DGCCRF INFORMATION NOTICE 2004 / 64 ON MATERIALS IN CONTACT WITH FOODSTUFFS

THIS TRANSLATION IS NON-OFFICIAL

ONLY THE ORIGINAL VERSION IN FRENCH IS LEGALLY BINDING



GENERAL DIRECTORATE OF COMPETITION, CONSUMPTION AND FRAUD REPRESSION 59, BD VINCENT AURIOL 75703 PARIS CEDEX 13

Ref: NI2004-64.doc

Project managed by Sandrine Gaquerel & Régine Costes Safety Phone number: 01 44 97 32 00 Fax: 01 44 97 24 86 Email: : c2@dgccrf.finances.gouv.fr

D.G. 845	T.P	TÉLÉDOC 051	N.A.F. / C.p.f
Materials in contact			

PARIS, 6th MAY 2004

Information Notice No.2004-64 (can be communicated within the meaning of the law of 17 July 1978)

Subject: materials in contact with foodstuffs

Summary: The purpose of this information notice is to specify the rules used to check and control the suitability of many materials to be in contact with foodstuffs It repeals and replaces the information notice No.2000-155 of 26th October 2000.

The decree No. 92-631 of 8th July 1992 which transposes the directive 89/109/CEE relating to materials and objects intended to be put in contact with foodstuffs, specifies that these materials mu st be inert with regards to foodstuffs.

To apply this principle of inertia to the different types of material, some application texts must define the rules (composition, purity criteria etc.) ensuring the suitability of each material category to be in contact with foodstuffs. Many specific directives in the field of plastics materials and regenerated cellulose films have thus been adopted and transposed by decree.

Furthermore, in the absence of a specific directive applicable to a particular type of material, the national regulations are applicable, such as the regulation relating to stainless steel, aluminium and to its alloys, rubber and silicon elastomers.

However, many materials are not subject to a specific regulation either at the European or National level, or are not completly regulated. It deals with This concerns cardboard,wood,lacquer, glues and adhesives and some metals and their alloys.

In addition, even for the regulated material categories , the rules to be used to check the conformity of the material or the object have to be clarified, as the field is complex.



To overcome these difficulties the DGCCRF (General Directorate of Competition, Consumption and Fraud Repression) has gathered the laboratories competent in the field of the materials in contact, material and transforming industries and agri-food industries within a workgroup called "the think-tank on regulations and methods for the assessment of the inertia of materials intended to be in contact with foodstuffs".

This workgroup has been meeting since 1992 (three meetings per years) and is carrying on working.

The workgroup is responsible for making sheets for the different types of materials to specify the methods to check their suitability for food contact within the framework of specific regulations, and in the absence of regulation.

These sheets are intended for laboratories working in the analysis of materials in contact, industries manufacturing and producing materials and objects for contact with foodstuffs, agri-food industries and official inspection services.

They deals with the following material categories:

- Plastic materials;
- Composites;
- Ceramics, glass, crystal, glass ceramics, enamelled objects;
- Paper and cardboard;
- Aluminium ;
- Stainless steel;
- Steel excluding packaging;
- Uncoated steel for packaging (black plate);
- Steel with metallic coating used for packaging (Tinplate)
- Steel with organic coating used for packaging;
- Cast iron;
- Tin;
- Zinc ;
- Various coated metals and whitened metal;
- Rubber.

This information notice repeals and replaces the information notice No.2000-155.

This document will also be displayed on the Directorate's website in the section called "Update on..." to allow the various operators concerned to have an easy acces.

Aline Peyronnet - Assistant director

CONTENTS

- 1. **GENERAL SHEET** (p. 4 8)
- 2. PLASTIC MATERIALS (p. 9 10)
- 3. **COMPOSITES** (p. 11 13)
- 4. PAPER AND CARDBOARD (p. 14 19)

5. GLASS-CRYSTAL-CERAMICS-GLASS CERAMICS-ENAMELLED OBJECTS. (p. 20 -

- 23)
- 6. **STAINLESS STEEL** (p. 24 29)
- 7. STEEL FOR PACKAGING:
 - Non-coated steel for packaging (blackplate). (p. 30 31)
 - Steel with metallic coating used for packaging (Tinplate). (p. 32 33)
 - Steel with organic coating used for packaging. (p. 34 37)

8. STEEL (UNPACKAGED):

- Non-coated steel (p. 38 39)
- Steel and stainless steel with metallic coating. (p. 40 42)
- Steel and stainless steel with organic coating (p. 43 45)

9. ALUMINIUM AND ALUMINIUM ALLOYS:

- Coated aluminium single use long duration contact (packaging). (p. 46 49)
- Coated aluminium repeated use short duration contact. (p. 50 52)
- Uncoated aluminium single use variable duration contact. (p. 53)
- Uncoated aluminium repeated use variable duration contact. (p. 54)

10. CAST IRON:

- Non-coated cast iron. (p. 55)
- Cast iron with metallic coating. (p. 56 57)
- Cast iron with organic coating. (p. 58 60)
- 11. **TIN** (p. 61)
- 12. **ZINC** (p. 62 63)

13. OBJECTS IN VARIOUS COATED METALS AND WHITENED METALS (p. 64 - 65)

14. **RUBBER** (p. 66 - 68)

GENERAL SHEET RELATING TO THE REGULATION OF MATERIALS IN CONTACT WITH FOODSTUFFS

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 are not directly deal with raw or intermediate materials (e.g.: polymeres granul 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.

 $\binom{1}{1}$ Foodstuffs, food products and drinks are hereafter referred to as "foodstuffs".

Page 5

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 rlating to oral contact.

<u>Organoleptic inertia:</u> 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.

<u>Period of validity of test reports:</u> 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 (particulary 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 appearencce of objects intended to be in contact with food but wich 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 material 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 particulary 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 contrat 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:

Page 8

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	Manufacturing of finished materials and objects: - Packaging; - Containers; - Kitchen utensils; - Machines and materials for agri-food industry; - Teats and dummies.	The manufacturer indicating that the materials and objects are intended to be in contact with food.	 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: 	
		Distribution of finished materials and objects.	The distributor responsible for the first marketing of the product .	 Issue declaration of conformity; Carry out labelling 	- 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.	Production and distribution of foods: 1) Users of materials and objects for: - Production; - Packaging; - Storage; - Transport of foodstuffs.	Users of these materials and objects.	Check conformity of material/object used for the relevant application .	
		2) Distribution of foodstuffs.	 Users of the materials and objects. Operator responsible for the first marketing of the pre-packaged foodstuffs 	Ditto Check conformity of packaging.	

PLASTIC MATERIALS

1. <u>Scope</u>

This section deals with materials and objects in plastic made entirely of plastic or composed of one or two layers each of which is made entirely of plastic and when they are as finished products, they are intended to be in contact with food products.

This section does not involve materials and objects which are not intended, under the current terms of use or in other reasonably expested conditions, to be in contact with foodstuffs, for example: floor, ceiling and wall coverings, vehicle dashboards, aprons, tablecloths, food trays. However, honeycomb trays in direct contact with foods are included.

2. <u>Restrictions of use for materials</u>

- Restrictions of use may exist for materials which contain some additives. All useful information shall be communicated to the laboratories.
- Recycled materials without the same guarantees as the new materials, for which they could substitute themselves cannot be used in contact with food in accordance with CSHPF [The Upper Council for Public Hygiene in France] notification dated 7/9/93 on recycled materials (published in the BOCCRF [Official Bulletin for Competition, Consumption and Repression of Fraud] dated 31/12/93).

Before the marketing of such materials, a file shall be presented to the AFSSA [French Food Safety Agency] notification . The file shall particulary, contain information relating to the waste sources used, the quality of the waste collection, the sorting methods used, the decontamination process implemented and its efficacy, the conformity of the finished material of the regulations and controls carried out on all manufacturing operations to prove that the finished materials produced meet the regulations relating to materials intended to be in contact with foodstuffs.

3. Definitions performance criteria for food contact

3.1 Texts to be used

3.1.1 Regulatory texts

The order of 2/01/2003 relating to materials and objects in plastic put in or intended to be in contact with foodstuffs, food and drink products (directive 2002/72/CE of 6th August, 2002).

3.1.2 Other texts

Information notice No 2003-27 from the DGCCRF relating to additives to plastic materials intended to be in contact with foods.

Other texts relating to plastic materials (circulars, circular letters, instructions etc) collected together in Brochure No. 1227 of the Official Journal.

3.2 Criteria to be used

At each stage of manufacturing of a material or an object, the producer shall check that the various constituents used are included in the positive lists.

When the product or material is finished, the manufacturer or the user should check that the inertia criteria are met, i.e.:

- The positive list and the supplier's limits of use have been respected, evidence of conformity from suppliers,

- Overall migration according to the order of 2/01/2003,
- Specific migration* of monomers and/or residual quantity of monomers in the material or
- object according to the order of 2/01/2003,
- Specific migration* of additives and/or quantity in the material of object.

* Checking specific migration limits is not mandatory if it can be established that the result of the overall migration test implies that the specific migration limits have not been passed, or that the specific migration limit cannot be passed even if all the residual substance migrated.

Respect for the specific migration limits can be checked by determining the quantity of the substance in the material provided that a relationship between this quantity and the value of the specific migration of the substance has been established either by a suitable experiment, or by applying generally recognised diffusion models (order dated 2/01/2003, article 8).

4. Acceptability limits

- Overall migration limit laid down with the order dated 2 January 2003 (Art. 2), i.e. 10 mg/dm² or 60 mg/kg of food according to the geometry of the material or the object. A material or an object whose migration level exceeds the overall migration limit by an amount not exceeding the analytical tolerance defined below will be considered as confom to the order (art.8 and chapter VI of the appendix to the order):
 - 20 mg/kg or 3 mg/dm³ in migration tests using rectified olive oil or its substitutes;
 - 12 mg/kg or 2 mg/dm³ in migration tests using other simulators laid down in directives 82/711/CEE and 85/572/CEE.
- Specific migration limits of monomers and/or maximum residual quantities of monomers in the material or the object (article 7 and chapter I of the annex to the order of 2/01/2003).
- Specific migration limits of additives and/or maximum quantities in the material or object if necessary, specified in the above text (in particular the article 7 of chapter II of the annexto the order of 2/01/2003).
- Specific migration limit of epoxy derivatives, the limits are specified in the order of 2 April 2003.

5. Rules to check the criteria defined in paragraph 3.

- In order to check the migration criteria, the following information shall be given to the laboratory:

- Material references;
- Nature of monomers and additives subject to specific migration limits or maximum residual quantities, without revealing confidential information;
- Contact conditions (duration and temperature);
- Type of foods in contact or simulator liquids.

- Test conditions according to directive 82/711/CEE amended by directives 93/8/CEE and 97/48/CEE, and directive 85/572/CEE (Order dated 2/01/2003, article 8):

- Temperature and contact duration;
- Simulator liquids (chosen according to the foods involved).

Methods to be used for overall migration according to the standards in the series NF EN 1186

Methods to be used for specific migration according to the experimental standards for the measurement of specific migrations from the series prEN 13130-1 to 28 or technical specifications CEN/TS of series 13130 part 1 to 28 a current work on CEN/TC 194 SC1 relating to the determination of BADGE, BFDGE and their derivatives as well as the NOGE and its derivatives.

COMPOSITES

1. SCOPE

- This section deals with composite materials and objects in which the plastic layer is in direct contact with food products, especially:

- Plastic/aluminium composite;
- Plastic/aluminium/paper composite;
- Plastic/paper/aluminium composite;
- Plastic/paper composite;
- Covering/plastic/paper composite (this type of composite is particularly used for manufacturing caps; the covering is made up of a "hot melt" material or a lacquer, the plastic part is often a metalised polyester).

Note: the paper part could be a flat or corrugated cardboard.

The following elements are not concerned:

- Cans (in steel or aluminium) and all covered metallic objects which are subject to specific sheets:
- Materials and objects which are not intended, under normal terms of use or in any reasonably expected conditions, to be in contact with foodstuffs, for example: floor, ceiling and wall coverings, vehicle dashboards, aprons, tablecloths, food trays. However, honeycomb trays in direct contact with foods are included.

2. Restrictions of use for materials

- Restrictions of use may exist for materials containing some additives. All useful information shall be communicated to the laboratories.
- Recycled materials which do not have the same guarantees as the new materials for which they could substitute themselves, cannot be used in contact with food according to CSHPF [The Upper Council for Public Hygiene in France] notification dated 7/9/93 on recycled materials (published in the BOCCRF [Official Bulletin for Competition, Consumption and Repression of Fraud] dated 31/12/93).

Before the amrketing of such materials, a file shall be presented to the AFSSA [French Food Safety Agency] notification. The file shall particulary contain information relating to the waste sources used, the quality of the waste collection, the sorting methods used, the decontamination process implemented and its efficacy, the conformity of the finished material with the regulations and controls carried out on all manufacturing operations to prove that the finished materials thus produced meet the regulations relating to materials intended to be in contact with foodstuffs.

3. Definition of inertia criteria

3.1 Texts to be used

3.1.1 Regulatory texts

Order dated 27/08/87 relating to aluminium and its alloys.

3.1.2 Other texts (to be used provisionally whilst waiting for specific regulation)

At each manufacturing stage of the composite, the producer shall check that the various constituents used appear in the positive lists.

- Order of 2/01/2003 relating to materials and objects in plastic put or intended to be in contact with foodstuffs, food and drink products (directive 2002/72/CE of 6th August, 2002).

- Information notice No 2003-27 from the DGCCRF relating to additives to plastic materials intended to be in contact with foods.

- Other texts relating to plastic materials (circulars, circular letters, instructions etc) put together in Brochure No. 1227 of the Official Journal.

- For plastic/paper composites where the plastic layer may not act as a "barrier", the paper shall meet the appropriate requirements (see sheet relating to paper and cardboard).

- Resolution of the European Council AP (96) 5 on surface coating intended to come into contact with foodstuffs.

3.2 Criteria to be used

At each manufacturing stage of a material or an object, the producer shall check that the various constituents used appear in the positive lists.

When the product or material is finished, the manufacturer or the user shall check that the inertia criteria are met, i.e.:

- The positive list and the limits of use have been respected, evidence of conformity from suppliers,
- Overall migration in accordance with the order of 2/01/2003.
- Specific migration* of monomers and/or residual quantity of monomers in the material or object in accordance with the order of 2/01/2003.
- Specific migration* of additives and/or quantity in the material of object
- Chemical composition of the aluminium;
- If necessary, Criteria defined in the sheet covering paper and cardboard .

* Checking specific migration limits is not obligatory if it can be established that the result of the overall migration test implies that the specific migration limits have not been exceeded, or that the specific migration limit cannot be exceeded even if all the residual substance migrated.

Respect of the specific migration limits can be checked by determining the quantity of the substance in the material provided that a relationship between this quantity and the value of the specific migration of the substance has been established either by a suitable experiment, or by the application of generally recognised diffusion models (order dated 2/01/2003, article 8).

4. Acceptability limits

- Overall migration limit laid down in the *order dated 2 January 2003* (Art. 2), i.e. 10 mg/dm² or 60 mg/kg of food depending on the geometry of the material or the object. A material or an object whose migration level exceeds the overall migration limit by an amount wich does not exceed the analytical tolerance defined below will be considered conform to the order (art.8 and chapter VI of the order annex):
 - 20 mg/kg or 3 mg/dm³ in migration tests using rectified olive oil or its substitutes;
 - 12 mg/kg or 2 mg/dm³ in migration tests using other simulators laid down in directives 82/711/CEE and 85/572/CEE.
- Specific migration limits of monomers and/or maximum residual quantities of monomers in the material or the object (article 7 and chapter I of the 2/01/2003 order annex).
- Specific migration limits of additives and/or maximum quantities in the material or object if necessary, specified in the above text (particulary article 7 of chapter II of the the 2/01/2003 order annex)
- Specific migration limit of epoxy derivatives, the limits are specified in the order of 2 April 2003.
- Limits of the composition of the aluminium and its components, laid down in the order dated 27/08/87.
- If necessary, limits mentionned in the sheet covering paper and cardboard.

5. Rules to check the criteria defined in paragraph 3.

- In order to check the migration criteria, the manufacturer shall give the following information to the laboratory:

- Material references;
- Nature of monomers and additives subject to specific limits of migration or maximum quantities, without revealing confidential information;
- Contact conditions (duration and temperature);
- Type of foods in contact or simulator liquids.

- Test conditions according to directive 82/711/CEE amended by directives 93/8/CEE and 97/48/CEE, and directive 85/572/CEE (Order dated 2/01/2003, article 8):

- Temperature and contact duration;
- simulator liquids (chosen according to the foodstuffs concerned) (for composites with a
 metallic layer, when the migration in the simulators exceed the fixed limits, a specific determination
 of the iron or aluminium migration (according to the metal of the layer) shall be carried out
 and the laboratory shall propose migration tests of these elements in the foods themselves.)
- Methods to be used for overall migration according to the standards in the set NF EN 1186, CEN/TS 14234 dated March 2003 (Polymer coverings on paper and board) and XP CEN/TS 14235 dated April 2003 (Polymer coverings on metallic substrates).
- Methods to be used for specific migration according to the experimental standards relating to the measurement of specific migrations from the series prEN 13130-1 to 28 or technical specifications CEN/TS of series 13130 part 1 to 28 and the current works of CEN/TC 194 SC1 about the determination of the BADGE, BFDGE and their derivatives as well as the NOGE and its derivatives.

PAPER AND CARDBOARD

1. Scope

- This section refers to paper and cardboard, hereafter called 'paper' below, manufactured from undyed or whitened cellulose base natural fibres, including recycled cellulose fibres from recovered recyclable paper and cardboard. Artificial fibres from regenerated cellulose can also be used in mixture with natural fibres. The paper can be white, undyed, coloured or be printed on the side which is not in contact with the food. Furthermore, the paper can contain synthetic fibres such as polyethylene fibres and functional additives. Materials and objects in stiff paper made up exclusively of paper and/or cardboard or composed of two or more layers of fibres each of which is made up exclusively of paper and/or cardboard and as a finished product are intended to be in contact with food products are also concerned.
- Coated papers or those which have undergone a surface treatment such as polymeric bonding for organic or mineral pigments are also concerned.
- Papers coated with wax or paraffin which are mentionned in the "Coated Paper and Cardboard" sheet, and composites which include, for example, a plastic film or aluminium sheet mentionned in the "Composites" sheet are not concerned here.
- This sheet does not deal with papers and cardboards which are so-called "active" with regard to foodstuffs and which are the subject of specific regulations. However, the medium shall comply with the principles of inertia as defined in this sheet.
- This sheet does not deal with materials and objects which are not intended, under normal and expected term of use, to be in contact with foodstuffs, for example: tablecloths, aprons, sets of placemats, dish cloths. However the sheet does cover household kitchen paper (until specific European directives have been published) and table napkins are concerned.

2. Restriction of use for materials

Recycled materials which do not have the same guarantees as the new materials for which they could substituted themselves, cannot be used in contact with foods according to CSHPF [The Upper Council for Public Hygiene in France] notification dated 07.09.93 on recycled materials (published in the BOCCRF [Official Bulletin for Competition, Consumption and Fraud Repression] dated 31/12/93). For paper-cardboard materials, recycled cellulose fibres can be used if they meet the requirements defined in the Guide to good practice for manufacturing of papers and cardboards and materials transformed in paper and cardboard which are intended to be in contact with foodstuffs.

3. Definitions of performance criteria for food contact

3.1. Texts to be used

- Texts relating to paper collected in brochure No.1227 written by the Directorate of the Official Journals
 of the French Republic.
- CSHPF Notification dated 13/10/98 (amended 12/05/99) about the use of fluorescent bleaching agents in papers intended for food use.
- Guide to good practices for manufacturinge papers and cardboards and materials transformed in paper and cardboard intended to be in contact with foodstuffs, approved on 09/09/97 by the Food and Nutrition department of the CSHPF.
- CSHPF Notification of 7/11/95 concerning inks and lacquers used for printing packaging intended to be in contact with foodstuffs.
- Order of 2nd January, 2003 relating to materials and objects in plastic put or intended to be in contact with foodstuffs, food and drink products, transposition of directive 2002/72/CE for the composition of synthetic fibres.
- Order of 2nd April 2003 relating to the use of some epoxidic derivatives in materials and objects put or intended to be in contact with foodstuffs, transposition of directive 2002/16/CE for constituents of papers containing epoxidic derivatives.

3.2. Criteria to be used:

3.2.1. Composition criteria

Please consult the composition criteria mentioned in the guide to good practices.

The criteria of use for the adjuvants used and specified in the mentioned regulations, when they exist, will be applied (maximum dose, specific tests).

When the paper is printed, please consult the notification mentioned above for allowed pigments and colorants, for solvents and purity criteria. The printed side must not be in contact with the food.

Page 16

<u>3.2.2.</u>

Purity criteria:

Purity requirements		Wet or fatty		Hot filtering
Systematic inspection	Dry foods	foods	Cooking	
Transfer of antimicrobial constituents	x	x	x	x
Organoleptic inertia	x	x	X	x
Pentachlorophenol (PCP) content	x	x	x	x
Polychlorobiphenyl (PCB) content	x	x	x	x
Content of extractable metal (Pb, Cd, Hg, Cr ^{VI}) content		x	x	x
Hot extraction				x

Frozen foods are considered as dry foods if they are not frozen or defrosted in their packaging; otherwise they are considered as wet and fatty foods.

_				Hot filtering
Purity requirements Inspection depending on additives	Dry foods	Wet or fatty foods	Cooking	
Additives with formaldehyde, glyoxal, fluorine base: dosing or migration of additives	Х	x	Not used	
Authorised optical blueing agents: maximum solidity on discharge or dosing of optical blueing agents		X	Not used	
In the absence of intentional processing by optical bleaching agents (for recycled papers): maximum fastness.		Х	Recycled fibres	not used
Colouring agents: maximum fastness to bleeding only for papers which have been deliberately coloured, or which appear to be coloured.		X	Colouring ag generally not used	ents: Not used

When recycled fibres are used, the free formaldehyde content will be systematically measured.

4. Acceptability limits

- Transfer of antimicrobial constituents: No inhibition zone should be observed with Bacillus subtilis and Aspergillus niger strains.

- Organoleptic inertia: checking of the absence of alteration of food taste and smell of the food according to the criteria of the method used:

- PCP content not detected at the threshold of 0.1 mg/kg of paper;

- PCB content • 2 mg/kg of paper;

- Content in metals extractable with water:

- Pb 3 mg/kg of paper
- Cd 0.5 mg/kg of paper
- Hg 0.3 mg/kg of paper
- Cr^{VI} ♦ 0.25 mg/kg of paper

- Fastness to bleeding colorants: a grade of 5 shall be obtained according to a scale between 1 and 5 during fastness to bleeding test..

- Fluorescent blueing agents (optical blueing agents):

- If admissible optical bleaching agents are added: a grade of 5 shall be obtained for the fastness to bleeding test or TEL (Theoretical Exposure Level) less than or equal to 50 µg/day/person;
- If there is no intentional treatment by optical blueing agents, a grade of 5 shall be obtained for the maximum fastness for fastness to bleeding test.

- Migration of additives possibly entering into the composition of the material:

- * Formaldehyde 1 mg/dm²;
- * Glyoxal 1.5 mg/dm² ;
- * Other adjuvants: the contents should not exceed the maximum doses of use given in the

Guide to good practices .

- Hot extraction: dry residue 10 mg/dm² or 10 mg/g of paper.

5. Analyses.

- Test methods to be used:
 - Absence of transfer of antimicrobial constituents: EN 1104;
 - Organoleptic inertia (atypical flavour): EN 1230-2;
 - Pentachlorophenol: EN/ISO 15320;
 - Polychlorobiphenyls: EN/ISO 15318;
 - Extractable metals: ENV 12 497 (Hg) and ENV 12 498 (Pb, Cr, Cd);
 - Formaldehyde: EN 1541;
 - Glyoxal: in the absence of the normalized method, methods such as BfR are used;
 - Fluorine: in the absence of a normalised method, a validated method is used, for example, Schöniger combustion and ionometric dosage;
 - Fastness to bleeding of colorants test: EN 646;
 - Fastness to bleeding of bleaching agents test: EN 648;
 - Preparation of an extract with cold water (except for cooking or hot filtering papers): EN 645;
 - Preparation of an extract with cold water (hot filtering papers): EN 647;
 - Dosage of soluble material in water: EN 920.

Page 19

SUMMARY TABLE

	1			
		Purity requirements	Acceptability limits	Analysis methods
		Transfer of antimicrobial agents	Absence of inhibition zone	EN 1104
		Organoleptic inertia	Absence of alteration in taste or smell of foods	EN 1230-2
	ods	PCP content	\leq 0.1 mg/kg of paper	EN/ISO 15320
	y fo	PCB content	\leq 2 mg/kg of paper	EN/ISO 15318
	D	Dosing of additive based on Formaldehyde, glyoxal or others.	Formaldehyde ≤ 1 mg/dm² Glyoxal ≤ 1.5 mg/dm² Others: maximum doses of use conform to the Guide to Good Practices	Formaldehyde: EN 1541 Glyoxal: no normalised method
		Transfer of antimicrobial agents	Absence of inhibition zone	EN 1104
		Organoleptic inertia	Absence of alteration in taste or smell of foods	EN 1230-2
		PCP content	\leq 0.1 mg/kg of paper	EN/ISO 15320
		PCB content	≤ 2 mg/kg of paper	EN/ISO 15318
	foods	Dosing of additive based on Formaldehyde, glyoxal or others.	Formaldehyde ≤ 1 mg/dm² Glyoxal ≤ 1.5 mg/dm² Others: maximum doses of use conform to the Guide to Good Practices	Formaldehyde: EN 1541 Glyoxal: no normalised method
	Wet or fatty	Extractable metal content	$\begin{array}{lll} Pb & \leq 3 \mbox{ mg/kg of paper} \\ Cd & \leq 0.5 \mbox{ mg/kg of paper} \\ Hg & \leq 0.3 \mbox{ mg/kg of paper} \\ Cr^{VI} & \leq 0.25 \mbox{ mg/kg of paper} \end{array}$	ENV 12 497 (Hg) ENV 12 498 (Pb, Cr, Cd)
Type of contact		Checking of fastness to bleeding test of optical bleaching agents	 If these authorized optical bleaching agents are added: a grade of 5 shall be obtained or TEL ≤ 50 g/day/person, If there is no intentional treatment by optical bleaching agents: a grade of 5 shall be obtained 	EN 648 or dosing EN 648
		Migration of colouring agents	A grade of 5 shall be obtained	EN 646
		Transfer of antimicrobial constituents	Absence of inhibition zone	EN 1104
		Organoleptic inertia	Absence of alteration in food taste or smell	EN 1230-2
	ring	PCP content	\leq 0.1 mg/kg of paper	EN/ISO 15320
	filte	PCB content	≤ 2 mg/kg of paper	EN/ISO 15318
	Hot	Extractable metal content	$Pb \le 3 mg/kg of paper$ $Cd \le 0.5 mg/kg of paper$ $Hg \le 0.3 mg/kg of paper$ $Cr^{VI} \le 0.25 mg/kg of paper$	ENV 12 497 (Hg) ENV 12 498 (Pb, Cr, Cd)
		Hot extraction	\leq 10 mg/dm ² or 10 mg/g paper	EN 920
		Transfer of antimicrobial constituents	Absence of inhibition zone	EN 1104
		Organoleptic inertia	Absence of alteration in food taste or smell	EN 1230-2
	_	PCP content	\leq 0.1 mg/kg of paper	EN/ISO 15320
	king	PCB content	≤ 2 mg/kg of paper	EN/ISO 15318
	Coo	Extractable metal content	$Pb \le 3 mg/kg of paper$ $Cd \le 0.5 mg/kg of paper$ $Hg \le 0.3 mg/kg of paper$	ENV 12 497 (Hg) ENV 12 498 (Pb, Cr, Cd)
			$Cr^{VI} \le 0.25 mg/kg$ of paper	

GLASS – CRYSTAL – CERAMICS – VITREOUS CERAMIC ENAMELLED OBJECTS

1. <u>Scope</u>

This section deals with materials made up of glass, crystal, ceramic, glass ceramic and enamelled objects and when they are finished products, are intended to be in direct contact with foodstuffs, food and drink products.

"glass" means a non-metallic inorganic material obtained by complete melting of raw materials at high temperatures, into a homogeneous liquid which cools down afterwards into a rigid state essentially without crystallisation. Glass materials can be combined together and/or decorated.

"ceramic" means a mixture of inorganic materials with a generally high clay and silicate content to which small quantities organic materials are added. Ceramic objects are firstly formed, and the shape obtained is fixed permanently by cooking. They can be glazed, enamelled and/or decorated.

"glass **ceramic**" means an inorganic non-metallic material obtained by melting of mainly mineral raw materials at high temperature, the homogeneous liquid being cooled down progressively after contitution then crystallised to a certain degree by heat treatment. Glass ceramic materials may be combined together and/or decorated.

"crystal" means inorganic non-metallic materials as described in directive 69-493 of 15/12/69.

"enamelled objects" means objects having a cast lining in one or more layers resulting from the melting or sintering of non-organic constituents.

2. Definitions of performance criteria for food contact

2.1 Texts to be used

2.1.1 Regulatory texts

• Order of 07/11/85 (Directive 84-500 of 15/10/84): limitation of quantities of lead and cadmium extractable from ceramic objects

2.1.2 Other texts

- **Standard ISO 6486/1 and 2:** ceramic articles in contact with food. Emission of lead and cadmium. Test methods, admissible limits (06/01/1981).
- **Standard ISO 7086/1:** articles in glass and vitreous ceramic in contact with foods. Emission of lead and cadmium. Test methods, admissible limits (15/11/1982).
- Standard NF EN 1388-1 and 2 (classification index D 25 501): materials and articles in contact with foodstuffs, silicate surface. Determination of the release of lead and cadmium (January 96).
- **B.O.C.C.R.F. Notification of 13/02/96:** transfer of chromium 6 from materials in contact with foodstuffs.

2.2 Criteria to be used

At the product or material stage, the manufacturer or the user shall check that the inertia criteria are met, i.e.:

- as far as ceramics are concerned, migration of lead and cadmium,
- as far as glass, crystal and glass ceramic are concerned, migration of lead and cadmium,
- as far as all enamelled or decorated objects are concerned (except ceramics), the migration of lead, cadmium and hexavalent chromium.

For internal surface treatments, they shall be carried out with products suitable to be in contact with food.

3. Acceptability limits

3.1 Ceramics and enamelled or decorated ceramics

	Lead	Cadmium
Category 1: Objects which can be filled and objects which cannot be filled whose internal depth measured between the lowest point and the horizontal plane passing through the upper edge is less than or equal to 25mm. Limits in mg/dm²	0.8	0.07
Category 2: Fillable objects other than: - Packaging or storage containers with a capacity up to 3 litres; - Cooking utensils. Limits in mg/l	4.0	0.3
<u>Category 3</u> : Cooking utensils; packaging and storage containers with a capacity up to 3 litres.		
Limits in mg/l	1,5	0,1
Oral contact (for all objects decorated externally over 20mm in width measured from the external edge).		
Limits in mg/article	2	0.2

3.2 Glass – crystal – glass ceramic – enamelled objects

	Lead	Cadmium
Category 1: Objects which can be filled and objects which cannot be filled (including cooking ustensils)whose internal depth measured between the lowest point and the horizontal plane passing through the upper edge is less than or equal to 25mm. Limits in mg/dm²	0.8	0.07
Category 2: Fillable objects other than: - Packaging or storage containers with a capacity up to 3 litres; - Cooking utensils. Limits in mg/l	4.0	0.3
Category 3: Cooking utensils (other than those in category 1) ; packaging and storage containers with a capacity up to 3 litres. Limits in mg/l	1,5	0,1
<u>Oral contact</u> (relating to objects decorated externally over a width of 20mm measured from the external edge). Limits in mg/article	2	0.2

* only concerns enamelled objects, whatever the support medium, other than ceramic, in direct contact with foodstuffs, food products and drinks.

4. Rules to check the criteria defined in paragraph 2.

4-1 Test conditions

- Washing of the samples according to the standards applicable to the material under consideration. - Simulator liquid: Acetic acid solution at 4 %.

- Temperature: 22°C ± 2°C.
- Contact time: 24 hours ± 30 mins.
- Contact conditions:
 - Categories 1-2-3: Fill up to 1mm to the overflowing point,
 - Carafes: Fill the carafe up to the overflowing point and insert softly the closer letting the excess acetic acid run away.
 - Oral contact: Immerse over 20 mm in height, measured all round the rim, of the upper part of a drinking container.

4-2 Test methods

- Determination of the specific migration of lead and cadmium by atomic absorption spectrophotometry or any other equivalent method with a detection limit at least equal to one tenth of the limits indicated in 3.1 and 3.2.

- Determination of chromium 6 by diphenylcarbazide colorimetry according to NF T 90 043 or any other equivalent method having (if possible) a detection limit at least equal to one tenth of the limits indicated in 3.2.

4-3 Results

For a tested object, when the migrations of lead, cadmium, chromium 6 or one of the three exceed the limits indicated in paragraph 3, but do not exceed these limits by more than 50%, the object is nevertheless considered conform if the quantities of lead, cadmium and chromium 6 from at least three other objects, similar in shape, dimensions, decoration and lacquer, and subjected to a test carried out in the conditions laid down in paragraph 4, do not exceed, on average, the limits fixed and if, for each of these objects, the limits are not exceeded by more than 50%.

STAINLESS STEEL

1. <u>SCOPE</u>

This section deals with stainless steel and objects made exclusively from stainless steel which as finished products are intended to be in direct contact with food products.

It does not involve materials and objects in stainless steel which are not intended, under normal terms of use or other generally expected conditions, to be in contact with foodstuffs (particulary pump axles).

The main examples of use for the different categories of stainless steels are specified in Annex B of standard NF A 36 711.

2. Definitions of performance criteria for food contact

2.1. Texts to be used

2.1.1 Regulatory texts

- Order of 13th January 1976 relating to materials and objects in stainless steel in contact with foodstuffs.
- Order of 15th November 1945 setting the list of materials likely to be used without adverse effect on public health in the manufacturing of measuring instruments.

2.1.2 Other texts

- Standard NF A 36 711 ": Non packaging steel Stainless steel intended for use in contact with foodstuffs, products and beverages for human and animal consumption.
- Information document BP A 36 720 "Cleaning stainless steels in food and health applications

2.2 Criteria to be used

Composition according to the order of 13th January 1976.

3. ACCEPTABILITY LIMITS

- Minimum chromium content: 13.0 p 100
- Possible added elements: Ta, Nb, Zr, Mo, Ti, Al, Cu with the following maximum contents:
 - -1 p 100 for Ta, Nb, Zr
 - -4 p 100 for Mo, Ti, Al, Cu
- Elements which are not mentionned in the order may be used within the limits of chemical composition defined in the attached tables 1 to 4.

Page 25

		-					-		•				
Type of steel									%	mass			
Name	Number	C Max.	SiMnPSNCrmaxmax.max.max.		Cr	Мо	Nb	Ni	Ті	Others			
X1CrNb15	1.4595	0.020	1.00	1.00	0.025	≤ 0.015	0.020	14.00 to 16.00		0.20 to 0.60			
X6Cr13	1.4000	0.08	1.00	1.00	0.040	<u><</u> 0.015 ^b		13.00 to 14.00					
X6CrAI13	1.4002	0.08	1.00	1.00	0.040	<u><</u> 0.015 [♭]		13.00 to 14.00					AI: 0.10 to 0.30
X2CrTi17	1.4520	0.025	0.50	0.50	0.040	<u><</u> 0.015	0.015	16.00 to 18.00				0.30 to 0.60	
X6Cr17	1.4016	0.08	1.00	1.00	0.040	<u><</u> 0.015 ^b		16.00 to 18.00					
X3CrTi17	1.4510	0.05	1.00	1.00	0.040	<u><</u> 0.015 ^b		16.00 to 18.00				4(C+N)+0.15 <ti≤0.80 <sup="">°</ti≤0.80>	
X3CrNb17	1.4511	0.05	1.00	1.00	0.040	<u><</u> 0.015		16.00 to 18.00		12 x C to 1.00			
X6CrMo17-1	1.4113	0.08	1.00	1.00	0.040	<u><</u> 0.015 ^b		16.00 to 18.00	0.90 to 1.40				
X2CrMoTi17-1	1.4513	0.025	1.00	1.00	0.040	<u><</u> 0.015	0.015	16.00 to 18.00	1.00 to 1.50			0.30 to 0.60	
X2CrMoTi18-2	1.4521	0.025	1.00	1.00	0.040	<u><</u> 0.015	0.030	17.00 to 20.00	1.80 to 2.50			4(C+N)+0.15 <ti<u><0.80 [°]</ti<u>	
X6CrNi17-1 *)	1.4017*)	0.08	1.00	1.00	0.040	<u><</u> 0.015		16.00 to 18.00			1.20 to 1.60		
X6CrMoNb17-1	1.4526	0.08	1.00	1.00	0.040	<u><</u> 0.015	0.040	16.00 to 18.00	0.80 to 1.40	7(C+N)+0.10 <nb<u><1.00</nb<u>			
X2CrNbZr17 *)	1.4590*)	0.030	1.00	1.00	0.040	<u><</u> 0.015		16.00 to 17.50		0.35 to 0.55			Zr <u>></u> 7x(C+N)+0.15
X2CrAlTi18-2	1.4605	0.030	1.00	1.00	0.040	<u><</u> 0.015		17.00 to 18.00				4(C+N)+0.15 <ti<u><0.80[°]</ti<u>	AI : 1.70 to 2.10
X2CrTiNb18	1.4509	0.030	1.00	1.00	0.040	<u><</u> 0.015		17.50 to 18.50		3C+0.3< Nb <u><</u> 1.00		0.10 to 0.60	
X2CrMoTi29-4	1.4592	0.025	1.00	1.00	0.030	<u><</u> 0.010	0.045	28.00 to 30.00	3.50 to 4.00			4(C+N)+0.15 <ti<u><0.80 °</ti<u>	

 Table 1 – Chemical composition (casting analysis) ^a of ferritic stainless steels

^a The elements which are not included this table cannot be added intentionally into the steel composition without the agreement of the purchaser, excepted those intended to produce the casting. All precautions must be taken to avoid the additon of elements from the scrap metal and raw materials used in production of elements likelly to affect the mechanical characteristics as well as the suitability for use of steel.

^b As far as bars, machine wire, profiles and the semi-finished products are concerned, a maximum sulphur content of 0.030% applies. For all products intended to be machined, a controlled sulphur content between 0.015 and 0.030% is recommended and authorised.

^c The steel can be stabilized by using of Titanium, Niobium or Zirconium. Taking into account the atomic weights of these elements and the Carbon and Nitrogen content, the equivalence shall be :

 $\begin{array}{ccc} \text{Ti} \simeq & \underline{7} \text{ Nb} \simeq & \underline{7} \text{ Zr} \\ & 4 & 4 \end{array}$

*) Grade of steel patented

Type of steel								% mass	;			
Name	Number	C	Si max.	Mn max	P max.	S	Cr	Cu	Мо	Nb	Ni	Others
X12Cr13	1.4006	0.08 to 0.15	1.00	≤ 1.50	0.040	≤ 0.015 ^c	13.00 to 13.50				≤ 0.75	
X20Cr13	1.4021	0.16 to 0.25	1.00	1.50	0.040	<u><</u> 0.015 [°]	13.00 to 14.00					
X30Cr13	1.4028	0.26 to 0.35	1.00	1.50	0.040	<u><</u> 0.015 [°]	13.00 to 14.00					
X38CrMo14	1.4419	0.36 to 0.42	1.00	1.00	0.040	<u><</u> 0.015	13.00 to 14.50		0.60 to 1.00			
X39Cr13	1.4031	0.36 to 0.42	1.00	1.00	0.040	<u><</u> 0.015 [°]	13.00 to 14.50					
X46Cr13	1.4034	0.43 to 0.50	1.00	1.00	0.040	<u><</u> 0.015 [°]	13.00 to 14.50					
X50CrMoV15	1.4116	0.45 to 0.55	1.00	1.00	0.040	<u><</u> 0.015 [°]	14.00 to 15.00		0.50 to 0.80			V = 0.10 to 0.20
X70CrMo15	1.4109	0.65 to 0.75	0.70	1.00	0.040	<u><</u> 0.015 [°]	14.00 to 16.00		0.40 to 0.80			
X39CrMo17-1	1.4122	0.33 to 0.45	1.00	1.50	0.040	<u><</u> 0.015 [°]	15.50 to 17.50		0.80 to 1.30		<u><</u> 1.00	
X105CrMo17	1.4125	0.95 to 1.20	1.00	1.00	0.040	<u><</u> 0.015 [°]	16.00 to 18.00		0.40 to 0.80			
X90CrMoV18	1.4112	0.85 to 0.95	1.00	1.00	0.040	<u><</u> 0.015 [°]	17.00 to 19.00		0.90 to 1.30			V = 0.07 to 0.12
X17CrNi16-2	1.4057	0.12 to 0.22	1.00	1.50	0.040	<u><</u> 0.015 [°]	15.00 to 17.00				1.50 to 2.50	
X2CrNiMoV13-5-2	1.4415	≤ 0.03	0.50	≤ 0.50	0.040	≤ 0.015	13.00 to 13.50		1.50 to 2.50		4.50 to 6.50	Ti: ≤ 0.010
												V: 0.10 to 0.50
X3CrNiMo13-4	1.4313	≤ 0.05	0.70	1.50	0.040	<u><</u> 0.015	13.00 to 14.00		0.30 to 0.70		3.50 to 4.50	N <u>></u> 0.020
X4CrNiMo16-5-1	1.4418	≤ 0.06	0.70	1.50	0.040	<u><</u> 0.015 [°]	15.00 to 17.00		0.80 to 1.50		4.00 to 6.00	N <u>></u> 0.020
X5CrNiCuNb16-4	1.4542	≤ 0.07	0.70	1.50	0.040	<u><</u> 0.015 [°]	15.00 to 17.00	3.00 to 4.00	≤ 0.60	5 x C to 0.45	3.00 to 5.00	
X6NiCrTiMoVB25-15-2	1.4980	0.03-0.08	1.00	1.00	0.025	≤ 0.015	13.50 to 16.00		1.00 to 1.50		24.0 0to 27.00	B: 0.0030 to 0.010
				to 2 00								AI: ≤ 0.35
												Ti: 1.90 to 2.30
												V: 0.10 to 0.50
X7CrNiAl17-7	1.4568	≤ 0.09	0.70	1.00	0.040	<u><</u> 0.015	16.00 to 18.00				6.50 to 7.80 ^d	AI = 0.70 to 1.50
X8CrNiMoAl15-7-2	1.4532	<u><</u> 0.10	0.70	1.20	0.040	<u><</u> 0.015	14.00 to 16.00		2.00 to 3.00		6.50 to 7.80	AI = 0.70 to 1.50
X5CrNiMoCuNb14-5	1.4594	<u><</u> 0.07	0.70	1.00	0.040	<u><</u> 0.015	13.00 to 15.00	1.20 to 2.00	1.20 to 2.00	0.15 to 0.60	5.00 to 6.00	

Table 2 – Chemical composition (casting analysis)^a of martensitic stainless steels and under precipitation hardening treatement

^a The elements wich are not included in the table cannot be added intentionally into the steel composition without the agreement of the purchaser, excepted of those intended to produce casting. All precautions must be taken to avoid the addition of elements from the scrap metal and raw materials used in the production of elements likely to affect the mechanical characteristics as well as the suitability for use of steel.

^b During calls for tender and order more limited carbon contents can be defined.

^b As far as bars, machine wire, profiles and the semi-finished products are concerned, a maximum sulphur content of 0.030% applies.

For all products intended to be machined, a controlled sulphur content between 0.015 and 0.030% is recommended and authorised.

^d For better cold deformability, the upper limit can be increased to 8.30%.

Type of steel				i	1		i	% ma	ss		i		
Name	Number	С	Si	Mn	Р	S	N	Cr	Cu	Мо	Nb	Ni	Ti
X5CrNi17-7	1.4319	≤ 0.07	≤ 1.00	≤ 2.00	0.045	≤ 0.030	≤ 0.11	16.00 to 18.00				6.00 to 8.00	
X10CrNi18-9	1.4325	0.04 to 0.15	≤ 1.00	≤ 2 .00	0.045	≤ 0.030	≤ 0.11	17.00 to 19.00				8.00 to 10.00	
X10CrNi18-8	1.4310	0.05 to 0.15	≤2.00	≤2.00	0.045	≤0.015	<u><</u> 0.11	16.00 to 19.00		≤0.80		6.00 to 9.50	
X2CrNiN18-7	1.4318	≤0.030	≤1.00	≤2.00	0.045	≤0.015	0.10 to 0.20	16.50 to 18.50				6.00 to 8.00	
X2CrNi18-9	1.4307	≤0.030	≤1.00	≤2.00	0.045	≤0.015 ^b	<u><</u> 0.11	17.50 to 19.50				8.00 to 10.00	
X2CrNi19-11	1.4306	≤0.030	≤1.00	≤2.00	0.045	≤0.015 ^b	<u><</u> 0.11	18.00 to 20.00				10.00 to 12.00 °	
X2CrNiN18-10	1.4311	≤0.030	≤1.00	≤2.00	0.045	≤0.015 ^b	0.12 to 0.22	17.00 to 19.50				8.50 to 11.50	
X5CrNi18-10	1.4301	≤0.07	≤1.00	≤2.00	0.045	≤0.015 ^b	<u><</u> 0.11	17.00 to 19.50				8.00 to 10.50	
X6CrNiTi18-10	1.4541	≤0.08	≤1.00	≤2.00	0.045	≤0.015 ^b		17.00 to 19.00				9.00 to 12.00 °	5xC to 0.70
X6CrNiNb18-10	1.4550	≤0.08	≤1.00	≤2.00	0.045	≤0.015		17.00 to 19.00			10xC to 1.00	9.00 to 12.00 °	
X4CrNi18-12	1.4303	≤0.06	≤1.00	≤2.00	0.045	≤0.015 ^b	<u><</u> 0.11	17.00 to 19.00				11.00 to 13.00	
X1CrNi25-21	1.4335	≤0.020	≤0.25	≤2.00	0.025	≤0.010	<u><</u> 0.11	24.00 to 26.00		<u><</u> 0.20		20.00 to 22.00	
X2CrNiMo17-12-2	1.4404	≤0.030	≤1.00	≤2.00	0.045	≤0.015 ^b	<u><</u> 0.11	16.50 to 18.50		2.00 to 2.50		10.00 to 13.00 °	
X2CrNiMoN17-11-2	1.4406	≤0.030	≤1.00	≤2.00	0.045	≤0.015 ^b	0.12 to 0.22	16.50 to 18.50		2.00 to 2.50		10.00 to 12.00 °	
X5CrNiMo17-12-2	1.4401	≤0.07	≤1.00	≤2.00	0.045	≤0.015 ^b	<u><</u> 0.11	16.50 to 18.50		2.00 to 2.50		10.00 to 13.00	
X1CrNiMoN25-22-2	1.4466	≤0.020	≤0.70	≤2.00	0.025	≤0.010	0.10 to 0.16	24.00 to 26.00		2.00 to 2.50		21.00 to 23.00	
X6CrNiMoTi17-12-2	1.4571	≤0.08	≤1.00	≤2.00	0.045	≤0.015 ^b		16.50 to 18.50		2.00 to 2.50		10.50 to 13.50 °	5xC to 0.70
X6CrNiMoNb17-12-2	1.4580	≤0.08	≤1.00	≤2.00	0.045	≤0.015		16.50 to 18.50		2.00 to 2.50	10xC to 1.00	10.50 to 13.50	
X2CrNiMo17-12-3	1.4432	≤0.030	≤1.00	≤2.00	0.045	≤0.015 ^b	<u><</u> 0.11	16.50 to 18.50		2.50 to 3.00		10.50 to 13.00	
X2CrNiMoN17-13-3	1.4429	≤0.030	≤1.00	≤2.00	0.045	≤0.015	0.12 to 0.22	16.50 to 18.50		2.50 to 3.00		11.00 to 14.00 °	
X8CrMnNiN18-9-5	1.4374	0.05 to 0.10	0.30 to 0.60	9.0 to 10.0	0.035	≤ 0.030	0.250 to 0.320	17.50 to 18.50	≤ 0.40	≤ 0.50		5.00 to 6.00	
X8CrMnCuNB17-8-3 ^{*)}	1.4597	≤ 0.10	≤ 2.00	6.50 to 8.50	0.040	≤ 0.030	0.15 to 0.30	16.0 0to 18.00	2.00 to 3.50	≤ 1.00		≤ 2.00	
X11CrNiMnN19-8-6	1.4369	0.07 to 0.15	0.50 to 1.00	5.0 to 7.5	0.030	≤ 0.015	0.20 to 0.30	17.50 to 19.50				6.50 to 8.50	
													"to be continued

Table 3 – Chemical composition (casting analysis) ^a of austenitic stainless steels

Page 28

		+											
Type of steel								% mass					
Name	Number	с	Si	Mn	Р	S	N	Cr	Cu	Мо	Nb	Ni	Ti
					max.								
X3CrNiMo17-13-3	1.4436	≤0.05	≤1.00	≤2.00	0.045	≤0.015 ^b	<u><</u> 0.11	16.50 to 18.50		2.50 to 3.00		10.50 to 13.00 °	
X2CrNiMo18-14-3	1.4435	≤0.030	≤1.00	≤2.00	0.045	≤0.015 ^b	<u><</u> 0.11	17.00 to 19.00		2.50 to 3.00		12.50 to 15.00	
X2CrNiMoN18-12-4	1.4434	≤0.030	≤1.00	≤2.00	0.045	≤0.015	0.10 to 0.20	16.50 to 19.50		< 4.00		10.50 to 14.00 °	
X2CrNiMo18-15-4	1.4438	≤0.030	≤1.00	≤2.00	0.045	≤0.015 ^b	<u><</u> 0.11	17.50 to 19.50		< 4.00		13.00 to 16.00 °	
X1CrNiSi18-15-4	1.4361	≤0.015	3.70 to 4.50	≤2.00	0.025	≤0.010	<u><</u> 0.11	16.50 to 18.50		<u><</u> 0.20		14.00 to 16.00	
X12CrMnNiN17-7-5	1.4372	≤0.15	≤1.00	5.50 to 7.50	0.045	≤0.015	0.05 to 0.25	16.00 to 18.00				3.50 to 5.50	
X2CrMnNiN17-7-5	1.4371	≤0.030	≤1.00	6.00 to 8.00	0.045	≤0.015	0.15 to 0.20	16.00 to 17.00				3.50 to 5.50	
X12CrMnNiN18-9-5	1.4373	≤0.15	≤1.00	7.50to 10.50	0.045	≤0.015	0.05 to 0.25	17.00 to 19.00				4.00 to 6.00	
X3CrNiCu19.9.2	1.4560	≤0.035	≤1.00	1.50 to 2.00	0.045	≤0.015	<u><</u> 0.11	18.00 to 19.00	1.50 to 2.00			8.00 to 9.00	
X3CrNiCu18-9-4	1.4567	≤0.04	≤1.00	≤2.00	0.045	≤0.015 ^b	<u><</u> 0.11	17.00 to 19.00	3.00 to 4.00			8.50 to 10.50	
X3CrNiCuMo17-11-3-2	1.4578	≤0.04	≤1.00	≤1.00	0.045	≤0.015	<u><</u> 0.11	16.50 to 17.50	3.00 to 3.50	2.00 to 2.50		10.00 to 11.00	
X1NiCrMoCu31-27-4	1.4563	≤0.020	≤0.70	≤2.00	0.030	≤0.010	<u><</u> 0.11	26.00 to 28.00	0.70 to 1.50	< 4.00		30.00 to 32.00	

Table 3 – Chemical composition (casting analysis) ^a of austenitic stainless steels (second part)

^a The elements wich are not included in the table cannot be added intentionally into the steel composition without the agreement of the purchaser, excepted of those intended to produce casting. All precautions must be taken to avoid addition of elements from the scrap metal and raw materials used in the production of elements likely to affect the mechanical characteristics as well as the suitability for use of steel.

^b As far as bars, machine wire, profiles and the semi-finished products are concerned, a maximum sulphur content of 0.030% applies. For all products intended to be machined, a controlled sulphur content between 0.015 and 0.030% s recommended and authorised.

^c When it is necessary to minimise the ferrite delta content for special reasons, for example forgeability of unsoldered tubes or low magnetic permeability, the maximum Ni content can be increased to the following values:

0.50 % (m/m) : 1.4571 1.00 % (m/m) : 1.4306, 1.4406, 1.4429, 1.4434, 1.4436, 1.4438, 1.4541. 1.4550 1.50 % (m/m) : 1.4404

*) Grade of steel patented. The Boron content is: B: 0.0005 to 0.0050

Page 29

Description			% mass											
Name	Number	C max	Si max	Mn max	P max	S max	N	Cr	Cu	Мо	Ni	W		
X2CrNiN23-4 *)	1.4362*)	0.030	1.00	2.00	0.035	0.015	0.05 to 0.20	22.00 to 24.0	0.10 to 0.60	0.10 to 0.60	3.50 to 5.50			
X2CrNiCuN23-4*	1.4655	0.030	1.00	2.00	0.035	0.015	0.05 to 0.20	22.00 to 24.00	1.00 to 3.00	0.10 to 0.60	3.50 to 5.50			
X2CrNiMoN29-7-2	1.4477	0.030	0.50	0.80 to 1.50	0.030	0.015	0.30 to 0.40	28.00 to 30.00	≤ 0.80	1.50 to 2.60	5.8 to 7.50			
X2CrNiMoSi18-5-3	1.4424	0.030	1.40 to 2.00	1.20 to 2.00	0.035	0.015	0.05 to 0.10	18.00 to 19.00		2.50 to 3.00	4.50 to 5.20			
X3CrNiMoN27-5-2	1.4460	0.05	1.00	2.00	0.035	0.015	0.05 to 0.20	25.00 to 28.00		1.30 to 2.00	4.50 to 6.50			
X2CrNiMoN22-5-3	1.4462	0.030	1.00	2.00	0.035	0.015	0.10 to 0.22	21.00 to 23.00		2.50 to 3.50	4.50 to 6.50			
X2CrNiMoCuN25-6-3	1.4507	0.030	0.70	2.00	0.035	0.015	0.15 to 0.30	24.00 to 26.00	1.00 to 2.50	2.70 to 4.00	5.50 to 7.50			
X2CrNiMoN25-7-4 *)	1.4410 *)	0.030	1.00	2.00	0.035	0.015	0.20 to 0.35	24.00 to 26.00		3.00 to 4.00	6.00 to 8.00			
X2CrNiMoCuWN25-7-4	1.4501	0.030	1.00	1.00	0.035	0.015	0.20 to 0.30	24.00 to 26.00	0.50 to 1.00	3.00 to 4.00	6.00 to 8.00	0.50 to 1.00		

Table 4 – Chemical composition (casting analysis) ^a of austeno-ferritic stainless steels

^a The elements wich are not included in the table cannot be added intentionally into the steel composition without the agreement of the purchaser, excepted of those intended to produce casting. Every precaution must be taken to avoid addition of elements from the scrap metal and raw materials used in the production of element likely to affect the mechanical characteristics as well as the suitability for use of steel.

^b As far as bars, machine wire, profiles and the semi-finished products are concerned, a maximum sulphur content of 0.030% applies.

For all products intended to be machined, a controlled sulphur content between 0.015 and 0.030% is recommended and authorised.

*) Grade of steel patented.

NON-COATED STEEL FOR PACKAGING (BLACKPLATE)

1. SCOPE

This section deals with materials and objects in steel ¹⁾ which as finished products are intended to be in direct contact with foodstuffs, food products and beverage for humans and animals consumption.

The products mentionned in sheets "Steel excluding packaging" and "Stainless Steel" are not concerned .

The main applications examples are the following elements:

- Tins for food products (sugar, tea, cakes, chocolate, flour, pastries etc.)
- Oil cans, kegs, barrels etc.

2. RESTRICTIONS OF USE

The use of non-coated blackplate must be restricted to fatty or wet contacts.

For cans and tins sold to non-professional users or final consumers, the restrictions of use relating to packaged products must indicated by the retailer.

3. DEFINITIONS OF PERFORMANCE FOR FOOD CONTACT

3.1 Texts to be used

3.1.1 Regulatory texts

• Order of 15th November 1945 setting the list of materials likely to be used without adverse effect on public health in the manufacturing of measuring instruments.

3.1.2 Other texts

- Guidelines from the Council of Europe relating to metals and alloys intended to be in contact with food.
- NF A 36-701 Steel for packaging Flat steel products intended for use in contact with foodstuffs, food products and beverage for human and animal consumption Non-coated steel (blackplate).

¹⁾ Definition according to NF EN 10020 "Definition and classification of grades of steel"

3.2. Criteria to be used

3.2.1. Steel Composition

The steel supplier certifies conformity with the requirements relating to the chemical composition specified in the table below.

Elements specified		Maximum contents in % mass
Al	Aluminium	1.0
As	Arsenic	0.030
В	Boron	0.05
С	Carbon	0.30
C	d + Pb + Hg ²⁾	0.0100
Cd	Cadmium ²⁾	0.0100
Pb	Lead ²⁾	0.0100
Hg	Mercury ²⁾	0.005
Cr	Chromium	0.50
Cu	Copper	0.40
Mn	Manganese	2.50
Мо	Molybdenum	0.10
N	Nitrogen	0.10
Nb	Niobium	0.10
Ni	Nickel	0.30
Р	Phosphorus	0.10
S	Sulphur	0.050
Si	Silicon	1.0
Sn	Tin	0.10
Ti	Titanium	0.30
V	Vanadium	0.10
W	Tungsten	0.10
Zr	Zirconium	0.050
Others elements taken individually ¹⁾ 0.050		
¹⁾ The chemical elements included included in the section "Others element taken individually" are those which may appear in very small quantities but which are not deliberately added during the manufacturing process of the steel.		
²⁾ The elements cadmium, lead and mercury are not deliberately added during the manufacturing process of the steel. The specification relating to the sum of these three elements refers to the order 98-638 of 20/07/1998 about the environmental requirements that have be taken into account during the design and manufacturing of packaging.		

Table – Chemical composition	1) 2)
------------------------------	-------

Unless otherwise specified, individual regulations do not apply.

3.2.2. Content of undesirable elements

Looking for the presence of lead, cadmium and arsenic.

4. ACCEPTIBILITY LIMITS

Pb + Cd ≤ 0.010 % As ≤ 0.030 %

Steel with metallic coating used for packaging (Tinplate)

1. SCOPE

This section deals with steel ¹⁾ with metallic coating and objects made entirely of steel with metallic coating which as finished products are intended to be in direct contact with foodstuffs, food products and beverage for human and animals consumption.

The products mentionned in sheets "Steel excluding packaging" and "Steel and Stainless Steel with metallic coating (unpackaged)".

The applications examples are the following elements:

- drink cans,
- cans for tinned food,
- packaging for dry foodstuffs,
- aerosol cans.

The material chosen must be in accordance with the term of use.

2. RESTRICTIONS OF USE

When consumers use them, the restrictions of use relating to contact with very acid products may be indicated.

3. DEFINITION OF PERFORMANCE CRITERIA FOR FOOD CONTACT

3.1 Texts to be used

3.1.1 Regulatory texts

- Order of 28th June 1912 amended about the coloration, conservation and packaging of foodstuffs and drinks
- Order of 15th November 1945 setting the list of materials likely to be used without adverse effect on public health in the manufacturing of measuring instruments.

3.1.2 Other texts

- Guidelines of the Council of Europe relating to metals and alloys intended to be in contact with food.
- NF EN 610 "Tin and tin alloys Ingot tin"
- NF A 36-702 Steel for packaging Flat steel products intended for use in contact with foodstuffs, food products and beverage for human and animas consumption – Steel coated with tin (blackplate or tinplate).

¹⁾ Definition according to NF EN 10020 "Definition and classification of grades of steel"

3.2 Criteria to be used

3.2.1 Steel Composition

The steel which makes up the support should meet the requirements specified in the sheet "Steel for packaging (Blackplate)".

3.2.2 Tin coating

The chemical composition of the tin used must comply with the regulations defined by EN 610 for the Sn 99.85 grade excepted for the lead content which shall be down to 0.010%.

3.2.3 Contents of the coating in undesirable elements

Looking for presence of lead, cadmium and arsenic.

4. ACCEPTABILITY LIMITS

Maximum contents of the coating in undesirable elements:

Pb < 0.010 % Cd < 0.010 % As < 0.030 %

Page 34

Steel with organic coating used for packaging

1. <u>Scope</u>

This section deals with steel ¹⁾ with organic coating and objects made entirely of steel with organic coating which as finished products are intended to be in direct contact with foodstuffs, food products and beverage for human and animals consumption.

The product mentionned in sheets "Steel excluding packaging" and "Steel and Stainless Steel with organic coating (excluding packaging)" are not concerned.

The principle examples of coating are as follows: lacquers, varnish, polymer films (PP, PE, etc.)

The principle application examples are the following elementss:

Drink cans; Food cans; packaging for dry foodstuffs, aerosol cans. Stoppers; Etc.

The material chosen must be in accordance with the term of use .

2. Restrictions of use

For cans and tins sold to non-professional users or final consumers, the restrictions of use relating to packaged products must be indicated by the retailer.

3. Definitions of preformance criteria for food contact

3.1 Texts to be used

3.1.1 Regulatory texts

Order of 15th November 1945 setting the list of materials likely to be used without adverse effect on public health in the manufacturing of measuring instruments.

¹⁾ Definition according to NF EN 10020 "Definition and classification of grades of steel"

- Coatings:
 - Order of 2nd April 2003 relating to the use of some epoxy derivatives in materials and objects put in or intended to be in contact with foodstuffs (BADGE, BFDGE, NOGE);
 - Order of 30th January 1984 relating to materials and objects containing vinyl chloride monomer intended to be in contact with foodstuffs and food and drink products;
 - Order of 30th January 1984 relating to official analysis methods relating to the determination of the content of vinyl chloride monomer in materials and objects intended to be in contact with foodstuffs, food and drink products and the determination of vinyl chloride transferred by the materials and objects to the foodstuffs, food and drink products put in contact with them;

3.1.2 Texts to be used provisionally while waiting for regulations about organic coatings for metals.

- Order of 2nd January, 2003 relating to materials and objects in plastic put in or intended to be in contact with foodstuffs.
- Notification from CSHPF of 13 February 1996.
- Resolution of Council of Europe AP (96)5 of 02/10/96.
- Information notice No 2003-27 from the DGCCRF relating to additives to plastic materials intended to be in contact with foods.
- Other texts relating to surface coating collecting in brochure 1227.

3.1.3 Other texts

NF A 36-703 Steel for packaging – Flat steel products intended for contact with foodstuffs, food products and beverage for human and animal consumption– Non-alloyed chromium coated steel.

3.2 Criteria to be used

3.2.1 Coating only

The coating supplier must ensure that the monomers and additives used are included in the positive list of constituents for plastic materials (order of 02/01/2003, Information notice No.2003-37 and brochure 1227 from the Official Journal of the French Government) or in the list in resolution AP (96) 5 of the Council of Europe relating to lacquers.

Among the substances mentionned in resolution AP(96) 5, the substances indicated in lists 1-1 & 1-2 have been evaluated by a scientific authority and their use does not appear to cause problems taking into account this evaluation. For a period of 5 years from the date of adoption of this sheet, the substances in lists 2-1 and 2-2 can be used if they have been authorised by a member state or by the FDA. This period should allow the industries to produce evidence relating to the safety of use for these substances .

When the material or metal is varnished, manufacturers shall check that overall migration is conforms to the limits defined by the order of 2 January 2003 (Directive 2002/72/CE) according to the measurement regulations mentionned below.

When a substance is subject to restrictions of use (particularly specific migration limit), the decree of 8 July 1992 implies that professionals check compliance with this limit. This verification can be done in several ways: by analysis (specific migration test), by calculation based on the residual quantity of the substance in the material or from the overall migration.

3.2.2 Support

The material which makes up the support must satisfy:

- In all cases, the requirements specified in the sheet "non-coated steel for packaging (Black Plate)";
- For Tinplate, the requirements specified in the sheet "Steel with metallic coating used for packaging (Tinplate)";
- For chromed steel, the requirements specified in standard NF A 36-703. <u>3.2.3.</u>

Finished product

Overall and specific migrations: cf 3.2.1.

4. Acceptability limits

- Overall migration limit for organic coverings laid down in the order dated 2 January 2003 (Art. 2), i.e. 10 mg/dm² or 60 mg/kg of food depending on the geometry of the material or the object. A material or an object whose migration level exceeds the overall migration limit by an amount not exceeding the analytical tolerance defined below will be considered as conform to the order (art.8 and chapter VI of the appendix to the order):
 - 20 mg/kg or 3 mg/dm³ in migration tests using rectified olive oil or its substitutes;
 - 12 mg/kg or 2 mg/dm³ in migration tests using other simulators laid down in directives 82/711/CEE and 85/572/CEE.
- Specific migration limit of the finished product: Cf. 3.2.1 In the case of epoxy derivatives, the limits are specified in the order of 2 April 2003.

5. Rules to check the criteria defined in paragraph 3.

5.1 Coating only

The coating manufacturer supplies to the the manufacturer of the ready-to-use packaging:

5.1.1 A certificate testifying that composition, overall migration and, if necessary, specific migrations, comply with the tests mentionned above;

5.1.2 An analysis report carried out on the approved coating indicating the results of inertia tests (overall migration and if necessary specific migrations) carried out on the coating put on an inert support (stainless steel or glass) with simulators chosen according to the use, according to directive 82/711 finally amended by directive 97/48 and directive 85/572/CEE.

Methods to be used for specific migration of BADGE, BFDGE and/or NODGE and their derivatives (cf. work in process of CEN/TC 194 SC1 concerning the determination of the BADGE, BFDGE and their derivatives as well as the NOGE and its derivatives).

5.2. Finished product

When the product is finished, the inertia is checked on the coating of the ready-to-use product (overall and specific migrations).

- Test conditions according to directives 82/711/CEE (lastly amended by directive 97/48/CEE) and 85/572/CEE:
 - Temperature and contact duration

Simulator liquids chosen according to the use:

Foodstuff	Simulator Liquid
Aqueous food (pH>4.5)	Distilled water or water of equivalent quality
Acid food (pH≤4.5)	Ethanol at 10% (v/v)
Alcoholic food	Ethanol at 10% (v/v). This concentration should be adapted according to the alcoholic content of the food if it exceeds 10% (v/v).
Fatty food	Oil or substitute simulator
Dry food	no migration test

Methods to be used for overall migration: see. standards of series NF EN 1186 and XP CEN/TS 14235 of April 2003 (polymer coatings on metallic supports).

STEEL (UNPACKAGED)

1. Scope

This section deals with materials and objects in steel ¹⁾ which as finished products are intended to be in direct contact with foodstuffs, food products and beverage for human and animals consumption.

The products mentionned in sheets "Steel for packaging" and "Stainless Steel" are not concerned.

The main applications examples are the following elements:

- Household articles: cake moulds, bread boards, frying pans, cutlery, cooking hobs.
- Equipment for agri-food industry: Silos and containers for dry foodstuffs (rice etc.)

2. Restriction of use

Steel objects intended to be in direct contact with food products must not be put in contact with acid foodstuffs or drink.

3. Definitions of performance criteria for food contact

3.1 Texts to be used

3.1.1 Regulatory texts

• Order of 15th November 1945 setting the list of materialslikely to be used without adverse effect on public health in the manufacturing of measuring instruments.

3.1.2 Other texts

- NF A 36-714 "Unpackaged Steel Flat steel products intended for contact with foodstuffs, food products or beverage for human and animals consumption – Uncoated (and stainless) steels";
- NF A 35-596 "Iron and steel products Carbon steels for cutlery".

3.2 Criteria to be used

The steel supplier certifies conformity with the requirements for chemical composition specified in the table below.

Specified elements		Maximum o in %	c ontents mass
Symbol	Name	Flat products	Long products
Al	Aluminium	1.00	2.00
As	Arsenic	0.030	0.030
В	Boron	0.050	0.050
С	Carbon	1.30	1.30
Cd	Cadmium	0.01	0.01
Cr	Chromium	1.60	2.50
Со	Cobalt	0.05	0.1
Cu	Copper	1.00	1.00
Mn	Manganese	2.50	2.50
Мо	Molybdenum	1.00	1.00
Ν	Azote	0.100	0.20
Nb	Niobium	0.20	0.20
Ni	Nickel	2.00	4.10
Р	Phosphorus	0.20	0.20
Pb	Lead	0.05	0.05
S	Sulphur	0.050	0.40
Si	Silicon	2.50	2.50
Sn	Tin	0.080	0.080
Ti	Titanium	0.30	0.30
V	Vanadium	0.30	0.30
Zr	Zirconium	0.20	0.20
Other elements taken individually excepted iron		0.050	0.050
¹⁾ The chemical elements included in the section "Others elements taken individually" are elements appearing in very small quantities but which are not deliberately added during the steel manufacturing process.			

Table – Chemical	composition	1)
------------------	-------------	----

4. Acceptability limits

4.1. Content of undesirable elements

Looking for the presence of lead, cadmium, arsenic and cobalt.

Lead \leq 0.05%; Cadmium \leq 0.1%; Arsenic \leq 0.30%; Cobalt \leq 0.050%.

Steel and stainless steel with metallic coating (unpackaged)

1. Scope

This section deals with steel ¹⁾ with metallic coating and objects made entirely of steel with metallic coating which as finished products are intended to be in direct contact with foodstuffs, food products and beverages for human and animals cosumption.

It does not involve materials and objects which are not intended, under normal term of use or other generally expected conditions, to be in contact with foodstuffs.

The products mentionned in sheets "Steel for packaging" and "Stainless Steel" are nor concerned.

The main examples of metallic coating for steel are : gold, silver, tin, aluminium, aluminium-silicon, nickel, chromium, quasi-crystal deposits, zinc or zinc alloys. Furthermore these materials may have a copper bonding intended to have coating

The main examples of metallic coating for stainless steel are :

gold, silver, chromium, quasi-crystal.

The main application examples are the following:

- Household articles: Inner rotisseries, baking sheets, dripping pans, chip fryer vapour barriers etc.;
- Equipment for agri-food industry: Tanks, grain silos etc.

2.Restrictions of use

Steel objects with zinc- or zinc alloy-based metallic coating shall not be used in direct contact with drinks and foodstuffs excepted for manufacturing operations or operations of conservation of chocolate and confectionary products without acid substances, for distillery operations, for roots, tubas, bulbs fruits with dry covering, seeds, dry vegetables and green vegetables and for quasi-crystal-based coatings.

To avoid incorrect conditions of use, the temperature limit for use must be specified on the labelling of the objects. For example, zinc- or zinc-alloy-based coatings shall not be used at temperatures up to 100°C (particulary chip fryers).

¹⁾ Definition according to NF EN 10020 "Definition and classification of grades of steel"

3. _ Definitions of performance criteria for food contact

3.1 Texts to be used

3.1.1 Regulatory texts

- Order of 27 August 1987 relating to materials and objects in aluminium and aluminium alloys in contact with foodstuffs (food and drink products).
- Order of 13th January 1976 relating to materials and objects in stainless steel in contact with foodstuffs.
- Order of 15th November 1945 setting the list of materials likely to be used without adverse effect on public health in the manufacturing of measuring instruments.
- Order of 28th June 1912 relating to coloration, conservation and packaging of foodstuffs and drinks

3.1.2 Other texts

- Circulars letter of 14 March 1931 "Chromium-metallic coating utensils"
- Guidelines of the Council of Europe relating to metals
- NF EN 610 "Tin and tin alloys Ingot tin"
- *NF A 36,712-1* "unpackaged Steel metallic coated flat steel products with intended for contact with foodstuffs, food products and beverages for human and animals consumption Part 1: zinc or zinc alloy coated (non-stainless) Steels ".
- *NF A 36,712-2* "unpackaged Steel metallic coated flat steel products with intended for contact with foodstuffs, food products and beverages for human and animals consumption Part 2: Aluminium coated or aluminium-silicium alloy coated (non stainless) steels ".
- NF A 36,712-3 "unpackaged Steel metallic coated flat steel products with intended for contact with foodstuffs, food products and beverages for human and animals consumption Part 3:Chromium coated (non stainless) steels"
- NF A 36,712-5 "unpackaged Steel metallic coated flat steel products with intended for contact with foodstuffs, food products and beverages for human and animals consumptions Part 5:Tin-coated (non-stainless) steels"

3.2 Criteria to be used

3.2.1 Composition of the steel

The steel making up the support must satisfy the inertia requirements specified in the sheets "Steel (unpackaged)" and "Stainless Steel".

3.2.3 Contents of the coating in undesirable elements

Looking fot the presence of lead, cadmium and arsenic.

3.2.3 Specific migration

Specific migration of Ni, Cr or Zn when the coating is based on Ni or Cr or Zn.

4. Acceptability limits

4.1 Maximum content of undesirable elements

Pb < 0.050 % Cd < 0.010 % As < 0.030 %

4.2 Specific Migration Limits

Specific migration of Ni: 0.5 mg/kg (waiting evaluation by AFSSA). Specific migration of Cr (metal): Specific migration of Zn: 10 mg/kg

5. Rules to check the criteria defined in paragraph 3.

- Test conditions according to directives 82/711/CEE (lastly amended by directive 97/48/CEE) and 85/572/CEE:
 - Temperature and contact duration;

Type of coatin	g Foodstuff	Simulator Liquid	Period
Ni, Cr, Zn	Aqueous food (pH>4.5)	Distilled water or water of equivalent quality	
Ni, Cr	Acid food (pH≤4.5)	Citric acid at 0.5% (p/v) on two different samples	
Ni, Cr, Zn	Alcoholic food	Ethanol at 10% (v/v). This concentration should be adapted according to the alcoholic content of the food if it exceeds 10% (v/v).	
Ni, Cr	Fatty food	Oil at 175°C	2 hours
Ni, Cr, Zn	Dry food	No migration test	
	Fatty food	Oil or substitute simulator at 100°C	2 hours

- Simulator liquids chosen according to the use:

For all objects cannot be filled, the surface/volume ratio adopted by convention is 6 dm² for 1 kg or 1 L of simulator.

Page 43

Steel and stainless steel with organic coating (unpackaged)

1. Scope

This section deals with steel ¹⁾ with organic coating and objects made entirely of steel with organic coating which as finished products are intended to be in direct contact with foodstuffs, food products and beverages for human and animals consumption.

It does not involve materials and objects which are not intended, under cnormal term of use or other generally expected conditions, to be in contact with foodstuffs.

The main applications examples are the followings elements:

- Household articles: frying pans, the interior of cake and spaghetti tins;
- Equipment for agri-food industry: barrels, tanks.

The objects mentionned in the sheet "Steel for packaging" are not concerned. Steels with organic coating used for the following applications are not concerned by the provisions mentionned in this sheet:

Outside covers of electrical household appliances; False ceilings, extractor hoods;

Walls and inner surfaces of premises;

Inner of cold rooms, refrigerated or isothermic lorries.

The main examples of coating are as follows: lacquers, varnish, polymer films (PTFE, resins, silicons, etc.)

2. Restrictions of use

To avoid incorrect conditions of use , the temperature limit for use must be specified on the labelling of objects.

3. Definitions of performance criteria for food contact

3.1 Texts to be used

3.1.1 Regulatory texts

- Order of 15th November 1945 setting the list of materials likely to be used without adverse effect on public health in the manufacturing of measuring instruments.
- Order of 13th January 1976 relating to materials and objects in stainless steel in contact with foodstuffs.

¹⁾ Definition according to NF EN 10020 "Definition and classification of grades of steel"

- Coatings:
 - Order of 2nd April 2003 relating to the use of some epoxy derivatives in materials and objects put in or intended to be in contact with foodstuffs (BADGE, BFDGE, NOGE);
 - Order of 30th January 1984 relating to materials and objects containing vinyl chloride monomer intended to be in contact with foodstuffs and food and drink products;
 - Order of 30th January 1984 relating to official analysis methods about the determination of the content of vinyl chloride monomer in materials and objects intended to be in contact with foodstuffs, food and drink products and the determination of vinyl chloride transferred by the materials and objects to the foodstuffs, food and drink products put in contact with them;

3.1.2 Other texts

- Order of 2nd January, 2003 relating to materials and objects in plastic put in or intended to be in contact with foodstuffs.
- Texts concerning coatings and lacquers brought together in brochure 1227 of the Official Journal of the French Government.
- Resolution AP 96-5 of the Council of Europe relating to surface coating.
- Directives 2002/16/EC of 20 February 2002 on the use of certain epoxy derivatives in materials and objects intended to be in food contact.
- Information notice No 2003-27 from the DGCCRF relating to additives to plastic materials intended to be in contact with foods.

3.2 Criteria to be used

3.2.1 Coating only

The coating supplier must ensure that the monomers and additives used are included in the positive list of constituents of plastic materials (order of 02/01/2003, Information notice No.2003-37 and brochure 1227 from the Official Journal of the French Government) or in the list in resolution AP (96) 5 of the Council of Europe relating to lacquers.

Among the substances mentionned in resolution AP(96) 5, the substances in lists 1-1 & 1-2 have been evaluated by a scientific authority and their use does not appear toc ause any problems taking into account to this evaluation. For a period of 5 years from the date of adoption of this sheet, the substances in lists 2-1 and 2-2 can be used if they have been authorised by a member state or by the FDA. This period should allow industries to produce evidence relating to the safety of use for these substances.

When the material or metal is varnished, manufacturers should ensure that overall migration complies with the limits laid down in the order of 2 January 2003 (Directive 2002/72/CE) according to the measurement regulations mentionned below.

When a substance is subject to restrictions of use (particularly specific migration limit), the decree of 8 July 1992 assumes that professionals must check compliance with this limit. This verification can be done in several ways: by analysis (specific migration test), by calculation based on the residual quantity of the substance in the material or from the overall migration.

3.2.2 Support

The steel making up the support must satisfy the inertia requirements specified in the sheets "Steel (excluding packaging)".

<u>3.2.3. Finished product</u> Overall and specific migrations: see 3.2.1.

4. Acceptability limits

- Overall migration limit for organic coverings laid down in the order dated 2 January 2003 (Art. 2), i.e. 10 mg/dm² or 60 mg/kg of food depending on the geometry of the material or the object. A material or an object whose migration level exceeds the overall migration limit by an amount not exceeding the analytical tolerance defined below will be considered as conform to the order (art.8 and chapter VI of the annex of the order):
 - 20 mg/kg or 3 mg/dm³ in migration tests using rectified olive oil or its substitutes;
 - 12 mg/kg or 2 mg/dm³ in migration tests using other simulators laid down in directives 82/711/CEE and 85/572/CEE.
- Specific migration limit of the finished product: Cf. 3.2.1 In the case of epoxy derivatives, the limits are specified in the order of 2 April 2003.

5. Rules to check the criteria defined in paragraph 3.

5.1 Coating only

The manufacturer of the material or the ready-to-use object asks his coating supplier for:

5.1.1 A certificate which proved that the composition, overall migration and, if necessary, specific migrations, comply with the tests mentionned above;

5.1.2 An analysis report indicating the results of inertia tests (overall migration and if necessary specific migrations) carried out on the coating put on an inert support (stainless steel or glass) with simulators chosen according to the use, according to directive 82-711 lastly amended by directive 97-48 mentionned above.

Methods to be used for specific migration of BADGE, BFDGE and/or NODGE and their specific migrations (see. current work of CEN/TC 194 SC1 concerning the determination of the BADGE, BFDGE and their derivatives as well as the NOGE and its derivatives).

5.2 Finished product

a) When the product is finished , inertia is checked on the coating of the ready-to-use product (overall and specific migrations).

- Test conditions according to directives 82/711/CEE (lastly amended by directive 97/48/CEE) and 85/572/CEE:
 - Temperature and contact duration
 - Simulator liquids chosen according to the use:

Foodstuff	Simulator Liquid
Aqueous foods (pH>4.5)	Distilled water or water of equivalent quality
Acid foods (pH≤4.5)	Ethanol at 10% (v/v).
Alcoholic foods	Ethanol at 10% (v/v). This concentration should be adapted according to the alcoholic content of the food if it exceeds 10 % (v/v).
Fatty foods	Oil or substitute simulator
Dry foods	No migration test

b) Looking for the absence of chromates on the interface of non-stick coatings, in the absence of evidence they are not used in the manufacturing process.

Limit of undisclosed Cr VI with a detection threshold of $5 \mu g/dm^2$ (see BOCCRF n°8 of 24 May 1996, notification from CSHPF meeting of 13 February 1996, p. 433 Brochure n°1227 15 July 2002 edition).

Page 46 ALUMINIUM AND ALUMINIUM ALLOYS

- <u>SHEET No.1:</u> COATED ALUMINIUM – SINGLE USE LONG DURATION CONTACT – (PACKAGING)

1. <u>Scope</u>

Objects in aluminium or aluminium alloys coated with an organic coating intended for single use and long duration contact. This section deals with packaging, the main examples are:

- Cans for sterilized preserved foods;
- Drink cans;
- Pressurized cans;
- Tubes;
- Dishes.

- Crown caps;
- Pharmacological blister ;
- Lacquered caps for milk products;
- Thin sheet of process cheese;
- 2. ____ Definitions of criteria for aptitude to food contact

2.1. TEXTS

2.1.1. Regulatory texts

- Coatings:
 - Order of 2nd April 2003 relating to the use of some epoxy derivatives in materials and objects put in or intended to be in contact with foodstuffs (BADGE, BFDGE, NOGE);
 - Order of 30th January 1984 relating to materials and objects containing vinyl chloride monomer intended to be in contact with foodstuffs and food and drink products;
 - Order of 30th January 1984 relating to official analysis methods relating to the determination of the content of vinyl chloride monomer in materials and objects intended to be in contact with foodstuffs, food and drink products and the determination of vinyl chloride transferred by the materials and objects to the foodstuffs, food and drink products put in contact with them;
 - Other texts brought together in brochure No. 1227 of the Official Journal of the French Government.
- Aluminium:
 - Order of 27 August 1987 relating to materials and objects in aluminium or aluminium alloys in contact with foodstuffs and food and drink products.

2.1.2. Texts to be used provisionally while waiting for regulations on organic coatings for metals.

- Order of 2nd January, 2003 relating to materials and objects in plastic put in or intended to be in contact with foodstuffs, food products and drinks.
- Resolution of the Council of Europe AP (96) 5 of 02/10/1996 on surface coating intended to come into contact with foodstuffs.
- Information notice No 2003-27 from the DGCCRF relating to additives of plastic materials intended to be in contact with foods.
- Texts relating to coatings and lacquers brought together in brochure 1227 of the Official Journal of the French Government.

2.2. CRITERIA TO BE USED

2.2.1 Coating only

 The coating supplier must ensure that the monomers and additives used are included in the positive list of constituents for plastic materials (order of 2 January 2003, Information notice No.2003-37 and brochure 1227 from the Official Journal of the French Government) or in the list in resolution AP (96) 5 of the Council of Europe relating to surface coating.

Among the substances mentionned in resolution AP(96) 5, the substances in of lists 1-1 & 1-2 have been evaluated by a scientific authority and their use does not appear to cause problems taking account this evaluation. For a period of 5 years from the date of adoption of this sheet, the substances in lists 2-1 and 2-2 can be used if they have been authorised by a member state or by the FDA. This period should allow the industries to produce evidence relating to the safety of use for these substances.

- When the material or metal is varnished, manufacturers shall check that overall migration conforms to the limits laid down in the order of 2 January 2003 (Directive 2002/72/CE) according to the measurement regulations mentionned below.
- When a substance is subject to restrictions of use (particularly specific migration limit), the *decree of 8 July 1992* (cf. articles 3 & 4) assumes that professionals must check compliance with this limit. This verification can be done in several ways: by analysis (specific migration test), by calculation based on the residual quantity of the substance in the material or from the overall migration.

2.2.2 Aluminium

Chemical composition according to the order of 27/08/1987.

2.2.3. Finished product

Overall and specific migrations: cf. 2.2.1.

3. Acceptability limits

- Overall migration limit for organic coverings flaid down in the order dated 2 January 2003 (Art. 2), i.e. 10 mg/dm² or 60 mg/kg of food depending on the geometry of the material or the object. A material or an object whose migration level exceeds the overall migration limit by an amount not exceeding the analytical tolerance defined below will be considered as conform to the order (art.8 and chapter VI of the annex of the order):
 - 20 mg/kg or 3 mg/dm³ in migration tests using rectified olive oil or its substitutes;
 - 12 mg/kg or 2 mg/dm³ in migration tests using other simulators laid down in directives 82/711/CEE and 85/572/CEE.

• Specific migration limit: Cf. 2.2.1 In the case of epoxy derivatives (BADGE BFDGE, NOGE), the limits are specified in the order of 2 April 2003. Aluminium must satisfy the purity criteria laid down in the order of 27th August 1987

- Fe + Si < 1% ;
- Ti ≤ 0.15 % ;
- Each of the following elements: Cr, Zn, Cu, Mn, Mg, Ni, Sn \leq 0.10 %;
- Each of the following elements: Pb, Ti, Be, and each of the impurities: ≤ 0.05 %;
- The copper content may reach 0.20 % if those of chromium and manganese contents are down to 0.05 %.

The aluminium alloy must comply with the following composition limits:

- Si \leq 13.5 % Sb \leq 0.4% Sn \leq 0.10%
- Mg \leq 11% Cr \leq 0.35%
- $Mn \le 4\%$ $Ti \le 0.3\%$
- Ni $\leq 3\%$ Zr $\leq 0.3\%$
- Fe $\leq 2\%$ Zn $\leq 0.25\%$
- Cu $\leq 0.6\%$ • Sr $\leq 0.2\%$
- As, Ta, Be, Ti, Pb, and each of the other present elements : $\leq 0.05\%$, total $\leq 0.15\%$.

:

4 Rules to check the criteria defined in paragraph 2.

4.1 COATING ONLY

The coating manufacturer supplies the ready-to-use packaging manufacturer with :

a) A certificate testifying that the composition, overall migration and, if necessary, specific migrations, comply with the tests mentionned above;

b) An analysis report indicating the results of inertia tests (overall migration) carried out on the coating put on inert support (stainless steel or glass) with simulators chosen according to the use, according to directive 82/711/CEE (lastly amended by directive 97/48/CEE), and 85/572/CEE.

2.1 ALUMINIUM ONLY

The aluminium manufacturer must supply the packaging manufacturer with:

a) A evidence of conformity with the order of 27/08/1987.

b) An analysis report of the chemical composition which must comply with the order of 27/08/1987.

4.3. FINISHED PRODUCT

a) Coating Inertia : inertia test (overall and specific migration) to be carried out on the coating of the ready-to-use packaging.

• Test conditions according to directives 82/711/CEE (lastly amended by directive 97/48/CEE) and 85/572/CEE:

:

- Temperature and contact duration
- Simulator liquids chosen according to the use:

Foodstuff	Simulator Liquid
Aqueous food (pH>4.5)	Distilled water or water of equivalent quality
Acid food (pH≤4.5)	Ethanol at 10% (v/v).
Alcoholic food	Ethanol at 10% (v/v). This concentration should be adapted according to the alcoholic content of the food if it exceeds 10% (v/v).
Fatty food	Oil or substitute simulator liquid
Dry food	No migration test

Methods to be used for overall migration according to standards in series NF EN 1186, XP CEN/TS 14235 of April 2003 (polymer coatings on metal support).

b) <u>Inertia of aluminium</u>: the manufacturer is responsible for testing the ready-touse product. The evaluation carried out through long duration tests according to procedures of

use product. The evaluation carried out through long duration tests according to procedures different from a manufacturer to another .

ALUMINIUM AND ALUMINIUM ALLOYS

<u>- SHEET No.2:</u> COATED ALUMINIUM – REPEATED USAGE – SHORT DURATION CONTACT

1. Scope

- Objects in aluminium or aluminium alloys coated with organically coating intended for repetitive use and short duration contact.
- The main examples are for:
- * Household articles: Saucepans, frying pans, dishes, flasks;
- * Household electrical cooking appliances such as pressure cookers.

2. Definitions of performance criteria for food contact

2.1. Texts

2.1.1. Regulatory texts

- Coatings:
 - Order of 2nd April 2003 relating to the use of some epoxy derivatives in materials and objects put in or intended to be in contact with foodstuffs (BADGE, BFDGE, NOGE);
 - Order of 30th January 1984 relating to materials and objects containing vinyl chloride monomer intended to be in contact with foodstuffs and food and drink products;
 - Order of 30th January 1984 relating to official analysis methods relating to the determination of the content of vinyl chloride monomer in materials and objects intended to be in contact with foodstuffs, food and drink products and the determination of vinyl chloride transferred by the materials and objects to the foodstuffs, food and drink products put in contact with them;
 - Other texts brought together in brochure No. 1227 of the Official Journal of the French Government.
- Aluminium:
 - Order of 27 August 1987 relating to materials and objects in aluminium or aluminium alloys in contact with foodstuffs and food and drink products.
- <u>2.1.2.</u> Texts to be used provisionally while waiting for regulations on organic coatings for metals.
 - Order of 2nd January, 2003 relating to materials and objects in plastic put in or intended to be in contact with foodstuffs, food products and drinks.
 - Resolution of the Council of Europe AP (96) 5 of 02/10/1996 on surface coating intended to come into contact with foodstuffs.
 - Information notice No 2003-27 from the DGCCRF relating to additives to plastic materials intended to be in contact with foods.
 - Texts relaing to coatings and lacquers brought together in brochure 1227 of the Official Journal of the French Government.

2.2.

Criteria to be used

2.2.1 Coating only

The coating supplier must ensure that the monomers and additives used are included in the positive list of constituents for plastic materials (order of 2 January 2003, Information notice No.2003-37 and brochure 1227 from the Official Journal of the French Government) or in the list in resolution AP (96) 5 of the Council of Europe relating to surface coating.
 Among the substances laid down in resolution AP(96) 5, the substances in lists 1-1 & 1-2 have been evaluated by a scientific authority and their use does not appear to cause problems taking account this evaluation. For a period of 5 years from the date of adoption of this sheet, the substances in lists 2-1 and 2-2 can be used if they have been authorised by a member state or by the FDA. This period should the industries to produce evidence relating to the safety of use for these substances .

- When the material or metal is varnished, manufacturers must ensure that overall migration conforms to the limits laid down in the order of 2 January 2003 (Directive 2002/72/CE) according to the measurement regulations mentionned below.
- When a substance is subject to restrictions of use (particularly specific migration limit), the *decree of 8 July 1992* (cf. articles 3 & 4) assumes that professionals shall check the compliance with this limit. This verification can be done in several ways: by analysis (specific migration test), by calculation based on the residual quantity of the substance in the material or from the overall migration.

2.2.2 Aluminium

Chemical composition according to the order of 27th

August 1987..

2.2.3. Finished product

Overall and specific migrations: cf. 2.2.1.

3. Acceptability limits

- Overall migration limit for organic coveringslaid down in the order dated 2 January 2003 (Art. 2), i.e. 10 mg/dm² or 60 mg/kg of food depending on the geometry of the material or the object. A material or an object whose migration level exceeds the overall migration limit by an amount not exceeding the analytical tolerance defined below will be considered as conform to the order (art.8 and chapter VI of the annex of the order):
 - 20 mg/kg or 3 mg/dm³ in migration tests using rectified olive oil or its substitutes;
 - 12 mg/kg or 2 mg/dm³ in migration tests using other simulators laid down in directives 82/711/CEE and 85/572/CEE.
- Specific migration limit: see 2.2.1 In the case of epoxy derivatives (BADGE BFDGE, NOGE), the limits are specified in the order of 2 April 2003.

4. Rules to check the criteria defined in paragraph 2.

4.1 Coating only

The coating manufacturer supplies the ready-to-use packaging manufacturer with :

a) A certificate testifying that the composition, overall migration and, if necessary, specific migrations, comply with the tests mentionned above;

b) An analysis report indicating the results of inertia tests (overall migration) carried out on the coating put on an inert support (stainless steel or glass) with simulators chosen according to the use, according to directive 82/711/CEE (lastly amended by directive 97/48/CEE), and 85/572/CEE.

4.2 ALUMINIUM ONLY

The aluminium manufacturer must supply the packaging manufacturer with:

a) An evidence of conformity to the order of 27/08/1987.

b) An analysis report of the chemical composition which must comply with the order of 27/08/1987.

4.3. Finished product

- a) Coating Inertia : inertia test (overall and specific migration) to be carried out on the coating of the ready-to-use packaging.
 - Test conditions according to directives 82/711/CEE (lastly amended by directive 97/48/CEE) and 85/572/CEE:

2

- Temperature and contact duration

Foodstuff	Simulator Liquid
Aqueous food (pH>4.5)	Distilled water or water of equivalent quality
Acid food (pH≤4.5)	Ethanol at 10% (v/v).
Alcoholic food	Ethanol at 10% (v/v). This concentration should be adapted according to the alcoholic content of the food if it exceeds 10% (v/v).
Fatty food	Oil or substitute simulator liquid
Dry food	No migration test

- Simulator liquids chosen according to the use:

Methods to be used for overall migration according to standards in series NF EN 1186, XP CEN/TS 14235 of April 2003 (Polymeric coatings on metal substrates).

b) Looking for absence of chromates on the interface of non-stick coatings, in the absence of evidence if they are used in the manufacturing process.

Limit in undisclosed Cr VI with a detection threshold of $5 \mu g/dm^2$ (see BOCCRF n°8 of 24 May 1996, notification from CSHPF meeting of 13 February 1996, p. 433 Brochure n°1227 15 July 2002 edition).

<u>SHEET No.3</u>: NON-COATED ALUMINIUM – SINGLE USAGE VARIABLE DURATION CONTACT

<u>1. Scope</u>

1.1 Objects in aluminium or alloys of aluminium which are non-coated and intended for

a single use only

1.2 This section deals often with packaging. The main examples are for:

- Pressurized cans
- Tubes
- Dishes
- Trays

- Chocolate paper
- Aluminium household goods
- Rings (chickens)
- Staples (sausages)

2. Restrictions of use

When consumers use them, the restrictions of use relating to contact with very acid products may be indicated.

3. Definitions of performance criteria for food contact

3.1 Regulatory texts

Order of 27/08/1987 relating to materials and objects in aluminium or aluminium alloys in contact with foodstuffs and food and drink products.

3.2 Criteria to be used

Chemical composition according to the order of 27/08/1987.

4.Rules to check the criteria defined in paragraph 3.

4.1 Aluminium

The aluminium manufacturer must supply the packaging manufacturer with:

a) A evidence of conformity to the order of 27/08/1987.

b) An analysis report of the chemical composition which must comply with the order of 27/08/1987.

4.2. Finished product

The packaging manufacturer checks inertia: The manufacturer is responsible for testing the ready-to-use product. It deals with long duration tests different from a manufacturer to another.

Page 54

- <u>SHEET No.4</u>: UNCOATED ALUMINIUM – REPETITIVE USE VARIABLE DURATION CONTACT

1. Scope

Objects in aluminium or alloys of aluminium which are uncoated, possibly anodised and intended for repetitive use.

The main examples are for:

* Household articles: saucepans, utensils, dishes;

* Equipment for agri-food industry: barrels, tanks, pipes, work surfaces, machines.

2. Restrictions of use

When consumers use them, the restrictions of use relating to contact with very acid products may be indicated.

3. Definitions of performance criteria for food contact

3.1 Regulatory texts

Order of 27/08/1987 relating to materials and objects in aluminium or aluminium alloys in contact with foodstuffs and food and drink products.

3.2 Criteria to be used

Chemical composition according to the order of 27/08/1987.

4. Rules to check the criteria defined in paragraph 3.

4.1 Aluminium

In all cases, the aluminium manufacturer must supply the object manufacturer with:

a) A evidence of conformity to the order of 27/08/1987;

b) An analysis report of the chemical composition which must comply with the order of 27/08/1987.

c) A test of sealing quality (Standard ISO 2143 or ISO 2931) if necessary.

4.2. Finished product

The object manufacturer check the inertia for industrial equipment only (example: beer barrels). The manufacturer is responsible for testing the ready-to-use product. It deals with long duration tests different from a manufacturer to another .

Page 55

CAST IRON

1. Scope

This material sheet deals with cast iron (Fe alloy, C) and objects made exclusively from cast iron which, as finished products, are intended to be in direct repetitive contact with food products.

The main application examples are the following elements:

- Household articles: hot plates, casseroles, racks, grinders, etc;
- Equipment for the agri-food industry: pipes, machine bodies, cooking elements etc.

2. Restrictions of use

Acid foods must not be let in the utensils before and after cooking.

3. Definitions of performance criteria for food contact

3.1 Texts to be used

No specific test.

3.2 Criteria to be used

• Looking for the presence of Pb.

4. Acceptability limits

Pb <u><</u> 0.05 %

CAST IRON WITH METALLIC COATING

1. Applicability

This material sheet deals with cast iron (Fe alloy, C) with a metallic coating and objects made exclusively of cast iron with a metallic coating which, as finished products, are intended to be in direct repetitive contact with food products.

Metallic coatings are the follows: Nickel, Chromium.

The main application examples are the following elements:

- Household articles: pastry trays, etc;
- Equipment for agri-food industry: cooking elements etc.

2. Definitions of performance criteria for food contact

2.1 Texts to be used

2.1.1 Regulatory texts

No specific test.

2.1.2 Other texts

- Circular letter of 14 March 1931 "Chromium-metallic coating utensils"
- Order of 15th November 1945 setting the list of materials able to be used without adverse effect on public health in the manufacture of measuring instruments.
- *Guidelines from the Council of Europe* relating to metals and alloys intended to be in contact with food.

2.2 Criteria to be used

2.2.1 Composition of the cast iron

The cast iron which makes up the support must satisfy the inertia requirements specified in the "Cast Iron" sheet.

2.2.2 Contents of the coating in undesirable elements

Looking for the presence of lead, cadmium and arsenic.

2.2.3 Specific migration

Specific migration of Ni, or Cr when the coating is based on Ni or Cr.

3. Acceptability limits

3.1 Maximum content in undesirable elements

Pb <u><</u> 0.05 % Cd <u><</u> 0.010 % As <u><</u> 0.030 %

3.2 Specific Migration Limits

Specific migration of Ni: 0.5 mg/kg (pending evaluation by AFSSA) Specific migration of Cr (metal): 5 mg/kg

4. Rules to check the criteria defined in paragraph 3.

• Test conditions according to directives 82/711 and 85/572 and their amendments (order of 16/05/1994):

Temperature and contact duration

• Simulator liquids chosen according to the use:

Foodstuff	Simulator Liquid	Period
Aqueous food(pH>4.5)	Distilled water or water of equivalent quality	
Acid food (pH≤4.5)	Citric acid at 0.5% (p/V)	
Alcoholic food	Ethanol at 10% (v/v). This concentration should be adapted according to the alcoholic content of the food if it exceeds 10% (v/v).	
Fatty food (Hot use)	Oil at 175°C	2 hours
Dry food	No migration test	

For all objects which cannot be filled, the surface/volume ratio adopted by convention is 6 dm² for 1 kg or 1 l of simulator.

CAST IRON WITH ORGANIC COATING

1. <u>Scope</u>

This material sheet deals with cast iron (Fe alloy, C) with an organic coating with or without an intermediate coating (metal or enamel) and objects made exclusively of cast iron with an organic coating which, as finished products, are intended to be in direct repetitive contact with food products.

The main examples of coating are the follows: lacquers, varnish, polymer films (PTFE, resins, silicons, etc.)

The main application examples are the following elements:

- Household articles: Dishes, fryers;
- Equipment for agri-food industry: cooking elements etc.

2. <u>Restrictions of use</u>

To avoid incorrect conditions of use, the temperature limit of use must be specified on the labelling of objects.

3. Definitions of criteria for aptitude to food contact

3.1 Texts to be used

3.1.1 Regulatory texts

- Coatings:
 - Order of 2nd April 2003 relating to the use of some epoxy derivatives in materials and objects put in or intended to be in contact with foodstuffs (BADGE, BFDGE, NOGE);
 - Order of 30th January 1984 relating to materials and objects containing vinyl chloride monomer intended to be in contact with foodstuffs and food and drink products;
 - Order of 30th January 1984 relating to official analysis methods about the determination of the content of vinyl chloride monomer in materials and objects intended to be in contact with foodstuffs, food and drink products and the determination of vinyl chloride transferred by the materials and objects to the foodstuffs, food and drink products put in contact with them;

3.1.2 Texts to be used provisionally while waiting for regulations on organic coatings

- Order of 2nd January, 2003 relating to materials and objects in plastic put in or intended to be in contact with foodstuffs.
- CSHPF Notification of 13 February 1996.
- Resolution AP (96)5 of 02/10/96 from the Council of Europe relating to surface coating
- Information notice No 2003-27 from the DGCCRF relating to additives to plastic materials intended to be in contact with foods.
- Other texts relating to lacquers and coatings brought together in brochure 1227 of the Official Journal of the French Government (JORF).

3.2 Criteria to be used

3.2.1 Coating only

The coating supplier must ensure that the monomers and additives used are included in the positive list of constituents for plastic materials (order of 02/01/2003, Information notice No.2003-37 and brochure 1227 from the Official Journal of the French Government) or in the list in resolution AP (96) 5 of the Council of Europe relating to surface coating.

Among the substances mentionned in resolution AP(96) 5, the substances in lists 1-1 & 1-2 have been evaluated by a scientific authority and their use does not appear to cause problems taking into account this evaluation. For a period of 5 years from the date of adoption of the current sheet, the substances in lists 2-1 and 2-2 can be used if they have been authorised by a member state or by the FDA. This period should allow industries to produce evidence relating to the safety of use for these substances .

When the material or metal is varnished, manufacturers should ensure that overall migration conforms to the limits laid down in the order of 2 January 2003 (Directive 2002/72/CE) according to the measurement regulations mentionned below.

When a substance is subject to restrictions of use (particularly specific migration limit), the decree of 8 July 1992 assumes that professionals must check compliance with this limit. This verification can be done in several ways: by analysis (specific migration test), by calculation based on the residual quantity of the substance in the material or from the overall migration.

3.2.2 Support

The cast iron which makes up the support must satisfy the inertia requirements specified in the "Cast Iron" and "Cast Iron with metallic coating" sheets.

When an enamel coating is present, it must satisfy the inertia requirements specified in the "glass, cristal, ceramic and enamelled objects" sheet.

3.2.3. Finished product

Overall and specific migrations: see 3.2.1.

4. Acceptability limits

- Overall migration limit for organic coveringslaid down in the order dated 2 January 2003 (Art. 2), i.e. 10 mg/dm² or 60 mg/kg of food depending on the geometry of the material or the object. A material or an object whose migration level exceeds the overall migration limit by an amount not exceeding the analytical tolerance defined below will be considered as conform to the order (art.8 and chapter VI of the annex of the order):
 - 20 mg/kg or 3 mg/dm³ in migration tests using rectified olive oil or its substitutes;
 - 12 mg/kg or 2 mg/dm³ in migration tests using other simulators laid down in directives 82/711/CEE and 85/572/CEE.
- Specific migration limit of the finished product: Cf. 3.2.1 In the case of epoxy derivatives, the limits are specified in the order of 2 April 2003.

5.Rules to check the criteria defined in paragraph 3.

5.1 Coating only

The manufacturer of the material or ready-to-use object asks his coating supplier for:

<u>5.1.1</u> A certificate which proved that the composition, overall migration and, if necessary, specific migrations, comply with the tests mentionned above;

<u>5.1.2</u> An analysis report indicating the results of inertia tests (overall migration and if necessary specific migrations) carried out on the coating aput on an inert support (stainless steel or glass) with simulators chosen according to usage, according to directive 82/711 lastly amended by directive 97/48 and directive 85/572/CEE.

5.2. Support

The rules laid down in the appropriate "Iron" and "Iron with metallic coating" sheets apply to the inertia of the support.

5.3. Finished product

The manufacturer of the objects checks:

- a) Coating Inertia : inertia test (overall migration) to be carried out on the coating of the ready-to-use object;
 - Test conditions according to directives 82/711/CEE (lastly amended by directive 97/48/CEE) and 85/572/CEE:

:

- Temperature and contact duration
- Simulator liquids chosen according to the use:

Foodstuff	Simulator Liquid
Aqueous food (pH>4.5)	Distilled water or water of equivalent quality
Acid food (pH≤4.5)	Ethanol at 10% (v/v).
Alcoholic food	Ethanol at 10% (v/v). This concentration should be adapted according to the alcoholic content of the food if it exceeds 10% (v/v).
Fatty food	Oil or substitute simulator liquid
Dry food	No migration test

Methods to be used for overall migration according to standards in series NF EN 1186, XP CEN/TS 14235 of April 2003 (Polymeric coatings on metal substrates).

b) Looking for absence of chromates on the interface of non-stick coatings, in the absence of evidence that they are not used in the manufacturing process.

Limit in undisclosed Cr VI with a detection threshold of $5 \mu g/dm^2$ (see. BOCCRF n°8 of 24 May 1996, notification from CSHPF meeting of 13 February 1996, p. 433 Brochure n°1227 15 July 2002 edition).

TIN AND TIN ALLOYS

1. Scope

This section deals with tin and tin alloys and objects coated with tin or tin alloy partially tinplated which, as finished products, are intended to be in direct repetitive contact with food products. The products mentionned in sheets "Steels with metallic coating used for packaging"

and "Steel and Stainless Steel with metallic coating (unpackaged)" are not concerned.

The main application examples are the following elements:

- Household articles: measuring instruments, pots, dishes, plates etc.;
- Equipment for the agri-foods industry, metal can closures, etc.

2. Restriction of use for materials

- Do not for use in contact with strongly acidic or basic foods or for heating foods at temperatures up to 150°C.
- Preserving foods in tin or tin alloy objects or objects which have been coated in tin or tin alloys is not advisable .

3. Definitions of performance criteria for food contact

3.1 Text to be used

3.1.1 Regulatory texts

- Order of 28th June 1912 relating to coloration, conservation and packaging of foodstuffs and drinks
- Order of 15th November 1945 setting the list of materials likely to be used without adverse effect on public health in the manufacturing of measuring instruments.

3.1.2 Other texts

 NF EN 611-1 Tin and Tin alloys – Pewter and pewterware – Part 1: Pewter.

3.2 Criteria to be used

3.2.1 Composition of the tin

Verification of tin content: $Sn \ge 97\%$

<u>3.2.2 Content in undesirable elements</u> Looking for the presence of lead, cadmium and arsenic.

3.2.2 Content in other elements

Looking for the presence of antimony and copper. \bullet Sb $\leq 2.5\%;$ Cu $\leq 1.5\%$

4. Acceptability limits

4.1 Maximum content in undesirable elements

- Pb ≤ 0.050%
- Cd ≤ 0.010 %
- As ≤ 0.030 %

4.2 Specific Migration Limits

Specific migration of Sb (see. notification from CSAH of 2 December 1999): 0.01 mg/kg.

ZINC

1. Scope

This section deals with materials and objects made exclusively of zinc which as finished products are intended to be in direct contact with foodstuffs, food products and beverage for human and animals consumption, and for repetitive usage.

The objects coated in zinc mentionned in the sheet "Steel and stainless steel with metallic coating (excluding packaging)" are not concerned.

The main application examples are thee following elements:

- Household articles: measuring instruments etc.;
- Equipment for agri-food industry: measuring instruments, chocolate products, confectionary etc.

2. Restriction of use for materials

- It is prohibited to put any drink or foodstuff intended for food use in direct contact with zinc, excepted manufacturing or preserving chocolate products and confectionary which do not contain liquid acid substances and for distillery operations.
- Use limited to the scope.

Any other use, a request for authorisation must be made to the DGCCRF accompanied by documentation proving inertia in the scope considered.

3. Definitions of performance criteria for food contact

3.1 Text to be used

3.1.1 Regulatory texts

- Order of 28th June 1912 relating to coloration, conservation and packaging of foodstuffs and drinks
- Order of 15th November 1945 setting the list of materials likely to be used without adverse effect on public health in the manufacturing of measuring instruments.

3.2 Criteria to be used

3.2.1 Composition of zinc

Check zinc content: Zn > 99.85 %.

3.2.2 Content of undesirable elements

Looking for the presence of lead, cadmium and arsenic.

3.2.3 Specific migration of Zn

4. Acceptability limits

4.1 Maximum content in undesirable elements

Pb <u><</u> 0.05% Cd <u><</u> 0.010 % As <u><</u> 0.030 %

4.2 Specific Migration Limits

Specific migration of Zn: 10 mg/kg

5. Rules to check the criteria defined in paragraph 3.

- Test conditions according to directives 82/711 and 85/572 and their amendments (order of 16/05/1994):
 - Temperature and contact duration
- Simulator liquids chosen according to the use:

Foodstuff	Simulator Liquid
Aqueous food (pH>4.5)	Distilled water or water of equivalent quality
Acid food (pH≤4.5)	Outside area of applicability
Alcoholic food	Ethanol at 10% (v/v). This concentration should be adapted according to the alcoholic content of the food if it exceeds 10% (v/v).
Fatty food (Hot use)	Oil or substitute simulator at 100°C for 2 hours
Dry food	No migration test

For all objects which cannot be filled, the surface/volume ratio adopted by convention is 6 dm² for 1 kg or 1 l of simulator.

Page 64

Objects in various coated metals (whitened metals)

1. <u>Scope</u>

This section deals with metallic materials and objects in whitened metal other than those mentionned in the another sheets relating to metals (see general sheet on metals) which, as finished products, are intended to be in contact with foodstuffs, food products and beverages for human and animals .

Definition of whitened metal: metallic object coated in a light white deposit such as silver, nickel, tin and chromium or a combination of these elements.

The main examples of metallic supports are as follows: copper or copper alloy, zinc or zinc alloy.

The main examples of metallic coatings in contact are as follows: nickel, silver, gold, tin and chromium.

The main application examples are the following elements: tea and coffee services, cups, metal drinking cups, plates, cake tongs and servers, cake moulds, salad servers etc.

This sheet does not include silvered metal.

2. Usage restrictions

Objects in various coated metals (whitened metal) intended to be in direct contact with food products must not be put in contact with acid foodstuffs or drink.

3. Definitions of performance criteria for food contact

3.1. Regulatory texts

- Order of 28th June 1912 relating to the conservation and packaging of foodstuffs and drinks,
- Order of 7 November 1985 relating to the limitation in the quantities of lead and cadmium which can be extracted from objects in ceramic or which are intended to be in contact with foodstuffs, food products and drinks,
- Order of 15th November 1945 setting the list of materials likelyto be used without adverse effect on public health in the manufacturing of measuring instruments.

3.2. Criteria to be used

3.2.1. Object the objects (support + coating)

The composition of the objects will be checked in particular to determine the content in copper, nickel, chromium and zinc and in undesirable elements lead, arsenic, cadmium.

3.2.2. Specific migration

Specific migration tests for the metals which are determined during this first research and which are likely to cause health problems will be carried out by choosing the most severe simulator liquid(s) and test conditions.

According to the composition of the objects the specific migrations of lead, cadmium, nickel, chromium, copper and zinc will be tested.

4. Acceptability limits

4.1. Maximum content in undesirable elements

 $\begin{array}{l} Pb \leq 0.050\% \\ Cd \leq 0.010\% \\ As \leq 0.030\% \end{array}$

4.2. Specific Migration Limits

Specific migration of Ni: 0.5 mg/kg (waiting evaluation by AFSSA) Specific total migration of Cr: 5 mg/kg Specific migration of Zn: 10 mg/kg Specific migration of Pb: 4 mg/kg Specific migration of Cd: 0.3 mg/kg

5. Rules to check the criteria defined in paragraph 3.

- Test conditions according to directives 82/711/CEE (lastly amended by directive 97/48/CEE) and 85/572/CEE:
 - Temperature and contact duration
 - Simulator liquids chosen according to the use:

Foodstuff	Simulator Liquid
Aqueous food (pH>4.5)	Distilled water or water of equivalent quality
Alcoholic food	Ethanol at 10% (v/v). This concentration should be adapted according to the alcoholic content of the food if it exceeds 10% (v/v).
Fatty food	Oil or substitute simulator, 2 hours at 175°C if for use at high temperature
Dry food	No migration test
Acid food (pH≤4.5)	Not include in the scope

For all objects which cannot be filled, the surface/volume ratio adopted by convention is 6 dm² for 1 kg or 1 l of simulator.

Page 66

RUBBER

1. Scope

This section deals with materials and objects in rubber which, as finished products, are intended to be in contact with food products.

Rubber means a natural or synthetic polymer with a high elastic stretcc rate made up of carbonaceous macromolecules generally obtained by cure. Thermoplastic elastomers, which do not require cure, are included in rubbers.

The main application examples are the following elements:

- Pressure cooker, jar and stopper seals;
- Pipes;
- Conveyor belts;
- Gloves;
- Gate parts;
- Dummies and teats.¹

The materials and objects in silicon elastomers and joints for cans are not included.

2. Restrictions of use for materials

• Restrictions of use may exist for materials which contain some additives. All useful information shall be communicated to the laboratories.

3. Definitions of performance criteria for food contact

3.1 Texts to be used

3.1.1 Regulatory texts

Order of 9 November 1994 relating to materials and objects in rubber intended to be in contact with foodstuffs.

3.1.2 Other texts

Order of 2 January 2003 relating to materials and objects in rubber intended to be in contact with foodstuffs.

Order of 25 November 1992 relating to materials and objects silicon elastomers intended to be in contact with foodstuffs.

Other texts (circulars, circular letters, instructions etc) put together in Brochure No. 1227 of the Official Journal of the French Government.

3.2 Criteria to be used

¹ Rubber dummies, although they are not in contact with foods, are mentionned in the order of 9 November 1994 relating to materials and objects in rubber in contact with foodstuffs.

Furthermore, the approval procedure for teats and dummies other than those in pure hot cured rubber has been removed by decree No.97-503 of 21 May 1997 which simplifies administrative measures.

At each manufacturing stage of of a material or an object, the producer shall ensure that the various constituents used are mentionned in the positive lists.

When the product or the material isfinished, the manufacturer or user shall check that the inertia criteria are met, i.e.:

- Compliance with the positive list (monomers and additives ²) and limitations of use in compliance with the order of 09/11/1994,evidence of conformity from supplier
- Overall migration according to the order of 09/11/1994.
- Specific migration of monomers and/or residual quantity of monomers in the material or object in accordance with the order of 09/11/1994 ³;
- Specific migration of additives ³ or quantity of additives in the material or object in accordance with the order of 09/11/1994;
- Volatile organic materials;
- Migration of N-nitrosamines and N-nitrosatable substances;
- Migration of aromatic amines;
- Migration of formaldehyde;
- Peroxides.

4. Acceptability limits

Criterion	Limit	
Overall migration	10 mg/dm² or 60 mg/kg according to the shape and capacity of the object	
	(analytic tolerance: cf. chapter VI of the annex to the order of 2 January 2003)	
Specific migration of monomers and additives	See. limits laid down in the order of 09/11/1994	
Volatile organic materials	0.5 %	
	All articles except dummies and teats:	
Migration of N-nitrosamines and N-	Ni-nitrosamines: 1 µg/dm ² .	
nitrosatable substances	N-nitrosatable substances: 10 µg/dm ² .	
	Teats and dummies:	
	Ni-nitrosamines: 10 µg/kg ⁴ .	
	N-nitrosatable substances: 100 µg/kg ⁴ .	
Migration of aromatic amines	1 mg/kg.	
Migration of formaldehyde	3 mg/kg.	
Peroxides.	Absence of positive reaction to peroxides according to the French pharmacopoeia, Xth edition.	

 $^{^{2}}$ For additives, reference may be made to the positive list provided for plastic materials while waiting for the amendment of the order of 09/11/1994.

³ Checking specific migration limits is not obligatory if it can be established that the result of the overall migration test implies that the specific migration limits have not been exceeded, or that the specific migration limit cannot be exceeded even if all the residual substance migrated.

Respect of the specific migration limits can be checked by determining the quantity of the substance in the material, provided that a relationship between this quantity and the value of the specific migration of the substance has been established either by a suitable experiment, or by the application of generally recognised diffusion models (order dated 2 January 2003, article 8).

¹ Limits expressed according to the rubber quantity

5. Rules to check the criteria defined in paragraph 3.

- To check the performance criteria to contact with food, the following information must be supplied to the laboratory:

- Nature of monomers and additives subject to specific migration limits or maximum residual quantities.
- Contact conditions (duration and temperature);
- Type of food in contact or simulator liquids.

Criteria	Test conditions	Test methods	
Overall migration Specific migration Aromatic amines ⁵ Formaldehyde ⁶	According to the category the object belongs to (A, B, C, D, T) see. annex III of the order of 09/11/1994	see order of 02/01/2003 and directives 82/711 amended and 85/572 + Overall migration: standards NF XP ENV 1186.	
N-nitrosamines and N- nitrosatable substan ces;		Articles other than dummies and teats: see method in the annex Teats and dummies: see appendix IV of the order of 09/11/1994	
Volatile organic materials	4 hours at105°C see order of 25/11/1992, annex III, section 2		
Peroxides.	French pharmacopoeia, Xth edition		

⁵ For secondary aromatic amines, there is no valid method of analysis, but if these substances are present in the material they will be detected as nitrosatable substances.

⁶ Primary aromatic amines and formaldehyde cannot be detected in the fat simulator, but the acid simulator, being the more extractive medium, the aqueous simulators are sufficient