



Packaging materials and articles intended to come into contact with food

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Client/supplier relationship guide

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Preamble

The food industries represented by ANIA and the packaging industries represented by CLIFE are conscious of the importance of food safety in our modern society. They therefore determined to join together in a common approach formalised by a commitment chart, signed in 2002.

This charter reflects an integrated approach to food safety, covering all of the links in the food chain to the end-consumer. In particular, it relates to the packaging link which is a factor in food safety.

The signatories wanted to materialize this approach based on the three following commitments, outlined in the charter:

- To ensure, above and beyond compliance to the regulations, their compliance with the opinions, best practices and recognised standards that apply to their activities, and to implement all necessary means to ensure the safety of their products;
- To reinforce the chain of safety through better information-sharing, and to assure the reliability of the information thus transmitted;
- To adapt, on their own initiative and as quickly as possible, their processes for advancing knowledge relating to food safety.

The charter constitutes a factor for progress; its ambition is to stimulate the collaboration between the food industries and packaging industries.

This is the context within which several tools have been developed, such as the declaration of compliance template, as well as this present clients/suppliers relationships guide for packaging materials and articles intended to come into contact with food.

These tools have been developed so that the companies can build and implement their strategies with greater efficiency, in order to include the issue of food safety in their relationships with suppliers and subcontractors.

This present guide relates to all packaging materials and articles defined in Annex 1 of (EC) no. 1935/2004; specifically:

- Those that are intended to come into contact with foodstuffs;
- Those that are already used in contact with foodstuffs;
- Those that can be reasonably expected to come into contact with foodstuffs, or that transfer their components to the foodstuffs during the course of their normal or foreseeable usage.

It also applies to packaging materials and articles that come into contact with foodstuffs for livestock and domestic animals / pets, as well as nipples and dummies.

It will be updated as needed.

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Glossary

A. Definition of types of packaging

From the EN 14182 standard

According to Directive 94/62/EC of 20 December 1994, regarding packaging and packaging waste, and according to standard EN 14182 (packaging – terminology – basic terms and definitions), packaging is defined as any product that is made of materials of any kind, intended to contain and protect specific merchandise, ranging from raw materials to finished products, in order to allow handling and delivery from producer to consumer or user, and to ensure their presentation. All “discardable” items used for this same purpose shall be considered as packaging.

Packaging can be divided into three types:

- **Primary packaging or sales packaging:** packaging designed to constitute a single sales unit at the point-of-sale for the end-user or the consumer. Example: a bar of chocolate.
- **Secondary packaging or grouped packaging:** packaging which constitutes, at the point of sale, a grouping of a certain number of sales units, whether the latter is sold as such to the consumer or whether it serves only as a means to replenish the display shelves at the point of sale. It can be removed from the product without affecting its characteristics. Example: flat cardboard sheets, plastic bundling.
- **Tertiary packaging or transportation packaging:** packaging designed to facilitate handling and transport of a number of sales units or grouped packaging in order to prevent physical handling and transport damage. Transport packaging does not include road, rail, ship and air containers. Example: cardboard box, palettes, corner pieces, film wrappers.

From Regulation (EC) no. 852/2004

In Regulation (EC) no. 852/2004, article 2, packaging is defined as follows:

- Wrapping: the placing of a foodstuff in a wrapper or container in direct contact with the foodstuff concerned.
 - The packaging corresponding to this wrapper or container, for example: a pack of biscuits, a plastic bottle of mineral water;
- Packaging: the placing of one or more wrapped foodstuffs in a second container.
 - The packaging corresponding to this container itself.

Generally, packaging is part of a packaging system. It is therefore important to know all of the components and their functions within the packaging system, as well as the conditions and the duration of storage before use, the use precautions and who is the end-user (food industry or consumer).

B. Direct and indirect contact

Regulation (EC) no. 1935/2004 distinguishes between these two types of contact within the normal and foreseeable conditions of use, without however providing a definition.

The ANIA-CLIFE platform proposes the following interpretation:

- **Direct contact:** with physical contact between the foodstuff and the material or article. Example: baby food jar.
- **Indirect contact:** without physical contact between the foodstuff and the material or article, but exposed to the volatile phases (or compounds) of the packaging material or article, and to the ambient volatiles phases.
Example: printed carton containing a plastic bag of cereals

C. Types of food/article contact after wrapping

These definitions are based in particular on Directive 85/572/EC.

Dry and similar contact

This relates to moisture- and/or fat-free food.
It related to food whitout moist and/or fat exudation.
Example: cheese with a thick crust.

In France, the following particularly relate to dry contact:

- Foodstuffs that are to be washed, peeled or shelled.
→ Example: fruits and vegetables, eggs in the shell.

Foods that are frozen and “thawed” outside of the packaging article. The variable freezing temperatures are defined per food in the amended French law of June 26, 1974. Example: ice creams

Moist and/or fat contact, and liquid contact

This concerns moisture-exuding foods and/or fatty foods. A generic food name can represent a great variety in the level of moisture exudation.

Example: chocolate, dry feed for domestic animals containing fat, chocolate-coated cereals.

Other types of contact

- Acidic contact: relates to foods with a $\text{pH} \leq 4.5$;
- Alcoholic contact : relates to food and alcoholic beverages above 10°;
- Contact with dairy products (ref. 5th amendment to Directive 2002/72/EEC on plastics).

D. Functional barrier

As noted in Directive 2002/72/EEC as amended (4th amendment by Directive 2007/19/EC) and Regulation (EC) no. 450/2009/CE on active and intelligent materials and articles intended to come into contact with foodstuffs, a functional barrier is a barrier consisting of one or more layers of the material intended to come into contact with the foodstuffs, which guarantees that the material or article in contact with the foodstuffs complies with Article 3 of Regulation (EC) no. 1935/2004.

In other words, a functional barrier prevents or reduces to an acceptable level migration to the foodstuffs.

Unauthorised substances may be used behind a functional barrier, as long as they fulfil certain criteria:

- They may not be classified as carcinogenic, mutagenic or toxic for reproduction (CMR – all categories) ;
- They must not be nanoparticles coming from nanotechnologies;
- Their migration must remain below a migration value limit (10 ppb).

Regulatory context

A. Purpose

This chapter lists the main regulations that must be taken into account by the client and supplier. This list is not exhaustive, and other specific laws apply. It will be updated regularly.

B. General safety requirements for products

Beyond specific texts applicable to packaging materials and articles that come into contact with foodstuffs, described below, two directives with a wider scope indicate the general obligations for product safety:

- **Directive 2001/95/EEC** of 3 December 2001 relating to the general safety of products;
- **Directive 85/374/EEC** of 25 July 1985 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.

C. The obligations of manufacturers of packaging materials and articles intended to come into contact with foodstuffs

- **Regulation (EC) no. 1935/2004** of 27 October 2004 concerning materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
- **Regulation (EC) no. 2023/2006** of 22 December 2006 regarding best practices for manufacturing materials and objects intended to come into contact with food.

D. The obligations of the food manufacturers with regards to health security

- **Regulation (EC) no. 178/2002** of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
- **Regulation (EC) no. 852/2004** du 29 April 2004 relating to the hygiene of foodstuffs.
- **Regulation (EC) no. 183/2005** du 12 January 2005 establishing food hygiene requirements for animal feed.

E. Mutual recognition principle

- Regulation (EC) no. 764/2008 of 9 July 2008 laying down procedures relating to the application of certain national technical rules for products lawfully marketed in another Member State and repealing Decision no. 3052/95/EC (see: mutual recognition p.9).

F. Official controls

- Regulation (EC) no. 882/2004 of 29 April 2004 regarding official controls performed to verify compliance with feed and food laws, and with provisions regarding animal health and animal welfare rules.

G. General compliance

- Decree 2007-766 of 10 May 2007 as modified, implementing the Code of Consumption regarding materials and objects intended to come into contact with foodstuffs. This decree is adopted in article R. 214-18 of the Code of Consumption.

H. Communication of information throughout the chain

From the producers of raw materials to the end-client: communication of information regarding the substances, mixtures or packaging materials and articles in contact with foodstuffs.

- Regulation (EC) no. 1935/2004 of 27 October 2004 concerning the materials and articles intended to come into contact with foodstuffs and repealing Directives 80/590/EEC and 89/109/EEC.

From the food industries to the processors (see: definition of the needs of the client, p. 11):

- Certain informations must be defined contractually, such as type of food in contact, the contact conditions, conditions of use, etc.

I. Supporting documents, providing evidence that the packaging materials and articles that come into contact with the foodstuffs comply with regulations

These documents must be available in the event of a control by the administration, and in the event of an alert or crisis by the users.

(See: declaration of compliance and supporting documents p. 25)

J. Recommended standards

- NF EN ISO 22 000 standard - food safety management system;
- EN 15593 standard – Management of hygiene in the production of packaging for foodstuffs.

Mutual recognition

A. Purpose

This is an opportunity covered in Regulation (EC) no. 764/2008, and in the French decree 2007/766 as amended, Article 3. It relates to any State or party to the agreement instituting the European Economic Area¹

It aims at the elimination of technical obstacles to the free movement within the European Union of a product legally marketed in another Member State, in the absence of harmonisation of regulations.

In other words, thanks to the principle of mutual recognition, the Member States of destination cannot forbid the sale within their territories of products that are legally marketed in another Member State and that are not subject to a community harmonisation, unless the technical restrictions fixed by the Member State of destination are justified, for example on the basis of recognised reasons of public interest.

B. Terms and definitions

Product

Pending publication of a list by the administration, any industrially manufactured product or agricultural product, including fishery products.

Technical regulations

Law, regulation or administrative provision of a Member State that is not subject to harmonisation at the Community level, compliance with which is mandatory for the utilisation or marketing of a product in the territory of a Member State, and which states:

- The required characteristics for the product (level of quality, performance, safety, dimensions, etc.) and the conformity evaluation procedures;
- Any other requirement imposed on the product with the intention of protecting the consumers or the environment.

Application of a technical regulation by the national authority pending production of proof

When a national authority impedes the marketing of a product in its territory, it must notify the economic operator in writing, specifying the technical rule upon which the decision is based, and providing technical and scientific elements justifying the decision.

¹ The European Economic Area regroups the Member States of the European Union, Iceland, Liechtenstein and Norway

After receiving the notification, the economic operator has an allotted time in which to submit its comments.

The national authority can accept or reject the arguments of the operator. It may grant an extension of the allotted time, equal to the original allotted time, depending on this complexity of the demand.

Product contact points

In order to provide the operators with the information they need, especially to launch an appeal, the Member States designate “product contact points”.

These provide, upon request and in a timely manner, the following information:

- The technical rules applying in the notifying Member State;
- The contact details for the national authorities;
- The available means of appeal;
- The contact details for any association or organisation that can provide practical assistance in putting together an appeal.

Nota bene:

When the destination of the packaging is in the European Economic Area, the following should be taken into account:

. In the absence of European regulatory harmonisation regarding the material, the authors of this guide consider that the reference legislation for the supplier of a material or article intended for contact with foodstuffs is the country of manufacture of the material or article,

. In the absence of national regulations regarding the material or the article, Regulations (EC) n°1935/2004 and (EC) n°2023/2006 apply

Outside the European Economic Area, certain third countries may have their own regulations.

Definition of the client needs

A. Purpose

This chapter recalls the principle contractual elements that the client must transmit to its supplier so that the latter can define the type of contact and adapt the material to the use.

The design of a packaging system should be the result of a joint analysis between the food producer and all of the suppliers of the components, each providing its specific expertise.

B. Information to provide

The client should provide information on the following elements, so that the manufacturer can respond relevantly to the requirements. These elements must be provided in writing and validated by both parties.

Type of information to be provided by the client	Details
Target market for the foodstuff to be packaged	Baby food (≤ 3 years) or "adult". Specifically, in the case of baby food certain substances have more strict migration limits, or are even prohibited.
Foodstuff to be packaged	Specify the foodstuff to be packaged, or intended to be in contact. If necessary, refer to the list from Directive 85/572/EEC as modified, which provides a list of foodstuffs as well as the simulants to be used in migration testing.
Description of the request	Specify the description and the function of all of the components of the packaging system or the article.
Type of packaging	Define if this is to be primary, secondary or tertiary packaging. (see: glossary p. 4).
Printing of the article	<ul style="list-style-type: none"> · Define if the material, or the transformed article, must be printed; · Define the type of ink and/or printing varnish used.
Type of contact	Determine if this is for a dry, humid and/or fatty contact (see: glossary p. 4). Nota bene: The components of the packaging, for example corks, box seals and food ingredients (e.g. wood chips to give wine and spirits a woody flavour) must be considered as dry food contact-types during their prerouting.
Treatment foreseen by client (if applicable)	<ul style="list-style-type: none"> · Specify if the product is frozen and thawed outside of the article ; · Specify the types of processes and the time/ temperature couples during which the material, or the article, is in contact with the foodstuff (sterilisation, hot filling, etc.); · Specify the maximum temperature for preserving the foodstuff in the packaging or in contact; · Specify the cooking temperature and time (conventional oven, microwave, etc.); · Other.
Duration of contact	Specify the amount of time during which the material or the transformed article will be in contact with the foodstuff (less than 2 hours, between 2 and 24 hours, more than 24 hours).
Specific requirements of the client	For example : <ul style="list-style-type: none"> · Specify if the material must offer some functionality or meet some specific requirement (resistance to water, etc.); · Indicate if the article must include some additional accessory (plastic window, pour-spout, etc.); · If the article does require an additional accessory, define the type of varnish, ink or glue used for the printing or the attachment of this element ; · Specify if the article must meet specific limits in terms of migration, etc.
Country of destination	Specify the country of destination of the material or the article.

Analysis of hazards

A. Purpose

This chapter describes the principle physical, chemical and biological hazards associated with packaging materials and articles in contact with foodstuffs.

B. Description of the hazards and control measures

The analysis of the hazards and the evaluation of the risks must be carried out in concert between all of the involved parties. They rely on some basic principles, in particular:

- The HACCP² method;
- The prerequisite programme (PRP).

Management examples are given in the ISO 22000 standard and the EN 15593 standard.

Non-exhaustive list of hazards :

Nature of the hazards		Examples of control measures
Physical	Example: foreign bodies such as glass.	PRP of ISO 22000 or EN 15593 standards and individual best practice guidelines.
Chemical	Migration / permeation of restricted substances present in the packaging materials and articles.	Regulatory compliance for the type of contact (more details in the following table).
	Set-off transfer / migration of printing ink and varnish components.	Compliance with Regulation (EC) no. 2023/2006 and with the recommendations of EuPIA on the subject.
	Contamination during manufacture.	PRP of ISO 22000 or EN 15593 standards and private best practice guidelines.
	Contamination by cleaning products, oils, greases or machine lubricants.	<ul style="list-style-type: none"> • Regulatory compliance for the type of contact. • PRP of ISO 22000 or EN 15593 standards and private best practice guidelines.

² HACCP : analysis of the hazards and the critical control points

	Conditions of use of the material by the consumers (cooking of printing inks and varnishes).	Obtain data from suppliers.
	Ionisation resistance.	Obtain data from suppliers.
	Reticulation conditions of, for example, glues and adhesives.	Obtain data from suppliers.
	Treatment of pallets and other components of the packaging system, pest control.	Obtain data from suppliers to avoid sources of contamination.
Biological	Example: contamination by the development of micro-organisms, bacteria, yeast, mould or water condensation.	Applicable up to $a_w^3 > 95\%$.
	Contamination by personnel and pests.	PRP of ISO 22000 or EN 15593 standards and individual best practice guidelines.

:

³ a_w : water activity

The potential impact of the following treatments must be considered (non-exhaustive list):

- Ionisation;
- Disinfection;
- Pulsed lights;
- Hot filtration;
- Industrial treatments:
 - Sterilisation;
 - Cooking (microwave and oven);
 - Hot filling;
 - Flash pasteurisation.

Furthermore, the domestic usage (microwave or oven cooking, freezing, boiling, etc.) must be taken into account.

C. Details for chemical hazards (by way of example)

Type of contact (see: glossary p. 4)	Comments
Humid and/or fatty contact	<p>Articles must be physically suitable for this type of contact, to take into account migration and permeation. In some cases, multiple layers are necessary to preserve the structure and / or prevent migrations.</p>
Dry contact and exposure to organic vapours	<p>Organic vapours can originate from:</p> <ul style="list-style-type: none"> - The components of the packaging system, because the materials do not all face restrictions regarding purity and organoleptic inertia. <i>Example 1: certain pallet treatments can emit pesticides that are unacceptable for contact with foodstuffs.</i> <i>Example 2: packaging materials that are organic in origin have a natural residual odour that is technically unavoidable.</i> - Foreign odour of the article in contact with the foodstuffs; (see sensory tests p. 18) ; - Exposure to a polluted atmosphere (exhaust fumes, etc.) or strong ambient odours, from the production to the delivery to the consumer; - Storage and transportation of loads together with loads that are not suitable for contact with foodstuffs. <p><i>Example: pallets of canned goods in cardboard boxes that are exempt from the requirements regarding suitability for contact.</i></p>

In order to ensure the optimal protection of the foodstuffs against potential sources of external contamination (see table above), priority should be given to efforts regarding primary packaging. There is no need to insist upon the same level of requirements for the other parts of the packaging system.

Hygiene of packaging materials and articles

A. Purpose

This chapter describes the general principles relating to the management of hygiene in the manufacturing of packaging intended for foodstuffs.

Extract from the preamble to the EN 15593 standard

“The hygiene of packaging is a shared responsibility, borne principally by the combined efforts of all parties involved in the chain.

Communication throughout the chain for foodstuff packaging is essential to ensure that all of the pertinent hazards associated with the hygiene of packaging are identified and properly controlled.”

B. Current regulatory base

- **Directive 2001/95/EEC** relating to General Product Safety:

According to Article 2, a safe product is one which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account, in particular the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance.

- **Regulation (EC) no. 178/2002** (see: regulatory context p. 4);

- **Regulation (EC) no. 852/2004** (see: regulatory context p. 4).

Annex II – chapter X - applicable to the wrapping and packaging of foodstuffs:

“The materials used for wrapping and packaging must not be a source of contamination”.

- **Regulation (EC) no. 183/2005** (see: regulatory context p. 4).

C. Means for controlling the hygiene of packaging materials and articles

The control of the hygiene of packaging is based firstly on an analysis of the hazards relating to the manufacturing and provision of the packaging materials and article. It is also based on the management of the PRP⁴ (prerequisite programmes) and the operational PRPs⁵

⁴ prerequisite programmes. This relates to good hygiene practices, such as those described in the ISO 22000 standard or in the EN 15593 in the case of packaging

⁵ operational PRPs: This relates to the base conditions and activities necessary for maintaining an appropriate hygienic environment, identified by the analysis of the hazards

D. Types of standards applied by the manufacturer of the material /article

• Standards

- ISO 22 000;
- EN 15 593.

• Private standards

- BRC/IOP⁶⁶;
- AIB⁷;
- FEFCO-ESBO⁸.

•Other standards, which result in a client audit

E. Hygiene elements taken into consideration during the audit

Firstly, the client and the supplier agree on the audit standards to be used (see: audit of the supplier by the client p. 28).

Elements of the hygiene policy

- Formal commitment by management;
- Availability of a hygiene manual.

Existence of a certification by an accredited third-party

Title, field and duration of validity.

The existence of such a recognition is viewed a priori positively, and constitutes an element of trust, but is not exclusive.

Main hygiene provisions and control points

• Indicative list (source: EN 15593 standard):

- Physical contaminants (foreign bodies);
- Chemical contaminants;
- Biological contaminants;
- Storage and distribution;
- Cleaning;
- Maintenance;
- Scraps and waste management;
- Factory-related requirements;
- Exterior zones;

⁶ BRC/IOP (British Retail Consortium / Institute of Packaging): Global standard for packaging and packaging materials

⁷ AIB (American Institute of Baking): Consolidated Standards for Packaging Facilities

⁸ FEFCO-ESBO: International Good Manufacturing Practice Standard for Corrugated & Solid Board

- Buildings;
- Equipments;
- Installations;
- Personnel;
- Access points and specific paths;
- Work clothes;
- Personal items;
- Personnel toilets and lockers;
- Eating, drinking, smoking or taking of medication;
- Injuries and illness;
- Visitors.

Sensory tests

A. Purpose

The packaging materials and articles that come into contact with foodstuffs must not deteriorate the organoleptic characteristics of the packaged foodstuff.

Certain food products are more susceptible to taste and/or odour modification, including chocolate products, fatty products and products intended to be reheated in their packaging.

B. Who carries out sensory tests?

Organoleptic inertia tests (olfactory tests and/or tests of flavour alteration such as the Robinson test, **must be carried out primarily by the supplier on the packaging material**, to ensure that there are no odours or foreign tastes.

If necessary, the tests can also be carried out by the foodstuff manufacturer on the foodstuff itself, to take into account the duration of the contact with the product.

C. Some potential sources of odours

There are a very large number of sources of odours coming from packaging materials and articles in contact with foodstuffs. Below are some examples:

- residual solvents from printing inks (ketones, acetates, alcohols, glycols);
- laminating solvents;
- adhesive compounds (acrylates);
- dry offset inks compounds (aldehydes);
- monomers (1-octene, styrene, acetaldehyde);
- residual compounds from recycled materials;
- compounds resulting from ionising treatments;
- treatment of wood (halogenated phenols, other fungicides);
- compounds from polymer degradation (pentamethylheptane, alkenes);
- by-products (2,4 pentanedione, products of phenolic antioxidant degradation such as 2,4-ditertiobutyl phenol, etc.) ;
- lubricants (fatty acid amides);
- contamination during the transportation of raw materials and/or during storage of the end-product.

D. Criteria to be taken into consideration

Reference standards on the methods to apply (odour tests and/or tests of flavour alteration).

- **ISO 13302 standard**- Method for assessing modifications to the flavour of foodstuffs due to packaging.

This is applicable to any material in contact (paper, cardboard, plastics, wood, pipes, kitchenware and booklets).

- **EN 1230 standard** – paper and board intended for contact with foodstuffs:

- Part 1-Odour;
- Part 2-Off-flavours;

- **IOCC 12 F** – Robinson test (test of flavour alterations) - International Organisation of Cocoa and Chocolate Companies.

For more information on the sources of foreign odours:

- Saxby: Food taints and off-flavours, second edition, 1996, ISBN 0 7514 0263 X;
- Charalambous: Off-flavours in food and beverages, 1992, ISBN 0-444-88558-7.

Transportation / storage / handling

A. Purpose

This chapter specifies the recommendations regarding the transportation, storage and handling of packaging materials and articles intended to come into contact with foodstuffs. These help to maintain the required qualities with regards to suitability for contact with food, cleanliness and hygiene.

B. Transportation

Contractual agreements with transport companies must include the rules on hygiene and cleanliness.

The transporter must ensure that the suitability for contact with food of the packaging materials and article is preserved, by preventing the risk of physical, chemical (including foreign odours) or microbiological contamination.

These risks may be associated with the poor condition or lack of cleanliness of the conveyance, and even the presence of products or product elements from a simultaneous or a previous load (cross-contamination), etc.

To do this, the transporter must ensure

- **The good condition of the conveyance**

- Waterproof tarp (on the roof);
- Floor and walls in good condition, dry, without holes and without roughness (no screws, bolts protruding, nails, wood scraps, etc.).

- **The cleanliness of the conveyance**

- No dust, oil or other liquid on the floor;
- No pests or foreign bodies;
- No strong foreign odours;
- No risk of chemical and/or microbiological contamination from a previous and/or simultaneous load (cross contamination).

If relevant, the transporter must respect the temperature and humidity conditions communicated by the sponsor.

C. Storage and handling

The supplier, the client and their sub-contractors must ensure that the suitability for contact with food, the hygiene and the cleanliness of the packaging materials and articles are preserved during storage and handling. They must prevent and control the risks of physical, chemical (including any foreign odour) or microbiological (related to poor condition or lack of cleanliness of the storage space, the presence of other stored products, etc.) contamination.

Moreover, these provisions also apply to the client, in the case of handling and during a partial use of products stored in manufacturing workshops.

Regarding the storage space

The supplier, the client or their sub-contractors must ensure:

- That the temperature and humidity in the storage space are compatible with the storage and utilisation requirements for the packaging materials and articles, with reference to industry codes and usages;
- That there are no sources of heat or areas exposed to high variability of temperature (frequently opened doors, ventilation systems, etc.);
- That the building is well sealed against dust, pests and water leaks that could contaminate the product;
- That an action plan is in force to deal with pests;
- That the cleanliness of the site is maintained (elimination of dust, spider webs and various solid and liquid wastes);
- That there is no cross-contamination with merchandise of a different nature or with a strong odour;
- That packaging materials and articles are not stored in direct contact with the floor, but on a pallet or platform, on a dry and clean surface;
- That packaging materials and articles being moved to the packaging sites are sheltered from precipitation (rain, condensation, water leaks or sprays) at all times.

Regarding the material or article itself

The supplier, the client or their sub-contractors must ensure:

- That the storage duration communicated by the supplier, if relevant, is respected;
- That the packages are maintained in the condition in which they were received, without being opened or unpacked until use;
- That the pallet is repacked after a partial removal of packaging, and that the unused packaging is kept in its original packaging;
- That no unused part of the product is contaminated, in order to preserve its integrity;
- That pallets are not stacked, in order to avoid any risk that the packaging in the lower pallets is damaged;
- That no heavy objects are placed on the packaging materials and articles, and that no one walks on them.

Traceability

A. Purpose

This chapter recalls the obligation to put in place a traceability system for incoming materials until their delivery, which is required for all the supply chain partners in the manufacturing chain for packaging materials and articles that come into contact with foodstuffs.

Experience has shown that the management of a food crisis can be compromised when it is not possible to retrace the path of the foodstuffs from their design to their delivery to the consumer.

Traceability is a means to be able to:

- carry out targeted withdrawals or recalls;
- provide consumers and businesses in the food sector with relevant information;
- provide the competent authorities with the means to analyse the risks;
- avoid any unnecessary disruption of trade.

B. Regulations

Traceability for the packaging industry is dealt with in Regulation (EC) no. 1935/2004.

Nota bene: Regulation (EC) no. 178/2002 relates to operators in the food business and the animal feed business.

C. The obligations of the parties

Traceability is obligatory for every involved party, from the reception of incoming materials to the delivery of the end-product.

Article 17 of Regulation (EC) no 1935/2004:

1. The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.
2. With due regard to technological feasibility, business operators shall have in place systems and procedures to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products covered by this Regulation and its implementing measures used in their manufacture are supplied. That information shall be made available to the competent authorities on demand.
3. The materials and articles which are placed on the market in the Community shall be identifiable by an appropriate system which allows their traceability by means of labelling or relevant documentation or information.

D. Information to be kept

The above regulation creates a general obligation for the supply chain actors in the food sector.

For the articles dealing with traceability, it is considered necessary to record the following information, classified into two categories according to degree of priority:

First category of information: information that should always be available for the competent authorities:

- Name and address of the supplier and the nature of the products supplied by this supplier.
- Name and address of the client and the nature of the products delivered to this client.
- Date of the transaction/delivery.

Second category of information: information whose storage is highly recommended.

- Volume and quantity.
- Batch number or unique supplier number, if any.
- More detailed description of the product.

E. Reaction time for the availability of traceability data

Regulation (EC) no. 1831/2003 does not provide specifics for the reaction time. However, it is however necessary to have a traceability system that makes it possible to deliver precise information rapidly, to avoid creating an obstacle to reactivity in the event of a crisis.

Information of the second category should be made available to the competent authority “as quickly as it is reasonably possible, with target dates appropriate to the circumstances”.

F. Duration of record keeping

Article 17 of Regulation (EC) no. 1831/2003 does not specify a minimum duration for keeping records. The authors of this guide propose to base this on the guidelines⁹ established by the Standing Committee on the Food Chain and Animal Health (SCFCAH) regarding Regulation (EC) no 1831/2003:

- For products without a specified lifespan, the records should be kept for a duration of five years (beginning from the date of manufacture of the products);
- For products with a lifespan of more than five years, it is necessary to keep records throughout the expected lifespan, plus six months;
- For highly perishable products with a durability date of less than three months, or unspecified, it is necessary to keep the records for at least six months after the date of manufacture or delivery.

⁹ Guidelines for the implementation of articles 11, 12, 16, 17, 18, 19 and 20 of Regulation 1831/2003/EEC on the General Food Law – conclusions of the Standing Committee on the Food Chain and Animal Health – 20 December 2004

The end-client must indicate the shelf life or use-by date applicable to its products to the packaging supplier, so that the latter can store the necessary information for an adequate time period.

Packaging put on the market is to be identifiable by an appropriate system allowing it to be traced through labelling on the pallet on which the packaging is delivered or by some other appropriate documentation.

Declaration of compliance and support documents

A. Purpose

This chapter describes the regulatory obligations of the supply chain actors, regarding the documentation relating to the suitability of the packaging materials and articles for contact with foodstuffs.

B. Regulatory framework

In compliance with Article 16 of Regulation (EC) no. 1935/2004, when a specific, harmonised measure requires it, the materials and objects must be accompanied by a written declaration attesting their compliance with the rules that apply to them.

This obligation is also reiterated and detailed in the following European texts:

- Regulation (EC) no 450/2009, active and intelligent materials;
- Regulation (EC) no 282/2008, recycled plastic materials;
- Directive 2002/72/EC and amendments, plastic materials;
- Directive 84/500/EC and amendments, ceramic articles;
- Directive 2007/42/EC, regenerated cellulose film.

In France, in compliance with the Decree 2007-766 modified by the Decree 2008-1469, all the materials and articles intended to come into contact with foodstuffs must be accompanied with a declaration of compliance, except at the point of sale or distribution free of charge to the final consumer.

C. The obligations of the various players in the chain

Each player in the chain is to issue a statement of composition or of compliance to its client, on the basis of information available or obtained regarding its product.

The chain is made up of four major players:

- Manufacturer of raw materials: additives, monomers, fibres, aluminium, lubricants, etc.;
- Manufacturer of intermediate products: resins, inks, adhesives, alloys, paper, glues, etc.
- Processor: printed films, containers, cardboard, glass bottles, etc.
- End-client (food industry, packer): the one who manufactures and/or packages the foodstuffs.

At every stage in the chain:

- The client must request a declaration of composition or compliance;
- The supplier must provide a declaration of composition or compliance and make available to the competent authorities all documents demonstrating this conformity: declaration of upstream suppliers and analytical results. Moreover, within the context of a specific request, or during a client audit, the end-client may insist on viewing these support documents (see: supplier audit by client p. 28). Utilisation of the joint ANIA-CLIFE template of declaration of compliance, as well as its regulatory annex, is recommended.

They are available on the ANIA website (www.ania.net) and on the CLIFE website (www.clife.fr)

Nota bene: The end-client must define its needs and relevant information to the supplier, so that this latter can deliver an adapted declaration of compliance, in connection with the other links in the chain (see. p. 11).

- Depending on the position in the chain, the contents of the declaration and of the support documents will vary.

Support documents for each player in the chain

	Manufacturer of raw materials	Manufacturer of intermediate products	Processor	End-client
Declaration of compliance	<p>Declares that the substances are:</p> <ul style="list-style-type: none"> • listed in the positive lists or regulatory text reference; • subject or not to restrictions (specifications such as purity criteria, SML, maximum quantities) ; • dual-use additives or not. 	<p>Declares that the mixes contain substances:</p> <ul style="list-style-type: none"> • listed in the positive lists or regulatory text reference; • that have been subjected to a hazard analysis (see. p.13) ; • have been developed in compliance with best practices for manufacturing; • are subject or not to restrictions (specifications such as purity criteria, SML, maximum quantities); • that are or are not dual-use additives. 	<p>Declares that the materials intended to come into contact are made up of substances:</p> <ul style="list-style-type: none"> • listed in the positive lists or regulatory text reference; • that have been subjected to a hazard analysis (see. p.13) ; • Have been developed in compliance with best practices for manufacturing; • are subject or not to restrictions (specifications such as purity criteria, SML, maximum quantities) ; • that are or are not dual-use additives. 	

			<p>Declares that the materials are suitable for food contact under the usage conditions that were requested of the processor by the end-client.</p> <p>Declares that the restrictions have been respected.</p>	
<p>Support documents</p>	<ul style="list-style-type: none"> • Proof of respect of the specifications : • Criteria of purity, grade, molecular weight, solubility, etc. 	<ul style="list-style-type: none"> • Declaration of composition by the producers of raw materials; • <input type="checkbox"/> Risk evaluation of non-listed molecules. 	<ul style="list-style-type: none"> • Declaration of composition by the producers of intermediate products and raw materials; • Proof of compliance with restrictions on representative samples, which can be consulted upon request (analytic results, calculations, etc.) 	<ul style="list-style-type: none"> • Declaration of compliance of the processors; • Proof of compliance with the regulations on the materials in contact with foodstuffs, which can be consulted upon request. <input type="checkbox"/>. <p><i>Example :</i> <i>analytic results</i></p> <ul style="list-style-type: none"> • Proof of compliance with food regulations, which can be consulted upon request. <p><i>Example : dual-use additives</i></p>

The declaration of compliance, and the documents used to support its creation, must be renewed at least every five years, as well as in any situation in which the compliance that was declared is no longer assured (new tests, changes in materials, changes in technology, evolution of the regulations, etc.).

Audit of the supplier by the client

A. Purpose

This chapter describes the reasons for which the client audits the supplier, and the principle points examined during this exercise.

B. Objectives of the audit

- To ensure that client expectations regarding a product are being satisfied, for example, lifespan, safety of foodstuffs, uniformity of materials delivered, flexibility to respond to needs and the ability to meet increased demand.
- To ensure the reliability of a supplier.
- To improve the quality and safety objectives for the client's foodstuffs.

The audit can be initiated at frequencies appropriate to the criticality of the material in contact and the food (baby food, fatty contact, packaged product to be reheated, etc.), and the supplier's capabilities.

The audit is a tool of progress for the client and the supplier.

C. Audit criteria (non-exhaustive list)

Before the audit begins, the client communicates the standard being used to the supplier.

The following criteria are then considered:

• Hygiene:

Best practices (based on professional guidelines);
EN 15593 standard (see: hygiene of packaging materials and articles p. 15):

- **Analysis of the hazards and risks:**
 - Physical (foreign bodies, especially glass);
 - Microbiological;
 - Chemical (including the chemical risks of raw materials, such as inks, varnishes, adhesives, polymers, paper, cardboard, treatment against vermin and against insects, treatment of wood palettes, lubricants and floor and machine cleaning products).
- **Storage;**
- **Transportation of the raw materials and the finished products;**
- **Cleaning;**
- **Equipment maintenance;**
- **Management of scraps and waste;**
- **Building and surroundings;**
- Etc.

- Control of the identified Critical points ;
- Organisation of quality assurance systems, quality control systems, documentation and compliance with the manufacturing best practices cited in Regulation (EC) no. 2023/20 06;
- Traceability:
 - Exercise on a designated lot;
 - Traceability of the controls on raw materials, partially finished products and finished products;
- Regulatory compliance:
 - Knowledge of regulatory and pararegulatory texts;
 - Enforcement of migration tests, sensory tests, declarations of composition or compliance for raw materials and for finished products;
- Performance of the laboratories:
 - Equipment;
 - Proficiency in using qualifying instruments;
 - Validation of methods;
 - Self-controls;
 - Instrument calibration;
 - Qualifications of the personnel;
 - Data recording;
 - Maintenance;
- Conditions for finished product release:
 - Positive release by the quality manager;
 - Release by exemption by the quality manager;
 - If applicable, storage of samples with regards to the lifespan of the packaged products.
- Internal audits;
- Handling of customer complaints;
- Recall procedures;
- Management of non-compliant products;
- Environment/waste management;
- Certifications (according to the standards used by the material manufacturer– see: hygiene of packaging materials and articles p. 15).

<h2>Thanks</h2>

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