality controls are carried out on the product obtained from the processes indicated above, which verify its adherence to the reference specification. Compliance with Regulation (EC) 2023/2006 ad amended and additions and traceability must be guaranteed for the entire production process.

B14a.1.4.5. Storage

Warehouse activities are managed to maintain product traceability. Consequently, the appropriate types of packaging of the material and the related identification labels must also be defined.

It must always be possible to trace the quality status of the products in stock through the appropriate codes and operating procedures/instructions.

B14a.1.4.6. Final product approval

The product is approved on the basis of verification of its compliance with the specification. Depending on the results of the tests envisaged by the specification, the quality level of the product is defined. After this phase, the product is made available for marketing.

B14a.1.4.7. Shipment

The preparatory activities for shipment require the approval of the companies that transport the product from the manufacturer to the end user. Carriers must also be selected on the basis of their ability to meet the quality requirements set by the companies in order to maintain the compliance of the transported product with the reference standards.

Transport documents are not necessarily part of the documentation required by the legislation on materials and articles in contact with foodstuffs (Food Contact Materials, FCMs), but they are part of other legislative obligations. However, transport documents may also include relevant and/or useful documentation (e.g. DoC, test reports, etc.) if not otherwise shipped to the customer. Therefore, if a correlation with compliance documents is available in the transport documentation, this could facilitate traceability paths.

B14a.2. Supporting documentation (for rubber substances / elastomers / mixtures/ compounds and masterbatch)

B14a.2.1. Introduction

The purpose of this section is to clarify the requirements in relation to SD required by Regulation (EC) 1935/2004 as amended concerning materials and articles intended to come into contact with foodstuffs.

Specific documentation elements applicable to the operator's position in the supply chain are identified.

The documents that make up the SD should be reviewed periodically to reflect potential changes in the composition of formulations, changes in materials and production processes, regulatory updates, changes in suppliers, or adaptations to technical progress.

The documents that make up the SD can also be made available and consulted through the use of databases or computer systems.

SD may concern a family of products: for example, the records of the controls carried out on a particular finished product are also recognized for products of the same type that present, compared to those of the material under test, compositional characteristics (e.g. lower dosage of the same additives), morphological (e.g. different thicknesses) and use (e.g. time, temperature) less critical.

B14a.2.2. SD for manufacturers of monomers, starting substances, additives authorized by DM 21/03/1973

B14a.2.2.1. Industry: substance manufacturers

Manufacturers of substances (monomers, starting substances, authorised additives, including for example PPA[36] and dyes) for use in rubber compounds for the production of articles intended for contact with food, although not required to comply with Regulation (EC) 2023/2006 as amended, have preferably implemented a quality management system (es. ISO 9001) that guarantees in particular the control of activities, of processes and traceability. These requirements also apply to substances imported into the EU (European Union).

The SD should contain at least the following information:

- Product identification (chemical name, trade name, etc.);
- Product specification (document containing the characteristics of the product in relation to the expected quality, e.g. titre, density, physical state, etc.);
- Purity requirements: information necessary to ensure compliance with specific provisions of the applicable legislation, with particular reference to substances also subject to restrictions in foodstuffs;
- Adequate information on chemical reactivity and possible degradation products and processes of the substance (e.g. oxidation products, hydrolysis, etc.):
- Information on the toxicological characteristics of the substance/product and available information on the toxicological characteristics of the decomposition products under foreseeable conditions of use, when known;
- Any limitations of use (if applicable; e.g. degradation of an additive at specified process temperatures) and any information on the stability of the product.

B14a.2.3. SD for manufacturers of elastomers, rubber compounds and masterbatch (as intermediates)

Manufacturers of elastomers, mixtures (e.g. pre-dispersed), rubber compounds and masterbatch for the production of articles intended for contact with food are required to comply with Regulation (EC) 2023/2006 and subsequent amendments and additions and have therefore implemented a quality management system (e.g. but not necessarily, according to the requirements of the ISO 9001 standard) that guarantees in particular the control of activities, of processes and traceability aimed at complying with the applicable requirements of Regulation (EC) 1935/2004 as amended These requirements also apply to rubber compounds and masterbatch imported into the EU.

SD can concern a single product or a group of products with similar compositional characteristics and coming from the same process, even employing worst case techniques.

Not all the documents indicated below must necessarily always be present in the collection of SD, but only the documents that, on a case-by-case basis, are necessary to support and justify the evaluations that allow the issue of the DoC.

B14a.2.3.1. Composition of elastomer, rubber compounds/masterbatch

The SD should contain at least the following information:

[36] Polymer Processing Aids

- Product description (e.g. SBR elastomer[37], NR[38] or NBR[39] compound containing kaolin, carbon black, plasticizer, cross-linking system);
- Trade name of the product(s)
- Product specification (document containing the characteristics of the product in relation to the expected quality, e.g. hardness, density, tensile properties, compression set, etc.; cross-linking conditions must be indicated);
- Information about the composition.

B14a.2.3.2. Collecting relevant information from suppliers

B14a.2.3.2.1. For substances authorized by DM 21/03/1973 (e.g. elastomers, elastomer additives, etc.)

The SD should contain at least the following information:

- Identification of the product(s);
- DoC compliant with the national legislation in force (DM 21/03/1973 as amended), including any restrictions/limitations on use and any information on the technical quality of the product;
- Adequate information on restricted substances in foodstuffs and, where appropriate, purity criteria in accordance with law in force.

B14a.2.3.3. Composition assessment documentation

The manufacturer must carry out an assessment of the composition of the material in order to support and formalise the decision to consider the product covered by the SD suitable for the production of articles intended for contact with food on the basis of:

- Information on the assessments carried out for the verification of the compliance of the composition of elastomers, rubber compounds/ masterbatch and any restrictions (QM/QMA[40] , etc.).

B14a.2.3.4. Documentation on the evaluation of substances subject to specific migration limit

Specific and overall migration tests are not mandatory for manufacturers of elastomers, rubber compounds and masterbatch; in any case, the manufacturer of the elastomer, rubber compound or masterbatch may carry out indicative tests to ensure that the overall migration limits are respected, and that substances with SML (Specific Migration Limit) do not exceed the limits set under certain conditions, if indicated in the DoC.

The SD could contain in this regard:

- Any information on the assessments carried out for the verification of the migration of substances with SML, obtained by means of tests, mathematical models, calculations or appropriate scientific argumentation (in accordance with the screening methods for the verification of the suitability of rubber compounds for the production of FCMs), e.g. to assess compliance under foreseeable conditions of use.

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37 SBR: *Styrene Butadiene Rubber*
38 NR: *Natural Rubber*
39 NBR: *Nitrile Butadiene Rubber or acrylonitrile-butadiene rubber*
40 Regulation (EU) 10/2001: QM/QMA = residual content per food contact surface area (QMA)

B14a.3. Points of correspondence between DoC and SD

SD contains some specific elements that are mentioned directly by the DC.

The DoC confirms to the next actor in the supply chain that the *compliance work* has been carried out, indicating where appropriate what further activities should be carried out by the user.

The reference documents for the DoC are at least:

SD prepared by substance manufacturers (monomers, starting substances, additives, PPAs[41])

- Product identification (chemical name, trade name, etc.);
- Purity requirements: information that may be necessary to ensure compliance with specific provisions of the applicable legislation, with particular reference to substances also subject to restrictions in foodstuffs;
- Any limitations of use (e.g. use not recommended for contact with fatty foods) present in the DoC must be justified in the SD.

SD prepared by elastomer, rubber compound and masterbatch manufacturers

- Product identification (chemical name, trade name: e.g. NBR compound[42]);
- Compliance declarations issued by raw materials suppliers;
- If necessary, information on the migration of substances with SML;
- Any limitations of use and any information on the stability of the product;
- Information that has been used to assess and support suitability for particular uses mentioned in the DoC.

B14a.4. Points of correspondence between GMP and SD

The requirements of Regulation (EC) 2023/2006 as amended do not apply to producers of starting substances (monomers, additives, PPAs, etc.) (*see* relevant articles of the Regulation and in the document *Rapporto ISTISAN* 23/4 Rev.) (8).

For manufacturers of elastomers, rubber compounds and masterbatch, some documents included in the GMP documentation are listed and are also part of the SD:

- Specifications of finished products (document containing the characteristics of the product in relation to the expected quality);
- Raw materials specifications;
- Information on any migration tests, if these are managed in the company's Quality System or GMP, otherwise they will be part of the SD relating to the specific compliance work for the product or group of products (*see* paragraph B14a.5).

[41] *Polymerisation Production AiSD*

[42] NBR: *Nitrile Butadiene Rubber, Acrylonitrile Butadiene Rubber, or Nitrile Rubber*

B14a.5. SD topics not necessarily covered by GMP documentation

Some topics supporting the compliance of food contact products may not necessarily be covered within the GMP system.

For example, the company may have produced during the development phase a guideline documentation useful for the evaluation of products, but considers it unnecessary for this documentation to be produced periodically and managed in the GMP system.

Below is a non-exhaustive list of these documents:

- Results of overall migration tests (if not already managed in the company's Quality System or GMP);
- Results of specific migration tests (if not already managed in the company's Quality System or GMP);
- Application of calculation models;
- Evaluations of the composition of rubber compounds and masterbatch;
- Technical documentation on applications and recommended conditions of use.

This does not imply the lack of such documentation, or the absence of compliance work, but only the non-systematic execution of this activity. The documentation will in any case be traceable and unequivocally attributable to the goods to which it refers.

Annex B14a

Sheets for supporting documentation of rubber food contact materials. Manufacturers of elastomers, rubber compounds and masterbatch

Regulatory references

Regulation (EC) 1935/2004 as amended
Regulation (EC) 2023/2006 as amended (where applicable)
Regulation (EU) 625/2017
DM 21/03/1973 as amended
DPR 777/1982
DL.vo 108/1992
DL.vo 29/2017
Note of the Ministry of Health no. 32249, 11/10/2011

To harmonize the sheets of all the supply chains, the nine points contained in Annex IV of Regulation (EU) 10/2011 as amended have been used, although this Regulation is not directly applicable to the supply chain of rubber.

Sheet B14a.a Economic operator issuing the compliance declaration

INDICATION	DESCRIPTION
Requirement 1	Identity and address of the economic operator issuing the DoC
Supporting documentation	Company and/or functional organization chart and/or delegation and/or management procedures and/or documentation deriving from the company policy establishing responsibilities
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6 art. 8, paragraph c
Regulation (EC) 1935/2004 as amended	art. 16 art. 2 paragraph d
Notes	If the Economic Operator issuing the DoC is the same Economic Operator that produces or imports, requirements 1 and 2 may coincide. To identify the responsibilities referred to this Requirements, please refer to Article 2 paragraph d Regulation (EC) 1935/2004 as amended

Sheet B14a.b Economic operator who produces or imports the good

INDICATION	DESCRIPTION
Requirement 2	Identity and address of the economic operator producing or importing: ❑ raw materials / substances ❑ intermediates/semi-finished products (rubber compounds/ masterbatch) ❑ finished products* *tick the relevant item*
Supporting documentation	Documentation proving the identity and address of the economic operator producing or importing rubber compounds or masterbatch as intermediates (e.g. specifications, transport documents, supply contracts, etc.)
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6 art. 8, paragraph c
Regulation (EC) 1935/2004 as amended	art. 16 art. 2.2, paragraph d
Notes	If the Economic Operator issuing the DoC is the same as the Economic Operator producing or importing, requirements 1 and 2 may coincide.

* B14a supply chain produces/imports only starting substances/materials or compounds/ *masterbatch* as intermediates

Sheet B14a.c Identity of the asset

INDICATION	DESCRIPTION
Requirement 3	Identity of the goods to which the DdC refers: ❑ raw materials / elastomers ❑ intermediates/semi-finished products (rubber compounds / masterbatch) ❑ finished products* *tick the relevant item*
Supporting documentation	Documentation for the identification of rubber compounds or masterbatch as intermediate materials (e.g. batch, catalogue, code numbers, etc.)
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6
Regulation (EC) 1935/2004 as amended	art. 16
Notes	Traceability documents, etc., can also be useful.

* B14a supply chain produces/imports only starting substances/materials or compounds/masterbatch as intermediates

Sheet B14a.d Functional barrier

INDICATION	DESCRIPTION
Requirement 4	Information on the possible functional barrier
Supporting documentation	Not applicable
Present guideline	Not applicable
DM 21/03/1973 as amended	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	This requirement does not apply to rubber compounds and masterbatches.

Sheet B14a.e Compliance with EU regulations/national legislation

INDICATION	DESCRIPTION
Requirement 5	Declaration of compliance with EU Regulations and/or national legislation where applicable
Supporting documentation	*With reference to DM 21/03/1973 as amended* ***Authorised and listed substances*** Supporting documentation: – use of substances on included in the positive list (Annex II - Section II - Rubbers) – technical quality assessment and impurity assessment
Present guideline	B14a.1.4.6; B14a.2.2; B14a.2.3
DM 21/03/1973 as amended	art. 15, 16, 17, 18 19
Regulation (EC) 1935/2004 as amended	art. 3; art. 16
Notes	-

Sheet B14a.f Restricted substances/materials

INDICATION	DESCRIPTION
Requirement 6	Adequate information about the substances and/or materials used and/or degradation products for which restrictions are in place
Supporting documentation	Supporting documentation: – the identification of restricted substances in accordance with national legislation (DM 21/03/1973 as amended) or confirms that no restricted substances are used – the available information on compliance with the restrictions applicable to the substances used (e.g. on the basis of calculation models)
Present guideline	B14a.2.3.3
DM 21/03/1973 as amended	art. 15, art. 18, annex II section 2
Regulation (EC) 1935/2004 as amended	art. 16
Notes	Specific and overall migration tests are not mandatory for manufacturers of rubber compounds/ masterbatch; in any case, the manufacturer of the rubber compound/masterbatch may carry out checks to ensure that the overall migration limits are not exceeded and that substances with SML do not exceed the limits set under certain conditions, if indicated in the DoC.

Sheet B14a.g Restricted substances/materials in foodstuffs

INDICATION	DESCRIPTION
Requirement 7	Adequate information on substances and materials used that are restricted in foodstuffs
Supporting documentation	Supporting documentation: – identification of substances used and also subject to restrictions in foodstuffs as reported in Regulations (EC) 1333/2008 and 1334/2008 – compliance with any criteria and purity requirements
Present guideline	B14a.2.3.2
DM 21/03/1973 as amended	-
Regulation (EC) 1935/2004 as amended	art. 16
Notes	Requirement not mandatory for rubber but useful reference

Sheet B14a.h Directions for use

INDICATION	DESCRIPTION
Requirement 8	Indications for the use of FCMs: ❑ types of food products with which it is intended to come into contact ❑ duration, treatment temperature and storage in contact with food ❑ contact test conditions (simulant, duration, temperature) ❑ ratio of contact surface area to volume for determining compliance of FCMs ❑ other Restrictions of Use *tick the relevant items*
Supporting documentation	*With reference to DM 21/03/1973 as amended* Documentation on: – compliance with the positive list – indication of specific migration tests to be carried out in relation to the formulation
Present guideline	B14a.2.3.3
DM 21/03/1973 as amended	art. 5 art. 8.b
Regulation (EC) 1935/2004 as amended	art. 3 art. 15 art. 16
Notes	-

Sheet B14a.i Date of declaration

INDICATION	DESCRIPTION
Requirement 9	Date of declaration
Supporting documentation	-
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6
Regulation (EC) 1935/2004 as amended	art. 16
Notes	-

B14b. RUBBER. PROCESSING: PRODUCTION OF FINISHED ARTICLES

B14b.1. Characterization of the sector

B14b.1.1. Field of application of guideline

The present guideline on the Supporting Documentation (SD) for the Declaration of Compliance (DoC) applies to all companies operating in the processing of rubber compounds for the production of finished rubber articles intended for contact with food pursuant to Regulation (EC) 1935/2004 as amended. That is, the production of finished articles that can be used as they are or subject to further finishing processing, such as die-cutting a sheet, fitting a hose, etc.

B14b.1.2. Applicable legislation

European legislation

- Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/CEE and 89/109/CEE as amended.
- Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as amended.
- Regulation (EU) 2017/625 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- Commission Directive 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N- nitrosatable substances from elastomer or rubber teats and soothers.

Italian legislation

- DPR 777/1982 - Decree of the Italian President of the Republic No. 777/1982 on implementation of the Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs as amended.
- DL.vo 108/1992 - Italian Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- DL.vo 29/2017 - Italian Legislative Decree No. 29/2017 on sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food.

– DM 21/03/1973 - Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, for contact with foodstuffs or substances for personal use as amended.

B14b.1.3. Relationships between GMP, SD, DoC

These guidelines list the criteria for the preparation of SD, for the purposes of Good Manufacturing Practice (GMP) and DoC, for the rubber compound processing industry.

This document applies to the production of finished articles that can be used as they are or subject to further finishing processing, such as die-cutting a sheet, fitting a hose, etc.

This document analyses the correlation between production activities and the contents of SD, DoC in relation to GMP and more generally with respect to the production phases of semi-finished and finished articles in vulcanized rubber corresponding to the types indicated above.

Figure B14b.1, for example, schematizes the flow of activities and documents relating to the production of semi-finished and finished rubber articles intended for contact with food. For a more detailed description, however, see chapter B14b.2.

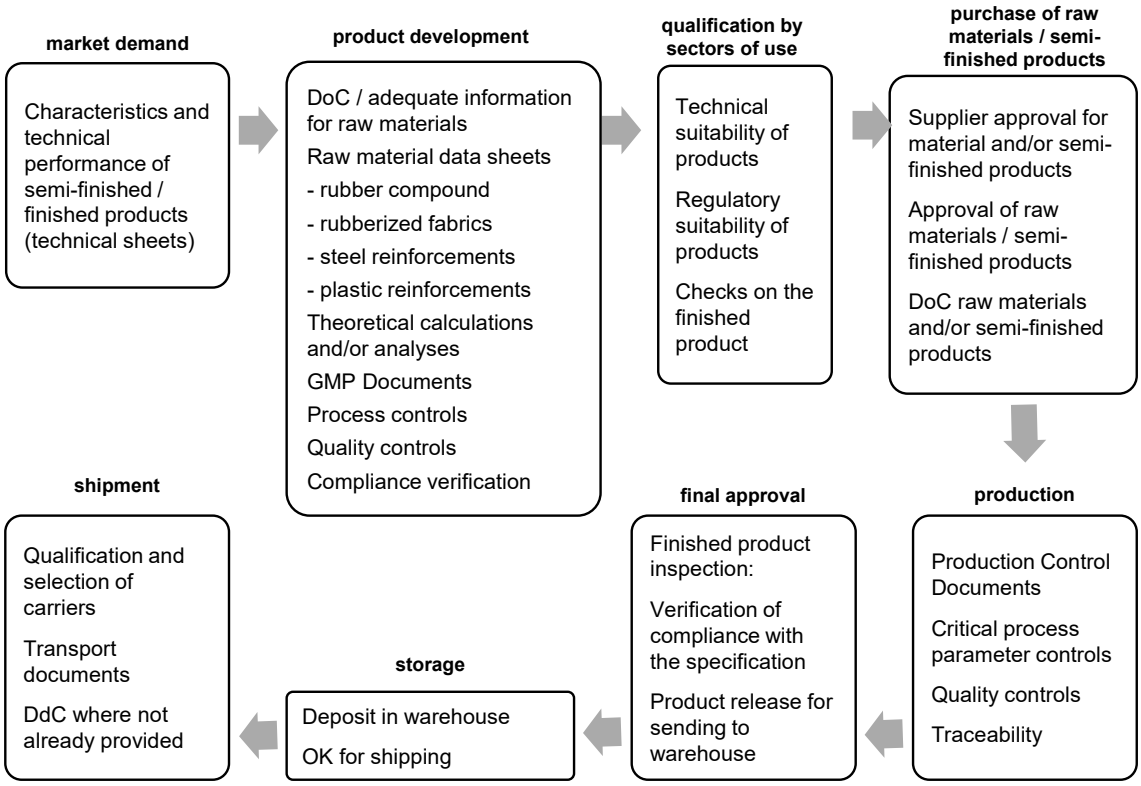

Figure B14b1. TRANSFORMATION (PRODUCTION OF FINISHED ARTICLES IN VULCANIZED RUBBER): production phases and correlation with SD for DoC

B14b.1.4. Industrial process: production of finished rubber items

The steps of the production process summarized in the flowchart are described below (*see* Figure 14b.1) and then the SD, the points of correspondence between DoC, SD and GMP standards as well as the topics of SDs not covered by the GMP system are analysed in detail.

B14b.1.4.1. Market demand and product development

Based on the needs deriving from the market, the company develops and/or modifies a product and/or a "product portfolio" capable of meeting the technical and legislative requirements deriving from the applications. It is possible to develop both specific products for customers and products dedicated to satisfying the needs expressed by the different applications identified on the market. In this case, a specific technical sheet is prepared that contains the physical-mechanical characteristics of the product.

In general, it is necessary to acquire information from the customer on the type of food that will come into contact with the finished article, as well as contact times / temperatures. In specific cases, additional information about particular conditions of use may be obtained from the customer if necessary.

We then proceed to request and evaluate the documentation (e.g. technical sheets, DoC or composition) provided by the producers of the raw materials.

All the parameters necessary for the control of production processes and the characteristics/performance to be subjected to quality control are defined.

B14b.1.4.2. Approval by the areas of use

In relation to the specific sector of use and the final application for which the product has been developed, the expected technical characteristics and more generally the regulatory suitability must be met.

In this regard, the analyses and/or evaluations provided for according to the intended use must be carried out on semi-finished or finished articles. The starting raw materials must be accompanied by the DoC or composition specification.

B14b.1.4.3. Purchase of raw materials and semi-finished products

The process of acquiring raw materials and semi-finished products involves the approval of one or more suppliers capable of supplying the raw materials/semi-finished products suitable for the production of the products under development and meeting the required technical and quality specifications.

A particular raw material or semi-finished product is identified by a technical specification that suppliers must always meet. The company shall promptly verify the supplier's ability to comply with the technical specifications and shall approve the raw material/semi-finished product of a specific supplier.

This process is applied to each raw material/semi-finished product and each supplier. The supplier shall accompany its raw material/semi-finished product with technical documentation and declarations of compliance/composition.

B14b.1.4.4. Production

For each product, the conditions that allow adequate control of the production process must be identified through the definition of a series of critical parameters and through these to carry out a control of the product and the process.

Adequate quality controls are carried out on the product, which verify its adherence to the reference specification.

Traceability must be guaranteed for the entire production process.

At the time of production, operators must have a technical sheet that provides all the information that must be used to produce the semi-finished or finished article in compliance.

In particular, for the different production technologies, the following information must be obtained:

- raw materials or semi-finished products to be used;
- technical parameters to be respected according to the transformation technologies adopted;
- process parameters, depending on the processing technology used, relevant to product quality.

All parameters must be reported on specific production sheets that must be part of the documentation of the GMP system. If part of them is necessary to establish the SD, they must be organized to be made available to the competent authorities.

B14b.1.4.5. Final product approval

All the checks required by the relevant legislation must be carried out on the finished rubber article to demonstrate its compliance with the use for which it is intended.

Only after all the checks, including quality checks, can the stocking be decided.

SD must be present in the company (or at predefined third-party facilities) but readily available to the competent authorities.

B14b.1.4.6. Storage

Warehouse activities are managed to maintain product traceability. Consequently, the appropriate types of product packaging and the related identification labels must also be defined.

It must always be possible to trace the quality status of the products in stock through the appropriate codes and operating procedures/instructions to ensure traceability.

B14b.1.4.7. Shipment

The preparatory activities for shipment require the approval of the companies that transport the product from the manufacturer to the end user.

Carriers must also be selected on the basis of their ability to meet the quality requirements set by the companies in order to maintain the compliance of the transported product with the reference standards.

Transport documents are not necessarily part of the documentation required by the legislation on FMCs, but they are part of other legislative obligations.

However, transport documents may also include relevant and/or useful documentation (e.g. DoC, technical data sheets, etc.) if not sent to the customer in another way. Therefore, if a correlation with compliance documents is available in the transport documentation, this could facilitate traceability paths.

B14b.2. Supporting documentation

B14b.2.1. Introduction

This section clarifies the requirements for SD required by Regulation (EC) 1935/2004 as amended and by DM 21/03/1973 as amended concerning rubber materials and articles intended to come into contact with foodstuffs.

The elements of the specific documentation applicable to the position of the operator (rubber processing industry) in the supply chain are identified.

The documents that make up the SD may be revised periodically to reflect changes in the composition of formulations, changes in materials and production processes, regulatory updates, changes in suppliers or adaptations to technical progress.

The documents that make up the SD should also be made available and searchable through the use of databases or computer systems.

SD may concern a family of products: for example, the records of the checks carried out on a particular finished product are also recognized for products of the same type that have, compared to those of the material under test, less critical morphological characteristics (e.g. different thicknesses) and use (e.g. time, temperature).

B14b.2.2. SD for finished rubber articles producers

Manufacturers of finished rubber articles intended for contact with food are required to comply with Regulation (EC) 2023/2006 as amended and additions and have therefore implemented a quality management system (e.g. but not necessarily ISO 9001) that guarantees in particular the control of activities, processes and traceability aimed at complying with the applicable requirements of Regulation (EC) 1935/2004 as amended.

In the case of multilayer articles in which the layer in direct contact with food is made of rubber (e.g. special hoses for the food industry) even if the concept of functional barrier is not directly applicable, the manufacturer of finished rubber articles remains responsible for ensuring the compliance of the finished article with Regulation (EC) 1935/2004 as amended.

Not all the documents indicated below must necessarily always be present in the collection of SD, but only the documents that, on a case-by-case basis, are necessary to support and justify the assessments that allow the DoC to be issued.

B14b.2.2.1. Composition

The SD should contain at least the following information:

- Product description (e.g. vulcanized NBR compound sheet[43]);
- Trade name of the product(s);
- Product specification (document containing the characteristics of the product in relation to the expected quality, e.g. hardness, density, tensile properties, compression set, etc.);
- About the composition.

B14b.2.2.2. Collecting relevant information from suppliers

With reference to Regulation (EC) 1935/2004 as amended and DM 21/03/1973 as amended, the SD should contain at least the following information:

- *Raw materials: rubber compounds*
  - Identification of the product(s);
  - Technical Data Scheet (TDS) Information
  - DoC of the supplier that includes references to national legislations, when applicable;
- *Non rubber raw materials*
  - Identification of the product(s);
  - Technical Product Quality (TPQ) Information
  - DoC of the supplier that includes references to national legislations, when applicable.

[43] NBR: Nitrile Butadiene Rubber, Acrylonitrile Butadiene Rubber, or Nitrile Rubber

B14b.2.2.3. Documentation on the evaluation of substances subject to the Specific Migration Limit

The SD should contain at least the following information:

- information on the presence of restricted substances;
- any information on the assessments carried out for the verification of the migration of substances with Specific Migration Limit (SML), obtained by means of tests, mathematical models, calculations or adequate scientific argumentation (in accordance with the screening methods for the verification of the compliance of materials and finished articles intended for contact with food) (e.g. to assess compliance under foreseeable and/or expected conditions of use).

Note. Specific and overall migration tests are not mandatory for rubber compound manufacturers and therefore may not be present in the SD; in any case, the manufacturer of rubber compounds may carry out indicative tests to ensure that substances with SML do not exceed the limits set under certain conditions, if indicated in the DoC.

B14b.2.2.4. Documentation on particular uses mentioned in the DoC

The SD should contain at least the following information:

- in the case of products with particular intended uses, information that has been used to assess and support compliance with such uses.

B14b.3. Points of correspondence between DoC and SD

The SD contains some specific elements that are directly referred to in the DoC.

As regards the SD prepared by producers of finished vulcanised rubber articles, the reference documents for the DoC are:

- Product description;
- DoC/composition issued by the supplier of the raw material;
- Migration tests, mathematical calculations, screening tests (for rubber objects);
- If necessary, information on the migration of substances with SML;
- Any limitations of use and any information on the stability of the product;
- Information used to assess and support suitability for particular uses referenced in the DoC.

B14b.4. Points of correspondence between GMP and SD

For manufacturers of vulcanized rubber products, some documents included in the GMP documentation are listed and are also used in SD.

- specifications of the raw materials used;
- product specifications and performance (finished articles);
- information about migration tests that are managed in the company’s quality system (GMP).

GMP documentation must provide evidence that the company has in place an SD management system that is used to determine compliance.

B14b.5. SD topics not necessarily covered by GMP documentation

Some topics supporting compliance of finished vulcanized rubber articles intended for food contact may not necessarily be covered within the GMP system.

For example, the company may have produced guidance documentation during development that is useful for product evaluation, but considers it unnecessary for this documentation to be produced periodically and managed in the GMP system.

Below is a non-exhaustive list of these documents:

- Results of overall migration tests (if not already managed in the GMP company quality system);
- Results of specific migration tests (if not already managed in the GMP company quality system);
- Application of calculation models;
- Technical documentation on end uses and recommended conditions of use.

This does not imply the lack of such documentation, or the absence of compliance work, but only the unsystematic execution of this activity. The documentation will in any case be traceable and unequivocally attributable to the goods to which it refers.

Annex B14b

Sheet for supporting documentation of rubber food contact materials. Finished items.

Regulatory references

Regulation (EC) 1935/2004 as amended
Regulation (EC) 2023/2006 as amended (where applicable)
Regulation (EU) 625/2017
DM 21/03/1973 as amended
DPR 777/1982
DL.vo 108/1992
DL.vo 29/2017
Note of the Ministry of Health no. 32249, 11/10/2011

To harmonize the sheets of all the supply chains, the nine points contained in Annex IV of Regulation (EU) 10/2011 as amended have been used, although this Regulation is not directly applicable to the supply chain of rubber.

Sheet B14b.a Economic operator issuing the compliance declaration

INDICATION	DESCRIPTION
Requirement 1	Identity and address of the Economic operator issuing the DoC on: ❑ intermediate products/ semi-finished products/ finished articles ❑ packaging *tick the relevant item*
Supporting documentation	Company and/or functional organization chart and/or delegation and/or management procedures and/or documentation deriving from the company policy establishing responsibilities
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6 art. 8, paragraph c
Regulation (EC) 1935/2004 as amended	art. 16 art. 2.2, paragraph d
Notes	If the economic operator issuing the DoC is the same economic operator that produces or imports, requirements 1 and 2 may coincide. To identify the responsibilities referred to this Requirements, please refer to Article 2 paragraph d Regulation (EC) 1935/2004 as amended

Sheet B14b.b Economic operator who produces or imports the good

INDICATION	DESCRIPTION
Requirement 2	Identity and address of the economic operator producing or importing: ❑ intermediate products/ semi-finished products/ finished articles ❑ packaging *tick the relevant item*
Supporting documentation	Supporting documentation: identity and address of the economic operator producing or importing finished items (e.g. specifications, transport documents, supply contracts, etc.).)
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6 art. 8, paragraph c
Regulation (EC) 1935/2004 as amended	art. 16 art. 2.2, paragraph d
Notes	If the Economic Operator issuing the DoC is the same as the Economic Operator producing or importing, requirements 1 and 2 may coincide. To identify the responsibilities referred to in this Requirements, please refer to art. 2 paragraph d of Regulation (EC) 1935/2004 as amended

Sheet B14b.c Identity of the asset

INDICATION	DESCRIPTION
Requirement 3	Identity of the goods to which the DoC refers: ❑ semi-finished products ❑ finished items *tick the relevant item*
Supporting documentation	Documentation for the identification of the asset (e.g. type of material/object, batch numbers, catalogue numbers, code numbers, etc.)
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6
Regulation (EC) 1935/2004 as amended	art. 16
Notes	For example, “O-ring made with vulcanized NBR compound” could be indicated. Traceability documents can also be useful, etc.

Sheet B14b.d Functional barrier

INDICATION	DESCRIPTION
Requirement 4	Information on any multilayer functional barrier article ❑ semi-finished products ❑ finished items *tick the relevant item*
Supporting documentation	*Semi-finished products* – documentation on investigations (documentary and/or analytical) to verify that the substances present are not CMR and/or in nanoform *Multilayer finished articles* (equipped with functional barrier) – evidence on the absence of substances classified as CMR or nanoform – analytical tests or other scientific evidence demonstrating that under the intended conditions of use, the migration of unauthorised substances is undetectable with a limit of detection of 0.01 mg/kg – transfer tests carried out on the finished article, or other scientific evidence, certifying the suitability.
Present guideline	B14b.2.2.4
DM 21/03/1973 as amended	art. 5
Regulation (EC) 1935/2004 as amended	art. 3
Notes	-

Sheet B14b.e Compliance with EU Regulations / National Legislation

INDICATION	DESCRIPTION
Requirement 5	Declaration of compliance with EU Regulations and/or national legislation where applicable ❑ semi-finished products ❑ finished items *tick the relevant item*
Supporting documentation	*With reference to Regulation (EC) 1935/2004 as amended and DM 21/03/1973 as amended* Documentation proving that the substances used are present in the positive list of the DM 21/03/1973 as amended (overall and specific migration tests, organoleptic tests)
Present guideline	B14b.2.2
DM 21/03/1973 as amended	art. 6, 15, 16, 17, 18, 19, annex. II section 2, annex III e IV
Regulation (EC) 1935/2004 as amended	art.3 e art. 16
Notes	In the case of complex articles, consisting of parts of vulcanized rubber and parts of other materials, the SD is prepared as indicated in this sheet for the rubber component and with reference to the relevant regulations for the other materials, if direct contact is foreseeable in the conditions of use. For the evaluation of the overall article, migration tests will be carried out under *the worst case* conditions if the conditions for the individual materials differ.

Sheet B14b.f Restricted substances/materials

INDICATION	DESCRIPTION
Requirement 6	Adequate information about the substances and/or materials and/or breakdown products for which restrictions are in place: ❑ semi-finished products ❑ finished items *tick the relevant item*
Supporting documentation	*With reference to DM 21/03/1973 as amended finished products* Supporting documentation: – identification of restricted substances (unique substance identification number, EEC reference number for packaging materials, CAS number, chemical name – available information on compliance with restrictions applicable to the substances used (SML, QM) (e.g. based on analyses, calculations or mathematical models)
Present guideline	B14b.2.2.3
DM 21/03/1973 as amended	art. 15, 18, annex II, section 2
Regulation (EC) 1935/2004 as amended	art. 16
Notes	-

Sheet B14b.g Restricted substances/materials in foodstuffs

INDICATION	DESCRIPTION
Requirement 7	Adequate information on substances and materials used that are restricted in foodstuffs ❑ semi-finished products ❑ finished items *tick the relevant item*
Supporting documentation	Supporting documentation: – identification of substances used also subject to restrictions in food products as reported in Regulations (EC) 1333/2008 and 1334/2008. – compliance with any criteria and purity requirements
Present guideline	B14b.2.2.2
DM 21/03/1973 as amended	-
Regulation (EC) 1935/2004 as amended	art. 16
Notes	Not mandatory for rubber but useful reference

Sheet B14b.h Directions for use

INDICATION	DESCRIPTION
Requirement 8	Indications relating to the use of FCMs. ❑ semi-finished products ❑ finished items Also specify: ❑ types of food products with which it is intended to come into contact ❑ duration, temperature of contact with food contact ❑ contact test conditions (simulant, duration, temperature) ❑ ratio of contact surface area to volume for determining compliance of FCMs ❑ other restrictions or information related to use *tick the relevant item*
Supporting documentation	Documentation proving compliance checks with the declared uses: – DoC of raw materials and/or – adequate information for inks or adhesives and/or – screening analysis reports and/or – migration tests and/or mathematical calculations and/or other scientific evidence
Present guideline	B14b.2.2.2 – B14b. 2.2.4
DM 21/03/1973 as amended	art. 5; art. 8.b
Regulation (EC) 1935/2004 as amended	art. 3, art. 15 and art. 16
Notes	-

Sheet B14b.i Date of declaration

INDICATION	DESCRIPTION
Requirement 9	Date of declaration ❑ semi-finished products ❑ finished articles *tick the relevant item*
Supporting documentation	-
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6
Regulation (EC) 1935/2004 as amended	art. 16
Notes	-

B15. FOOD PACKAGING MACHINES

B15.1. Characterization of the sector

B15.1.1. Field of application of guideline

Present guideline on Supporting Documentation (SD) for Declaration of Compliance (DoC) applies to companies that produce food packaging machines[44]

B15.1.2. Applicable legislation

European legislation

- Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/CEE and 89/109/CEE as amended.
- Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as amended.
- Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food as amended.
- Regulation (EU) 2017/625 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- Regulation (EU) 2020/1245 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.
- Directive 2006/42/EC implemented by Legislative Decree 27 January 2010 n. 17 relating to machinery and which modifies Directive 95/16/EC (recast).

Italian legislation

- DPR 777/1982 - Decree of the Italian President of the Republic No. 777/ on implementation of the Directive 76/893/EEC on materials and articles intended to come into contact with foodstuffs as amended.
- DL.vo 108/1992 - Italian Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- DM 21/03/1973 - Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, for contact with foodstuffs or substances for personal use as amended.

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

- DM 76/2007 - Ministerial Decree No. 76/2007 on regulation regarding the hygienic discipline of materials and articles of aluminium and aluminium alloys intended to come into contact with foodstuffs.
- DL.vo 29/2017 - Italian Legislative Decree No. 29/2017 on sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and 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[45]
- Note DGSAN 20072-P 20/05/2014 «Indications for checks on objects made of metal alloys and on objects coated with porcelain enamel intended for contact with food».

B15.1.3. Relationships between GMP, SD, DoC

In this Guidelines, it analyses the content and correlation between SD and DoC with reference to Good Manufacturing Practice (GMP) standards relating to the production phases of packaging machine parts intended for contact with food.

Figure B15.1 represents, for illustrative purposes, the correlation flows between activities and documents relating to the various phases of product development and implementation. For a more detailed description, however, see chapter B15.2.

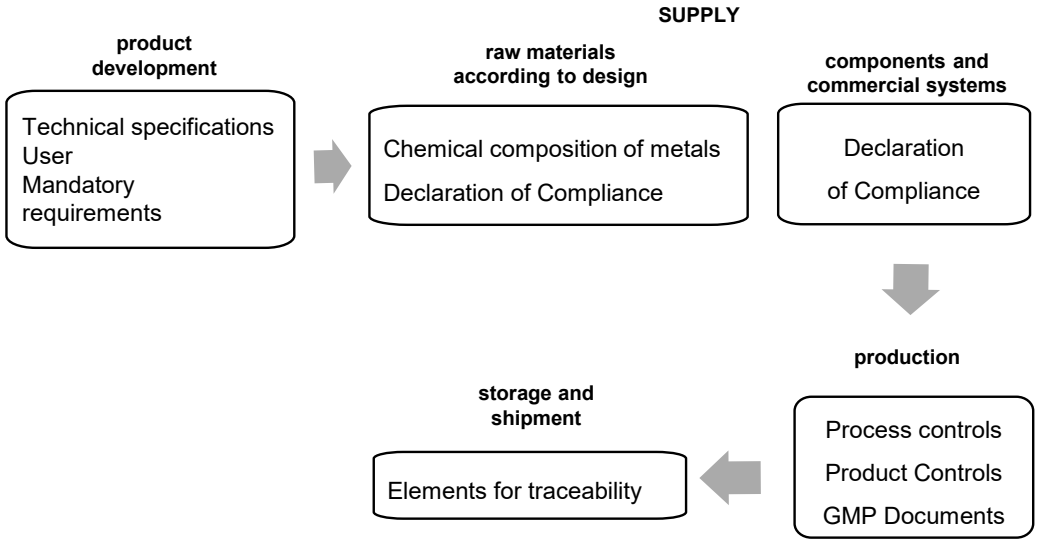

Figure B15.1 MACHINE: production phases and correlation with SD for DoC

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

B15.1.4. Industrial production processes of food packaging machines

Flow diagrams and detailed descriptions of the production steps of the machines are described in section B15.1.3 in the document *Rapporto ISTISAN* 23/4 Rev. (8) and the activities covered by this document are shaded in the flowchart in that document.

Manufacturers of food packaging machines are required to comply with Regulation (EC) 2023/2006 and subsequent amendments and additions and must therefore implement a quality management system such as to guarantee, in particular, process control and traceability. This system does not necessarily have to be ISO 9001.

B15.1.4.1. Definition of product specifications and purchase of raw materials

On the basis of the user's requirements and the mandatory requirements, the design bodies define the technical specifications of the machine, which must be obtained in the production cycle.

Initially, the business functions responsible for procurement purchase:

metallic and non-metallic raw materials,

commercial components and systems,

accompanied by appropriate documentation: chemical analysis of raw materials and metallic components, declaration of compliance of non-metallic raw materials, commercial components and systems. The necessary documentation is defined in the technical design specifications.

It is good practice to provide for the qualification of suppliers according to the procedures of the Quality Management System, as required in the document *Rapporto ISTISAN* 23/4 Rev. section B15.2.1.2. see also paragraph B15.1.4.5 below.

Quality control verifies the compliance of products with design specifications, including the required documentation and traceability.

B15.1.4.2. Production

For each process/product, the conditions that allow adequate control of the production process must be identified through the definition of a series of control parameters by means of which both the compliance of the product with respect to technical specifications and food contact is ensured.

Traceability must be guaranteed for the entire production process.

B15.1.4.3. Warehouse

The products procured and checked are stored awaiting assembly or shipment of spare parts, to ensure the preservation of quality and, if applicable, of the documentation necessary for the declaration of compliance and traceability.

B15.1.4.4. Assembling the machine

During the assembly phase of the machine, all the components are assembled, verifying the traceability of the parts made of materials and articles in contact with foodstuffs (Food Contact Materials, FCMs) and, if required, filling in the list of traceable parts with the traceability code.

B15.1.4.5. Internal tests

Internal tests are aimed at verifying that specific and, where applicable, overall migrations comply with legal limits, as well as verifying the functionality of the machine.

B15.1.4.6. Disassembly, packaging and shipment

In this phase, the machine is dismantled (if necessary), protected with suitable packaging to protect it adequately and shipped to the user's site. Transport documents could include documents pertaining to FCMs and various legislative obligations such as, for example, instruction manuals, traceability, compliance declarations, test results, etc., if not otherwise shipped.

Particular attention must be paid to the packaging and shipment of FCMs spare parts. Each FCMs spare part must be accompanied by a Declaration of Compliance and accompanied by a symbol indicating its destination, as well as instructions on the cleaning operations to be carried out before installation.

Note. Product checks may be carried out by the manufacturer or by the subcontractor or by an external laboratory. In all solutions, the SD must be filed neatly to be shown to the competent supervisory authority in the event of a request. Any provision of SD or part of it to customers will be the result of a commercial agreement.

There can be many ways of selecting materials and/or suppliers, but in any case, it is necessary for the company to have the necessary documentation to demonstrate how the starting materials were chosen. The approval of the supplier and materials is a legislative requirement clearly expressed in art. 5, paragraph 2, of Regulation (EC) 2023/2006 as amended. For more information, please refer to chapter A3.2 in the document *Rapporto ISTISAN* 23/4 Rev. (8).

B15.2. Supporting documentation

B15.2.1. Introduction

The purpose of this section is to clarify the requirements in relation to the SD required by Regulation (EC) 1935/2004 as amended concerning materials and articles intended to come into contact with foodstuffs, applicable to the food packaging machinery chain.

The documents that make up the SD should be revised when necessary to take into account changes in materials and production processes, customizations requested by customers, regulatory updates, changes in subcontractors or adaptations to technical progress.

SD can concern a family of machines: for example, the records of the checks carried out on a particular machine model are also recognized for machines of the same type that have less critical characteristics of use (e.g. time, temperature). In the absence of this information, the manufacturer must carry out the necessary tests.

B15.2.2. SD from machine manufacturers

Machines for packaging food products use a significant number of commercial materials and components: raw metal materials (e.g. steel sheets, aluminium, special alloys), non-metallic raw materials (e.g. plastic sheets, rubbers, silicone pipes), commercial components (e.g. pumps, solenoid valves, fittings, metal and synthetic pipes). Depending on the type of supply, the manufacturer may (request specific documentation as an integral part of the supplies, as specified below.

In the absence of the necessary information, the manufacturer must carry out the appropriate tests.

B15.2.2.1. SD from metal parts manufacturers

The SD should contain at least the following information:
- chemical composition (in compliance with DM 76/2007) drawn up in accordance with the UNI EN 10204 standard;
- recording of radioactivity control for metal from outside recycled scrap;
- traceability.

B15.2.2.2. SD from non-metallic parts manufacturers

Non-metallic raw materials are often subject to patents and subcontractors are not always willing to provide SD on the composition of materials, production processes, and adjuvants used in production processes.

Therefore, the manufacturer can only demand from the subcontractor the DoC to Regulation (EC) 1935/2004 as amended in the conditions of use of the materials: type/characteristics of foodstuffs, temperature range, pressure and contact times.

In any case, the subcontractor must guarantee the traceability of the product or production batch.

B15.2.2.3. SD from commercial components and systems

Commercial components and systems are also often subject to patents and subcontractors are not always willing to provide SD on the composition of materials, production processes, and adjuvants used in production processes.

Therefore, the minimum SD that the manufacturer must ask the subcontractor is the Declaration of Compliance with Regulation (EC) 1935/2004 as amended in the conditions of use of the materials: type of food, temperature range, pressure and contact times.

In any case, the subcontractor must guarantee the traceability of the product or production batch.

B15.2.3. Product control

Quality Control has the function of checking that the products procured comply with the design specifications. Any additional tests to the SD will be attached.

B15.2.4. Storage

The warehouse function guarantees the traceability and status of the materials procured.

B15.2.5. Assembling the machine

The assembly function, which can be divided into assembly of sub-assemblies and final assembly of the machine, has the task of recording the traceability codes of the machine components received from the warehouse. The registration document must be filed and kept in the Technical File of the machine. It is obviously specific to each machine, even if the SD refers to a machine model or a batch of machines.

B15.2.6. Internal tests

The internal tests are intended to verify and document compliance with Regulation (EC) 1935/2004 as amended, with reference to art. 3 where it is prescribed that materials in contact with food must not transfer components to food products in such quantities as to constitute a danger to human health. [46]

Packaging machines use a significant number of materials in contact with food, such as, for example, metals and metal alloys, coatings, plastics, silicones. Consequently, verify the compliance of each machine with art. 3 of the regulation becomes a complex operation.

In addition, internal tests can rarely be carried out using the packaging materials and foods used by the user, also due to difficulties in storing the characteristics of the food at the premises of the machine manufacturer. If possible, the input and output feed could be analysed to highlight the possible transfer of substances (components) from the machine to the feed. In the event of exceedances of specific or overall migration limits, it would still be difficult to identify the machine component(s) to which these exceedances should be attributed.

A rigorous method, albeit theoretical, consists in calculating the transfer of components to the food by quantifying the transfer of each component as a function of its functionality (surface in contact, temperature and contact time, pressure) starting from a data archive (database) of tests performed for each type of material. The sum of the individual transfers produces the specific and overall migrations attributable to the machine and allows compliance with the applicable legislation to be verified.

B15.2.6.1. Simplification of internal tests

Alternatively, for machines similar to other designs, compliance with applicable regulations can be ensured for machines of the same model if the compliance of a machine has been verified. All the more so if the application is less critical than the sample machine.

Please refer to Part C for further information on the sector.

B15.3. Points of correspondence between DoC and SD

SD contains some specific elements that are mentioned directly by the DoC, namely:

- Product description;
- Internal verification tests;
- Limitations of use;
- Applicable legislation.

B15.4. Points of correspondence between GMP and SD

For machine manufacturers, some documents included in the GMP documentation are listed that are also used in the SD:

- Specifications of finished products;
- Raw materials specifications;

[46] Checks for any changes in the composition of the product and deterioration of the organoleptic characteristics of the food should be carried out in accordance with product specifications.

- Information on analysis and composition or migration calculations if these are managed in the Company's Quality System or GMP.

B15.5. SD topics not necessarily covered by GMP documentation

Some topics supporting the compliance of products in contact with food may not necessarily be managed within the GMP system of a given company organization.

The SD listed in the previous paragraphs is indicative and evaluated in the light of current practices. Each manufacturer must assess the SD necessary to ensure the product's compliance with applicable legislation and establish the specific documentation to be collected and kept and the documentation that is not essential, but still traceable in case of need.

Annex B15 - A

Sheet for supporting documentation of food packaging machines

Regulatory references

Regulation (EC) 1935/2004 as amended
Regulation (EC) 2023/2006 as amended (where applicable)
Regulation (EC) 10/2011 as amended
Directive 2006/42/EC
Regulation (EU) 625/2017
Regulation (EU) 2020/1245
DM 21/03/1973 as amended
DM 76/2007
DPR 777/1982
DL.vo 108/1992
DL.vo 29/2017
DGSAN 20072_P/2014

To harmonize the sheets of all the supply chains, the nine points contained in Annex IV of Regulation (EU) 10/2011 as amended have been used, although this Regulation is not directly applicable to the supply chain of food packaging machines.

Sheet B15.a Economic operator issuing the compliance declaration

INDICATION	DESCRIPTION
Requirement 1	Identity and address of the economic operator issuing the DoC
Supporting documentation	Company and/or functional organization chart and/or delegation and/or management procedures and/or documentation deriving from the company policy establishing responsibilities
Present guideline	A1.3.2.2
Regulation (EC) 10/2011 as amended	art.15.2, annex IV.1
Regulation (EU) 2020/1245	-
DM 21/03/1973 as amended	art.6 art.8, paragraph c
DM 76/2007	art.8
Regulation (EC) 1935/2004 as amended	art. 16.2 art. 2.2, paragraph d
Notes	If the economic operator issuing the DoC is the same as the economic operator producing or importing, requirements 1 and 2 may coincide. To identify the responsibilities referred to this Requirements, please refer to article 2 paragraph d) of Regulation (EC) 1935/2004 as amended

Sheet B15.b Economic operator who produces or imports the good

INDICATION	DESCRIPTION
Requirement 2	Identity and address of the economic operator producing or importing: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished product *tick the relevant item*
Supporting documentation	Documentation proving the identity and address of the economic operator producing or importing raw materials/substances, intermediate/semi-finished products or finished products (e.g. specifications, transport documents, supply contracts, etc.)
Present guideline	A1.3.2.2
Regulation (EC) 10/2011 as amended	art.15.2, annex IV.2
Regulation (EU) 2020/1245	-
DM 21/03/1973 as amended	art.6 art.8, paragraph c
DM 76/2007	art. 8
Regulation (EC) 1935/2004 as amended	art. 16.2 art. 2.2, paragraph d
Notes	If the Economic Operator issuing the DoC is the same as the Economic Operator producing or importing, requirements 1 and 2 may coincide. To identify the responsibilities referred to in this Requirements, please refer to Article 2 paragraph d) of Regulation (EC) 1935/2004 as amended

Sheet B15.c Identity of the asset

INDICATION	DESCRIPTION
Requirement 3	Identity of the asset to which the DdC refers: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished product *tick the relevant item*
Supporting documentation	Documentation for the identification of the asset (e.g. type of material/object, batch numbers, catalogue numbers, code numbers, etc.)
Present guideline	A1.3.2.2
Regulation (EC) 10/2011 as amended	art. 15, annex IV.3
Regulation (EU) 2020/1245	-
DM 21/03/1973 as amended	art.6
DM 76/2007	art. 1
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	Traceability documents, etc., are also useful.

Sheet B15.d Functional barrier

INDICATION	DESCRIPTION
Requirement 4	Information on any functional barrier
Supporting documentation	Not applicable
Present guideline	Not applicable
Regulation (EC) 10/2011 as amended	Not applicable
Regulation (EU) 2020/1245	Not applicable
DM 21/03/1973 as amended	Not applicable
DM 76/2007	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	-

Sheet B15.e Compliance ai Regolamenti

INDICATION	DESCRIPTION
Requirement 5	Declaration of compliance with EU Regulations and/or national legislation where applicable
Supporting documentation	Supporting documentation: – the results of analysis of the chemical composition of the metal alloy used – the subcontractor's certificate/analysis report – the compliance declarations of subcontractors
Present guideline	B1.2.2 - B1.2.4
Regulation (EC) 10/2011 as amended	art. 15.2, art.19, annex IV.5
Regulation (EU) 2020/1245	-
DM 21/03/1973 as amended	art.10
DM 76/2007	art.8, paragraph 2 art.4, paragraph 1 annex I and II
Regulation (EC) 1935/2004 as amended	art. 3 art. 6
Notes	-

Sheet B15.f Restricted substances/materials

INDICATION	DESCRIPTION
Requirement 6	Adequate information about the substances and/or materials used for which restrictions apply
Supporting documentation	DoC of the subcontractor
Present guideline	B15.2.2.1
Regulation (EC) 10/2011 as amended	art. 9, art. 15, annex IV.6
Regulation (EU) 2020/1245	annex V capo 2 point 2.1.3
DM 21/03/1973 as amended	art.9.4, art. 9.4 bis annex II
DM 76/2007	art.4 paragraph 2 (use as a technological adjuvant)
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	-

Sheet B15.g Restricted substances/materials in foodstuffs

INDICATION	DESCRIPTION
Requirement 7	Adequate information on substances and materials used that are restricted in foodstuffs
Supporting documentation	Not applicable
Present guideline	Not applicable
Regulation (EC) 10/2011 as amended	art. 11.3, art. 15, annex IV.7
Regulation (EU) 2020/1245	-
DM 21/03/1973 as amended	art.9.4 art. 9.4 bis annex II
DM 76/2007	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	This requirement does not apply

Sheet B15.h Directions for use

INDICATION	DESCRIPTION
Requirement 8	Information on the use of FCMs: ❑ types of food products with which it is intended to come into contact ❑ duration, treatment temperature and storage in contact with food ❑ ratio of contact surface area to volume for determining compliance of FCMs ❑ other restrictions of use *tick the relevant items*
Supporting documentation	Documentation proving compliance checks for the declared uses (e.g., notes on declarations, labels, or other documents sent to the customer)
Present guideline	Par. B15.2.6 Par. B15.2.7
Regulation (EC) 10/2011 as amended	art. 13-15, annex IV.8 –IV.9
Regulation (EU) 2020/1245	-
DM 21/03/1973 as amended	art. 8
DM 76/2007	art. 5 art. 6
Regulation (EC) 1935/2004 as amended	art.15
Notes	-

Sheet B15.i Date of declaration

INDICATION	DESCRIPTION
Requirement 9	Date of declaration
Supporting documentation	-
Present guideline	A1.3.2.2
Regulation (EC) 10/2011 as amended	art. 15.2, annex IV.4
Regulation (EU) 2020/1245	-
DM 21/03/1973 as amended	art. 6
DM 76/2007	art.8
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	-

Annex B15 - B

Declaration of Compliance “merged”

In the event that the FCMs problem concerns machinery, it should be noted that the Guide to the application of the “machinery” directive 2006/42/EC, drawn up by the European Commission, states that, where the machinery is subject to other EU regulations, in addition to the machinery directive, compliance with other EU directives or regulations must also be declared. The manufacturer may draw up a single EC declaration of compliance concerning other regulations or directives, provided that the declaration contains all the information required by each directive.

Therefore, it is certainly admissible that the machinery is accompanied by a single declaration of compliance that contains both the reference to the Machinery Directive (EC) 2006/42 and the reference to Regulation (EC) 1935/2004 as amended.

The issuance of a specific declaration pursuant to Regulation (EC) 1935/2004 as amended, however, may derive from contractual commitments, or constitute a free “commercial” choice following a detailed request by the user company.

The issuance of a declaration of compliance with Regulation (EC) 1935/2004 as amended remains binding for machine parts or components supplied subsequently, provided that they are intended for contact with food.

In both cases, it is important to always indicate the exact type of food product for which the machine is intended to be used, with any limits of use.

On the subject of the declaration of compliance, in addition to the citation of Regulation (EC) 1935/2004 as amended, however, the indication of the specific legislative provisions applicable in the field of suitability for contact with food for individual material remains a certainly practicable method, as well as compliance in general with Regulation (EC) 2026/2006 (see A1.3.2.2 EU laws and national legislation on DoC).

B16. FOOD GASES DISTRIBUTION EQUIPMENT

B16.1. Characterization of the sector

B16.1.1. Field of application of guideline

The present guideline on Supporting Documentation (SD) for the Declaration of Compliance (DoC) applies to all manufacturing companies of food gases distribution equipment. A distribution equipment is formed by a set of components interconnected to each other so as to create a single and functional system with the aim of supplying the food additive gas to the point of use.

The process of creating a food additive gas distribution system consists of the assembly – at the user's site – of specific components such as the following items, covered by this guideline:

- cryogenic tanks and/or cylinders for gas storage;
- vaporization systems;
- pressure reduction systems;
- pipes and fittings;
- valves and accessories.

B16.1.2. Applicable legislation

European legislation

- Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/CEE and 89/109/CEE as amended.
- Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as amended.
- Regulation (EU) 2017/625 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- Regulation (EC) no. 10/2011 on plastic materials and articles intended to come into contact with food.
- Directive 2014/68/EU on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment.

Italian legislation

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

- DL.vo 108/1992 - Italian Legislative Decree No. 108/1992 on implementation of the Directive 89/109/EEC on materials and articles intended to come into contact with foodstuffs.
- DL.vo 29/2017 - Italian Legislative Decree No. 29/2017 on sanctioning discipline for the violation of provisions referred to in Regulations (EC) 1935/2004, 1895/2005, 2023/2006, 282/2008, 450/2009 and 10/2011, concerning materials and articles intended to come into contact with food.
- DM 21/03/1973 - Ministerial Decree of 21st March 1973 on hygienic discipline of packaging, recipients, utensils, for contact with foodstuffs or substances for personal use as amended
- DM 76/2007 - Ministerial Decree No. 76/2007 on regulation regarding the hygienic discipline of materials and articles of aluminium and aluminium alloys intended to come into contact with foodstuffs.

B16.1.3. Relationships between GMP, SD, DoC

This guideline, the content and correlation between the SD and the DoC and the DoC themselves are analysed with reference to the GMP (Good Manufacturing Practice) standards relating to the construction phases of food additive gas distribution systems.

Figure B16.1 represents, for example, the correlation flows between activities and documents relating to the various phases of development and construction of a plant. For a more in-depth description, however, see the chapter B16.2.

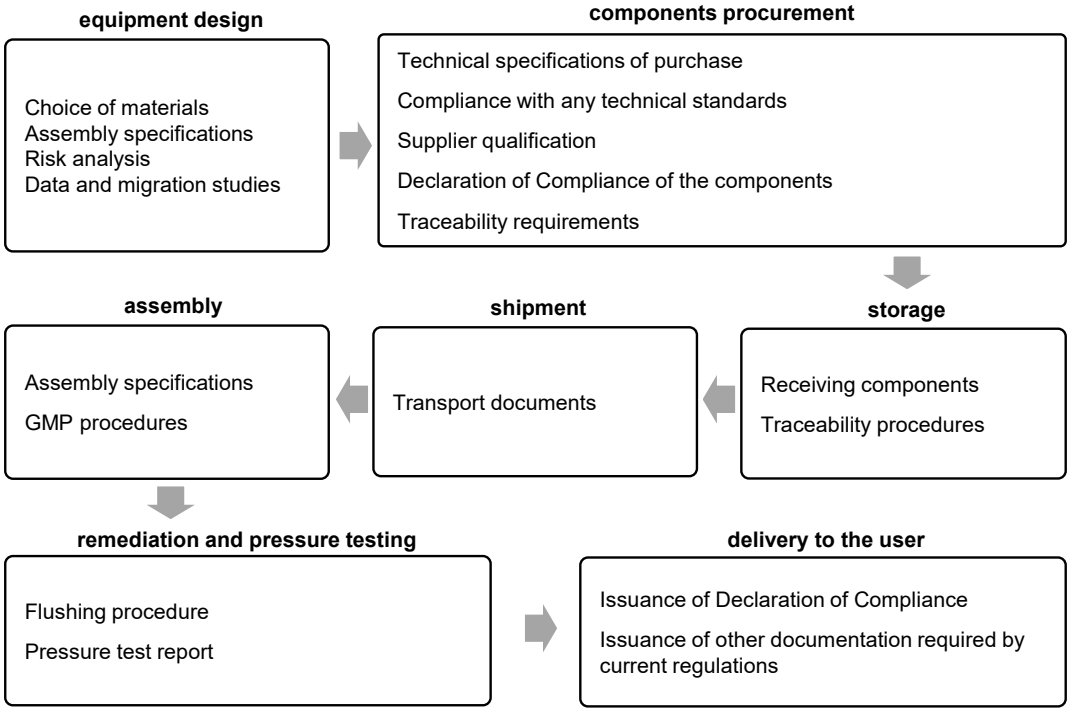

Figure B16.1. FOOD ADDITIVE GAS DISTRIBUTION EQUIPMENT: production phases and correlation with SD for DoC

B16.1.4. Production process of a food additive gases distribution equipment

The flow diagrams and detailed descriptions of the production phases of the equipment are described in points B16.1.3 in the document *Rapporto ISTISAN* 23/4 Rev. (8).

Manufacturers of food gases distribution systems are required to comply with Regulation (EC) 2023/2006 as amended and must therefore implement a quality management system (es. ISO 9001 or other) such as to ensure, in particular, process control and traceability.

B16.1.4.1. Equipment design

Based on the user's needs, the equipment design is carried out, and the construction scheme is developed taking into account regulations in force for materials and articles in contact with foodstuffs (Food Contact Materials, FCMs). This phase of the production process requires collaboration between user and producer to define the use of the food additive gas and the related plant.

During the design phase, the specific technical aspects related to the choice of components/materials and their assembly are also defined.

To complete the design phase, the compliance of the components with food contact is also assessed with the possible support of scientific documentation and/or DoC for FCMs.

B16.1.4.2. Component procurement

The system components are purchased according to predefined purchase specifications. The specifications detail the requirement for suitability of the components from a technical and a food safety point of view, together with the compliance with current regulations – Regulation (EC) 1935/2004 as amended, Regulation (EC) 2023/2006 as amended, PED Directive 2014/68/EU.[47] Component suppliers must issue their own DoC to the equipment manufacturer. The latter, in addition to certifying the compliance of the material with the legal requirements, constitutes an indispensable part of the SD for the producer which must be kept available to the competent authority upon request.

In addition, the requirements related to the traceability of the components themselves are requested and at the same time the information is recorded and stored.

The components purchased are taken in charge by the manufacturer and checked with regard to the accompanying documentation and compliance with the order together with the integrity of the packaging. The documentation provided by the component manufacturers (e.g. technical data sheets, compliance declarations, etc.) is requested and evaluated in relation to the specifications of use and/or foreseeable instruction for use.

It is good practice to implement a supplier qualification process, as required in the document *Rapporto ISTISAN* 23/4 Rev. (8) to paragraph B16.2.1.2.

B16.1.4.3. Component storage

The materials, appropriately identified by type, are stored in accordance with the provisions of company procedures.

Data on quantity, location and traceability are entered into the management systems.

[47] This Directive (known as PED, Pressure Equipment Directive) does not directly address compliance for food safety, but applies to the design, manufacture and conformity assessment of pressure equipment and assemblies with design pressure greater than 0.5 bar.

Storage involves the need to maintain suitable packaging of the component to preserve its integrity and maintain adequate hygienic conditions.

B16.1.4.4. Shipment

Depending on the equipment design, the components are taken from the warehouse – of the equipment manufacturer or component supplier – and shipped to the installation site.

Also in this phase, the traceability of the individual component is guaranteed with the help of the Transport Documents.

The integrity of the packaging is further checked upon the arrival of the material.

B16.1.4.5. Assembly

The components that are part of the food gases distribution system are unpacked and positioned according to the equipment design.

Subsequently, the interconnection pipes between the system components are assembled, in order to guarantee a single and functional whole.

The assembly phase involves the creation of permanent joints (welds), or connections with threaded or compression fittings. All assembly operations must refer to GMP in order to maintain the compliance with food contact of the components.

B16.1.4.6. Cleaning and pressure testing

Once assembled at the installation site, each distribution equipment is subjected to a flushing with inert food gas, in order to eliminate traces of impurities deriving from the processes during the assembly phase.

Subsequently, the equipment is subjected to a pressure test (testing) with inert food gas to verify the quality of the assembly according to the operating pressure indicated in the project.

B16.1.4.7. Delivery of the equipment to the user

Once the equipment has been completed and tested, the DoC is issued together with the documentation required by current regulations (e.g. use and maintenance manual).

By transmitting the aforementioned documents to the user, the manufacturer formally “delivers” the equipment.

B16.2. Supporting documentation

B16.2.1. Introduction

The purpose of this section is to clarify the requirements in relation to SD required by Regulation (EC) 1935/2004 as amended concerning materials and articles intended to come into contact with foodstuffs.

Specific documentation elements applicable to the operator’s position in the supply chain are identified.

The documents that make up the SD should be revised to reflect potential changes in production processes, changes in materials, components, regulatory updates, qualification of new suppliers or technological evolutions.

The SD is drawn up taking into account the types of equipment; in the event that the equipment have similar characteristics and intended uses, part of the SD can be the same.

B16.2.2. SD for manufacturers of food additive gas distribution equipment

In the production of food gases equipment, for the purposes of FCMs compliance, the SD should contain the DoC to Regulation (EC) 1935/2004 as amended for the components used in the equipment, or, in the absence of these, the equipment manufacturer is responsible for preparing documentation on the activities carried out to ensure compliance with FCMs laws.

B16.3. Points of correspondence between DoC and SD

SD can contain some specific elements that are mentioned directly by the DoC.

B16.4. Points of correspondence between GMP and SD

Some elements that are already part of the GMP documentation of the production cycle can also enter the SD, for example:

- specifications and performance of the components used;
- scientific documentation;
- elements for traceability;
- equipment specifications and performance.

The GMP documentation should provide evidence that the company has in place an SD management system that is used to determine compliance.

B16.5. SD topics not necessarily covered by GMP documentation

Some topics supporting compliance of food additive gas distribution systems may not necessarily be managed within the GMP system of a given business organization. For example, the company may have produced during the development phase an indicative documentation useful for the evaluation of the equipment, but considers it unnecessary for this documentation to be produced periodically and managed in the GMP system.

Below is a non-exhaustive list of these documents:

- results of overall and/or specific migration tests (if not already managed in the company quality system - GMP)
- application of mathematical models for migration screening
- technical documentation on applications and recommended conditions of use.

This does not imply the lack of such documentation but only the unsystematic execution of some activities. The documentation will in any case be traceable with a direct link to the asset in question.

Annex B16

Sheets for supporting documentation of food gases distribution equipment

Regulatory references

Regulation (EC) 1935/2004 as amended
Regulation (EC) 2023/2006 as amended (where applicable)
Regulation (EC) 10/2011 as amended.
Regulation (EU) 625/2017
DM 21/03/1973 as amended
DM 76/2007
DPR 777/1982
DL.vo 108/1992
DL.vo 29/2017

To harmonize the sheets of all the supply chains, the nine points contained in Annex IV of Regulation (EU) 10/2011 as amended have been used, although this Regulation is not directly applicable to the supply chain of food additive gas distribution equipment.

Sheet B16.a Economic operator issuing the compliance declaration

INDICATION	DESCRIPTION
Requirement 1	Identity and address of the economic operator issuing the DoC
Supporting documentation	Registration in the Register of Companies of the Chamber of Commerce Communication pursuant to art. 6 of DL.vo 29/2017 relating to establishments that carry out activities concerning FCMs
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art.6
DM 76/2007	art.8
Regulation (EC) 1935/2004 as amended	art. 16 art. 2.2, paragraph d
Notes	If the Economic Operator issuing the DoC is the same Economic Operator that produces or imports, requirements 1 and 2 coincide. To identify the responsibilities referred to this Requirement, please refer to art. 2 paragraph d of Regulation (EC) 1935/2004 as amended, which unequivocally defines the figure of the economic operator.

Sheet B16.b Economic operator who produces or imports the good

INDICATION	DESCRIPTION
Requirement 2	Identity and address of the economic operator producing or importing: - finished product (food gases distribution equipment)
Supporting documentation	Registration in the Register of Companies of the Chamber of Commerce Communication pursuant to art. 6 of Legislative Decree 29/2017 relating to establishments that carry out activities concerning FCMs
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art.6 art.8, paragraph c
DM 76/2007	art. 8
Regulation (EC) 1935/2004 as amended	art. 16 art. 2, paragraph d
Notes	If the economic operator issuing the DoC is the same economic operator that produces or imports, requirements 1 and 2 coincide. The economic operator is unequivocally defined by art. 2 paragraph d of Regulation (EC) 1935/2004 as amended

Sheet B16.c Identity of the asset

INDICATION	DESCRIPTION
Requirement 3	Identity of the asset to which the DoC refers: ❑ raw materials/substances ❑ intermediates/semi-finished products ❑ finished product (food gases distribution equipment) *tick the relevant item*
Supporting documentation	Use and maintenance manual; labelling
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6
DM 76/2007	art. 1
Regulation (EC) 1935/2004 as amended	art. 15, art.16.2
Notes	-

Sheet B16.d Functional barrier

INDICATION	DESCRIPTION
Requirement 4	Information on any functional barrier
Supporting documentation	Not applicable
Present guideline	Not applicable
DM 21/03/1973 as amended	Not applicable
DM 76/2007	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	-

Sheet B16.e Compliance with EU regulations/national legislation

INDICATION	DESCRIPTION
Requirement 5	Declaration of compliance with EU Regulations and/or national legislation where applicable
Supporting documentation	– use of components equipped with DoC FCMs constituting the food gases distribution equipment – scientific studies and/or technical reports proving compliance with migration limits – risk assessment for components without DoC FCMs used in the production process.
Present guideline	B16.2.2
DM 21/03/1973 as amended	art.10
DM 76/2007	art.8, paragraph 2 art.4, paragraph 1 annex I e II
Regulation (EC) 1935/2004 as amended	art. 3 art. 16
Notes	-

Sheet B16.f Restricted substances/materials

INDICATION	DESCRIPTION
Requirement 6	Adequate information about the substances and/or materials used and/or degradation products for which restrictions are in place
Supporting documentation	Not applicable
Present guideline	Not applicable
DM 21/03/1973 as amended	Not applicable
DM 76/2007	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	-

Sheet B16.g Restricted substances/materials in foodstuffs

INDICATION	DESCRIPTION
Requirement 7	Adequate information on substances and materials used that are restricted in foodstuffs
Supporting documentation	Not applicable
Present guideline	Not applicable
DM 21/03/1973 as amended	Not applicable
DM 76/2007	Not applicable
Regulation (EC) 1935/2004 as amended	Not applicable
Notes	-

Sheet B16.h Directions for use

INDICATION	DESCRIPTION
Requirement 8	Information on the use of FCMs: ❑ types of food products with which it is intended to come into contact ❑ duration, treatment temperature and storage in contact with food ❑ ratio of contact surface area to volume for determining compliance of FCMs ❑ other restrictions of use *tick the relevant items*
Supporting documentation	Operation and maintenance manual
Present guideline	B16.1.4.8 B16.4
DM 21/03/1973 as amended	art. 8
DM 76/2007	art. 5, art. 6
Regulation (EC) 1935/2004 as amended	art. 15 art. 16
Notes	-

Sheet B16.i Date of declaration

INDICATION	DESCRIPTION
Requirement 9	Date of declaration
Supporting documentation	Delivery documentation of the finished product *(food gases distribution equipment)*
Present guideline	A1.3.2.2
DM 21/03/1973 as amended	art. 6
DM 76/2007	art.8
Regulation (EC) 1935/2004 as amended	art. 16.2
Notes	The date of the DoC may not coincide with the date of delivery.

PART C
Use of non-legislative documents in evaluation processes

Introduction

The verification of the aspects of the quality assurance connected with the quality standards adequate for food contact use should ensure that the finished product will not endanger human health or bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties.

Therefore, the business operator should always perform an evaluation of compliance of the product both to the legislative requirements applicable for FCMs and to the general requirements of art. 3 of the Regulation (EC) 1935/2004 as amended.

It is desirable that this evaluation involves also the food industry.

In the evaluation process, when specific issues are afforded for which a specific EC or Italian legislation does not exist or it is not complete, non-legislative documents may be used, too, as useful supporting tools. Some examples are:

- Opinions of the Scientific Committee of Food of the EC Commission and Opinions of the European Food Safety Authority (EFSA);
- Opinions national, EU or not EU Authorities on food safety (es. *Bundesinstitut für Risikobewertung* German, *Food Standard Agency* English, *Food and Drug Administration* American, etc.);
- Council of Europe Resolutions;
- Relevant documents, wherever possible officially adopted by national and/or European industrial associations.

Documents adopted by industry associations

Some examples, non-exhaustive, of the possible sources of information adopted by national and/or European industrial associations are given below:

- Assoenologi, FederlegnoArredo, Unione Italiana Vini, Università Cattolica del Sacro Cuore 2012: *Il sughero - Manuale tecnico per il corretto utilizzo dei tappi*
- 2004: Assoimballaggi / FederlegnoArredo
  Imballaggi ortofrutticoli: linea guida per la caratterizzazione delle prestazioni e lo sviluppo di un sistema di rintracciabilità.
- Assovetro
  2018: Obblighi per materiali e oggetti a contatto con gli alimenti – Codice di comportamento dell'Industria Italiana del Vetro da Imballaggio (Quaderno Assovetro N. 4).
- Confédération Européenne du Liège
  2018: Codice internazionale per la produzione dei tappi di sughero. Versione 7.
- Confederation of European Paper Industries
  2013: Industry guideline for the compliance of paper & board materials and articles for food contact.
- Conseil Européan de l'Industrie des Peintures, des Encres d'Imprimerie et des Couleurs d'art 2007: *Code of practice for coated articles where the food contact layer is a coating* and related documents.

- European Metal Packaging
  2009*: Guide to good manufacturing and hygiene practices for metal packaging in contact with food.*
- European Printing Ink Association
  2020: *EuPIA Guideline on printing inks applied to food contact materials.*
  2017*: EuPIA EuPIA Guidance for Risk Assessment of Non-Intentionally Added Substances (NIAS) and Non-Listed Substances (NLS) in printing inks for food contact materials*
  2016*: EuPIA Good Manufacturing Practices for the Production of Packaging Inks for food contact materials.*
  2011: *EuPIA Guideline on Printing inks applied to the non-food contact surface of food packaging materials and articles*.
- Fédération Européenne des Industries de Colles et Adhésifs
  2022: *FEICA Guidance for food contact status declaration for adhesives.*
  2015: *FEICA Guideline for Good Manufacturing Practice of food packaging adhesives in Reference to Regulation (EU) No 2023/2006.*
- FederlegnoArredo, Agris, Unione Italiana Vini, Università Cattolica del Sacro Cuore
  2011: *Nuovo Disciplinare sulle metodiche analitiche per il controllo del tappo di sughero ad uso enologico.*
- Flexible Packaging Europe, CITPA
  2011*: Code for good manufacturing practices for flexible and fibre base packaging for food.*
- Plastics Europe Association of Plastic Manufacturers
  2012: *Guidelines for good manufacturing practice for plastic materials and articles intended for food contact applications.*
- Plastics Europe, Cefic-FCA, EUPC, FPE
  2014*: Risk assessment of non-listed substances (NLS) and not-intentionally added substances (NIAS) under article 19 of the European Commission Regulation (EU) No 10/2011 on plastics materials and articles intended to come into contact with food*.
- National Research Council of Italy (CNR)
  2019: *Study on migration processes of metal and non metal elements in a food gases distribution equipment*.
  2022: *ISO 4531:2022 Vitreous and porcelain enamels — Release from enamelled articles in contact with food — MethoSD of test and limits.* ISO (Organization for Standadization)
- UNI (Ente Italiano di Normazione)
  1997: *UNI EN 1388-2:1997 Materiali e articoli in contatto con gli alimenti. Superfici silicate. Determinazione della cessione di piombo e cadmio da superfici silicate diverse dal materiale ceramico.*
- Santè Publique Securitè de la Chaine Alimentaire Environnement (Belgio)
  1992*: ARRETE ROYAL du 11 MAI 1992 concernant les matériaux et objets destinés à entrer en contact avec les denrées alimentaires*.

CEPE Documents

On the website of the *Conseil Européan de l'Industrie des Peintures, des Encres d'Imprimerie et des Couleurs d'Art* (CEPE) (https://cepe.org/food-contact/documents/) the following documents are available:

- 2002 *Bisphenol a migration from can coatings - health implications for the consumer.*
- 2004 *Industrial guidelines on traceability of materials and articles for food contact.*
- 2006 *Guide to good hygiene and manufacturing practices for metal cans, packaging and closures for foodstuffs*.
- 2007 *Code of practice for coated articles where the food contact layer is a coating – Annexes II & III: inventory list for coatings intended to come into contact with food - compiled lists approved by the Council of Europe.*
- 2009 *Code of practice for coated articles where the food contact layer is a coating. (Edition 4).*
- 2009 *Coated articles where the food contact layer is a coating - Declaration of Compliance*.
- 2009 *Framework Resolution RESAP (2004)1 on Coatings Intended to Come Into contact with Foodstuffs - Version 3*
- 2010 *Code of practice for coated articles where the food contact layer is a coating - Annex X(a): Good Manufacturing Practices (GMP) Food Contact Coatings*.
- 2012 *Code of Practice for Coated Articles where the Food Contact Layer is a Coatings - Annex X(b): Good Manufacturing Practices (GMP) for the production of heavy-duty coatings intended to come into contact with food.*
- 2016 *Code of Practice for Coated Articles where the Food Contact Layer is a Coating - Annex XI: List of dual use substances*.
- 2017 *TSC34 Migration Testing Guidelines for rigid Metal Packaging Coated With Organic Coatings Intended for Direct Food Contact. VERSION 6.3*
- 2019 *TSC33 NIAS guidelines for coated rigid metal packaging intended for direct food contact. VERSION 1.7.5*

Note. Since the documents mentioned are not legally binding, the final assessment remains the responsibility of the Manufacturer/Economic Operator who must ensure that the product meets the declared conformity requirements.

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