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INTERGRAF AND FTA EUROPE

GUIDE TO APPLYING FOOD CONTACT MATERIALS LEGISLATION

GUIDANCE DOCUMENT

Contents

Introduction

Intergraf and **FTA Europe** have come together to produce a guidance document for printing and converting companies which make printed food contact materials.

Intergraf is the trade association promoting and protecting the interests of the graphic industry at European level. **FTA Europe** represents the flexo printing industry, the main technology for printed packaging in Europe. Their Secretariats share an office in Brussels. Both organisations are engaged in advocacy towards the EU institutions, events, and Europe-wide industry projects.

Food contact materials are increasingly a topic of focus for both EU and national legislators in Europe. Concern about harmful chemical migration means that strict rules are in place which must be applied by printers and converters.

This document is a guide to the applicable legislation and the basic legal requirements for food packaging printers. The aim is to help printers demonstrate that they are legally compliant. The guide should be viewed as the basic best practice advice which all printers should follow.

The complexity of proving compliance is in part due to the lack of harmonised legislation at EU level for all substrates. As this guide was developed, the European Commission was reviewing all legislation applicable to food contact materials and announced that new legislation would be announced in 2022. This guide serves the purpose of bringing together all legal requirements in the absence of a clear legal framework.

Regardless of size, all producers throughout the food contact material supply chain must fulfil their obligations under EU and national rules. With this in mind, we provide an ordered check list, so that printers can be sure that all steps have been followed, and risk of contamination has been minimised.

We also provide templates for the all-important declaration of compliance (by substrate) which you are very welcome to extract and use. As some national legislation may apply in your country of production or country of export, we advise you to supplement this guide with the recommendations of your national printing association. Details on how to contact your national experts are provided in the final section. Intergraf's dedicated FCM Task Force will also produce shorter guides on specific topics, like testing, over the course of 2021.

Packaging is a highly innovative and growing market in Europe. Legislative updates will need to respond to this, particularly to ensure that small converters can easily demonstrate compliance with food safety rules.

We hope that you find this guide useful in ticking off all the necessary steps. Happy printing!

"Food packaging is a growing market for printers, but the legislative framework is complex. With this guide, Intergraf and FTA Europe provide practical advice to help printers demonstrate compliance.

Beatrice Klose, Secretary General of Intergraf and FTA Europe

Part A: Best practice for compliance

A1: EU legislation

At EU level, general regulations are in place, and also some specific regulations for plastics and a few other substrates. All food contact materials sold on the EU market must adhere to these standards, regardless of whether the producer is located inside or outside of the EU; or is big or small. The regulations are applicable to all sectors at all stages of production, processing and distribution.

All substrates:

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

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

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

Plastic food contact materials and articles:

COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food and 15 amendments

AMENDMENTS: 1282/2011 – 1183/2012 – 202/2014 – 865/2014 – 174/2015 – 1416/2016 – 752/2017 – 79/2018 – 213/2018 – 831/2018 – 37/2019 – 988/2019 – 1338/2019 – 1245/2020

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.

Please consider that additional national legislation may also apply in the printer's country of production or country of export. See section 'About us' for information on your national association, which can advise you.

A2: Definitions

The following definitions illustrate the most important terms used in the applicable legislation.

Good Manufacturing Practices or GMP:

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

Global Migration:

Sometimes also referred to as 'overall migration'. This is the determination of the amount of substances that migrate from the material to a simulant liquid that reproduces the extractive capabilities of the food. This test cannot determine which substances have migrated from the tested material to the simulant, but it can quantify them. The contact conditions (time and temperature) are determined by current legislation, based on the actual conditions of use of the material. Simulant liquids can be aqueous, oily, or alternative liquids can be used.

Specific Migration

The quantification of certain substances (monomers, additives, plasticizers, elements and metals) in a simulant liquid. This test is of great importance for molecules regulated by regulations that impose a specific migration limit (SML).

Functional barrier

The barrier layer that prevents the migration of a substance above a value of 0.01 mg / kg of food (10 ppb).

Formulations:

Formulations are the composition of the input components of the semifinished or finished products. The inputs are used in the phases of the manufacturing process.

In the formulation, as well as the inputs, applying new technologies can be considered (in line with the system and objectives of the GMPs).

Business:

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

Materials and articles in Contact with Foodstuffs (FCMs):

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

Business operator:

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

Manufacturing or production processes:

All the phases of converting of raw materials, starting substances and semi-finished articles for obtaining semi-finished articles and finished products. In the manufacturing process, within the context of the Regulation (EC) 2023/2006, the phases of storage and handling of the raw materials, starting substance and semi-finished articles are considered along with the final phases of packaging the semi-finished article and finished product and stacking on pallets as well as the storage and transport phases.

Quality Assurance System (QAS):

The total sum of the organised and documented arrangements. The QAS ensures that materials and articles are of the quality required to ensure compliance with the rules applicable to them and the quality standards necessary for their intended use (from the Regulation (EC) 2023/2006, art. 3).

Quality Control System (QCS):

The systematic application of measures established within the Quality Assurance System that ensure compliance of starting materials and intermediate and finished materials and articles with the specification determined in the Quality Assurance System (from the Regulation (EC) 2023/2006, art. 3).

Specifications:

Regulation (EC) 2023/2006 art. 3 provides specifications for raw materials and semi-finished products. These must conform with the requirements of the legislation and other technical requirements.

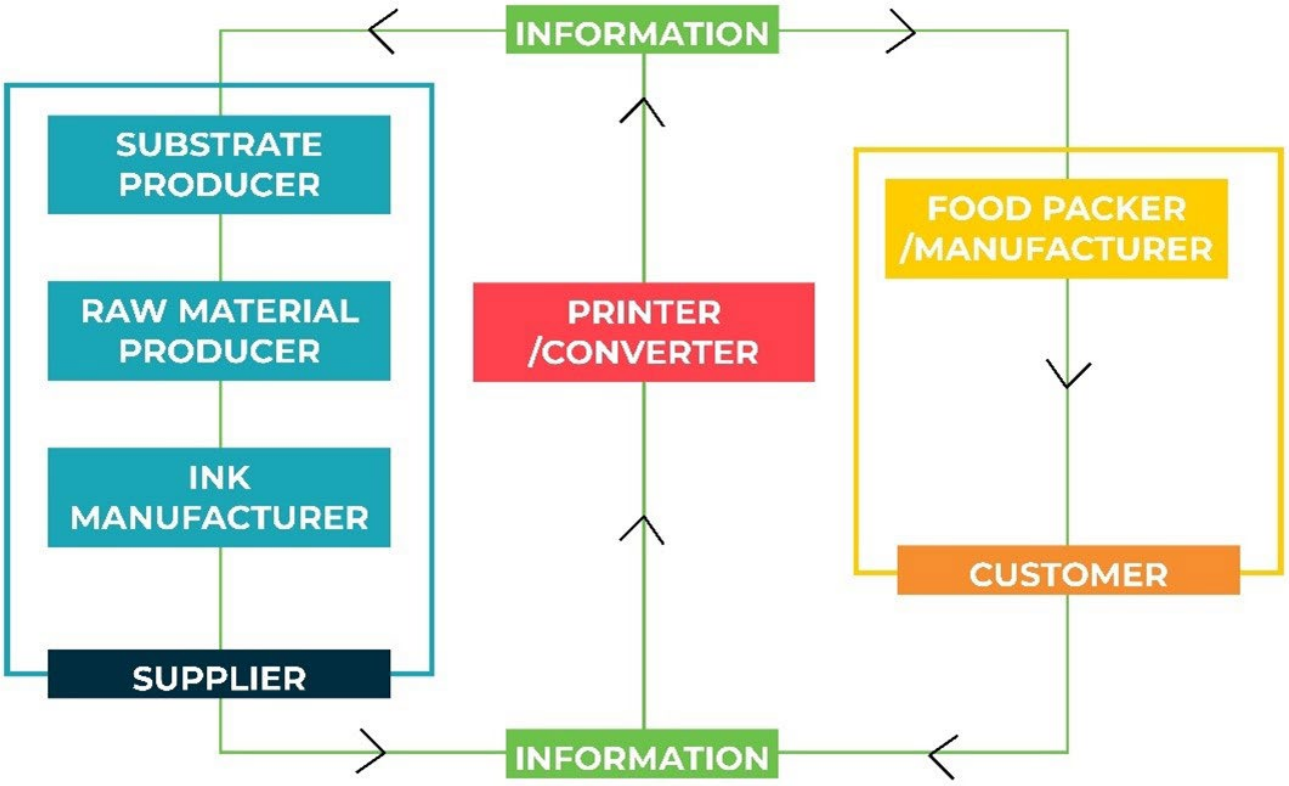
Generic use

The marketing of materials and objects for which the conditions of use and the food to be packaged are not known. In this case, the manufacturer declares any limitations. The declaration of compliance is always required.

Migration modelling

A mathematical algorithm that allows to estimate the maximum quantity of a substance that can migrate from packaging into the food it holds. The model is based on chemical diffusion laws and scientific evidence.

A3: General overview of working with FCMs



The printer is responsible to ensure that at all production stages minimise contamination risk of the final product, and of course the end consumer. Printers must set up an appropriate system of assurance to ensure that risk of contamination is minimised. Documentation is also crucial to prove that the correct steps have been taken. This must be made available to the competent authorities. At the end of the process, printers must produce a declaration of compliance (DoC) for their customer. This declaration is based on the printer's assurances that the correct steps have been made, as well as the information provided by the supplier. It is important to bear in mind the consequences for failing to complete the various steps sufficiently: recalls of contaminated products can have serious legal and business implications. For paper and cardboard packaging there is no specific European legislation defining the obligation to submit a DoC. However, it is mandatory to demonstrate compliance with the framework regulation (EC) 1935/3004 and in particular with Article 3.

A3.1 Important considerations

Information in the supply chain:

Of crucial importance is communication throughout the value chain. Each supplier is responsible for providing information to the next, to enable that producer to confidently declare that their product complies with the applicable legislation. The

printer should base their testing procedures on the information and assurances provided by their suppliers. Sufficient information must be provided by the supplier and documented both by the supplier and the printer. This should then aid the printer to demonstrate compliance. Section A4 provides more detail on this.

The CAST Project GMP guidelines (1) state that value chain communication is the "most effective approach for consolidating the cooperative relations that have to be set up between the parties and to guarantee the exchange of data and knowledge relevant to conformity [...] Obviously, in the absence of this information it transpires that the packaging supplier/ producer cannot be considered responsible for the related aspects." In other words, if a printer has not recieved sufficient information from its suppliers, demonstrating compliance is practically impossible and the printer cannot take responsibility for the safety of the packaging.

Documents which prove the compliance of each input and resulting product should be available to share with the competent authorities. Information and data can be shared with customers only on the basis of a commercial agreement and if necessary after a confidentiality agreement. Without prejudice to legislative obligations, with the aim of guaranteeing the safety of food products, more detailed information relating to the composition of the materials which will have contact with food can be obtained by resorting to confidentiality agreements that protect the ownership of the manufacturer's intellectual property. This allows the user to better understand the components of the material he intends to use.

Transparency, traceability and cooperation within the value chain is essential to improving legal compliance.

Packaging performance:

Considerations about how the food's packaging needs to perform is essential to ensuring the right materials are used, and the packaging is legally compliant. Any changes to product lines need to be communicated by the customer to the printer. For instance, if the recipe changes and a food now contains a moist ingredient, the packaging will need to be adjusted.

Before starting a new print job, the printer should consider the characteristics of the product. Is the food product solid or grated? Liquid or hard? Fatty? Potential to melt? Is there potential for the material to contact food, even if this was not intended? Think about tray liners at takeout restaurants, where food may feasibly end up. Storage conditions and transport are also important to think about. The materials utilised must be able to fulfil all these needs. In the worst case that the packaging is unsuitable, and migration should occur, costly recalls of the product could fall on the printer. This could also mean that the printer failed to prove compliance with the law.

Flexible Packaging Europe's GMP guidelines (2), designing for compliance means a combination of:

- the choice of substrates
- the choice of other raw materials
- the composition of laminates
- the application of inks, adhesives, varnishes and other coatings
- the choice of the production techniques and
- the geometrical design (e.g., surface/volume ratio especially for infant foods)

1. CAST Project. Guidelines for the application of the Regulation (EC) 2023/2006 to the supply chain of materials and articles intended to come into contact with food. Edited by Maria Rosaria Milana, Massimo Denaro, Roberta Feliciani, Antonino Maggio, Antonella Maini and Giorgio Padula 2011, xii, 193 p. Available under ISTISAN 11/37, https://www.iss.it/rapporti-istisan (2011)
2. Flexible Packaging Europe in cooperation with CITPA, 'Code for good manufacturing practices for flexible and fibre-based packaging for food', p.11, July 2011

Migration testing:

EU regulation requires printers to demonstrate that the final product is compliant with the law. All producers in the food contact supply chain - from the ink producer to the food packer - must demonstrate that their processes and resulting product is legally compliant. The printer, after careful internal verification of the information received, should also declare that their suppliers have provided the relevant documentation proving the acceptable test results that have been carried out. An acceptable test result will have followed the recommended procedures, described below, such as worst case scenario testing.

Whilst information from suppliers is necessary to ensure that the correct procedures have been followed to minimise contamination during production and transport, an internal analysis must be carried out by the printer. Testing for all combinations of materials and inks is an impossible task. Therefore, processes need to be in place to ensure the risk of migration is as low as possible, and within legal boundaries. Analytical tests, screening tests or mathematical evaluations, modelling can be used. Testing must be documented in case the control authorities require it.

Migration modelling or theoretical risk analyses are key here. Flexible Packaging Europe (3) recommends taking the following approaches:

- Worst case: Testing for the worst-case scenario means the results can be applied to less critical conditions. If the test results are acceptable in the most difficult situation means you can assume it is also acceptable in other situations and therefore do not need to make additional tests.
- the "Family Approach", whereby all the products within a suitably defined product family, are considered to comply with the restrictions applicable to them, upon evidence that an appropriate selection of individual samples complies with those restrictions by a sufficiently wide margin. Worst case testing can be used under the family approach.
- the "Building Blocks Concept", whereby evidence of compliance with applicable restrictions for a number of products, or parts of them, leads to the conclusion that other products made by different combinations of identical or similar components or raw material grades, can be considered to comply with those restrictions too.

Printers do not need to test every single product and surface. Screening of each 'family' of substances or substrates must be based on the worst-case scenario. If the results are acceptable for this worst-case scenario, it is safe to assume that others in the family are also acceptable. This reduces the level of testing which needs to be carried out.

Hygiene :

This section is taken from the CAST project guidelines (4). Whilst the Regulation on GMPs does not prescribe a Hygiene Control System; the existing voluntary standards such as ISO 22000, UNI EN 15593, BRC are valid examples of systems that can be used to ensure the respect of the hygiene requisites in packaging and semi-finished products. At any rate the analysis of the hygienic requisites, whether important in terms of position in the production chain, should consider:

3. Flexible Packaging Europe in cooperation with CITPA, 'Code for good manufacturing practices for flexible and fibre-based packaging for food', p.14, July 2011
4. CAST Project. Guidelines for the application of the Regulation (EC) 2023/2006 to the supply chain of materials and articles intended to come into contact with food. Edited by Maria Rosaria Milana, Massimo Denaro, Roberta Feliciani, Antonino Maggio, Antonella Maini and Giorgio Padula 2011, xii, 193 p. Available under ISTISAN 11/37, https://www.iss.it/rapporti-istisan (2011)

- hygiene of the personnel and cleanliness of the workplace
- risks of material contamination.

The possible cause of contamination of the materials and the articles during storage, processing and handling must be identified, kept under control, minimised, or completely removed where possible, this through adequate measures.

For example, these measures should include:

- prevention of risks of contamination from insects, rodents and/or other animals
- a company policy of hygiene of the environments and equipment
- rules for respecting hygiene during the storage, handling and shipping of materials and objects
- specific training of the personnel
- definition of eating areas that are separate from the production sections.

A4: Check list of responsibilities and actions (all substrates)

☑ Tick off each point of the check lists to ensure your production process is in strict compliance with EU regulation on food contact materials and GMPs.

Actioning the phases described below aims to help the printer to enusre that the end-product complies with the legislative, technical and performance requisites to guarantee the safety and suitability for the intended use. During each phase, an evaluation of the risk of contamination should be made. Potential sources and actions to prevent contamination should be identified. This checklist should be combined with the relevant substrate-specific information in Part B. Part A5 provides more information on the documentation required.

Quality Assurance Systems:

- ☐ Establish and maintain a Quality Assurance System and Quality Control System capable of fulfilling the legal requirements
- ☐ Ensure the system runs is appropriate for the company size, and technical and human resources available. It must guarantee compliance with applicable FCM legislation.
- ☐ Update the system if legislation changes (all parts of the production system).
- ☐ Document all activities of the Quality Assurance System for the competent authority's control purposes.
- ☐ Establish rules and procedures that regulate the company's activities. Cover at least the following points:
    - ☐ compliance with the requisites of the legislation in force
    - ☐ human resources and training
    - ☐ design and development of the product
    - ☐ selection of starting material and suppliers
    - ☐ arrival and control of raw material and storage
    - ☐ processes for non-compliant materials and time frames for this
    - ☐ production processes and traceability of the raw materials used
    - ☐ rules for intermediate products and semi-processed articles
    - ☐ quality control of the finished product
    - ☐ storage, handling and shipment
    - ☐ complaints and corrective and preventive actions.

Human resources and training:

- ☐ Appoint a business operator who is responsible for the management of the resources and the activities required to guarantee legal compliance at all levels of the organisation.
- ☐ Entrust competent and trained people with operative aspects if preferred (who have the means to confirm that the law is complied with).

- ❒ Set up cooperation with the Competent Authorities to enable inspections.
- ❒ Inform company personnel of the principles of GMPs, and the objectives of the law.
- ❒ Operate and implement procedures for personnel training for tasks that might affect compliance.
- ❒ Ensure that personnel assigned to GMP control activities are qualified (relevant training and experience).
- ❒ Maintain a record of the training process for all personnel.

Design and development of the product:

- ❒ Products are to be designed to be compliant with legislative requirements for FCM.
- ❒ Packaging material produced must:
  - ❒ Comply with the performances for intended final use
  - ❒ Comply with requisites of the legislation
  - ❒ Be produced with raw materials that have at all phases been produced in accordance with the legal requirements
- ❒ The following information must be provided by the customer to the printer:
  - ❒ nature of the food product to be packed
  - ❒ surface/volume ratio
  - ❒ shelf life of the product to be packed
  - ❒ filling, closure and preservation techniques of the final pack
  - ❒ thermal preservation processes that the pack along with its contents will be subjected to
  - ❒ modifications made to new product to ensure packaging is still suitable and compliant
- ❒ All this must be documented.

***NOTE** This is not an exhaustive list. For instance, when the produced goods go to the stockroom, the buyer and the concrete application may not yet be define. In this case, the printer must verify and declare the limitations.*

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

- ❒ Only use approved starting material which has been sent by the supplier with the relevant data to guarantee legal compliance (conditions of use, information from the supplier on tests etc.). Approved means that the converter has verified that the supplier meets all the legal requirements (where applicable) or has provided adequate information.
- ❒ Check the declaration of compliance provided by the suppliers contains the necessary information.
- ❒ Ensure traceability according to the EU Regulation on food contact materials and articles (see Annex for further traceability guidance).
- ❒ Check that the materials conform with the EU Regulation on GMPs, based on the information

provided by the suppliers.

- ❒ Store the materials in an adequately controlled area.
- ❒ Recommended: Use materials from qualified suppliers
- ❒ Recommended: Periodical visits (audits) to the supplier.
- ❒ Ensure that this has all been documented.

Raw materials:

- ❒ Check that raw materials have been delivered with their accompanying documents.
- ❒ Check that raw materials are not damaged and are packed in accordance to specifications agreed with supplier.
- ❒ Take samples to Quality Control and:
    - ❒ Store non-compliant materials in a designated area
    - ❒ Store materials checked for compliance separately from un-checked materials (either physically or via an IT system).
    - ❒ Move materials approved by Quality Control to the manufacturing area for processing.
- ❒ Write a written report if there are any reservations about the material.
- ❒ Store pallets in the raw material storage area according to company rules of procedure.
- ❒ Enter data on quantity and location into operating system.
- ❒ Double check the material is suitable for the job.
- ❒ Use materials on a 'first in, first out' basis (oldest should be used first).
- ❒ Remove protective packaging from the materials.
- ❒ Ensure that storage conditions do not risk contamination or deterioration of the material.
- ❒ Only use inks that are certified for indirect food contact.

Conformity of the production system:

- ❒ Ensure that the Quality Assurance System proffers sufficient attention to the most critical points of the production system that pose a risk to the legislative and technical compliance of the final product.
- ❒ All documentation must be available for the competent authorities' review.
- ❒ Rules and procedures must be put in place for the entire production process, including rules and corrective actions for dealing with non-conforming products

Documentation of procedure/instructions:

- ❒ Ensure that every production phase is regulated through adequate documentation (manuals, technical rules etc.) that is readily available to personnel and kept updated.

Finished product storage:

- ❒ Ensure that Quality Control assesses the final product.
- ❒ Only ship products which have been assessed as compliant with the original design stage and

legal requirements AND that have the correct documentation.

- ☐ Ensure that the product complies with the values and/tolerances entered in the product technical specifications or the specific legislation. Testing may be necessary here.

***NOTE** It is not always necessary to carry out lengthy tests. However, if a long test is required (e.g., migration test), the material cannot be shipped until the printer receives the results.*

- ☐ Additionally check (not legal requirements):
  - ☐ size (print pitch, etc.)
  - ☐ colour measure (density, etc.)
  - ☐ print machine conditions
  - ☐ set-off.
- ☐ Pack according to the specifications from the customer.
- ☐ Store in accordance with the procedures that regulate the storage of finished products (i.e., separate to unfinished, unchecked, or non-compliant products)
- ☐ Insert data on quantity, location, and comments by Quality Control into the company's information system.

Distribution, shipment and transportation:

- ☐ Establish a delivery plan with the customer.
- ☐ Check that Quality Assurance has not provided negative feedback, which would prevent the product from being shipped
- ☐ Check that the final product is accompanied by the correct documentation (transport document, certificate of conformity etc.)
- ☐ Ship to the final destination via the use of approved and trusted carriers.
- ☐ Ensure that the customer knows they are responsible for ensuring the shipping is in line with requirements of the final customer.
- ☐ If previously agreed that the printer/converter is responsible for the transport to the destination, instructions and procedures must be put in place to avoid damage or contamination in transit.
- ☐ Consider:
  - ☐ Periodic checks
  - ☐ Safety and hygiene
  - ☐ Checks on additional couriers
  - ☐ Risks of damage or contamination

Returned products:

- ☐ Segregate any products returned by the customer deemed non-compliant from all other production materials and products to avoid contamination.
- ☐ A procedure for disposal or destruction is advised.
- ☐ Seek legal advice if products have been recalled due to suspicion of contamination.

A5: Documents for compliance

All the documents concerning the Quality Assurance System (procedures, specifications, formulations, etc.) and all the activity under the Quality Control System (instructions, registrations of control data, machine setup data, tolerances and measurements etc.) must be organised in a paper or electronic archive. This archive must be immediately accessible and easily consultable on request by the competent authorities.

Traceability documents constitute an integral part of the printer's obligations under Art. 17 of the Regulation (EC) 1935/2004. The documents should also include copies of the DOC issued by the customers (Art.16), and the conditions for tests, calculations and analyses, which have been carried out by internal and external laboratories. This all helps to demonstrate legal compliance.

The documentation should be updated if there are substantial changes to production processes or legislative requirements (EU or national). Printers are advised to contact their national printing association for advice on recent legislative changes. Please see the final page of this document for contact information.

The declaration of compliance (DoC) is a key document to prove that all the necessary steps have been taken, based on the information provided to the printer by their supplier. The following section includes a draft suggested template which could be used.

Part B: Substrate-specific guidelines

Section B brings together specific advice on each substrate included in this guidance document. Companies producing packaging or other materials which are intended to come into contact with food should combine this advice with the check list in Part A4 and information in Part A5.

B1: Paper & board

B2: Flexible packaging and plastics

B1: Paper and board

Examples of paper and board FCM include printed flat cardboard cartons, corrugated cardboard boxes, and paper bags.

B1.1: Guidance

EUPIA 'EuPIA Guidance on Migration Test Methods for the evaluation of substances in printing inks and varnishes for food contact materials', p.6 on '4.2.1 Preparation of test samples Printing and drying', 2nd amendment August 2020.

FEICA, the Association of the European Adhesive & Sealant Industry, 'FEICA Guideline for Good Manufacturing Practice of food packaging adhesives in Reference to Regulation (EU) No 2023/2006', March 2015.

FEFCO (European Federation of Corrugated board manufacturers) in cooperation with ESBO and ISA 'International Good Manufacturing Practice Standard For Corrugated & Solid Board', p.6 on 'Converting Corrugated and Solid Board into Packaging', January 2006.

FEFCO in cooperation with ESBO and ISA 'Acceptance Conditions and Procedure for Certifying Bodies International Good Manufacturing Practice Standard For Corrugated & Solid Board', January 2006.

Alliance for Beverage Cartons and the Environment; CCB, CEPI, CITPA, ETS, ECMA, FEFCO, 'Food contact guidelines for the compliance of paper & board materials and articles', p. 9 on 'Paper and board converting operations', March 2019.

ECMA, Good Manufacturing Practice Guide 2.0, A management tool for folding carton companies - guiding their policies on food safety, 2021

CEPI, 'Food Contact Guidelines for the Compliance of Paper and Board Materials and Articles', 2019 & February 2021 corrigendum.

B1.2: Declaration of Compliance (DOC) template

General advice:

- Use a company letterhead
- The phrase 'information as provided by the customer/supplier' is key
- Information on the food should be provided by the customer, and could be based on Annex III, Table 2 of the Regulation (EU) 10/2011 (suggested for paper, but only obligatory for plastics).
- The person who is liable should be in charge of one of the following areas at the company: quality control, R&D, laboratory, technical management and other equivalents
- A company stamp should be included on the document.
- The annex is optional, not compulsory.

Extractable DoC template →

DECLARATION OF COMPLIANCE FOR MATERIALS AND OBJECTS INTENDED TO COME INTO CONTACT WITH FOOD PRODUCTS

Destination company:

Recipient (if information is available):

1. Declaring company

Company name:

Company address:

Contact email address and telephone number:

2. Packing information

Trade name (if applicable):

Specification, and / or stratigraphy with inks and adhesives specifying the side in contact:

3. Product information

According to the information provided by *[insert customer name]*:

Product description:

Food category and reference:

Conditions of use (time, temperature, heat treatments, modified atmosphere):

4. Compliance

Based on the best available information from *[customer name]* regarding the product, as well as information provided by the material suppliers and internal evaluation, it is declared that the material described above complies with:

EU legislation:

- Regulation 1935/2004/EC and subsequent updates and modifications
- Regulation2023/2006/EC and subsequent updates and modifications
- *Additional national laws - check with your local trade association*

5. Testing

It is declared that *[tick]*:

❒ The food category or the substrate (specify the material) does not require overall migration tests

❒ The food category requires overall migration tests carried out under the following conditions:
Simulant/relevant reading:
Time and temperature or OM test:

The tests were carried out assuming that 1 kg of food comes into contact with 6 dm2 of the product.
*(**NOTE**: If the surface / volume ratio is different, specify which data was used)*

SPECIFIC MIGRATION

The packaging contains the following substances subject to specific migration limits:

Substance name:
CAS number and / or FCM and / or PM REF:
SML of the substance:
(NOTE: Only the substances for which information has been recieved from the suppliers should be declared.)
The material complies with the specific migration limits and the statement is *[tick]*:

❒ *Based on calculations (**NOTE**: see Art. 18 Reg. (EU) 10/2011 plastics Regulation – recommended but not obligatory for paper)*

The calculations were performed assuming that 1 kg of food comes into contact with 6 dm2 of the product.
*(**NOTE**: If the surface / volume ratio is different, specify which data was used)*

❒ Based on analytical tests carried out in the following conditions:

Simulant/relevant reading:
Time and temperature or OM test:

The calculations were performed assuming that 1 kg of food comes into contact with 6 dm2 of the product.
*(**NOTE**: If the surface / volume ratio is different, specify which data was used)*

❒ Screening test on the migration of the substances carried in accordance with the relevant legislation, where applicable. *(See Art. 18 Reg. (EU) 10/2011 and Annex V, Chapter 2, par.2.2 - recommended but not obligatory for paper)*

The screening tests were performed assuming that 1 kg of food comes into contact with 6 dm2 of the product.
*(**NOTE**: If the surface / volume ratio is different, specify which data was used)*

6. Final statement

The user of the food contact material has the responsibility of notifying the company (which writes the document) of any restrictions deriving from the compositional ingredients (such as additives and flavouring) of the food product to be packaged.

Industrial or business usage of the material specified herein must comply with the relevant legal requirement as well the technical suitability for its intended purpose.

The validity of this certificate shall start from the date specified below. The statement remains valid as long as *[tick]*:

❒ no substantial changes in the composition and / or in the production process of the material will intervene or produce considerable modification of its essential requirements for compliance.

OR

❒ as long as the legislative references cited therein are not modified or updated in such a manner as to require a new evaluation of the compliance.

Date:

Signature and function:

Annex – Declaration of compliance

7. Functional barrier *[tick]*

❒ A functional barrier is not in the supplier product

❒ There is a functional barrier in the supplied product

The XXX layer of the product supplied acts as a functional barrier. The layer separates the food from monomers and / or additives which are not listed in the Regulation and are present in the outer layers.

It is confirmed that:

a. The non-listed substances are not classified as CMR (mutagenic, carcinogenic or toxic to reproduction) in accordance with the criteria set out in paragraphs 3.5, 3.6 and 3.7 of Annex I of the CLP Regulation (EC) No 1272/2008.
b. The non-listed substances are not in nanoform as defined in the Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696 / EU).
c. In the conditions of intended use, the migration of non-listed substances is not detectable with a detection limit of 0.01 mg / kg.

The packaging contains the following non-listed substances:

Substance name:

CAS number and / or FCM and / or PM REF:

8. NIAS (Not Intentionally Added Substances)

*(**NOTE**: Often requested by the customer but not obligatory for paper under the law)*

According to information in our possession, received from our suppliers, the product supplied *[tick]:*

❒ Contains "no known NIAS". (NIAS - Not Intentionally Added Substances).

If present, a risk assessment has been carried out on these substances in accordance with Article 19 of the framework Regulation (EU) 10/2011.

9. Printing inks

Based on the information received from our suppliers, it is declared that the inks used for the manufacture of the product are formulated and manufactured in accordance with the EuPIA *"Guideline on Printing Inks applied to Food Contact Materials"* . The inks do not contain substances listed in the EuPIA exclusion policy.

OPTIONAL:

- All the starting substances of the inks are listed in the Swiss Ordinance on substances and articles in contact with food, Section 12 (articles 33-35), Annex 2, and Annex 10.

10. Adhesives

Based on the information received from our suppliers, it is stated that the adhesives used in the manufacture of the product are formulated in accordance with FEICA guideline relating to GMP (Good Manufacturing Practices) in the production of adhesives and sealants used for packaging intended to come into contact with food.

OPTIONAL:

- The adhesives in this product comply with the FDA 21 CFR Section 175.105.
- The adhesives in this product comply with the recommendation BfR XXVII

11. Supporting documentation

Under Article 16 of the framework Regulation (EU) 10/2011, we inform you that suitable documentation is present in our company to demonstrate and support all the points of this declaration of conformity. This documentation is available to the official control authorities that request it.

B2: Flexible packaging and plastics

Examples of flexible packaging include plastic films, laminates, and sachets.

B2.1: Guidance

Joint Research Centre, *'Practical guidelines on the application of migration modelling for the estimation of specific migration'*, 2015.

EUPIA, p.6 on *'EuPIA Guidance on Migration Test Methods for the evaluation of substances in printing inks and varnishes for food contact materials'*, *'4.2.1 Preparation of test samples Printing and drying'*, 2nd amendment August 2020.

FEICA, the Association of the European Adhesive & Sealant Industry, '*FEICA Guideline for Good Manufacturing Practice of food packaging adhesives in Reference to Regulation (EU) No 2023/2006*', March 2015.

Flexible Packaging Europe in cooperation with CITPA, '*Code for good manufacturing practices for flexible and fibre-based packaging for food*', July 2011. See:

- Developing packaging materials, p.12
- Recycled plastics, p.25
- Migration, p.14

'*CAST Project Guidelines for the application of the Regulation (EC) 2023/2006 to the supply chain of materials and articles intended to come into contact with food*', 2009. See examples of some characteristic parameters that can be kept under control:

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

B2.2: Declaration of Compliance (DoC) template

- Use a company letterhead
- The phrase 'information as provided by the customer/supplier' is key
- Information on the food should be provided by the customer, and could be based on Annex III, Table 2 of the Regulation (EU) 10/2011
- The person responsible for signing the document should be in charge of one of the following areas at the company: quality control, R&D, laboratory, technical management and other equivalents
- A company stamp should be included on the document.
- The annex is optional, not compulsory.
- For OM testing, see Annex V, paragraph 3, Table 3 of the Regulation (EU) 10/2011)

Extractable DOC template →

DECLARATION OF COMPLIANCE FOR MATERIALS AND OBJECTS INTENDED TO COME INTO CONTACT WITH FOOD PRODUCTS

Destination company:

Recipient (if information is available):

1. Declaring company

Company name:

Company address:

Contact email address and telephone number:

2. Packing information

Trade name (if applicable):

Specification, and / or stratigraphy with inks and adhesives specifying the side in contact:

3. Product information

According to the information provided by *[insert customer name]*:

Product description:

Food category and reference:

Conditions of use (time, temperature, heat treatments, modified atmosphere):

4. Compliance

Based on the best available information from [customer name] regarding the product, as well as information provided by the material suppliers, it is declared that the material described above complies with:

EU legislation:

- Regulation 1935/2004/EC and subsequent updates and modifications
- Regulation2023/2006/EC and subsequent updates and modifications
- Regulation 10/2011/EU and subsequent updates and modifications
- *Additional national laws - check with your local trade association*

5. Testing

It is declared that *[tick]*:

❒ The food category or the substrate (specify the material) does not require overall migration tests

❒ The food category requires overall migration tests carried out under the following conditions:
Simulant/relevant reading:
Time and temperature or OM test:

The screening tests were performed assuming that 1 kg of food comes into contact with 6 dm2 of the product.
*(**NOTE**: If the surface / volume ratio is different, specify which data was used)*

6. Migration of substances subject to a specific migration limit

The packaging contains the following substances subject to specific migration limits:

Substance name:
CAS number and / or FCM and / or PM REF:
SML of the substance:

The material complies with the specific migration limits and the statement is *[tick]*:

❒ Based on calculations (see Art. 18 Reg. (EU) 10/2011)

The screening tests were performed assuming that 1 kg of food comes into contact with 6 dm2 of the product.
*(**NOTE**: If the surface / volume ratio is different, specify which data was used)*

❒ Based on analytical tests carried out in the following conditions:
Simulant/relevant reading:
Time and temperature or OM test:

The screening tests were performed assuming that 1 kg of food comes into contact with 6 dm2 of the product.
*(**NOTE**: If the surface / volume ratio is different, specify which data was used)*

❒ Screening test on the migration of the substances carried in accordance with the relevant legislation, where applicable. *(See Art. 18 Reg. (EU) 10/2011 and Annex V, Chapter 2, par.2.2)*

The screening tests were performed assuming that 1 kg of food comes into contact with 6 dm2 of the product.
*(**NOTE**: If the surface / volume ratio is different, specify which data was used)*

7. Dual Use Additives

The material contains *[tick]*:

❒ No substances regulated by Regulation 1333/08 / EC and/or Regulation 1334/08 / EC (substances called “dual use” additives).

❒ The following substances regulated by Regulation 1333/08 / EC and/or regulation1334/08 / EC (substances called “dual use” additive)

Substance name:

CAS number and / or FCM and / or E-number:

8. Final statement

The user of the food contact material has the responsibility of notifying the company (which writes the document) of any restrictions deriving from the compositional ingredients (such as additives and flavouring) of the food product to be packaged.

Industrial or business usage of the material specified herein must comply with the relevant legal requirement as well the technical suitability.

The validity of this certificate shall start from the date specified below. The statement remains valid as long as *[tick]*:

❒ no substantial changes in the composition and / or in the production process of the material will intervene or produce considerable modification of its essential requirements for compliance

OR

❒ as long as the legislative references cited therein are not modified or updated in such a manner as to require a new evaluation of the compliance.

Date:

Signature and function:

Annex – Declaration of compliance

1. Compliance with Regulation Framework (EU) 10/2011 *[tick]*

❒ Plastic films used in this project are made only with monomers, other starting substances and additives which are authorised under Regulation (EU) 10/2011.

❒ The plastic film layers used in this project which are not separated from the food by a functional barrier, are

☐ produced only with monomers and / or other starting substances and additives which are authorised under Regulation (EU) 10/2011.

☐ Our plastic film suppliers have informed us that substances added intentionally, non-listed in Annex I of the Regulation, comply with the requirements of the framework Regulation. For these substances, a risk assessment in accordance with Article 19 of the Regulation (EU) 10/2011 has been performed

2. Functional barrier *[tick]*

☐ In the supplied product there is no functional barrier

☐ In the supplied product there is a functional barrier

The XXX layer of the product supplied acts as a functional barrier. The layer separates the food from monomers and / or additives which are not listed in the Regulation and are present in the outer layers.

It is confirmed that:

a. The non-listed substances are not classified as CMR (mutagenic, carcinogenic or toxic to reproduction) in accordance with the criteria set out in paragraphs 3.5, 3.6 and 3.7 of Annex I of the CLP Regulation (EC) No 1272/2008.
b. The non-listed substances are not in nanoform as defined in the Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696 / EU).
c. In the conditions of intended use, the migration of non-listed substances is not detectable with a detection limit of 0.01 mg / kg.

The packaging contains the following non-listed substances:

Substance name:

CAS number and / or FCM and / or PM REF:

3. NIAS (Not Intentionally Added Substances)

According to information in our possession, received from our suppliers, the product supplied *[tick]*:

☐ Contains “no known NIAS”. (NIAS - Not Intentionally Added Substances).

For these substances (if present) a risk assessment in accordance with Article 19 of the framework Regulation (EU) 10/2011 was performed.

4. Recycled plastic *[tick]*

☐ The product supplied does not contain recycled plastics material as defined by and subject to Regulation (EC) No 282/2008.

☐ The product supplied contains recycled plastics derived from authorised number XX of the EC Registry recycling

process in accordance with Regulation (EC) 282/2008. The supplier confirms that the raw material used for recycling, the recycling process and the recycled plastic meet the specifications for which the authorisation was granted in accordance with Regulation (EC) 282/2008.

5. Printing inks

Based on the information received from our suppliers, it is declared that the inks used for the manufacture of the product are formulated and manufactured in accordance with the EuPIA guideline *"on printing inks applied to the surface not in contact with the food materials of objects destinated to come into contact with food."* Additionally, the inks do not contain substances listed in the EuPIA exclusion list.

OPTIONAL:

- All the starting substances of the inks are listed in the Swiss Ordinance on substances and articles in contact with food, Section 8b, packaging inks, art. 26e-26i, Annex 6.

6. Adhesives

Based on the information received from our suppliers, it is stated that the adhesives used in the manufacture of the product are formulated in accordance with FEICA guideline relating to GMP (Good Manufacturing Practices) in the production of adhesives and sealants used for packaging intended to come into contact with food.

The adhesive is cross-linked in such a way that, when it is tested in conditions of time and temperature as stringent recognised as the actual conditions of use, the product delivered does not release, in the food or in food simulant, primary aromatic amines (PAA) in an amount at or above the detection limit of 0.01 mg / kg food, as required by Annex II of Regulation (EU) 10/2011.

OPTIONAL:

- Adhesives and starting substances do not fall within the scope of Regulation (EU) 10/2011. It states, however, that the starting materials for adhesives in this product are listed in Regulation (EU) 10/2011.

OPTIONAL:

- The adhesives in this product comply with the FDA 21 CFR Section 175.105.
- The adhesives in this product comply with the recommendation BfR XXVII

7. Supporting documents

Under Article 16 of the framework Regulation (EU) 10/2011, we inform you that suitable documentation is present in our company to demonstrate and support all the points of this declaration of conformity. This documentation is available to the official control authorities that request it.

Part C: FAQ

Q1 What does GMP mean?

It is short for Good Manufacturing Practices.

Q2 How are the GMPs defined?

GMPs are defined as "those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof".

Q3 What is Regulation (EC) 2023/2006?

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

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

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

a. endanger human health;

b. bring about an unacceptable change in the composition of the food; or

c. bring about a deterioration of the organoleptic characteristics thereof.

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

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

Q6 What are the production chains of the different materials?

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

Q7 Who is responsible for ensuring the application of the GMPs?

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

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

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

Q9 What are the quality management systems?

The Quality Assurance System defines the sum total of arrangements made with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use.

Q10 Do businesses have to be certified?

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

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

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

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

Yes. A certified Quality System (i.e., EN.ISO 9000, BRC) stands as an excellent basis for implementing the GMPs, that all the same should not be confused with the Quality System in itself. These systems can what is more already include the GMPs but cannot in themselves be considered a sufficient condition.

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

The obligations laid down in the Regulation (EC) 2023/2006 do not consider the size of the business but, in the foreword (comma 6) it is stated that "The rules on GMPs should be applied proportionately to avoid undue burdens for small businesses". As well as that, in art. 5 ("Systems of quality assurance" it is laid down that "the system has to [...] be applied considering the size of the business, so as not to constitute and excessive burden for the business").

Q14 What is FCM traceability?

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

Q15 How do you ensure an adequate hygiene level?

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

Q16 How do you prevent contamination?

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

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

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

Q18 Does one have to involve all company personnel?

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

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

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

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

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

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

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

Q22 What does one need to do for the documentation?

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

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

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

Q24 What should one do to manage GMPs of raw materials?

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

Q25 How does one manage the change?

Any variation in a given process that has influence on the conformity and requisites on FCMs (ie the use of a new raw material, a new formulation, or a new machine) should be evaluated before the implementation. The GMP system should be re-evaluated at each change to check any need for a potential review of the system. Documentary traces of any changes should be kept.

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

The handling, transport and storage conditions should be organised in way which avoids adulterations and contaminations both of raw materials, as well as semi-processed and finished articles.

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

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

Q28 How does one check the effectiveness of the GMPs?

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

Q29 Who checks the application of the GMPs?

The implementation of controls as to the application

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

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

The Italian ministry of Health has issued Circular 24th January 2006 “Materials and objects intended for food contact: responsibility of the Enterprises and the Food Industry”. The Circular can be found at the web address: http://www.ministerosalute.it/imgs/ C_17_normativa_745_allegato.pdf

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

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

Annex

Traceability guidelines

Introduction

Framework Regulation (Regulation (EC) N ° 1935/2004) requires all producers of materials and articles intended to come into contact with food products to set up a traceability system that facilitates the tracing of all the materials along the supply chain. This should cover their origin and batches of production. To further guarantee the safety of the final consumer, when a problem arises, it should be possible to trace it back along the entire food chain and isolate the batches under investigation and to identify the raw material which caused the problem.

This document provides practical tips on putting in place a system which can trace all the raw materials used in the production cycle by putting them in direct connection with the finished product that is sent to customers.

Please note, it is not technically possible to have greater precision in a continuous industrial process, therefore in some cases (e.g., returned printing inks) approximations have been proposed that are dictated by daily experience.

Packaging production cycle is always well circumscribed and temporally delimited. This allows to obtain, for a specific identified batch, a good traceability of raw materials with a limited margin of uncertainty.

It is recalled and underlined that these guidelines constitute a reference document to be used on a voluntary basis but do not relieve the operator of the legal responsibilities provided for by regulation 1935/2004 / EC, Article 17, where it speaks of a traceability system to be apply based on technological feasibility. The margins of uncertainty suggested in some cases are a simple indication deriving from work experience.\

Field of application

The Framework Regulation 1935/2004 / EC applies to any type of material or object intended for contact with food, regardless of its composition.

This guide applies to packaging intended for contact with food placed on the market and to raw materials used for the manufacture of said materials intended for contact with food.

Definitions

Traceability:

A set of systems that each operator adopts to correlate their products with the raw materials used to produce them (for the definition see UNI EN ISO 9001/2008).

There are two levels of traceability:

Level 1: internal traceability of the activities of each operator. This level concerns the systems that each operator adopts to correlate their products to the raw materials used to produce them.

Level 2: traceability between different operators. The transmission of information along the supply chain belongs to this level. From any point downstream, and in particular starting from the point of sale, it is necessary to trace back the supply chain and understand who produced the material or object.

This also implies that, in the opposite direction, the material or object can be followed from any point along the supply chain up to retail. To achieve full traceability both levels must be active.

Tracking

“The ability to build back the history of a material or object intended for contact with food from the point of sale to that of manufacture, identifying all the appropriate information” (5).

5. Joint Research Centre, ‘Practical guidelines on the application of migration modelling for the estimation of specific migration’, 2015.

The definition of 'production batch" is not unique and varies from company to company. On the basis of the production practices of the associated companies, a definition is suggested that in usual practice is the most commonly used, although it is not the only one:

Batch identification

In packaging production process, the batch normally corresponds to the identification code of a production made with or without temporal discontinuity according to the cycle (sequence of machine operations and seasonings) predefined in the registry. The identification code is unique and is shown on the label of delivery documents and pallets. The typical units of measurement that are used to express the size of a lot are: linear meter, km, square meter, number of pieces, kg.

Other definitions are not excluded a priori, which may be agreed between customer and supplier from time to time. It is essential that the converter makes it explicit which definition it refers to in its traceability system.

EU legislation

Regulation (EC) n. 1935/2004 - Article 17 requires the following:

- ☑ The traceability of materials and objects must be guaranteed at all stages to facilitate the control, collection of defective products, the communication of information to consumers and the attribution of responsibility.
- ☑ Taking due account of technological feasibility, economic operators must have systems and procedures that allow the identification of the companies from which and to which the materials and objects and, where appropriate, the substances and products, regulated by the regulation and related implementing measures, used in their processing. This information is made available to competent authorities upon request.
- ☑ The materials and objects placed on the EU market must be identifiable by an adequate system that allows their traceability through labelling or relevant documentation or information.

Traceability models

It should be noted that the raw materials are delivered both in transport packaging (e.g. pallets, reels, bags, octa bins, drums etc.), and loose (in tanks or cisterns) therefore each material must have its own traceability path and must be able to be identified at internal part of a production batch according to its use.

Normally, upon delivery, the MP (raw materials) are accompanied by information on labels (text and / or bar codes) and on documents accompanying the load. The traceability of MP batches can be based on supplier labels (manual traceability) or on receipt you can apply labels with customised "barcodes" that allow you to uniquely manage the goods.

Let's now analyse the different types of raw materials:

Raw materials:

To address the issue of raw materials, we divide by type:

a. Raw materials: plastic film in reels, paper in reels /pallets of paper-cardboard / Aluminium

In order to guarantee the complete traceability of the rolled materials, the following information must always be available:

- ☑ Name of the supplier and the type (grade) of raw material;

- ☑ Lot number and / or production shift and / or order number; and/or
- ☑ roll number/pallet number.

Other information, not mandatory for traceability, but certainly useful as supporting documentation, are the following:

- ☑ Place and date of production and, where required, certification of compliance with current legislation; and
- ☑ Analysis certificates showing compliance with specifications.

There are critical aspects that must be taken into consideration for the correct application of company traceability; in particular it is necessary to refer to:

- ☑ management and archive of counter-samples;
- ☑ correspondence between the information present in the delivery note and those present on the labels of the reels, pallets or other; and
- ☑ package splitting operation if the pallets contain more reels.

When the material is brought to the department for use, it is important during production that:

- ☑ for each pallet/reel of raw material used, the exact moment in which it starts to be used is recorded; and
- ☑ that the same reel of raw material (e.g. PET, ALL), if used for the production of several subjects (material codes), is registered several times.

At the end of production, when there is a return of raw materials in stock, it is necessary that:

- ☑ the original supplier label is kept, especially in the event of a complaint; and
- ☑ the label is updated taking into account the quantity consumed.

In general, if different management systems are used in the company (e.g. for the warehouse and production), their interface should be checked.

a. Inks, Varnishes, Lacquers, Coatings

The starting containers are drums, tanks, or cans. The ink can be transferred to the printing machine via pipeline or through drums that must be identified.

Many colours are obtained by mixing different inks therefore the recipe or composition should be registered. It is preferable to consider, where possible, the corrections made on the machine.

Keep in mind that if an anomaly (e.g., contamination) is identified on a printed material, it is important to trace which of the colours is attributable (in fact, in general there are 3-8 colours).

Returns management: Several batches / remnants of the same colour can be mixed in a tank. It is preferable to have a complete trace of the recipes; each loading-unloading should then be recorded.

b. Adhesives

The starting containers can be drums or tanks. It is important to always keep the traceability of both the adhesive batch and the catalyst batch (for bi-component adhesives).

It is important that on the same pallet (e.g., catalyst cans) there are no containers of different batches.

It is important, during the production of a batch, to record the subsequent additions of adhesive to the tray and to take into account the moment in which the drums / tanks are changed.

c. Auxiliary products (cold seal, hot melt, waxes, etc.)

The starting containers can be drums, bags, tanks, etc. It is important to always maintain the traceability of the auxiliary batch.

Any corrections or additions of other components must be recorded. It is important that on the same pallet (e.g., cold seal drums) there are no containers

of different lots.

It is important, during the production of a batch, to record the subsequent additions of product to the tray and to take into account the time in which the drums / tanks / bags are changed.

If at the end of the processing, there is a production return this must be recorded and the data of the production batch of origin must be reported.

d. Solvents

They are not considered components of the finished product and therefore their traceability may not be required. However, before unloading, it is recommended to check their composition.

Semi-finished products:

As already mentioned, for productions operations, the materials used must be recorded at the exact moment of use.

It is also important to record the significant events that occur during the production processes (e.g., machine stops, speed changes ...) (traceability of events).

a. Rewinding of the printout (specific for flexible packaging production)

Since rewinding can be performed after printing and / or laminating to remove defects, it is important to track these events. Consider that the reels, after rewinding, may have a shorter length and therefore it is necessary to evaluate the possible updating of the labels.

It is necessary to keep the traceability of any printed reels that are spliced together before lamination (which, however, exposes the risk of loss of traceability). In general, it would be useful to know the exact location and type of defect selected.

b. Cutting process: mother-daughter reel matching (specific for flexible packaging production)

It is essential for each daughter reel produced during the cutting operation to keep track of the mother reel of origin.

Since the same subject is frequently printed on multiple tracks, it is important to know from which position of the mother reel band the daughter reel was obtained. Track numbering (graphic design) improves traceability in these cases. Also, in this case, as for rewinding, it would be useful to know how many meters have been eliminated near to each defect.

Consequently, it is useful to know how many splices (and why they were made) are present in a daughter reel and at what distance from the core and / or from the outside they are. It is essential to keep representative samples of all mother reels produced.

c. Envelopes and formats (specific for flexible packaging production)

In the event that the company sells envelopes, lids, formats, the box containing them must be traced with the minimum information (lot and reel that generated them).

Pallet labelling:

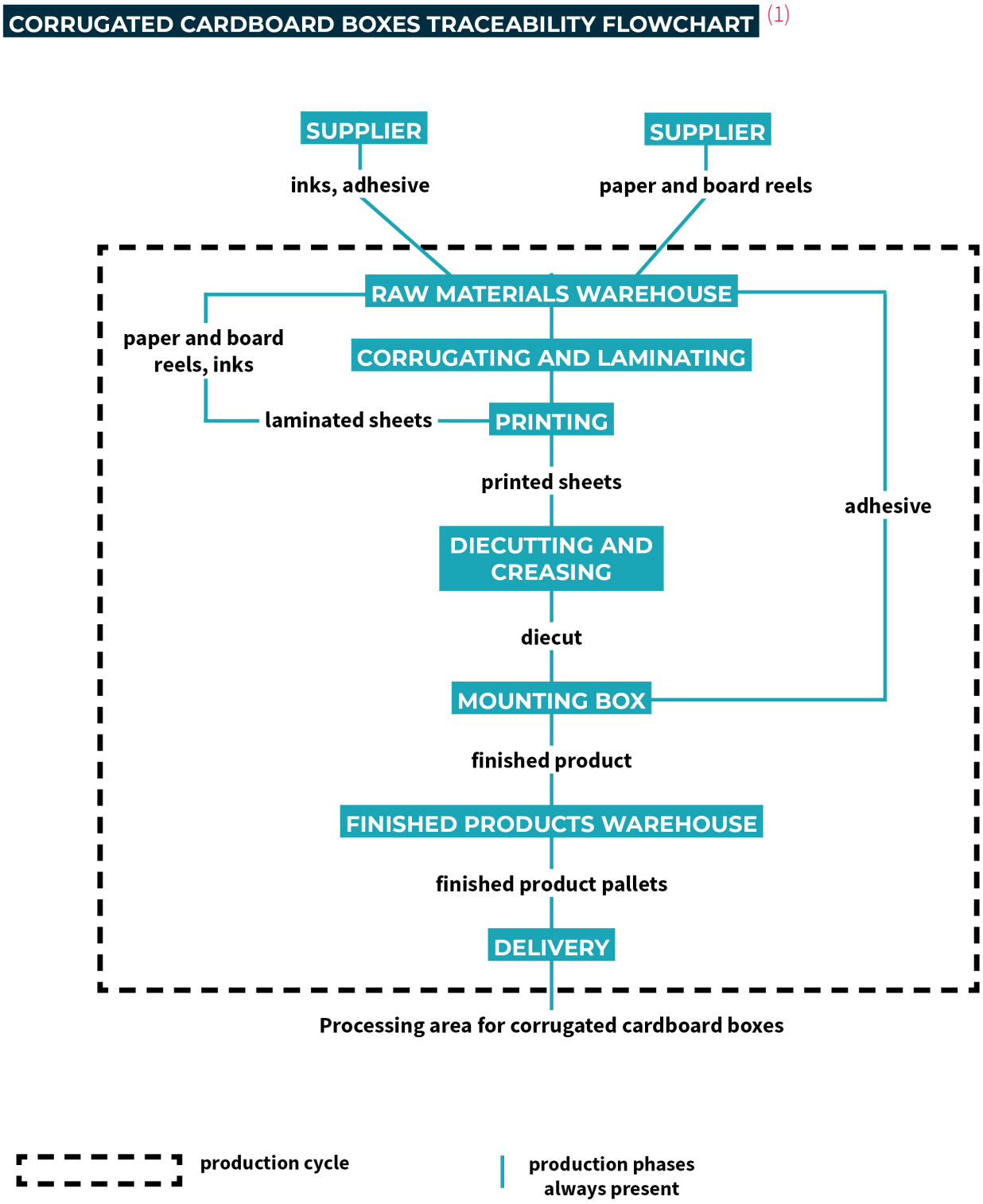
The information to be reported on the logistic label is therefore:

- ☑ Lot;
- ☑ N ° of the pallet;
- ☑ Quantity; and
- ☑ Deadline (where applicable).

It is advisable to label pallets, where possible, with barcodes compliant with the GS1 system (Serial shipping container code; GS1 number consisting of 18 characters for the unique identification of the pallet; it is configured as GS1-128 bar code symbology).

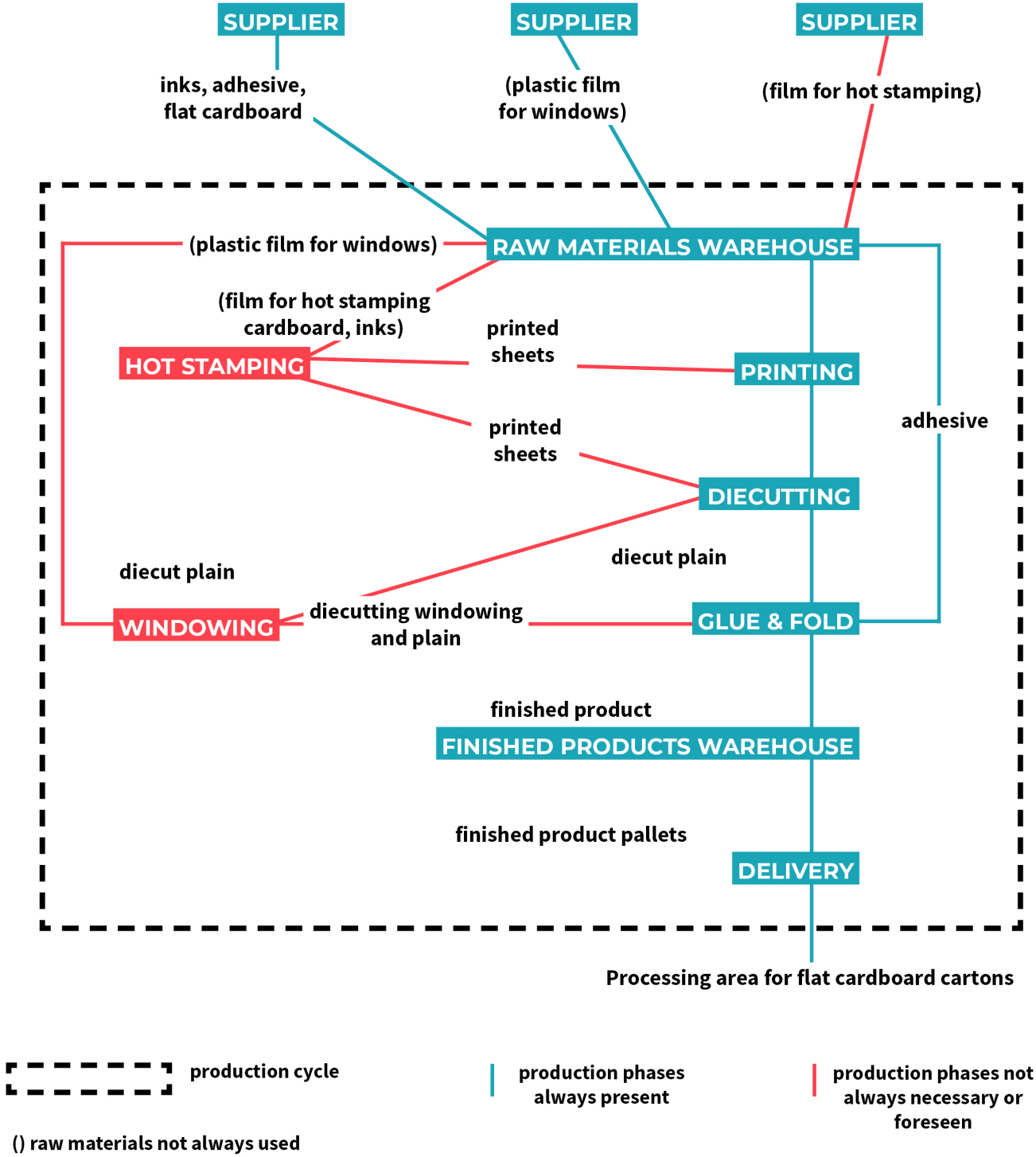
Traceability flowcharts →

Traceability flowcharts

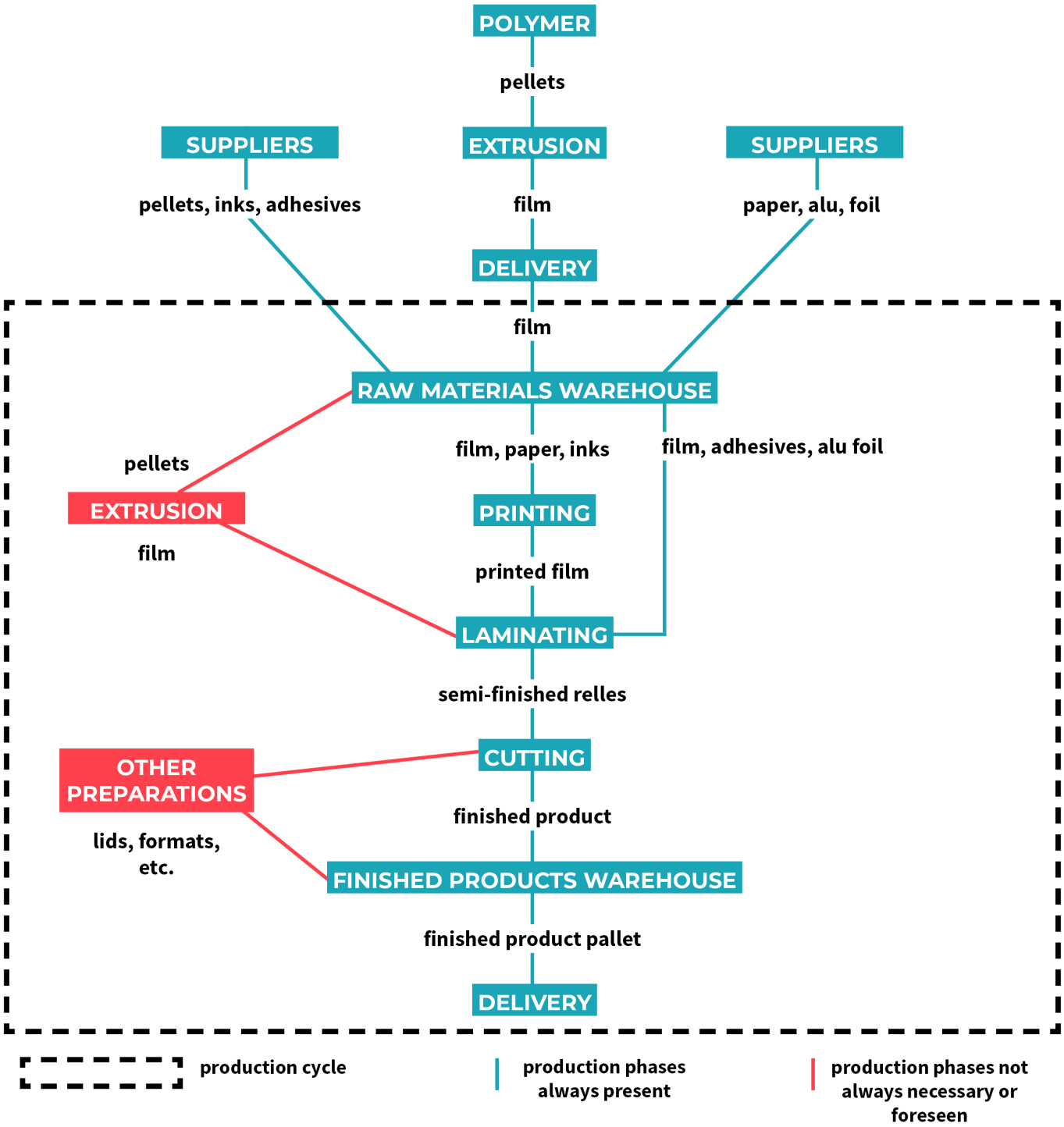


1. CAST Project. Guidelines for the application of the Regulation (EC) 2023/2006 to the supply chain of materials and articles intended to come into contact with food. Edited by Maria Rosaria Milana, Massimo Denaro, Roberta Feliciani, Antonino Maggio, Antonella Maini and Giorgio Padula 2011, xii, 193 p. Available under ISTISAN 11/37, https://www.iss.it/rapporti-istisan (2011)

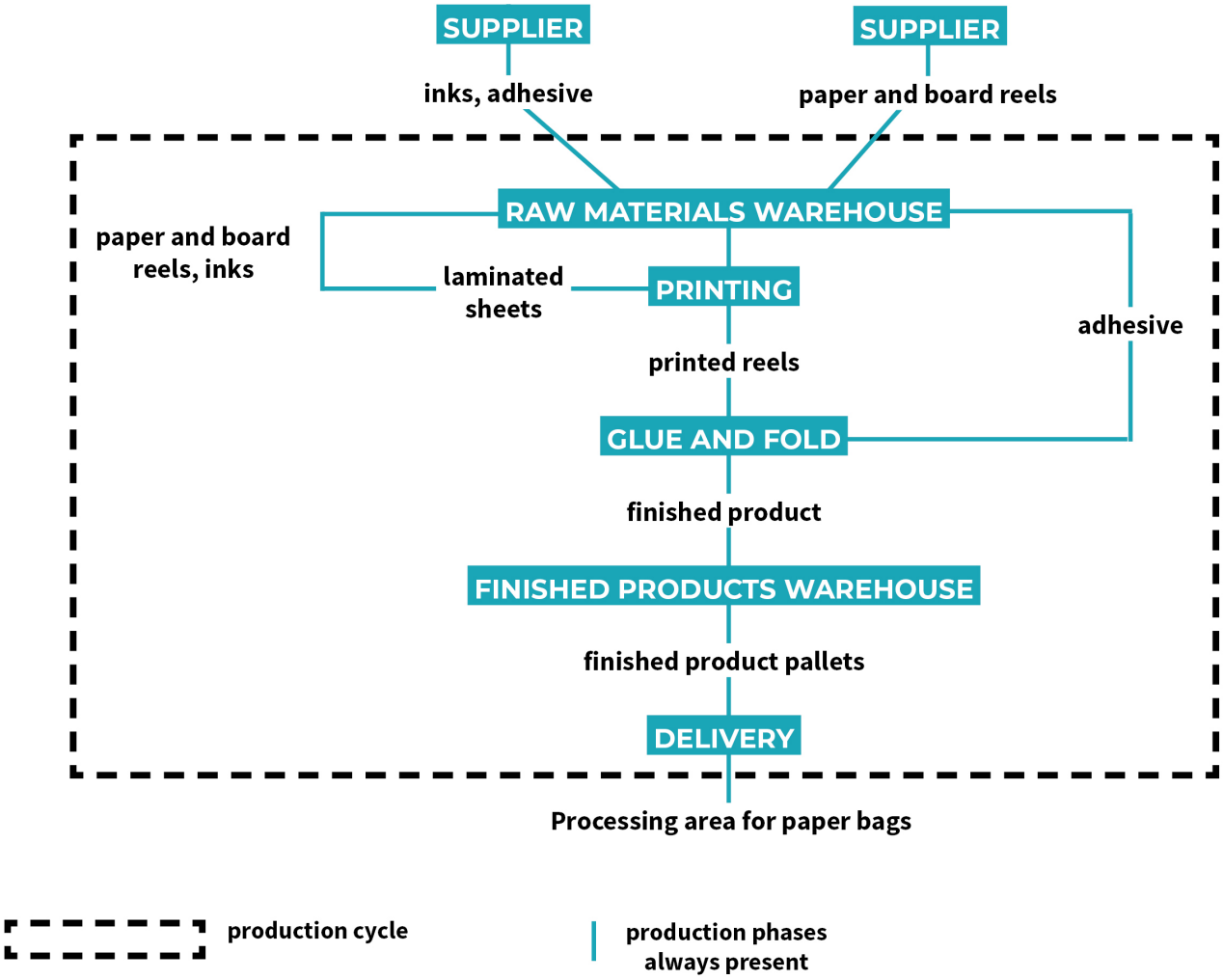
FLAT CARDBOARD CARTONS TRACEABILITY FLOWCHART (1)



FLEXIBLE PACKAGING TRACEABILITY FLOWCHART



PAPER BAGS TRACEABILITY FLOWCHART



Final recommendations

Filling is the extreme limit downstream of the traceability of packaging materials.

When the packaging is filled with food, its information overlaps and coincides with that of the food guaranteed by:

- ☑ expiry date or TMC (mandatory for almost all foodstuffs); and
- ☑ date of packaging and / or lot number.

The person carrying out the filling must record and keep specific information regarding the packaging material (reel number) used for each foodstuff, and the connection between the two information flows must not be interrupted.

Product recall

It is important to have a procedure for managing the recall of the product. Critical defects (for the final consumer) that may give rise to the withdrawal from the market of the finished product must be carefully considered. For these defects it is appropriate to define the appropriate preventive and monitoring actions. It is useful to periodically and preferably simulate the withdrawal of the product together with the customer. In the event of a recall, it is the responsibility of the agri-food or distribution company to communicate to the producer the information relating only to the non-compliant product batch.

About us

Intergraf is the trade association promoting and protecting the interests of the graphic industry at European level. It represents 21 member federations from 20 countries in Europe. The members are national printing federations who represent the sector in their national contexts.

Intergraf's main task is to work with its members and the European Union to support the sector's competitiveness. This is done through advocating, informing and networking. Intergraf is also a European social partner, representing employers in the graphic industry.

If you require more specific support regarding any of the elements covered in this guide, please contact your national association. Contact information for each association across Europe is available here: www.intergraf.eu/members/members.

FTA Europe represents the common interests of the European flexographic printing industry. Flexographic, or flexo, printing machines use flexible relief plates which can be used for printing on a wide range of materials (substrates). Flexo is the single largest printing process in Europe and is a growing sector. In 2018, the valued output of the flexo printing industry was €39.2 billion. FTA Europe's activities include: industry alignment and representing a common voice; education and training projects; sharing best practice; creating a professional network; EU advocacy; and events and industry awards

If you require more specific support regarding any of the elements covered in this guide, please contact your national association. Contact information for each association across Europe is available here: www.fta-europe.eu/category/members.

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