

<p style="text-align: center;">GENERAL SHEET RELATING TO THE REGULATION OF MATERIALS IN CONTACT WITH FOODSTUFFS</p>
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The basic text regulating the suitability of materials and objects intended to be in contact with foodstuffs, food products and drinks ⁽¹⁾ is the decree No.92-631 of 8th July 1992. The regulations applicable to the various operators concerned, for the relevant materials and objects, come from this text.

1. Scope of the decree of 8th July, 1992.

The text applies to the following materials and objects:

- Finished products;
- Intended to be in contact with foodstuffs;
- Or put in contact with the foodstuffs for which they are intended.

Consequently, these regulations do not directly deal with raw or intermediate materials (e.g.: polymer granules before constitution of the object). The manufacturer of the material or the finished object is responsible for ensuring next to his suppliers or by any other means that the raw materials and the processes he uses enable him to meet his obligations.

The materials and objects are divided into:

- Packages and packaging,
- Kitchen receptacles and utensils,
- Materials, machines and equipment used in the production, storage or transport of foodstuffs,
- Teats and dummies.

The foodstuffs concerned are food and drink: (including water intended for human or animal consumption and natural mineral waters):

- As well as finished products as intermediate products,
- Which are intended for human or animal consumption.

The following elements are not concerned:

- Coating materials
- Fixed installations for distributing drinking water.

2. Obligations applicable to materials

2.1. Principle of inertia (article 3 of the decree):

Materials and objects shall be inert with regard to foodstuffs. They must particularly not:

- Release constituents in quantities which endanger health (of man or animals);
- Cause an unacceptable change in the composition of the foodstuff;
- Alter the organoleptic properties of the foodstuff.

⁽¹⁾ Foodstuffs, food products and drinks are hereafter referred to as "foodstuffs".

The principle of inertia also implies that the materials and objects will not absorb liquid foodstuffs (crazing on ceramics for example) except if good use of these materials and objects is based on their structure. In any case, the article concerned shall not allow a microbial development from absorbed foodstuffs or drinks.

In some cases, orders include specific provisions to allow the article 3 of the decree to be applied to a specific material category (e.g. plastic materials, rubber, etc.).

These orders may include:

- Positive lists of authorized constituents;
- Purity criteria applicable to certain of some constituents;
- Particular terms of use;
- Specific migration limits;
- An overall migration limit;
- Measures relating to oral contact.

Organoleptic inertia: In practice, tests reproducing the actual terms of use are carried out by using the foodstuffs themselves. However, tests could be carried out thanks to simulators by using the current texts, such as the standard NF XP V 09 009, especially for objects whose final destination is not known.

Period of validity of test reports: A maximum period of 5 years is proposed. If changes likely to cause alterations in the inertia of the material or object occur during this period, the tests must be carried out again.

2.2. Written declaration of conformity (article 8):

Except during sale or free distribution to the final consumer, a written declaration testifying the conformity (particularity with the principle of inertia laid down in article 3, and with the application orders) shall be attached to materials and objects intended to be in contact with foodstuffs.

As this obligation concerns the materials themselves and not to an operator, the seller and buyer have additional and reciprocal obligations (cf. billing obligation):

- The seller shall issue this declaration;
- The buyer shall demand it to prove his good faith if the material are proved to be non conform in the future.

Excepted for the objects clearly intended to be in contact with food due to their shape, e.g.: Crockery, kitchen utensils, etc.

2.3. Indications attached to the materials and objects intended to be in contact with s foodstuffs (article 7):

- Either "for food contact " or "suitable for food use";
- Or a specific mention relating to their use;
- Or a symbol;
- Specific term of use, if necessary;
- Either the name or the corporate name and the address or the head office address, or the registered trademark of the manufacturer or the seller settled in a member state of the European Union;
- Specific mentions laid down in order, if necessary.

Excepted for the objects clearly intended to be in contact with food, due to their shape , e.g.: Crockery, kitchen utensils, etc.

2.4. Negative declaration (article 9):

The objects which the appearance of objects intended to be in contact with food but which do not meet the regulatory requirements, shall have a visible and indelible statement (or symbol) showing that they should be put in contact with food.

3. Operators concerned by the "materials in contact" regulations

The scope is divided between materials and objects intended to be in contact with food and materials and objects put in contact with food. Two main types of operator are concerned by these regulations:

- 1) The operators who carry out operations in the production and distribution of materials and objects (manufacturing, transformation, distribution, marketing). At this stage, the materials and objects are intended to be in contact with food (1st point of the scope);
- 2) The operators who operate in the production and distribution of foodstuffs (production and distribution of foodstuffs). The latter are either the direct users of the materials or objects that they use in contact with food, during production, transport, storage or distribution of the foodstuffs, or distributors of already packaged food (pre-packed foodstuffs). At this stage the materials and objects are put in contact with foodstuffs (2nd point of the scope).

Consequently, the following elements are prohibited for marketing:

- 1) Materials and objects intended to be in contact with food that do not comply with the regulations;
- 2) Foodstuffs which have been in contact with non conform materials and objects .

4. Definition of responsibilities

Consequently, responsibility is defined as the general obligation of conformity laid down in the article L 212-1 of the Code of consumption on which is based the decree (article L.214-1 sanctions laid down in the article L.214-2). According to this obligation, the operator, responsible for marketing at the first time the product, shall check its conformity with the regulations in force. As far as materials in contact are concerned and taking into account the obligations described in point 2, the products concerned by the general obligation of conformity are the materials and the objects themselves as well as the foodstuffs put in contact with these materials and objects.

The operators responsible for the first marketing of these products are not only the manufacturers but also importers.

Thus, during the product life cycle , the legal responsibility of conformity concerns several different types of operator and particularly the manufacturers or importers of materials and the food industries. To enable each operator to define in a better way their responsibilities which cannot all be covered by the regulations, some information shall be defined in a contract such as the destination of the materials, the type of food in contact, the term of use etc.

Definition of market: the market is either the European Union for harmonised regulations within the community, or France for non-harmonised fields. Indeed, the article 11 of the framework directive "materials" n°89/109/CEE allows for the use of national provisions which, in the absence of specific directives, govern some materials categories. In this case, the relevant market is located in France.

The harmonised fields are : plastic materials (monomers), vinyl chloride monomer, nitrosamines and nitrosatables in dummies and teats, ceramics (transfer of lead and cadmium), regenerated cellulose film.

The fields regulated by the French regulation are: Rubber, silicon elastomers, aluminium, stainless steel.

Additives for plastic materials are partially harmonised.

When they exist, the product shall meet the harmonised community obligations. When there are only national regulations, or when a community regulation coexists with several national regulations (additives for plastic materials, for example), a product marketed in a specific country must meet national obligations, or community obligations (for the harmonised part) and national obligations (for the non-harmonised part). If the product is marketed in several countries, it shall meet the obligations of each country in addition to any harmonised community obligations.

For semi-finished products (e.g. empty packaging manufactured in country A, intended to package a finished food product in country B), whatever the manufacturing country is, the applicable regulation is the regulation of the country of the finished product i.e. the material or object put in contact with food , is to be marketed (in the example given, the regulations applicable to the empty packaging manufactured in country A are the regulations of country B where the finished packaged product will be marketed for the first time).

Taking into account the operations laid down in the Code of consumption and the various operators involved, the obligations arising from the article L.212-1 relating to the general obligation of conformity and the article L.214-1 relating to the application measures specified in the decree n°92-631 of 8th July, 1992 are included in the following table:

**Summary table:
Obligations relating to materials in contact with foodstuffs
arising from the code of consumption**

Scenario	Products concerned	Operations laid down in the decree No.92-631	Legal responsibility	Operator responsible of the first marketing of the product	Other operators
Materials and objects intended to be in contact with foodstuffs	The materials and objects themselves	<p>Manufacturing of finished materials and objects:</p> <ul style="list-style-type: none"> - Packaging; - Containers; - Kitchen utensils; - Machines and materials for agri-food industry; - Teats and dummies. <p>Distribution of finished materials and objects.</p>	<p>The manufacturer indicating that the materials and objects are intended to be in contact with food.</p> <p>The distributor responsible for the first marketing of the product .</p>	<ul style="list-style-type: none"> - Check compliance of raw materials and constituents with regulatory requirements; - Check conformity of finished product with inertia requirements; - Issue written declaration of conformity (except where dispensation given); - Label materials and objects - Check conformity of the imported product; - Issue declaration of conformity; - Carry out labelling 	<ul style="list-style-type: none"> - Check labelling - Request declaration of conformity.
Materials and objects put in contact with foods	The foodstuffs which have been put in contact with the materials and objects.	<p>Production and distribution of foods:</p> <p>1) Users of materials and objects for:</p> <ul style="list-style-type: none"> - Production; - Packaging; - Storage; - Transport of foodstuffs. <p>2) Distribution of foodstuffs.</p>	<p>Users of these materials and objects.</p> <p>- Users of the materials and objects.</p> <p>- Operator responsible for the first marketing of the pre-packaged foodstuffs</p>	<p>Check conformity of material/object used for the relevant application .</p> <p>Ditto</p> <p>Check conformity of packaging.</p>	