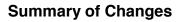
French DGCCRF Published New Methodology Documents for Food Contact Materials and Articles



French DGCCRF (General Directorate for Competition Policy, Consumer Affairs and Fraud Control) published new Methodology Documents for food contact materials made of metals, inorganic materials (except metals), organic materials issued from synthetic components and organic materials issued from plant fibers. These documents are replacing DGCCRF Notes of Information 2004-64, 2006-156, 2013-98 and 2013-186.



DM/4B/COM/001 (metals and alloys)

- Includes new requirements for release of 21 elements for coated and non-coated metals or metal alloys
- Revises the limit of metal composition in certain metals/metal alloys or metal plating
- Specifies test conditions: specification of simulants to be used, applicable time and temperature test conditions according to the nature of articles

Elements	Specific release limit (SRL) values in mg/kg food simulant	Elements	Specific release limit (SRL) values in mg/kg food simulant
Li	0.048	As	0.002
Be	0.01	Мо	0.12
AI	5	Ag	0.08
V	0.01	Cd	0.005
Cr	0.25	Sn	100
Mn	1.8	Sb	0.04
Fe	40	Ba	1.2
Co	0.02	Hg	0.003
Ni	0.14	TI	0.0001
Cu	4	Pb	0.01
Zn	5		

DM/4B/COM/002 (inorganic materials, especially glass, crystal, ceramic, glass ceramic, enamel)

- Includes the migrations of aluminum, cobalt and arsenic which were previously referenced in an official letter addressed to a professional organization (DGGCRF/18 April 2014) except drinking rim area
- Modify the limit for aluminium from 0.9 mg/kg to 1 mg/kg and the detection limit for arsenic from 0.001 mg/kg to 0.002 mg/kg.

DM/4B/COM/003 (organic materials made of synthetic components, especially plastic, rubber, complex material)

• No technical change from the previous DGCCRF notes of information 2004-64, 2013-98 and 2013-186

DM/4B/COM/004 (organic materials made of plant fibers, especially paper and board, with or without coating)

- Inclusion of tablecloths made of paper in the scope of food contact requirements,
- No technical change from the previous DGCCRF notes of information no. 2004-64 and 2006-156

Further information: The full text can be found at: (In French)

http://www.economie.gouv.fr/dgccrf/Materiaux-au-contact-des-denrees-alimentaires

CONTACT INFORMATION:

If you have any comments and/or questions regarding these requirements, please contact your customer service representative or contact us via email at info@us.bureauveritas.com

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Regulation (EC) No 1935/2004 of 27 October 2004 states that the materials and articles that come into contact with or that are intended for contact with foodstuffs must be inert towards the foodstuffs.

For the application of this principle of inertness to different types of material, application texts must specify rules (composition, purity criteria, etc.) that ensure the suitability of each material category for food contact application. At the European Union level, specific directives have thus been adopted, e.g. in relation to ceramic articles and regenerated cellulose film, and have been transposed into law. Several regulations have been adopted, e.g. in relation to plastic materials and active or intelligent materials.

In addition, in the absence of any specific text applicable at the European Union level to a given type of material, national regulations apply, such as those concerning stainless steel, aluminium and its alloys, rubber and silicone elastomers.

However, a certain number of materials are not yet covered by specific regulations, at either the European Union or national levels, or else are incompletely regulated. Complex materials are addressed in certain provisions of the European Union regulation on plastic materials, but are not fully regulated by a specific text.

To overcome these difficulties, the DGCCRF brought together competent laboratories in the domain of materials in contact, representatives of food contact materials industries, processors, food industries and distributors in a working group named "Think tank on regulations and methods of verification for the inertness of food contact materials".

As part of this group's work, information briefs have been drawn up for different types of material to specify the methods of checking their suitability for food contact under specific regulations or in the absence of a regulatory text.

This information brief is intended for laboratories analysing materials in contact with food, industrial manufacturers and distributors of materials and articles intended for contact with food, food industries and official inspection bodies.

GENERAL INFORMATION BRIEF CONCERNING THE REGULATION OF MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD

Regulation (EC) No 1935/2004 (or '*Framework Regulation*') of the European Parliament and of the Council of 27 October 2004 sets **general requirements** applying to materials and articles intended to come into direct or indirect contact with foodstuffs, food products or beverages placed on the market in the European Union to ensure a high level of consumer protection. It states that other **specific requirements** for certain materials may be adopted.



1. SCOPE OF THE FRAMEWORK REGULATION

The text applies to materials and articles, including active and intelligent materials:

• intended to come into contact with food.

or

• already in contact with food and intended for that purpose.

or

• that can reasonably be expected to come into contact with food or to transfer their constituents to food.¹

By food (or foodstuffs) is meant food as defined in Article 2 of Regulation (EC) No 178/2002.

The text does not apply to materials or articles that are not intended to come into contact with foodstuffs under normal or foreseeable conditions of use, e.g. floor, ceiling and wall coverings, shelves and tables,² automobile dashboards, aprons,³ inside walls of refrigerators (except for bins), check-out conveyor belts, etc.

Unwrapped foods must not be placed in direct contact with floor, ceiling or wall coverings, shelves or tables not intended for that purpose, check-out conveyors, etc. For these applications, and more generally for equipment, worktops and surfaces intended for contact with foodstuffs, food operators must make sure in particular that the general hygiene provisions in Regulation (EC) No 852/2004 (and in particular in Annex II thereto) are complied with so that these items are not a source of contamination.

The materials and articles covered by the provisions of the regulation are:

- Packing and packaging of foodstuffs including containers, boxes, bottles, film, paper, etc. used to protect or conserve foodstuffs (including kitchen wrapping).
- Tableware and crockery, kitchen utensils and parts of electrical kitchen appliances intended to come into direct contact with foodstuffs (bowls, various containers, etc.).
- Feeding bottles and baby bottle teats, cups, etc.
- Machinery and equipment used for the production, processing, storage or transport of foodstuffs,* e.g. blenders, mincers, kneaders, extruders, cooking and deep freezing equipment, measurers, conveyers, pumps, cutting tools, fixed tanks (storage, fermentation, pasteurisation, etc.), transport tanks (tanker trucks and waggons, etc.), pipes, tubes and fittings, etc.

* The food areas of machineries and equipment must comply with the rules for materials intended for contact with foodstuffs. The other areas must not contaminate or spoil the foodstuffs.

• Active materials (e.g. absorbers for moisture, gases: ethylene, oxygen, etc., materials that deliberately release authorised substances into foodstuffs, etc.) and intelligent materials (e.g. freshness indicators).

¹ Table napkins and kitchen paper towels are considered as reasonably likely to come into contact with foodstuffs.

² Except when these surfaces are specifically intended to come into contact with foodstuffs.

³ Except for aprons specifically intended for handling foodstuffs in food industries.

• Miscellaneous articles such as labels, clips, table napkins, kitchen paper towels, fruit baskets and sleeves used for milking animals...

The following are not subject to the provisions of the Framework Regulation:

- Materials and articles supplied as antiques.
- Covering or coating materials, such as the materials covering cheese rinds, prepared meat products or fruits, which form part of the food and may be consumed together with this food (covered by regulations for foodstuffs).
- Fixed public or private water supply equipment, which are covered by specific regulations.

The materials and articles intended to come into contact with feed and babies' soothers are not subject to the provisions of the Framework Regulation, but are covered by the national provisions in Decree No 92-631 of 8 July 1992.

2. REQUIREMENTS APPLICABLE TO MATERIALS

2.1 General requirements: Principle of inertness (Article 3 of Framework Regulation)

Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- endanger human health
- bring about an unacceptable change in the composition of the food
- bring about a deterioration in the organoleptic characteristics thereof

Verifications shall be based on the application of approved methods of analysis, or if no such methods exist, on internationally recognised methods, or failing that, on other appropriate methods suitable for the intended purpose.

Period of validity of test reports: A maximum period of 5 years is proposed. If any changes likely to modify the inertness of the material have occurred during that period, the tests must be repeated.

2.2 Organoleptic inertness

In practice, the tests are carried out by reproducing the real conditions of use with actual foodstuffs. However, tests may be carried out using simulants, in accordance with existing standards, such as ISO EN 13302 or EN 1230-2 for paper and cardboard, in particular for articles whose final destination is not known.

2.3 Special requirements: active and intelligent materials

Active materials and articles intended to come into contact with foodstuffs are materials and articles intended to extend the shelf-life or to maintain or improve the condition of packaged food. They are designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food.

They should be distinguished from materials and articles which are traditionally used to release their natural ingredients into specific types of food, such as wooden barrels.

<u>Intelligent materials and articles intended to come into contact with foodstuffs</u> are materials and articles designed to monitor the condition of packaged food or the surrounding environment.

These two types of materials and articles are specifically covered by Regulation (EC) No 450/2009 of 29 May 2009. <u>EU Guidance</u> has been drawn up to the above regulation.

2.4 Specific requirements

In order to take into account the specific technological characteristics of each type of material and article subject to the provisions of the Regulation, the restrictions and conditions of use, and the substances used to make materials and articles may be set out in specific European Union measures.

These specific measures may comprise:

- Positive lists of authorised substances.
- Purity criteria applicable to some of these substances.
- Special conditions of use.
- Specific migration limits.
- An overall migration limit.
- Measures concerning oral contact.

EU specific measures mainly concern the following materials:

- Plastic materials and articles [Regulation (EU) No 10/2011 of 14 January 2011].
- Recycled plastic materials and articles[Regulation (EC) No 282/2008 of 27 March 2008].
- Active and intelligent materials and articles [Regulation (EC) No 450/2009 of 29 May 2009].
- Ceramics [Council Directive (84/500/EEC) of 15 October 1984].
- Regenerated cellulose film [Commission Directive 2007/42/EC of 29 June 2007].

In the absence of any specific European Union measures, the Framework Regulation does not prevent Member States from maintaining or adopting **national provisions**, on condition that they obey the principle of mutual recognition.

This principle results from the 'Cassis de Dijon' ruling of 20 February 1979 (case 120/78) made by the Court of Justice of the European Union (ECJ) and the Orders that followed it: any product lawfully manufactured and marketed in a Member State must in principle be available for sale in all the other Member States. Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 lays down procedures relating to the application of this principle.

The specific French national measures concern the following materials:

- Rubber [Order of 9 November 1994] (updating process).
- Silicone elastomers [Order of 25 November 1992].
- Aluminium [Order of 27 August 1987].
- Stainless steel [Order of 13 January 1976].

Other specific measures are in force concerning food contact materials:

- Order of 27 June 1912 [packaging of foodstuffs] and Order of 15 November 1945 [measuring instruments and containers].
- Order of 8 September 1999 [cleaning products for materials and articles intended to come into contact with foodstuffs, food products or beverages for human or animal consumption] and Decree No 73-138 dated 12 February 1973.
- Order dated 12 August 1986 [treatment by ionising radiation of materials and articles placed or intended to come into contact with foodstuffs, food products or beverages].

2.5 Written declaration of compliance (Article 16 of the Framework Regulation)

2.5.1 In accordance with Article 16 of the Framework Regulation, the specific measures of the European Union require that the materials and articles listed in Annex I of the Framework Regulation shall be accompanied by a written declaration stating that they comply with the rules applicable to them.

The purpose of this declaration is to strengthen the responsibility and coordination among the different operators so as to ensure the compliance of the materials and articles by a declaration of compliance with the applicable regulatory texts, the communication of information at different stages to allow the establishment or verification of the compliance of materials and articles (in particular, information about substances), and to ensure the safe, appropriate use of these materials and articles (in particular, information on time of contact and temperature, and type of foodstuff).

The declaration of compliance with the Framework Regulation does not cover only those aspects relevant to health safety (Point a, Section 1 of Article 3), but also indicates that:

- The materials and articles shall be manufactured in compliance with good manufacturing practices prescribed by the Framework Regulation and the regulation on good manufacturing practice.
- The company implements a traceability system.
- The material or article does not bring about an unacceptable change in the composition of the food or a deterioration in it organoleptic properties.

The declaration of compliance shall be established in such a way that the **articles it covers are readily identifiable** (description of articles, traceability information, references, photographs, etc.).

At the European Union level, the following materials are currently concerned: plastics, recycled plastics, regenerated cellulose films, epoxy derivatives, ceramics, and active and intelligent materials.

In particular:

A declaration of compliance must be made available for **plastic materials and articles**, products from intermediate stages of their manufacturing as well as for substances intended for the manufacturing of those materials and articles at the marketing stages other than at the retail stage,

in accordance with the model given in Annex IV of Regulation (EU) No 10/2011 (Article 15 of the regulation).

This declaration tells the customer that a product meets the requirements of the European Union regulations for plastics, and Regulation (EC) No 1935/2004, and gives the customer the appropriate information needed to establish or verify the product's compliance.

Ceramic articles must be accompanied by a declaration of compliance "*at the various marketing stages*, *including retail sale but excluding delivery to the final consumer*" pursuant to Article 5.1 of the Order of 7 November 1985 (as amended). The requirement to supply a written declaration for ceramic articles that have not yet come into contact with foodstuffs, **including at the retail stage**, serves in particular to distinguish ceramic articles intended for contact with food from those intended and used for decoration.

2.5.2 In the absence of specific measures, and pursuant to Article 16, the Framework Regulation does not prevent Member States from retaining or adopting national provisions for **declarations** of compliance for materials and articles not covered by harmonised measures.

Article 6 of Decree No 2007-766 of 10 May 2007 amended by Decree No 2008-1469 of 30 December 2008 states that at marketing stages other than sale or free distribution to the final consumer, materials and articles intended to come into contact with foodstuffs (*that are not already covered by specific European Union measures*) shall be accompanied by a written declaration of compliance with the provisions of Articles 3 and 4 of the Regulation of 27 October 2004.

The declaration of compliance relates to a material or article delivered by a supplier to a customer. It is issued by the business operator (*natural or legal persons responsible for ensuring that the requirements of Regulation (EC) No1935/2004 are met within the business under their control*) for the benefit of users in food industries (including those making direct delivery to the consumer) and distributors of materials and articles.

The requirement to declare does not apply to materials and articles whose characteristics show that they are obviously meant to come into contact with foodstuffs. These materials and articles are **exclusively** items of tableware (plates, bowls, glasses, etc.) and containers for culinary use (dishes, salad bowls, pans, etc.) whose **shape** shows they are obviously intended for contact with food.

The written declaration of compliance need not be physically attached to goods (delivery note, invoice, etc.) nor be sent every time a customer receives an order for the same goods.

It is made available to customers in paper or electronic form, or, with the customer's agreement, is downloadable from an Internet site, in which case it will be necessary to make sure **the link to the articles covered by the declaration of compliance is clearly identifiable** (description of articles, traceability information, references, photographs, etc.).

The declaration of compliance shall be updated in the event of changes in regulations or other changes liable to modify the inertness of the material or the article (*composition or purity* of substances or materials or articles).

The declaration of compliance shall be communicated without delay to the inspecting authorities on their request.

2.6 Technical documentation (Article 16 of the Framework Regulation, specific texts, consumer code, article 7 of the regulation (EU) No 2023/2006 of 23rd of December 2006 concerning good manufacturing practices) :

Article 16 of the Framework Regulation states that appropriate documentation shall be made available to demonstrate the compliance of materials with the rules applicable to them. This documentation (composition of materials and articles, treatments carried out, specific migration tests, overall migration tests, organoleptic tests, calculations and other evidence of compliance, etc.) shall be made available to the competent authorities on request.

This documentation may be made available to customers as a part of customer-supplier relations.

Article 7 of the regulation (EU) n°2023/2006 foresee "the business operator shall establish and maintain appropriate documentation in paper or electronic format with respect to specifications, manufacturing formulae and processing which are relevant to compliance and safety of the finished material or article."

It also provides that "the business operator shall establish and maintain appropriate documentation in paper or electronic format with respect to records covering <u>the various</u> <u>manufacturing operations performed which are relevant to compliance and safety of the</u> finished material or article and with respect to the results of the quality control system."

The specific texts contain special requirements concerning the documentation that must be made available to demonstrate the compliance or safety of the materials and articles.

See also:

<u>Consumer Code</u>, Legislative Part – Book IV – Heading I:

- Compliance Chapter II General compliance requirement Art. L.411-1: Requirement to perform and provide evidence of the checks and inspections carried out.
- Compliance Chapter IV Application measures Art. L 412-1: Execution measures; Subparagraphs 2 and 3 Sanctions in the event of infringement of decrees as provided for in Articles L. 412-1 and L. 412-2 and in the event of sale before the result of analysis of goods recognised as fraudulent.

Consumer Code, Legislative Part – Book IV – Heading II:

• Safety – Chapter I – Prevention of risks Art. L 421-3: General requirement for professionals to ensure the safety of products and services, requirement to inform consumers of the risks inherent to a product, requirement for the entity responsible for marketing to adopt measures that, given the characteristics of the products supplied, will allow current information to be obtained on the risks that the marketed products may present, and to plan the necessary measures to keep these risks in check.

2.7 Labelling (Article 15 of the Framework Regulation)

2.7.1 Materials and articles which are not yet in contact with food when placed on the market shall be accompanied by:

(1) The words "for food contact", or a specific indication as to their use, or the symbol prescribed by the regulations.⁴

The indication or symbol serve to indicate that an article that is not obviously intended for contact with food is in fact intended for contact with food. It does not automatically mean that the material or article can be used in all contact conditions (duration, temperature, foodstuff); see (2) below. Its presence is reserved for those materials and articles compliant to by Article 3 of the Framework Regulation (and Article 4 when applicable), and to specific European Union measures or, in the absence of such measures, national provisions applicable to those materials and articles.

In addition, it is important to avoid confusing situations that could suggest to users that secondary outer packaging (e.g. grouping packaging) bearing the symbol is itself suitable for contact with food although it is not intended for such use.

(2) If necessary, special instructions to be observed for safe and appropriate use, e.g. maximum temperature of use, conditions of use in a conventional oven or microwave oven, non-use with certain types of food, instructions for cleaning before first use, etc.,

The presence of multiple instructions for use (e.g. indicated on both the packaging and the article itself) that prove conflicting or contradictory must be avoided. Such multiple instructions may mislead the consumer about the usability of materials and articles, especially if they result in different conditions of use. When the case is unclear, the most restrictive conditions of use should be applied – at least as restrictive as the actual contact conditions – when verifying the compliance of these materials and articles.

(3) The name (or trade name) **AND** address⁵ (or registered office) of the manufacturer, processor, **or** seller established in a European Union Member State.

(4) Adequate labelling or identification to ensure traceability.

(5) In the case of active materials or articles, information on the permitted use or uses, and other relevant information, such as the name and quantity of the substances released by the active component so as to enable food business operators to comply with the food legislation in force.

The information required in Points 1 to 5 shall be conspicuous, clearly legible and indelible. Retail trade shall be prohibited if the information required under Points 1, 2 and 5 is not given in a language easily understood by purchasers.

2.7.2 Conditions of labelling according to user

Labelling should support users in the safe and correct use of materials and articles. Such labelling may vary according to the user.

At the retail stage, the aforementioned information shall be displayed on:

a) the materials and articles or on their packaging.

or

b) labels affixed to the materials and articles or to their packaging.

or

⁴ Articles whose characteristics show that they are obviously intended for contact with food are exempted.

⁵ Physical address

c) a notice in the immediate vicinity of the materials and articles and clearly visible to purchasers. However, for the information specified in Section 1, Point c *of Article 15 of the Framework Regulation*, this option shall be open only if, for technical reasons, that information or a label bearing it cannot be affixed to the materials and articles at either the manufacturing or the marketing stage. This option shall remain exceptional given the many possible ways articles can be packaged (blister, staple, box, sachet, label, hook, bag, etc.).

At the marketing stages other than the retail stage, the information specified above shall be displayed on:

a) the accompanying documents.

or

b) the labels or packaging.

or

c) the materials and articles themselves.

Wholesalers and trade outlets that also sell consumer products play both roles and are subject to the more stringent labelling rules.

2.7.3 At the retail stage, the labelling information must be available and accessible at the time of purchase by the consumer, and if necessary during the subsequent use of the material or article.

By indicating the labelling information on the finished product as far upstream as possible, the entity responsible for marketing ensures that the consumer has effective access to this information.

National provisions

French regulations state provisions (Article 2 of Decree No 2007-766 of 10 May 2007 as amended) to impose visible, indelible marking on articles that are not intended for contact with foodstuffs, despite their appearance.

Business operators are advised that such marking will not exempt them from the legal requirements if the article falls under Regulation (EC) No 1935/2004. Hence articles that can be reasonably expected to come into contact with foodstuffs (according to their markings, appearance and shape, sale location and sector, selling conditions, etc.) shall not be thus marked, and shall comply with the provisions of the above regulations.

Examples: presentation plates, certain decorative plates, paper table place mats used in catering, etc.

This is a national measure that has been notified, and for which a mutual recognition clause is planned.

2.7.4 Specific labelling for active and intelligent materials:

Articles 4 and 15 of the Framework Regulation:

Adequate labelling or information should support users in the safe and correct use of active materials and articles.

This information concerns permitted use or uses, as well as other relevant information, such as:

• the names of released substances **and**

• the quantities of substances released by the active component.

so as to enable food business operators who use these materials and articles to comply with any other relevant Community provisions, or in their absence, national provisions applicable to food, including the provisions on food labelling.

Active and intelligent materials and articles already in contact with foodstuffs shall be labelled appropriately to enable consumers to identify inedible parts and to inform them clearly of the active or intelligent nature of the materials or articles.

Food business operators shall submit a declaration of compliance to users in food industries to enable them to use active or intelligent materials or articles safely and in compliance with the regulations for foodstuffs, including the provisions concerning the labelling of foodstuffs.

Article 11 of Regulation (EC) No 450/2009

To allow identification by the consumer of non-edible parts, active or intelligent materials and articles or parts thereof shall be labelled whenever they are perceived as edible:

a) with the words "DO NOT EAT"; and

b) as always where technically possible, with the symbol reproduced in Annex I of the above regulation.

2.8 Traceability (Article 17 of the Framework Regulation)

The traceability of materials and articles intended to come into contact with foodstuffs is ensured <u>at all stages</u> in order to facilitate control, the recall of defective products, consumer information, and the attribution of responsibility.

With due regard to technological feasibility, business operators must have in place systems and procedures to allow identification of **the businesses from which and to which** materials or articles and, where appropriate, substances or products covered by the Framework Regulation and its implementing measures used in their manufacture, are supplied. This information must be made available to the competent authorities on demand.

The materials and articles which are placed on the market in the Community must be identifiable by an appropriate system which allows their traceability by means of relevant labelling, documentation or information.

The labelling details of Article 15 for materials not yet in contact with food shall comprise adequate labelling or identification conferring traceability on the material or article.

3. OPERATORS CONCERNED BY THE REGULATION: "MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS"

Requirement to report risks

Pursuant to <u>Article L. 423-3 of the Consumer Code</u>, professional operators (manufacturers, importers, distributors, etc.) must, as soon as they are themselves informed thereof, inform the competent authorities of any risks presented by products they have marketed for purchase by consumers, and state the measures they have taken to offset those risks. This requirement also applies to materials intended for contact with foodstuffs (see <u>Notice to economic operators on</u>

the implementation of the requirement to report risks and measures taken (Official Journal of the French Republic (JORF) No 0036 of 11 February 2012)

3.2 Good manufacturing practices for materials and articles

The purpose of Regulation (CE) No 2023/2006 of the European Commission of 22 December 2006 amended by Regulation (EC) No 282/2008 of 27 March 2008 on good manufacturing practices for materials and articles intended to come into contact with food, in application of Regulation No 1935/2004, is to lay down rules relating to good manufacturing practice (GMP) for the groups of materials listed in Annex I of the aforementioned Framework Regulation, and for combinations of these materials. This Regulation applies to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances.

This regulation implies that all business operators should ensure quality management of their activity (**quality assurance and quality control systems**) adapted to their position in the supply chain. Quality assurance includes the **selection of starting materials to meet pre-established specifications**, guaranteeing the compliance of the material or object with the rules applicable to it.

Regulation (EC) No 2023/2006 provides for the establishment and maintenance of appropriate documentation, made available to the competent authorities at their request. This documentation may contain:

- Traceability information, and if relevant, production records
- Information concerning the different manufacturing operations carried out that are relevant to ensuring the compliance or safety of the finished product.
- Conditions of storage and handling, in particular so as to prevent contamination by setoff.
- Results from the quality control system.
- Manufacturing formulas, specifications and purity criteria for the selected starting materials, risk analysis results, changes of supplier, etc.
- Conditions and results of tests on finished products.
- Deviations and corrective actions taken in the event of changes in the manufacturing process.

Detailed rules of good manufacturing practice are appended to the regulation (printing inks, plastic recycling processes).

As part of good manufacturing practice, it is not recommended to put printed surfaces*(face in direct contact with food), whether or not they are overlaid with a transparent coating, in direct contact with foodstuffs, as this practice introduces an important risk of contamination of the foodstuffs by components of the printing ink.

* Surfaces of a material (paper and cardboard, plastic, etc.) marked with printing ink. This does not apply to decorations that are a structural part of the materials, having been bonded or embedded within them (e.g. by a thermal "baking" process) so as to form one single layer, or printing inks whose components are foodstuff ingredients, on condition that these components have no technological role in the packaged foodstuff (see Regulation (EC) No. 1333/2008 as amended, and Regulation (EU) No 231/2012 as amended).

3.3 Liability of operators in the chain (chemical inertness)

The economic operators (manufacturers, processors, users) are liable for the compliance of the materials and articles with Article 3 of the Framework Regulation, to the extent of the operations conducted under their supervision (manufacture, storage, transport) and according to the intended conditions of contact, or where not known, foreseeable conditions of contact.

An economic operator introducing or generating a substance in a product is responsible for the compliance of that substance. This responsibility applies to impurities in the substance, and any degradation and/or decomposition products linked to the intended use that can form at this stage or at a later stage in the intended use.

The compliance of materials and articles shall be demonstrated as far upstream as **possible** in the chain by manufacturers and processors. Economic operators shall be responsible for declaring the compliance of the materials and articles in predefined conditions:

- Conditions of contact: time, temperature, type of foodstuff, type of contact (single or repeated use).
- If relevant: conditions of storage and transport of materials.
- If relevant: support, conditions of application, frequency of use, and other relevant variables, etc.

When compliance cannot be declared, all the relevant information must be supplied* in relation to the next stage (composition of materials, concentration and purity of substances entering into the composition, etc.) to enable the operator downstream to carry out this task.

* if necessary, as part of confidentiality agreements.

Concerning **professional users** of materials and articles intended to come into contact with food, Section 1 of Article 17 of Regulation (EC) No 178/2002 requires **food and feed business operators** to verify that foodstuffs comply with the rules that are applicable to them. Subject to confidentiality requirements these operators must have access to relevant information concerning materials and articles intended for the packaging of foodstuffs, and must possess technical documentation concerning the compliance and safety of the materials and articles brought into contact with foodstuffs.

Article 1 of Regulation (EC) No 852/2004 states that "the primary responsibility for food safety rests with the food business operator", and states that the general implementation of procedures based on HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility. The first principle of HACCP, as defined in Article 5 of this regulation, is the identification of "any hazards that must be prevented, eliminated or reduced to acceptable levels."

The food business operators must therefore implement risk analysis procedures to verify that the marketed foodstuffs do not adversely affect human health, in particular through the migration of chemical substances constituting hazards as defined in Regulation (EC) No 852/2004, from those materials

To fulfil this obligation, professional users shall take care that foodstuffs come into contact only with materials intended for that purpose by the entity responsible for their marketing. To this end, the users must make sure that the materials used are accompanied by a declaration of compliance with the applicable regulatory texts when the regulations require it, or if not, they must enquire of their supplier whether the materials or articles are intended for food contact.

The use by agrifood operators of materials or articles that are obviously not intended to come into contact with foodstuffs is an infringement of the obligations specified in Article 5 of Regulation (EC) No 852/2004 combined with the provisions concerning equipment in Annex II thereto.

Users must take notice of the informations contained in the declaration of compliance.

Users must also make sure they use materials in the conditions of contact (time, temperature, repeated or single use, etc.) described in the declaration of compliance, or in the absence thereof, according to the instructions for use on the labelling, or in the absence of adequate instructions for use, according to the normal or reasonably expected conditions of use. Also, users may themselves verify the compliance of these materials or articles in real conditions of contact with foodstuffs (by tests on materials or on the foodstuffs themselves).

If the use of the materials differs from the predefined use, or if the agrifood company carries out one or more operations that can be construed as being part of their manufacture, a procedure shall be carried out to verify their compliance.

Agrifood users shall make sure that their plant and equipment are serviced and replaced at due intervals.

Information for end-consumers concerning the safe, appropriate use of pre-packaged foodstuffs shall be given by labelling of the foodstuff.

4. SANCTIONS (CONSUMER CODE)

It is forbidden to hold for sale, to sell or to give away any materials or articles intended to come into contact with foodstuffs that do not meet the requirements specified in Regulation (EC) No 1935/2004 and the regulations for its application or Orders issued pursuant to Article 3 of Decree No 2007-766.

Infringement of Articles 1 to 5 and 15, 16 and 17 of the Framework Regulation (EC) No 1935/2004 of 27 October 2004, of regulations for its application, of Articles 1 to 7 of Regulation (EC) No 2023/2006, of Decrees issued by the Conseil d'Etat (French Supreme Administrative Court) pursuant to Article L. 412-1 and the measures for their execution (national Orders), which are not confounded with an offence for fraud or falsification provided for in Articles L. 454-1 to L. 451-3 and L. 412-7 (7°), incur 5th class sanctions as specified in Article R. 451-1.



1- GENERAL INTRODUCTION

Article 3 of **Regulation** (EC) No 1935/2004 of 27 October 2004 foresees that food contact materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health, bring about an unacceptable change in the composition of the food or bring about a deterioration in the organoleptic characteristics thereof.

For certain categories of materials, the implementing legislation for this Regulation defines rules (composition, purity standards, etc.) for ensuring compliance with this inertness. In this way, specific directives, such as those concerning ceramic articles and regenerated cellulose films, as regulations, including ones dealing with plastic materials or active and intelligent materials, were adopted.

Moreover, in the absence of specific legislation that is applicable EU-wide for a given type of material, national regulations shall apply, such as those in France relating to stainless steel, aluminium and its alloys, rubbers and silicone elastomers.

Nevertheless, a certain number of materials have not yet been the subject of specific regulations, either at EU or national level, or are regulated in an incomplete fashion.

This is the case for metals and alloys, which are the subject of several European Union provisions in Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food, and several national pieces of legislation, but which are not fully regulated by a specific text.

In the absence of a specific regulatory text, the DGCCRF has drafted sheets for various types of materials. They are primarily intended for official control departments and laboratories. These sheets specify the means for verifying the food contact suitability of metals and alloys, and more specifically the means for verifying the principle of inertia set out in Article 3 of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004.

They have been the subject of a prior consultation with stakeholders representatives (competent laboratories in the area of FCMs, manufacturers and processors of such materials, agri-food industries, distributors, etc.).

They are available on the DGCCRF website so that operators can, in complete transparency, become informed about certain criteria and means used by the departments as part of official inspections.

The criteria listed in these sheets are not exhaustive. Other relevant criteria may be taken into account, depending on the nature, origin and composition of the materials, as well as treatments to which they are subjected.

The purpose of this document is to specify the means for verifying the food contact suitability of metals and alloys.

The sheets that make up this document may be distributed and are available on the DGCCRF's website in the section devoted to food contact materials: <u>http://www.economie.gouv.fr/dgccrf/Materiaux-au-contact-des-denrees-alimentaires</u>

2- SCOPE OF APPLICATION



Reference is made to the lead sheet dealing with the scope of application of the metals and alloys sheet and its general structure.

3- SPECIFIC DEFINITIONS AND ABBREVIATIONS

<u>Framework regulation</u>: Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004

<u>FCMs</u>: Food contact materials



LEAD METALS AND ALLOYS SHEET

Last update of regulatory texts and reference documents referred to in these sheets: 1 April 2017

Last update of criteria referred to in these sheets: 1 April 2017

These sheets deal with **metals and alloys used in food contact materials** within the meaning of the regulatory framework.

They focus on uncoated metals and alloys, as well as those with metallic (nickel, tin, chrome, etc.) or organic coatings.

They do not address enamelled materials, those with inorganic coatings or those with hybrid organic/inorganic coatings (such as those derived from the sol-gel process).

For general regulatory texts applicable to metals and alloys used in food contact materials, please refer to the <u>sheet on general regulations</u> as well as the following regulations: Regulation (EC) No 1935/2004, Regulation (EC) No 2023/2006, Regulation (EC) No 852/2004 and Regulation (EC) No 178/2002.

Other reference documents and texts include :

- Resolution CM/Res(2013)9 on metals and alloys and its Technical Guide
- Regulation (EU) No 10/2011 and the JRC Guidelines on Testing Conditions.

Some metals and alloys are covered by a specific sheet. They are as follows:

- Stainless steel (sheet no. 1)
- Aluminium and aluminium alloys (sheet no. 2)
- Steel for packaging (sheet no. 3) and uncoated steel excluding packaging (sheet no. 4)
- Uncoated steel and stainless steel excluding packaging (sheet no. 5)
- Unalloyed pig-iron (sheet no. 6)
- Tin and tin alloys (sheet no. 7)
- Zinc and zinc alloys (sheet no. 8)
- Articles with various metal coatings (sheet no. 9).

Release and migration testing to check whether the metals and alloys covered by a specific sheet are **in compliance with Article 3 of Regulation (EC) No 1935/2004 of 27 October 2004** shall be carried out on the basis of the test specifications set out in Appendix II, depending on the nature of the materials and alloys under consideration (bare metals and alloys / metals and alloys with a metallic coating / metals and alloys with an organic coating).

The Specific Release Limits (SRLs) to be observed for these metals and alloys are listed in Appendix I.

For the purposes of demonstrating compliance with Article 3 of the aforementioned Regulation of 27 October 2004, migration and release testing take precedence over composition testing. With respect to materials and articles with organic coatings, migration tests performed on the final product take precedence over those performed by placing the coating on an "inert" support.



Nevertheless, metals and alloys that fall within the scope of a specific national regulatory text listing the full set of composition criteria (only for materials and articles in **stainless steel or in aluminium and aluminium alloys**) are not covered by migration testing (except in cases of thermochemical treatment) and should be in compliance with these regulatory criteria.

Similarly, packaging must, in all cases, comply with the requirements in terms of concentration levels (lead, cadmium, mercury and hexavalent chromium) set out in Directive 94/62/EC of 20 December 1994 on packaging and packaging waste.

The test specifications and SRLs listed in Appendices I and II may be used as references for checking compliance with Article 3 of the framework regulation for types of metals and alloys listed in Appendix III (which are not the subject of a specific sheet).

From a **food compliance** standpoint and, in the context of the broad application of procedures based on Hazard Analysis and Critical Control Point (HACCP) principles set out in Regulation (EC) No 852/2004, food sector operators must put in place risk analysis procedures in order to check that food placed on the market is not a hazard to human health, particularly due to the migration of chemical substances, similar to risks within the meaning of Regulation (EC) No 852/2004, based on materials (industrial equipment or food packaging).



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SHEET NO. 1: UNCOATED STAINLESS STEEL

1. Scope of application

This sheet deals with uncoated stainless steel and with articles consisting exclusively of stainless steel which, as final products, are intended for food contact, including articles and equipment used to produce, process, store and transport food.

The primary examples of usage for the various stainless steel families are set out in Appendix B of standard NF A 36-711.

2. Specific limitations on the use of materials

No specific limitations within the context of this document.

3. Definition of food contact suitability criteria

3.1 Reference texts

3.1.1 Regulatory texts

- Order of 13 January 1976 related to materials and articles made of stainless steel in contact with food products;
- Order of 15 November 1945 establishing a list of materials that may be used without harm to public health for the production of measuring instruments.

3.1.2 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"
- standard NF EN 10088-1: Stainless steels. List of stainless steels;
- Information document BP A 36 720 "Cleaning stainless steels in food and health applications".

3.2 Criteria

The criteria used are those contained in the Order of 13 January 1976, which foresees composition criteria, but does not foresees migration criteria.

4. Acceptability limits

Minimum chromium content: 13.0%

Additional alloying elements: Ta, Nb, Zr, Mo, Ti, Al and Cu, with the following maximum contents: - Ta, Nb, Zr: 1%

- Mo, Ti, Al, Cu: 4%

Elements not listed in the Order may be used within the chemical composition limits defined in Tables 1 to 4 in Appendix IV.

<u>NOTE</u>: Some grades of stainless steel are governed by standard NF 36-711: 2002 (confirmed standard unchanged in 2012) while others are governed by standard NF EN 10088-1: 2014. The associated names are taken from standard NF EN 10088-1, but with the contents amended to comply with the composition requirements defined above.



5. Rules for checking the criteria defined in Paragraph 3

5.1 Stainless steel

The stainless steel manufacturer supplies the manufacturer of the final product with the following:

- a) a written declaration of compliance with the Order of 13 January 1976;
 - b) An analysis report of the chemical composition, which must be in compliance with the Order of 13 January 1976.

5.2 Final product

The manufacturer must ensure that the composition of the stainless steel is in compliance with the composition criteria in the Order of 13 January 1976, which are listed in Paragraph 4.

If the composition of the stainless steel is in compliance with the composition criteria listed in Tables 1 to 4 in Appendix IV of the present document, it is deemed to have met these criteria.

6. Thermochemical processes

Thermochemical processes are sometimes used on stainless steel to improve their tribological behaviour (resistance to abrasion, adhesion and resistance to scoring). They may include the following processes:

- Nitriding of martensitic stainless steel (hardened coating that is generally 0.3 mm thick)
- Surface enrichment (generally 30 µm) using carbon, nitrogen or both (for austenitic stainless steel);
- Nitrogen enrichment of ferrite (generally up to 2 mm) for austenitic-ferritic stainless steel.

<u>NOTE</u>: As examples:

- "Kolstering" is a process used for the carbon surface enrichment of austenitic stainless steel - The "Nivox", "Stainihard" and "Expanite Low T" processes are used for the nitrogen and carbonnitrogen surface enrichment of austenitic stainless steel

- The "IPSEN Solnit" and "Expanite HighT" processes are used for the nitrogen enrichment of ferrite for austenitic-ferritic stainless steel

Whenever such treatments are used, compliance with Article 3 of Regulation (EC) No 1935/2004 is checked on the basis of the **test specifications set out in Appendix II** (metals and alloys that are uncoated or that have a metallic coating) and the **Specific Release Limits (SRLs) given in Appendix I.**



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SHEET NO. 2: ALUMINIUM AND ALUMINIUM ALLOYS

Sheet No. 2a

COATED ALUMINIUM AND ALUMINIUM ALLOYS (WITH ORGANIC COATING) SINGLE USE – LONG-TERM CONTACT (PACKAGING) REPEATED USE – SHORT-TERM CONTACT

<u>1. Scope</u>

This sheet deals with food contact articles in aluminium or aluminium alloy with an organic coating intended to come into contact with food.

It distinguishes between single-use articles intended for long-term contact and repeated-use articles for short-term contact. Single-use articles intended for long-term contact are packaging, the primary examples of which are as follows:

- Food tins
- Drink cans
- Coffee pods
- Pressurised containers
- Varnished lidding foils for dairy products
- Tubes
- Thin foil for cheese products
- Cups

Repeated-use articles for short-term contact include the following:

- Household articles: pots, pans, dishes, flasks, etc.
- Household cooking appliances such as pressure cookers

This document does not deal with hybrid organic/inorganic coatings (such as those derived from the sol-gel process).

2. Specific limitations on the use of materials

No specific limitations within the context of this document

3. Definition of food contact suitability criteria

3.1 Texts

3.1.1. Regulatory texts

- Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food ;
- Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, amended;
- Act 2010-729 of 30 June 2010 amended by Act 2012-1442 of 24 December 2012 regarding the suspension of marketing of all packaging containing bisphenol A intended to contain food products;



• Order of 27 August 1987 related to materials and articles in aluminium or aluminium alloy in contact with food products, foodstuffs and beverages.

3.1.2 Other texts

- The Council of Europe's Framework Resolution ResAP(2004)1 on coatings intended to come into contact with foodstuffs;
- standard NF EN 601: Aluminum and aluminium alloys Castings Chemical composition of castings for use in contact with foodstuffs;
- standard NF EN 602: Aluminium and aluminium alloys Wrought products Chemical composition of semi-final products used for the fabrication of articles for use in contact with foodstuffs;
- standard NF EN 15136: materials and articles in contact with foodstuffs –Epoxy derivatives subject to limitation – Determination of BADGE, BFDGE and their hydroxylated and chlorinated derivatives in food simulants;
- French archival documents dealing with varnishes: CSHPF opinion (NOR: ECOC9810281V (BOCCRF no. 17 of 15 September 1998, Circular of 4 April 1969 (JO of 4 June 1969), Circular of 29 May 1978 (completion of previous circular, unpublished in JO), Circular no. 159 of 23 June 1950 (JO of 20 July 1950), CSPHF opinion of 4 November 1985, Circular no. 162 of 25 April 1952 (JO of 13 May 1952), Circular no. 165 of 12 January 1954 (JO of 20 January 1954), Circular no. 175 of 25 March 1959 (Jo of 16 April 1959), Order of 3 September 1959, Opinion of the CSHPF (NOR: FCEC9610111V), Circular no. 172 of 26 June 1956 (JO of 7 July 1956), Instruction of 30 November 1987, CSHPF opinion (NOR: ECOC9810281V, BOCCRF no. 17 of 15 September 1998);
- "Good manufacturing practices for the production of coatings intended to come into contact with food" – European Council of the Paint, Printing Ink and Artists' Colours Industry (CEPE).

3.2 Criteria

<u>3.2.1 Base</u>

Aluminium or aluminium alloy bases meet the composition requirement set out in the Order of 27 August 1987.

3.2.2 Coating only

3.2.2.1 Varnishes / coatings

There is no specific French national legislation or harmonised EU regulation that covers food contact vanishes and coatings, or a positive list of constituents* for such vanishes and coatings.

The following lists of monomers, starting substances and additives are reference lists for varnish constituents:

- Substances (monomers, starting substances and additives) listed in Regulation (EU) No 10/2011 of 14 January 2011, amended, taking account of determined restrictions and/or specifications (SMLs, residual contents, purity criteria, etc.);
- Varnishes and coatings substances assessed by the European Food Safety Authority (EFSA) using its own guidelines and which have been the subject of a favourable opinion by the EFSA;
- Substances that have been the subject of a favourable opinion by the Scientific Committee on Food (SCF) (Lists 0 to 4) (website: http://ec.europa.eu/food/fs/sc/scf/index_en.html)
- List of assessed substances in Framework Resolution ResAp (2004) 1 on the varnishes in Part A: List 1 of monomers and Part C: List 1 of additives ;
- Varnish and coatings substances assessed in application of the European Food Safety Authority's guidelines, or equivalent guidelines, and which have been the subject of a favourable opinion by a competent scientific body in one of the EU Member States, Turkey



or a State which is party to the agreement on the European Economic Area (taking account of determined restrictions and/or specifications);

 Varnish and coatings substances that are the subject of an authorisation in a regulatory text by an EU Member State concerning food contact varnishes, based on a scientific assessment conducted since 1991 in accordance with SCF/EFSA guidelines and which have been the subject of a favourable opinion by a competent scientific body in an EU Member State, taking account of determined restrictions and/or specifications (SMLs, residual contents, purity criteria, etc.).

Other constituents may be used in the production of coatings and varnishes, provided that a risk assessment in compliance with internationally-recognised scientific risk assessment principles can be provided to demonstrate compliance with Article 3 of the aforementioned Regulation (EC) No 1935/2004.

Specifically, constituents that have been the subject of an authorisation in a regulatory text by an EU Member State concerning food contact varnishes, based on a scientific assessment conducted prior to 1991 applying the criteria existing at the time, may be used provided that supplementary toxicological data can be provided based on the nature of these constituents and their migration and exposure levels, in order to demonstrate compliance with Article 3 of Regulation (EC) No 1935/2004.

Constituents used in the manufacture of varnishes and coatings, including their impurities, which have not been the subject of a scientific risk assessment in accordance with EFSA guidelines or equivalent guidelines and a favourable opinion by the EFSA or a competent scientific body in an EU Member State, must not be classified as Category 1 or 2 carcinogenic, mutagenic and reprotoxic substances (CMRs) in accordance with <u>Regulation (EC) No 1272/2008 of 16 December 2008, amended</u>, and must not be in a nanometric form.

Compliance with the criteria of Regulation (EC) No 1895/2005 of 18 November 2005 concerning BADGE and its derivatives.

Act 2010-729 of 30 June 2010, amended by Act 2012-1442 of 24 December 2012 suspends the import and placing on the market, either free of charge or against payment, of any packaging, container or utensil comprising bisphenol A and intended to come into direct contact with all foodstuffs as from 1 January 2015 (see the DGCCRF's implementation guidelines).

*NOTE: The term constituent covers substances.

3.2.2.2 Non-stick coating

In the absence of proof of the non-use of chromates in the manufacturing process, search for the presence of chromates in the non-stick coating interface.

3.2.3 Final product

Materials and articles at the finished-product stage (coated metals) must meet requirements with respect to 1) specific migration* of those coating constituents that are subject to specific limits, 2) specific release limits for metals, alloy components and impurities listed in Appendix I of this document, 3) overall migration limits, and 4) where appropriate, residual contents of constituents, under normal or foreseeable usage conditions.

* Verification of specific migration limits provided shall not be compulsory, if it can be established that the migration potential, calculated based on the residual content of the substance in the material or article and assuming complete migration of this substance (or by applying generally recognised diffusion models based on scientific evidence that are established in a way as to overestimate real migration levels) does not exceed the specific migration limit.



4. Limits of acceptability

4.1 Aluminium and aluminium alloys alone / enamel coating used as an undercoat

The aluminium must comply with the purity criteria foreseen in the Order of 27 August 1987:

-Fe + Si < 1%

-Ti ≤ 0.15%

- For each of the following elements: Cr, Zn, Cu, Mn, Mg, Ni, Sn \leq 0.10%

- Each of the following elements: Pb, Tl, Be, and each of the impurities: ≤ 0.05%

- The copper content can reach 0.20% of those for chromium and magnesium are less than 0.05%

The aluminium alloy must comply with the following composition limits:

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

4.2 Final product

The **specific migration limits** and the maximum and/or residual quantities of monomers, other starting substances and additives are those of Annex I of Regulation (EU) No 10/2011 of 14 January 2011 for the constituents that are listed there, or those found in relevant scientific opinions and assessments.

The specific release limits of metals, alloy components and impurities are those set out in Appendix I of this document.

The limits for epoxy derivatives are those set out in Regulation (EC) 1895/2005.

The **overall migration limit** is 10 mg/dm² of the food contact area. An exception has been made for food contact materials and articles for infants less than 12 months old and small children one to three years old, for whom the overall migration limit is 60 mg/kg of food simulant.

For hexavalent chromium, the limit is non-detection with a detection threshold of $5 \mu g/dm^2$ (Opinion by the CSHPF, Session of 13 February 1996, BOCCRF no. 8 of 24 May 1996).

5. Rules for checking the criteria defined in Paragraph 2

5.1 Aluminium and aluminium alloys alone

The manufacturer of aluminium and aluminium alloy shall supply the packaging manufacturer with: a) A written declaration of compliance with the Order of 27 August 1987

b) An analysis report of the chemical composition, which must be in compliance with the Order of 27 August 1987.



5.2 Coating only

To verify the criteria, the following information must be provided to the laboratory in charge of analyses*, which may have to sign a confidentiality agreement:

- **Coating references** (so as to allow them to be identified), description of the coated metal, coating family ;
- Identity of substances, type of restrictions for monomers, other starting substances and additives for which SMLs (Specific Migration Limits) or maximum residual quantities have been established, and, where appropriate, the impurities, products of degradation or other substances likely to pose a risk to human health;
- Information concerning the use of the materials and articles: type of foodstuffs (of simulants), duration of contact and real contact temperature for these foodstuffs Where appropriate, specific information about labelling and real surface area/volume ratio.

The manufacturer of the coating provides the manufacturer of the material or article with a written declaration of compliance with Regulation (EC) No 1935/2004, attesting to the compliance of the composition and, on the basis of migration tests carried out with the coating applied to an "inert" support (stainless steel or glass), of the overall migration and, where appropriate, the specific migrations of the coating's constituents that are subject to a specific migration limit, under test conditions that are representative of real usage. In the case of use of dual use additives, these shall be identified.

* in the case of outsourced testing

5.3 Final product

At the stage of the final product, the inertia of the coating is checked on the ready-for-use article (specific migration/release of the constituents and overall migration).

The manufacturer of the final product checks this inertia by means of specific migration/release tests and overall migration tests on the food simulants or foodstuffs on the basis of the specifications set out in Appendix II (uncoated metals and alloys or those with a metallic coating).

Verification of specific migration limits provided shall not be compulsory, if it can be established that the migration potential, calculated based on the residual content of the substance in the material or article and assuming complete migration of this substance (or by applying generally recognised diffusion models based on scientific evidence that are established in a way as to overestimate real migration levels) does not exceed the specific migration limit.

For packaging of foodstuffs with a long shelf life, the match between packaging and foodstuff is checked by means of long-term testing, following a protocol specific to each manufacturer, in such a way as to ensure that the packaging has been effectively adapted to real usage conditions (mechanical and chemical resistance, etc.). These tests can also be in the form of accelerated ageing tests using a methodology based on scientific principles.



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SHEET NO. 2: ALUMINIUM AND ALUMINIUM ALLOYS

SHEET No. 2b UNCOATED ALUMINIUM AND ALUMINIUM ALLOYS SINGLE USE – LONG-TERM CONTACT VARIABLE DURATION OF CONTACT

1. Scope

This sheet deals with uncoated food contact articles in aluminium or aluminium alloy intended to come into contact with food.

It distinguishes between single-use articles (packaging) and repeated-use articles (possible anodised). Single-use application essentially relates to:

- Pressurised containers
- Chocolate paper Tubes Aluminium for household use
- Trays Rings (chicken) Trays – Staples (sausage)

Examples of repeated-use articles are as follows:

- Household articles: pots, pans, utensils
- Agri-food industry equipment: vats, tankers, piping, work surfaces, machines

2. Specific limitations on the use of materials

For materials and articles intended for the final consumer, usage restrictions are given for contact with highly acidic products.

3. Definition of food contact suitability criteria

3.1. Regulatory texts

 Order of 27 August 1987 related to materials and articles in aluminium or aluminium alloy in contact with food products, foodstuffs and beverages

3.2 Other texts

- standard NF EN 601: Aluminium and aluminium alloys Castings Chemical composition of castings for use in contact with foodstuffs;
- standard NF EN 602: Aluminium and aluminium alloys Wrought products Chemical composition of semi-finished products used for the fabrication of articles for use in contact with foodstuffs.K

3.3 Criteria

The criteria used are those contained in the Order of 27 January 1987, which foresee chemical composition criteria, but does not foresee migration limit criteria.

4. Limits of acceptability

The aluminium must comply with the purity criteria foreseen in the Order of 27 August 1987:

- -Fe + Si < 1%
- -Ti ≤ 0.15%
- For each of the following elements: Cr, Zn, Cu, Mn, Mg, Ni, Sn ≤ 0.10%
- Each of the following elements: Pb, Tl, Be, and each of the impurities: $\leq 0.05\%$



- The copper content can reach 0.20% of those for chromium and magnesium are less than 0.05%

The aluminium alloy must comply with the following composition limits:

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

5. Rules for checking the criteria defined in Paragraph 3

5.1 Aluminium and aluminium alloys

The manufacturer of aluminium and aluminium alloy shall supply the manufacturer of the final product with:

a) A written declaration of compliance with the Order of 27 August 1987;

b) An analysis report of the chemical composition, which must be in compliance with the Order of 27 August 1987.

5.2 Final product

The manufacturer of the final product shall ensure compliance with the Order of 27 August 1987.



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SHEET NO. 3: STEEL FOR PACKAGING

Sheet No. 3a UNCOATED STEELS (BLACKPLATE)

1. Scope of application

This sheet deals with materials and articles made of steel ⁽¹⁾which, as final products, are intended for direct food contact.

It does not deal with articles covered by the "Non-packaging steel" and "Stainless steel" sheets.

Application essentially relates to:

- Food product tins (sugar, tea, cakes, chocolate, flour, pasta, etc.);
- Tins of oil, barrels, vats, etc.

2. Specific limitations on the use of materials

Use of uncoated blackplate should be limited to contact with oily and/or dry foodstuffs.

For tins sold to non-professional users or to final consumers, the usage limitations with respect to the packaged products must be indicated by the reseller.

3. Definition of food contact suitability criteria

3.1 Reference texts

3.1.1. Regulatory texts

• Order of 15 November 1945 establishing a list of materials that may be used without harm to public health for the production of measuring instruments.

3.1.2 Other texts

 Standard NF 10334: Steel for packaging – flat steel products intended for use in contact with foodstuffs, products and beverages for human and animal consumption – *Non-coated steel* (*blackplate*).

⁽¹⁾ Definition according to standard NF EN 10020: Definition and classification of grades of steel



3.2 Criteria

3.2.1. Composition of the steel

Verification of the content of elements that make up the steel.

3.2.2 Maximum content in undesirable elements

In particular, verification of the content in lead, cadmium, arsenic and cobalt.

3.2.3 Specific Release Limits

Release limit for elements added intentionally and undesirable elements.

4. Acceptability limits

4.1 Composition of the steel

The supplier of the steel attests to the compliance with the chemical composition requirements set out in the following table.

Table — Chemical composition according to standard NF 10334 (1) (2)

Specified elements		Maximum content in % in mass	
Al	Aluminium	1.0	
As	Arsenic	0.030	
В	Boron	0.05	
С	Carbon	0.30	
Cd + Pb + Hg + Cr (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	
Other elements addressed separately (1)		0.050	
(1) The chemical elements included under the heading "Other elements addressed separately" are those which may appear in			



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extremely small quantities, but which are not added intentionally during the steel manufacturing process. (2) Cadmium, lead, and mercury are not added intentionally during the steel manufacturing process. The specification concerning the sum of these three elements refers to Article R.543-45 of the French Environmental Code (Regulatory part, Book V, Title IV, Chapter II, Section 5) which enacts Directive 94/62/EC of 20 December 1994 on packaging and packaging waste into French legislation. Unless otherwise specified, the individual requirements do not apply.

The manufacturer must ensure that the composition of the steel is consistent with these criteria.

4.2 Maximum content in undesirable elements

Pb < 0.010%

Cd < 0.010%

As < 0.030%

Co < 0.050%

4.3 Specific Release Limits

Refer to the release limits set in Appendix I and, in particular, the release limits of lead, cadmium, arsenic and cobalt.

5. Rules for checking the criteria defined in Paragraph 3

5.1 Steel

The manufacturer of the steel provides the manufacturer of the packaging with a report analysing the chemical composition.

5.2 Final product

On the final product, inertia is checked on the ready-for-use article (specific release).

The manufacturer of the final product checks this inertia by means of release tests on the foodstuffs or food simulants on the basis of the specifications set out in Appendix II (uncoated metals and alloys or those with a metallic coating).



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SHEET NO. 3: STEEL FOR PACKAGING

SHEET No. 3b TIN-COATED STEEL (TINPLATE)

1. Scope of application

This sheet deals with tin or tin alloys and objects coated exclusively in tin or tin alloy or partially tin-plated, which as final products are intended for food contact⁽¹⁾.

It does not deal with articles covered by the "Non-packaging steel" and "Steel and stainless steel with metallic coating (excluding packaging)" sheets.

Application essentially relates to:

- Food tins
- Packaging for dry ingredients

2. Specific limitations on the use of materials

The choice of materials must be in keeping with the conditions of use.

It is forbidden to put any beverages or foodstuffs in direct contact with recipients, utensils and equipment that are tin-plated or welded with tin containing more than 0.5% of lead or more than 3/10,000ths of arsenic or less than 97% of tin determined as metastannic acid. For materials and articles intended for the final consumer, usage restrictions are given for contact with highly acidic products.

3. Definition of food contact suitability criteria

3.1 Reference texts

3.1.1. Regulatory texts

- Order of 28 June 1912, amended, concerning the colouring, preservation and packaging of food products and beverages ;
- Order of 15 November 1945 establishing a list of materials that may be used without harm to public health for the production of measuring instruments.

3.1.2 Other texts

- Standard EN 610: Tin and tin alloys Ingot tin ;
- standard NF 10333: Steel for packaging flat steel products intended for use in contact with foodstuffs, products and beverages for human and animal consumption – Non-coated steel (blackplate).

3.2 Criteria

<u>3.2.1. Composition of the steel and coating</u> Verification of the content of elements that make up the steel and the coating.

⁽¹⁾Definition according to standard NF EN 10020: Definition and classification of grades of steel.



3.2.2 Maximum content in undesirable elements

In particular, verification of the content in lead, cadmium, arsenic and cobalt for the steel and lead, cadmium and arsenic for the tin coating.

3.2.3 Specific Release Limits

Release limit for elements added intentionally and undesirable elements.

4. Acceptability limits

4.1. Composition of the steel and coating

The steel meets the chemical composition requirements set out in the "Steel for packaging (blackplate)" sheet.

The chemical composition of the tin used must comply with the requirements given in standard EN 610 for the grade Sn 99.85 with the exception of the lead content, which must be less than 0.0100%.

4.2 Maximum content in undesirable elements

Steel:

Pb < 0.010%

Cd < 0.010%

As < 0.030%

Co < 0.050%

Tin:

The chemical composition of the tin used must comply with the requirements given in standard EN 610 for the grade Sn 99.85 with the exception of the lead content, which must be less than 0.0100%.

4.3 Specific Release Limits

Refer to the release limits set in Appendix I and, in particular, the release limits of impurities: lead, cadmium, arsenic and cobalt.

5. Rules for checking the criteria defined in Paragraph 3

5.1 Steel

The manufacturer of the steel provides the manufacturer of the packaging with a report analysing the chemical composition. It attests to the compliance with the chemical composition requirements set out in the "Steel for packaging (blackplate)" sheet.

5.2 Coating only

The manufacturer of the tin coating provides the manufacturer of the final products with a report analysing the chemical composition. It attests to the compliance with the specifications set out in 4.1.

5.3 Final product

The manufacturer of the final product verifies the composition of the steel and the tin coating.

At the stage of the final product, the inertia of the coating is checked on the ready-for-use article (specific release).

The manufacturer of the packaging checks this inertia by means of release tests on the food simulants or foodstuffs or on the basis of the specifications set out in Appendix II (uncoated metals and alloys or those with a metallic coating).



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SHEET NO. 3: STEEL FOR PACKAGING

Sheet No. 3c COATED STEEL (WITH ORGANIC COATING)

1. Scope of application

This sheet deals with steel (tinplate, blackplate and chromium-coated steel) for packaging with an organic coating and articles made of steel (tinplate, blackplate and chromium-coated steel) with an organic coating which, as final products, are intended to come into direct contact with **foodstuffs**.

It does not deal with articles covered by the "Non-packaging steel" and "Steel and stainless steel with metallic coating (excluding packaging)" sheets.

The primary examples of coatings are the following: lacquers, varnishes and polymer films.

Application essentially relates to:

- Drink cans
- Food tins
- Packaging for dry ingredients
- Aerosol dispensers
- Cappings
- Household packaging (interiors of cookie or spaghetti tins)

2. Specific limitations on the use of materials

The choice of materials must be in keeping with the conditions of use.

For materials and articles sold to the final consumer, the usage instructions of the packaged products shall be indicated by the reseller.

3. Definition of food contact suitability criteria

3.1 Reference texts

3.1.1. Regulatory texts

- Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food;
- Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, amended;
- Act 2010-729 of 30 June 2010 amended by Act 2012-1442 of 24 December 2012 regarding the suspension of marketing of all packaging containing bisphenol A intended to contain food products;
- Order of 15 November 1945 establishing a list of materials that may be used without harm to public health for the production of measuring instruments;
- Order of 13 January 1976 related to materials and articles made of stainless steel in contact with food products.

3.1.2 Other texts

 The Council of Europe's Framework Resolution ResAP(2004)1 on coatings intended to come into contact with foodstuffs;



- Standard NF 10335: Steel for packaging flat steel products intended for use in contact with foodstuffs, products and beverages for human and animal consumption – Non-alloyed chromium-coated steel.
- standard NF EN 15136: materials and articles in contact with foodstuffs –Epoxy derivatives subject to limitation – Determination of BADGE, BFDGE and their hydroxylated and chlorinated derivatives in food simulants;
- French archival documents relating to varnishes: see sheet no. 2a ;
- "Code of Practice for Coated Articles Where the Food Contact Layer Is a Coating" European Council of the Paint, Printing Ink and Artists' Colours Industry – CEPE.

3.2 Criteria

3.2.1 Coating only

3.2.2.1 Varnishes/coatings

There is no specific French national legislation or harmonised EU regulation that covers food contact varnishes/coatings, or a positive list of components* for such varnishes/coatings.

The following lists of monomers, starting substances and additives are reference lists for coating constituents:

- Substances (monomers, starting substances and additives) listed in Regulation (EU) No 10/2011 of 14 January 2011, amended, taking account of determined restrictions and/or specifications (SMLs, residual contents, purity criteria, etc.);
- Varnishes and coatings substances assessed by the European Food Safety Authority (EFSA) using its own guidelines and which have been the subject of a favourable opinion by the EFSA;
- Substances that have been the subject of a favourable opinion by the Scientific Committee on Food (SCF) (Lists 0 to 4) (website: <u>http://ec.europa.eu/food/fs/sc/scf/index_en.html</u>);
- List of assessed substances in Framework Resolution ResAp (2004) 1 on the varnishes in Part A: List 1 of monomers and Part C: List 1 of additives) ;
- Varnish and coatings substances assessed in application of the European Food Safety Authority's guidelines, or equivalent guidelines, and which have been the subject of a favourable opinion by a competent scientific body in one of the EU Member States, Turkey or a State which is party to the agreement on the European Economic Area (taking account of determined restrictions and/or specifications);
- Varnish and coatings substances that are the subject of an authorisation in a regulatory text by an EU Member State concerning food contact varnishes, based on a scientific assessment conducted since 1991 in accordance with SCF/EFSA guidelines and which have been the subject of a favourable opinion by a competent scientific body in an EU Member State, taking account of determined restrictions and/or specifications (SMLs, residual contents, purity criteria, etc.).

Other constituents may be used in the production of coatings and varnishes, provided that a risk assessment in compliance with internationally-recognised scientific risk assessment principles can be provided to demonstrate compliance with Article 3 of the aforementioned Regulation (EC) No 1935/2004.

Specifically, constituents that have been the subject of an authorisation in a regulatory text by an EU Member State concerning food contact varnishes, based on a scientific assessment conducted prior to 1991 applying the criteria existing at the time, may be used provided that supplementary toxicological data can be provided based on the nature of these constituents and their migration and exposure levels, in order to demonstrate compliance with Article 3 of Regulation (EC) No 1935/2004.

Constituents used in the manufacture of varnishes and coatings, including their impurities, which have not been the subject of a scientific risk assessment in accordance with EFSA guidelines or equivalent guidelines and a favourable opinion by the EFSA or a competent scientific body in an



EU Member State, must not be classified as Category 1 or 2 carcinogenic, mutagenic and reprotoxic substances (CMRs) in accordance with <u>Regulation (EC) No 1272/2008 of 16 December 2008,</u> <u>amended</u>, and must not be in a nanometric form.

Compliance with the criteria of Regulation (EC) No 1895/2005 of 18 November 2005 concerning BADGE and its derivatives.

Act 2010-729 of 30 June 2010, amended by Act 2012-1442 of 24 December 2012 suspends the import and placing on the market, either free of charge or against payment, of any packaging, container or utensil comprising bisphenol A and intended to come into direct contact with all foodstuffs as from 1 January 2015 (see the DGCCRF's implementation guidelines).

*NOTE: The term constituent covers substances.

3.2.2.2 Non-stick coatings

In the absence of proof of the non-use of chromates in the manufacturing process, search for the presence of chromates in the non-stick coating interface.

3.2.3 Final product

Materials and articles at the finished-product stage (coated metals) must meet requirements with respect to 1) specific migration* of those coating constituents that are subject to specific limits, 2) specific release limits for metals, alloy components and impurities listed in Appendix I of this document, 3) overall migration limits, and 4) where appropriate, residual contents of constituents, under normal or foreseeable usage conditions.

* Verification of specific migration limits provided shall not be compulsory, if it can be established that the migration potential, calculated based on the residual content of the substance in the material or article and assuming complete migration of this substance (or by applying generally recognised diffusion models based on scientific evidence that are established in a way as to overestimate real migration levels) does not exceed the specific migration limit.

4. Acceptability limits

4.1 Steel only

The steel meets the chemical composition requirements set out in the "Uncoated steels for packaging (blackplate)" and "Tin-coated steel" sheets.

In the case of chromium-coated steel, specific requirements are laid out in the standard NF EN 10335.

4.2 Final product

The **specific migration limits**, maximum and/or residual quantities of monomers, other starting substances and additives are those of in Annex I of Regulation (EU) No 10/2011 of 14 January 2011 for the constituent elements listed therein, or those found in relevant scientific opinions and assessments.

The specific release limits of metals, alloy components and impurities are those set out in Appendix I of this document.

The limits for epoxy derivatives are those set out in Regulation (EC) 1895/2005.

The **overall migration limit** is 10 mg/dm² of the food contact area. An exception has been made for food contact materials and articles for infants (less than 12 months old) and small children (one to three years old), for whom the overall migration limit is 60 mg/kg of food simulant.

For hexavalent chromium, the limit is non-detection with a detection threshold of 5 μ g/dm² (Opinion of the CSHPF, Session of 13 February 1996, BOCCRF no. 8 of 24 May 1996).



5. Rules for checking the criteria defined in Paragraph 3

5.1 Steel only

The manufacturer of the steel provides the manufacturer of the packaging with a report analysing the chemical composition.

5.2 Coating only

To verify the criteria, the following information must be provided to the laboratory in charge of analyses,* which may have to sign a confidentiality agreement:

- **Coating references** (so as to allow them to be identified), description of the coated metal, coating family ;
- Identity of substances, type of restrictions for monomers, other starting substances and additives for which SMLs (Specific Migration Limits) or maximum residual quantities have been established, and, where appropriate, the impurities, products of degradation or other substances likely to pose a risk to human health ;
- **Information concerning the use of the materials and articles**: type of foodstuffs (or simulants), duration of contact and real contact temperature for these foodstuffs. Where appropriate, specific information about labelling and real surface area/volume ratio.

The manufacturer of the coating provides the manufacturer of the material or article with a written declaration of compliance with Regulation (EC) No 1935/2004, attesting to the compliance of the composition and, on the basis of migration tests carried out with the coating applied to an "inert" support (stainless steel or glass), of the overall migration and, where appropriate, the specific migrations of the coating's constituents that are subject to a specific migration limit, under test conditions that are representative of real usage. In the case of use of dual use additives, these shall be identified.

* in the case of outsourced testing

5.3 Finalproduct

At the stage of the final product, the inertia of the coating is checked on the ready-for-use article (specific migration/release of the constituents and overall migration).

The manufacturer of the finalproduct checks this inertia by means of specific migration/release tests and overall migration tests on the food simulants or foodstuffs on the basis of the specifications set out in Appendix II (metals and alloys with an organic coating).

Verification of specific migration limits provided shall not be compulsory, if it can be established that the migration potential, calculated based on the residual content of the substance in the material or article and assuming complete migration of this substance (or by applying generally recognised diffusion models based on scientific evidence that are established in a way as to overestimate real migration levels) does not exceed the specific migration limit.

For packaging of foodstuffs with a long shelf life, the match between packaging and foodstuff is checked by means of long-term testing, following a protocol specific to each manufacturer, in such a way as to ensure that the packaging has been effectively adapted to real usage conditions (mechanical and chemical resistance, etc.). These tests can also be in the form of accelerated ageing tests using a methodology based on scientific principles.



SHEET NO 4: UNCOATED STEEL (EXCLUDING PACKAGING)

1. Scope of application

This sheet deals with materials and articles made of uncoated, non-stainless steel¹ which, as final products, are intended for direct food contact.

It does not deal with articles covered by the "Steel for packaging" and "Stainless steel" sheets.

Application essentially relates to:

- Household articles: cake moulds, bread boards, frying pans, cutlery, cooking hobs.
- Agri-food industry equipment: silos and containers for dry foodstuffs (rice, etc.) or tubers.
- This sheet does not deal with high-alloy steels listed in Appendix III.

2. Specific limitations on the use of materials

It is recommended not to place these materials into contact with very acidic foodstuffs or beverages.

3. Definition of food contact suitability criteria

3.1 Reference texts

3.1.1. Regulatory texts

 Order of 15 November 1945 establishing a list of materials that may be used without harm to public health for the production 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 nonstainless) steels"
- NF A 35-596 "Iron and steel products Carbon steels for cutlery"

3.2 Criteria

3.2.1. Composition of the steel

Verification of the content of elements that make up the steel.

3.2.2 Maximum content in undesirable elements

In particular, verification of the content in lead, cadmium, arsenic and cobalt.

3.2.3 Specific Release Limits

Release limit for elements added intentionally and undesirable elements.

4. Acceptability limits

4.1. Composition of the steel

The supplier of the steel attests to the compliance with the chemical composition requirements set out in the following table.

Table — Chemical composition*

Specified elements	Maximum content
	in % mass

¹ Definition according to the standard NF EN 10020: Definition and classification of grades of steel



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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	Nitrogen	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 tak	en individually except iron	0.050	0.050
* The chemical elements included under the heading "Other elements taken individually" are			

* The chemical elements included under the heading "Other elements taken individually" are those which may appear in extremely small quantities, but which are not deliberately added during the steel manufacturing process.

4.2 Maximum content in undesirable elements

Pb < 0.05%

Cd < 0.01%

As < 0.03%

Co < 0.05%

4.3 Specific Release Limits

Refer to the release limits set in Appendix I and, in particular, the release limits of lead, cadmium, arsenic and cobalt.

5. Rules for checking the criteria defined in Paragraph 3

5.1 Steel only

The steel manufacturer provides the manufacturer of the finished article or item with a report analysing the chemical composition.

5.2 Final product

On the final product, inertia is checked on the ready-for-use article (specific release).

The manufacturer of the final product checks this inertia by means of release tests on the foodstuffs or food simulants on the basis of the specifications set out in Appendix II (uncoated metals and alloys or those with a metallic coating).



SHEET NO 5: COATED STEEL AND STAINLESS STEEL (EXCLUDING PACKAGING)

SHEET NO 5a

STEEL AND STAINLESS STEEL WITH METALLIC COATING

1. Scope of application

This sheet deals with steel¹ or stainless steel with metallic coating and objects made entirely of steel or stainless steel with metallic coating, which as final products are intended for food contact.

It does not deal with articles covered by the "Steel for packaging" and "Stainless steel" sheets.

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

The main examples of stainless steel metallic coatings are: gold, silver, chromium, quasicrystals. **This sheet does not deal with** articles in silver-plated metal, pending the outcome of work/discussions ongoing at the Council of Europe, on these types of articles (see Sheet No 9, "Articles coated in sundry metals").

Application essentially relates to:

- household articles: flatware, tableware, inner rotisseries, baking sheets, chip fryer dripping pans and vapour barriers
- agri-food industry equipment: tankers, grain silos, etc.

2. Specific limitations on the use of materials

It is recommended not to use steel or stainless steel coated in zinc or zinc alloys in contact with acidic foodstuffs.

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 above 100°C.

3. Definition of food contact suitability criteria

3.1. Reference texts

3.1.1 Regulatory texts

- Order of 13 January 1976 related to materials and articles made of stainless steel in contact with food products;
- Order of 15 November 1945 establishing a list of materials that may be used without harm to public health for the production of measuring instruments;
- Order of 28 June 1912 concerning the colouring, preservation and packaging of food products and beverages.

3.1.2 Other texts

• NF EN 610: Tin and tin alloys – Ingot tin ;

¹Definition according to the standard NF EN 10020: Definition and classification of grades of steel



- NF A 36 712-1: Unpackaged Steel metallic coated flat steel products intended for contact with foodstuffs, food products and beverages for human and animal consumption – Part 1: zinc or zinc alloy coated (non-stainless) steels ;
- NF A 36 712-2: Unpackaged Steel metallic coated flat steel products intended for contact with foodstuffs, food products and beverages for human and animal consumption – Part 2: aluminium or aluminium alloy coated (non-stainless) steels ;
- NF A 36 712-3: Unpackaged Steel metallic coated flat steel products intended for contact with foodstuffs, food products and beverages for human and animal consumption – Part 3: chromium-coated (non-stainless) steels;
- NF A 36 712-5: Unpackaged Steel metallic coated flat steel products intended for contact with foodstuffs, food products and beverages for human and animal consumption – Part 5: tin-coated (non-stainless) steels.

3.2 Criteria

3.2.1. Composition of the steel

Verification of the content of elements that make up the steel.

3.2.2 Maximum content in undesirable elements

Verification of the content in undesirable elements: lead, cadmium and arsenic.

3.2.3 Specific Release Limits

In particular, release limits of nickel, chrome or zinc when the coating has a nickel, chrome or zinc base; copper when a copper undercoat is used to improve adhesion, or depending on the composition of coatings.

4. Acceptability limits

4.1. Composition of the steel

The steel used as a support meets the chemical composition requirements set out in the "Non-packaging steel" and "Stainless steel" sheets.

4.2. Maximum content in undesirable elements

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

4.3 Specific Release Limits

Refer to the release limits set in Appendix I and, in particular, the release limits of nickel, chromium, zinc and copper according to the composition of the items, and the release limits of impurities: lead, arsenic and cadmium.

5. Rules for checking the criteria defined in Paragraph 3

5.1 Steel and stainless steel only

The steel or stainless steel manufacturer supplies the manufacturer of the final product with the following:

a) A written declaration of compliance with the Order of 13 January 1976 for stainless steels ;

b) An analysis report of the chemical composition, which must be in compliance with the Order of 13 January 1976 for stainless steels.

5.2 Final product

On the final product, inertia is checked on the ready-for-use article (specific release).

The manufacturer of the final product checks this inertia by means of release tests on the foodstuffs or food simulants on the basis of the specifications set out in Appendix II (uncoated metals and alloys or those with a metallic coating).



SHEET NO 5: COATED STEEL AND STAINLESS STEEL (EXCLUDING PACKAGING)

SHEET NO 5b

STEEL AND STAINLESS STEEL WITH ORGANIC COATING

1. Scope of application

This section deals with steel¹ or stainless steel with organic coating and objects made entirely of steel or stainless steel with organic coating, which as final products are intended for food contact.

It does not deal with articles covered by the "Steel for packaging" sheet.

It does not deal with steel with organic coating used in the following applications: outside covers of electrical household appliances; false ceilings; extractor hoods; walls and fittings of rooms; interiors of cold rooms, refrigerated or isothermic lorries.

Application essentially relates to:

- household articles such as pots and pans
- agri-food industry equipment: vats, tankers.

The primary examples of coatings are the following: lacquers, varnishes and polymer films (PTFE, resins, silicons, etc.).

2. Specific limitations on the use of materials

To avoid incorrect conditions of use for materials and articles intended for end consumers, the temperature limit for use must be specified on the labelling of objects.

3. Definition of food contact suitability criteria

3.1 Reference texts

- 3.1.1 Regulatory texts
 - Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food;
 - Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, amended;
 - Act 2010-729 of 30 June 2010 amended by Act 2012-1442 of 24 December 2012 regarding the suspension of marketing of all packaging containing bisphenol A intended to contain food products;
 - Order of 15 November 1945 establishing a list of materials that may be used without harm to public health for the production of measuring instruments;
 - Order of 13 January 1976 related to materials and articles made of stainless steel in contact with food products.

3.1.2 Other texts

 The Council of Europe's Framework Resolution ResAP(2004)1 on coatings intended to come into contact with foodstuffs;

¹ Definition according to the standard NF EN 10020:Definition and classification of grades of steel



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- NF EN 15136: materials and articles in contact with foodstuffs Epoxy derivatives subject to limitation – Determination of BADGE, BFDGE and their hydroxylated and chlorinated derivatives in food simulants;
- Sheets on steels not for packaging ;
- French archive documents on varnishes: see Sheet No 2a;
- "Code of Practice for Coated Articles Where the Food Contact Layer Is a Coating" European Council of the Paint, Printing Ink and Artists' Colours Industry – CEPE.

3.2 Criteria

3.2.1 Support/enamel coating used as an undercoat

Verification of the content of elements that make up the steel used as a support.

Where applicable, the composition of the enamel coating used as an undercoat must be compatible with use in contact with food for the organic coating (content in undesirable elements, notably lead, cadmium and arsenic).

Nevertheless, inertia is tested on the ready-for-use article.

3.2.2 Coating only

3.2.2.1 Varnishes/coatings

There is no specific French national legislation or harmonised EU regulation that covers food contact varnishes/coatings, or a positive list of components* for such varnishes/coatings.

The following lists of monomers, starting substances and additives are reference lists for coating constituents:

- Substances (monomers, starting substances and additives) listed in Regulation (EU) No 10/2011 of 14 January 2011, amended, taking account of determined restrictions and/or specifications (SMLs, residual contents, purity criteria, etc.);
- Varnishes and coatings substances assessed by the European Food Safety Authority (EFSA) using its own guidelines and which have been the subject of a favourable opinion by the EFSA;
- Substances that have been the subject of a favourable opinion by the Scientific Committee on Food (SCF) (Lists 0 to 4), website: <u>http://ec.europa.eu/food/fs/sc/scf/index_en.html</u>;
- List of assessed substances in Framework Resolution ResAp (2004) 1 on the varnishes in Part A: List 1 of monomers and Part C: List 1 of additives ;
- Varnish and coatings substances assessed in application of the European Food Safety Authority's guidelines, or equivalent guidelines, and which have been the subject of a favourable opinion by a competent scientific body in one of the EU Member States, Turkey or a State which is party to the agreement on the European Economic Area (taking account of determined restrictions and/or specifications);
- Varnish and coatings substances that are the subject of an authorisation in a regulatory text by an EU Member State concerning food contact varnishes, based on a scientific assessment conducted since 1991 in accordance with SCF/EFSA guidelines and which have been the subject of a favourable opinion by a competent scientific body in an EU Member State, taking account of determined restrictions and/or specifications (SMLs, residual contents, purity criteria, etc.).

Other constituents may be used in the production of coatings and varnishes, provided that a risk assessment in compliance with internationally-recognised scientific risk assessment principles can be provided to demonstrate compliance with Article 3 of the aforementioned Regulation (EC) No 1935/2004.

Specifically, constituents that have been the subject of an authorisation in a regulatory text by an EU Member State concerning food contact varnishes, based on a scientific assessment conducted prior to 1991 applying the criteria existing at the time, may be used provided that supplementary toxicological data can be provided based on the nature of these constituents and their migration and exposure levels, in order to demonstrate compliance with Article 3 of Regulation (EC) No 1935/2004.



Constituents used in the manufacture of varnishes and coatings, including their impurities, which have not been the subject of a scientific risk assessment in accordance with EFSA guidelines or equivalent guidelines and a favourable opinion by the EFSA or a competent scientific body in an EU Member State, must not be classified as Category 1 or 2 carcinogenic, mutagenic and reprotoxic substances (CMRs) in accordance with <u>Regulation (EC) No 1272/2008 of 16 December 2008, amended</u>, and must not be in a nanometric form.

Compliance with the criteria of Regulation (EC) No 1895/2005 of 18 November 2005 concerning BADGE and its derivatives.

Act 2010-729 of 30 June 2010, amended by Act 2012-1442 of 24 December 2012 suspends the import and placing on the market, either free of charge or against payment, of any packaging, container or utensil comprising bisphenol A and intended to come into direct contact with all foodstuffs as from 1 January 2015 (see the DGCCRF's implementation guidelines).

*NOTE: The term constituent covers substances.

3.2.2.2 Non-stick coating

In the absence of proof of the non-use of chromates in the manufacturing process, search for the presence of chromates in the non-stick coating interface.

3.2.3 Finalproduct

Materials and articles at the final-product stage (coated metals) must meet requirements with respect to 1) specific migration* of those coating constituents that are subject to specific limits, 2) specific release limits for metals, alloy components and impurities listed in Appendix I of this document, 3) overall migration limits, and 4) where appropriate, residual contents of constituents, under normal or foreseeable usage conditions.

* Verification of specific migration limits provided shall not be compulsory, if it can be established that the migration potential, calculated based on the residual content of the substance in the material or article and assuming complete migration of this substance (or by applying generally recognised diffusion models based on scientific evidence that are established in a way as to overestimate real migration levels) does not exceed the specific migration limit.

4. Acceptability limits

4.1 Steel or stainless steel only

The steel used as a support meets the chemical composition requirements set out in the "Uncoated steels for packaging (blackplate)" or "Tin-coated steel" sheets or in the standard NF EN 10335 for chromed steel.

Stainless steel must meet the chemical composition requirements set out in the Order of 13 January 1976.

The manufacturer verifies this composition.

The supplier of the stainless steel attests to the compliance with the chemical composition requirements, and the manufacturer checks these compositions.

4.2 Final product

The **specific migration limits**, maximum and/or residual quantities of monomers, other starting substances and additives are those of Annex I of Regulation (EU) No 10/2011 of 14 January 2011 for the constituents listed therein, or given in other relevant scientific assessments and opinions.

The specific release limits of metals, alloy components and impurities are those set out in Appendix I of this document.



The limits for epoxy derivatives are those set out in Regulation (EC) 1895/2005.

The **overall migration limit** is 10 mg/dm² of the food contact area. An exception has been made for food contact materials and articles for infants less than 12 months old and small children one to three years old, for whom the overall migration limit is 60 mg/kg of food simulant.

For hexavalent chromium, the limit is non-detection with a detection threshold of 5 μ g/dm² (Opinion of the CSHPF, Session of 13 February 1996, BOCCRF no. 8 of 24 May 1996).

5. Rules for checking the criteria defined in Paragraph 3

5.1 Steel or stainless steel only

The steel or stainless steel manufacturer supplies the manufacturer of the final product with the following :

a) An analysis report of the chemical composition and a written declaration of compliance with the Order of 13 January 1976 for stainless steels;

b) An analysis report of the chemical composition for steel.

5.2 Coating only

To verify the criteria, the following information must be provided to the laboratory in charge of analyses,* which may have to sign a confidentiality agreement:

- **Coating references** (so as to allow them to be identified), description of the coated metal, coating family ;
- Identity of substances, type of restrictions for monomers, other starting substances and additives for which SMLs (Specific Migration Limits) or maximum residual quantities have been established, and, where appropriate, the impurities, products of degradation or other substances likely to pose a risk to human health;
- Information concerning the use of the materials and articles: type of foodstuffs (or simulants), duration of contact and real contact temperature for these foodstuffs Where appropriate, specific information about labelling and real surface area/volume ratio.

The manufacturer of the coating provides the manufacturer of the material or article with a written declaration of compliance with Regulation (EC) No 1935/2004, attesting to the compliance of the composition and, on the basis of migration tests carried out with the coating applied to an "inert" support (stainless steel or glass), of the overall migration and, where appropriate, the specific migrations of the coating's constituents that are subject to a specific migration limit, under test conditions that are representative of real usage. In the case of use of dual use additives, these shall be identified.

* in the case of outsourced testing

5.3 Final product

At the stage of the finalproduct, the inertia of the coating is checked on the ready-for-use article (specific migration/release of the constituents and overall migration).

The manufacturer of the finalproduct checks this inertia by means of specific migration/release tests and overall migration tests on the food simulants or foodstuffs on the basis of the specifications set out in Appendix II (metals and alloys with an organic coating).

Verification of specific migration limits provided shall not be compulsory, if it can be established that the migration potential, calculated based on the residual content of the substance in the material or article and assuming complete migration of this substance (or by applying generally recognised diffusion models based on scientific evidence that are established in a way as to overestimate real migration levels) does not exceed the specific migration limit.

For packaging of foodstuffs with a long shelf life, the match between packaging and foodstuff is checked by means of long-term testing, following a protocol specific to each manufacturer, in such a way as to ensure that the packaging has been effectively adapted to real usage conditions



(mechanical and chemical resistance, etc.). These tests can also be in the form of accelerated ageing tests using a methodology based on scientific principles.



SHEET NO 6: UNALLOYED CAST IRON

SHEET NO 6a

UNALLOYED CAST IRON UNCOATED OR WITH METALLIC COATING

1. Scope of application

This sheet deals with cast iron (an alloy of iron and carbon, with carbon content ranging from 2.1% to 6.7%), unalloyed, and either uncoated or not with a metallic coating, as well as objects made exclusively of unalloyed cast iron (uncoated or not with a metallic coating) which as final products are intended for food contact.

The main examples of metallic coatings are: nickel and chromium

Application essentially relates to:

- Household articles: cooking hobs, baking sheets, cooking utensils, grills, grinders, etc.
- Agri-food industry equipment: pipes, machine casings, cooking elements, etc.

2. Specific limitations on the use of materials

Do not leave utensils in contact with acidic foodstuffs before or after cooking.

3. Definition of food contact suitability criteria

3.1 Regulatory texts

Order of 15 November 1945 establishing a list of materials that may be used without harm to public health for the production of measuring instruments.

3.2 Criteria

3.1.2. Maximum content (cast iron only + coating where applicable)

Verification of the content in undesirable elements. In particular, verification of the content in lead, cadmium and arsenic.

3.2.2 Specific Release Limits

In particular, the release limits of lead, cadmium, arsenic, iron, and in the presence of a metallic coating, chromium and nickel.

4. Acceptability limits

4.1 Maximum content (medium + coating where applicable)

 $Pb \le 0.050\%$ $Cd \le 0.010\%$ $As \le 0.030\%$

$AS \le 0.030\%$

4.2 Specific Release Limits

Refer to the release limits set in Appendix I and, in particular, the release limits of lead, cadmium, arsenic, iron, and in the presence of a metallic coating, chromium and nickel.

5. Rules for checking the criteria defined in Paragraph 3

5.1 Cast iron only/metallic coating

The manufacturer of the cast iron provides the manufacturer of the final product with a report analysing the chemical composition.



The manufacturer of the metallic coating provides the manufacturer of the final product with a report analysing the chemical composition.

5.2 Final product

The manufacturer of the final product verifies the composition of the cast iron and, where applicable, the metallic coating.

On the final product, inertia is checked on the ready-for-use article (specific release of metals, alloy components and impurities).

The manufacturer of the final product checks this inertia by means of release tests on the foodstuffs or food simulants on the basis of the specifications set out in Appendix II (uncoated metals and alloys or those with a metallic coating).



SHEET NO 6: UNALLOYED CAST IRON

SHEET NO 6b UNALLOYED CAST IRON WITH ORGANIC COATING

1. Scope of application

This sheet deals with unalloyed cast iron (an alloy of iron and carbon, with carbon content ranging from 2.1% to 6.7%), with an organic coating, with or without an intermediary coating (of metal or enamel), as well as objects made exclusively of unalloyed cast iron with an organic coating which as final products are intended for food contact (repeated use or not).

The primary examples of coatings are the following: lacquers, varnishes and polymer films (PTFE, resins, silicons, etc.)

Application essentially relates to:

- Household articles: serving dishes, fryers, cooking utensils
- Agri-food industry equipment: cooking elements, etc.

This sheet does not deal with articles with hybrid organic/inorganic coatings (such as those derived from the sol-gel process).

2. Specific limitations on the use of materials

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

3. Definition of food contact suitability criteria

3.1 Reference texts

3.1.1. Regulatory texts

- Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food;
- Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, amended;
- Act 2010-729 of 30 June 2010 amended by Act 2012-1442 of 24 December 2012 regarding the suspension of marketing of all packaging containing bisphenol A intended to contain food products (the case for household articles for this sheet);

3.1.2 Other texts

- The Council of Europe's Framework Resolution ResAP(2004)1 on coatings intended to come into contact with foodstuffs;
- NF EN 15136: Materials and articles in contact with foodstuffs Epoxy derivatives subject to limitation – Determination of BADGE, BFDGE and their hydroxylated and chlorinated derivatives in food simulants;
- French archive documents on varnishes: see Sheet No 2a;
- "Code of Practice for Coated Articles Where the Food Contact Layer Is a Coating" European Council of the Paint, Printing Ink and Artists' Colours Industry – CEPE ;

3.2 Criteria

3.2.1 Support/enamel coating used as an undercoat

Verification of the content of elements that make up the cast iron used as a support.



Where applicable, the composition of the enamel coating used as an undercoat must be compatible with use in contact with food for the organic coating (content in undesirable elements, notably lead, cadmium and arsenic).

Nevertheless, tests are carried out on the ready-for-use article.

3.2.2 Coating only

3.2.2.1 Varnishes/coatings

There is no specific French national legislation or harmonised EU regulation that covers food contact varnishes/coatings, or a positive list of components* for such varnishes/coatings.

The following lists of monomers, starting substances and additives are reference lists for coating constituents:

- Substances (monomers, starting substances and additives) listed in Regulation (EU) No 10/2011 of 14 January 2011, amended, taking account of determined restrictions and/or specifications (SMLs, residual contents, purity criteria, etc.);
- Varnishes and coatings substances assessed by the European Food Safety Authority (EFSA) using its own guidelines and which have been the subject of a favourable opinion by the EFSA;
- Substances that have been the subject of a favourable opinion by the Scientific Committee on Food (SCF) (Lists 0 to 4), website: <u>http://ec.europa.eu/food/fs/sc/scf/index_en.html</u>;
- List of assessed substances in Framework Resolution ResAp (2004) 1 on the varnishes in Part A: List 1 of monomers and Part C: List 1 of additives ;
- Varnish and coatings substances assessed in application of the European Food Safety Authority's guidelines, or equivalent guidelines, and which have been the subject of a favourable opinion by a competent scientific body in one of the EU Member States, Turkey or a State which is party to the agreement on the European Economic Area (taking account of determined restrictions and/or specifications);
- Varnish and coatings substances that are the subject of an authorisation in a regulatory text by an EU Member State concerning food contact varnishes, based on a scientific assessment conducted since 1991 in accordance with SCF/EFSA guidelines and which have been the subject of a favourable opinion by a competent scientific body in that EU Member State, taking account of determined restrictions and/or specifications (SMLs, residual contents, purity criteria, etc.).

Other constituents may be used in the production of coatings and varnishes, provided that a risk assessment in compliance with internationally-recognised scientific risk assessment principles can be provided to demonstrate compliance with Article 3 of the aforementioned Regulation (EC) No 1935/2004.

Specifically, constituents that have been the subject of an authorisation in a regulatory text by an EU Member State concerning food contact varnishes, based on a scientific assessment conducted prior to 1991 applying the criteria existing at the time, may be used provided that supplementary toxicological data can be provided based on the nature of these constituents and their migration and exposure levels, in order to demonstrate compliance with Article 3 of Regulation (EC) No 1935/2004.

Constituents used in the manufacture of varnishes and coatings, including their impurities, which have not been the subject of a scientific risk assessment in accordance with EFSA guidelines or equivalent guidelines and a favourable opinion by the EFSA or a competent scientific body in an EU Member State, must not be classified as Category 1 or 2 carcinogenic, mutagenic and reprotoxic substances (CMRs) in accordance with <u>Regulation (EC) No 1272/2008 of 16 December 2008, amended</u>, and must not be in a nanometric form.

Compliance with the criteria of Regulation (EC) No 1895/2005 of 18 November 2005 concerning BADGE and its derivatives.



Act 2010-729 of 30 June 2010, amended by Act 2012-1442 of 24 December 2012 suspends the import and placing on the market, either free of charge or against payment, of any packaging, container or utensil comprising bisphenol A and intended to come into direct contact with all foodstuffs as from 1 January 2015 (see the DGCCRF's implementation guidelines).

*NOTE: The term constituent covers substances.

3.2.2.2 Non-stick coating

In the absence of proof of the non-use of chromates in the manufacturing process, search for the presence of chromates in the non-stick coating interface.

3.2.3 Final product

Materials and articles at the final-product stage (coated metals) must meet requirements with respect to 1) specific migration* of those coating constituents that are subject to specific limits, 2) specific release limits for metals, alloy components and impurities listed in Appendix I of the present sheet, 3) overall migration limits, and 4) where appropriate, residual contents of constituents, under normal or foreseeable usage conditions.

* Verification of specific migration limits provided shall not be compulsory, if it can be established that the migration potential, calculated based on the residual content of the substance in the material or article and assuming complete migration of this substance (or by applying generally recognised diffusion models based on scientific evidence that are established in a way as to overestimate real migration levels) does not exceed the specific migration limit.

4. Acceptability limits

4.1 Cast iron only

The supplier of the cast iron attests to the compliance with the chemical composition requirements set out in the "Unalloyed cast iron uncoated or with metallic coating" sheet. The manufacturer verifies this composition.

4.2 Final product

The **specific migration limits** and the maximum and/or residual quantities of monomers, other starting substances and additives are those of Annex I of Regulation (EU) No 10/2011 of 14 January 2011 for the constituents that are listed there, or those found in relevant scientific opinions and assessments.

The specific release limits of metals, alloy components and impurities are those set out in Appendix I of this document.

The limits for epoxy derivatives are those set out in Regulation (EC) 1895/2005.

The **overall migration limit** is 10 mg/dm² of the food contact area. An exception has been made for food contact materials and articles for infants less than 12 months old and small children one to three years old, for whom the overall migration limit is 60 mg/kg of food simulant.

For hexavalent chromium, the limit is non-detection with a detection threshold of 5 μ g/dm² (Opinion of the CSHPF, Session of 13 February 1996, BOCCRF no. 8 of 24 May 1996).

5. Rules for checking the criteria defined in Paragraph 3

5.1 Cast iron only

The manufacturer of the cast iron provides the manufacturer of the final product with a report analysing the chemical composition.



5.2 Coating only

To verify the criteria, the following information must be provided to the laboratory in charge of analyses,* which may have to sign a confidentiality agreement:

- **Coating references** (so as to allow them to be identified), description of the coated metal, coating family ;
- Identity of substances, type of restrictions for monomers, other starting substances and additives for which SMLs (Specific Migration Limits) or maximum residual quantities have been established, and, where appropriate, the impurities, products of degradation or other substances likely to pose a risk to human health;
- Information concerning the use of the materials and articles: type of foodstuffs (of simulants), duration of contact and real contact temperature for these foodstuffs. Where appropriate, specific information about labelling and real surface area/volume ratio.

The manufacturer of the coating provides the manufacturer of the material or article with a written declaration of compliance with Regulation (EC) No 1935/2004, attesting to the compliance of the composition and, on the basis of migration tests carried out with the coating applied to an "inert" support (stainless steel or glass), of the overall migration and, where appropriate, the specific migrations of the coating's constituents that are subject to a specific migration limit, under test conditions that are representative of real usage. In the case of use of dual use additives, these shall be identified.

* in the case of outsourced testing

5.3 Final product

The manufacturer of the final product verifies the composition of the cast iron.

At the stage of the final product, the inertia of the coating is checked on the ready-for-use article (specific migration/release of the constituents and overall migration).

The manufacturer of the final product checks this inertia by means of specific migration/release tests and overall migration tests on the food simulants or foodstuffs on the basis of the specifications set out in Appendix II (metals and alloys with an organic coating).

Verification of specific migration limits provided shall not be compulsory, if it can be established that the migration potential, calculated based on the residual content of the substance in the material or article and assuming complete migration of this substance (or by applying generally recognised diffusion models based on scientific evidence that are established in a way as to overestimate real migration levels) does not exceed the specific migration limit.



Fiche MCDA n°1 (V02 – 01/04/2017) Food contact suitability of metals and alloys - Only the French version is the official version -

SHEET NO 7: TIN AND TIN ALLOYS

1. Scope of application

This sheet deals with tin or tin alloys and articles coated exclusively in tin or tin alloy or partially tin-plated, which as final products are intended for food contact.

• This sheet does not deal with tin-coated articles covered by the "Steel for packaging with metallic coating" and "Steel and stainless steel with metallic coating (excluding packaging)" sheets and foodstuffs in tins and beverages in cans whose maximum tin content is regulated by Regulation (EC) No 1881/2006 of 19 December 2006.

- Application essentially relates to:
 - Household articles: Measuring instruments, pots, dishes, plates, utensils, etc.
 - Agri-food industry equipment, closures for metal tins, etc.

2. Specific limitations on the use of materials

- It is forbidden to put any beverages or foodstuffs in direct contact with recipients, utensils and equipment that are tin-plated or welded with tin containing more than 0.5% of lead or more than 3/10,000ths of arsenic or less than 97% of tin determined as metastannic acid (Order of 28 June 1912);
- It is recommended not to use these materials in contact with highly-acidic or highly-alkaline foodstuffs or to heat the foodstuffs to temperatures of over 150°C ;
- Moreover, it is not advisable to preserve foodstuffs in household articles or agri-foodstuff equipment made from tin or tin alloy or coated in tin or tin alloy.

3. Definition of food contact suitability criteria

3.1 Reference texts

3.1.1 Regulatory texts

- Commission Regulation (EC) No 1881/2006 of 19 December 2006 (amended) setting maximum levels for certain contaminants in foodstuffs;
- Order of 28 June 1912 concerning the colouring, preservation and packaging of food products and beverages;
- Order of 15 November 1945 establishing a list of materials that may be used without harm to public health for the production of measuring instruments.

3.1.2 Other texts

- Decree no. 76-492 of 28 May 1976 implementing the Act of 1 August 1905 on fraud control, in respect of trading in tin articles;
- Standard NF EN 611-1 Tin and tin alloys Pewter and pewterware Part 1: Pewter (*to be reviewed*).

3.2 Criteria

3.2.1 Maximum content

In particular, check the content in tin, lead, cadmium, arsenic, antimony and copper.

3.2.2 Specific Release Limits

In particular, release limits of tin, antimony, arsenic, copper, lead and cadmium.



4. Acceptability limits

4.1 Maximum content

 $\begin{array}{l} Sn \geq 97 \ \% \\ Pb \leq 0.050\% \\ Cd \leq 0.010\% \\ As \leq 0.030\% \\ Sb \leq 2.5\% \\ Cu \leq 1.5\% \end{array}$

4.2 Specific Release Limits

Refer to the release limits set in Appendix I and, in particular, those for tin, antimony, arsenic, copper, lead and cadmium.

5. Rules for checking the criteria defined in Paragraph 3

5.1 Tin or tin alloy alone

The manufacturer of the tin or tin alloy provides the manufacturer of the finished material or article with a report analysing the chemical composition.

5.2 Final product

The manufacturer of the final product verifies the composition of the tin or tin alloy.

On the final product, inertia is checked on the ready-for-use article (specific release).

The manufacturer of the final product checks this inertia by means of release tests on the basis of the specifications set out in Appendix II (uncoated metals and alloys or those with a metallic coating).



Fiche MCDA n°1 (V02 – 01/04/2017) Food contact suitability of metals and alloys - Only the French version is the official version -

SHEET NO 8: ZINC AND ZINC ALLOYS

1. Scope of application

This sheet deals with zinc or zinc alloys and articles constituted exclusively of zinc or zinc alloys, and zinc-coated metals, which as final products are intended for food contact.

This sheet does not deal with zinc-coated objects covered by the "Steel and stainless steel with metallic coating (excluding packaging)" sheet.

- Application essentially relates to:
 - Household articles: measuring instruments, etc.
 - Agri-food industry equipment: measuring instruments, chocolate, confectionery production, etc.

2. Specific limitations on the use of materials

- It is forbidden to put any beverages or foodstuffs in direct contact with zinc and galvanised iron, except for producing or preserving chocolate and confectionery products which do not contain liquid acidic substances and for distillery operations. Direct use of zinc and galvanised iron has been extended to roots, tubers, bulbs, fruit with husks, seeds, dry vegetables and leaf vegetables.
- Use restricted to the field of application.
- It is recommended not to use other metals and alloys coated in zinc or zinc alloys for contact with acidic foodstuffs.

3. Definition of food contact suitability criteria

3.1 Reference texts

3.1.1 Regulatory texts

- Order of 28 June 1912 concerning the colouring, preservation and packaging of food products and beverages;
- Order of 15 November 1945 establishing a list of materials that may be used without harm to public health for the production of measuring instruments.

3.1.2 Other texts

- Standard EN 1179 Zinc and zinc alloys Primary zinc September 2003 (characteristics of zinc);
- Standard EN 12844 Zinc and zinc alloys Castings Specifications February 1999 (characteristics of zinc alloys);



3.2 Criteria

3.2.1 Composition of zinc (articles only in zinc)

Verification of the content in impurities (lead, cadmium, iron, tin, copper, aluminium).

3.2.2 Maximum content in undesirable elements

In particular, verification of the content in lead, cadmium and arsenic.

3.2.3 Specific Release Limits

In particular, release limits of zinc, lead, cadmium and arsenic.

4. Acceptability limits

4.1 Content in impurities (articles in zinc alone)

Total of content in impurities $\leq 0.15\%$ (lead, cadmium, iron, tin, copper, aluminium).

4.2 Maximum content in undesirable elements

 $\begin{array}{l} Pb \leq 0.05\% \\ Cd \leq 0.010\% \\ As \leq 0.030\% \end{array}$

4.3 Specific Release Limits

Refer to the release limits set in Appendix I and, in particular, the release limits of zinc, lead, cadmium and arsenic.

5. Rules for checking the criteria defined in Paragraph 3

5.1 Zinc and zinc alloys

The manufacturer of the zinc or zinc alloy provides the manufacturer of the final products with a report analysing the chemical composition.

5.2 Final product

On the final product, inertia is checked on the ready-for-use article (specific release).

The manufacturer of the final product checks this inertia by means of release tests on the foodstuffs or food simulants on the basis of the specifications set out in Appendix II (uncoated metals and alloys or those with a metallic coating).



SHEET NO 9: ARTICLES COATED IN SUNDRY METALS

1. Scope of application

This sheet deals with metals and alloys with a metallic coating ("white metal"), other than those already covered by the other sheets on metals, which as final products are intended for food contact.

<u>White metal</u>: metallic article covered with a fine white deposit (thin layer) such as silver, nickel, tin, chromium, copper, or a combination of these elements.

The main examples of metal mediums are as follows: copper or copper alloy, zinc or zinc alloy, tin or tin alloy, stainless steel

The main examples of contact metallic coatings are nickel, silver, gold, copper, tin and chromium.

Application essentially relates to: tea or coffee services, bowls, tumblers, trays, cake tongs and servers, pie dishes, cutlery, etc.

This sheet also deals with other sundry metal articles with a metallic coating.

This sheet does not deal with articles in solid silver or silver-plated metal, pending the outcome of work/discussions ongoing at the Council of Europe on these types of articles.

Only articles (excluding jewellery) that are at least 500 thousandths silver-coated, bearing a manufacturer's hallmark and that are at least 10 microns thick, may be classified as silver-plated articles. Silver-coated articles that do not meet these criteria may not be called "silver-plated metal" but "white metal".

2. Specific limitations on the use of materials

- It is recommended not to use articles in sundry metals coated in white metal for contact with acidic foodstuffs.
- Where applicable, refer to the restrictions on use set out in the sheets on single metals (zinc and tin).

3. Definition of food contact suitability criteria

3.1. Reference texts

3.1.1. Regulatory texts

- Order of 28 June 1912 concerning the colouring, preservation and packaging of food products and beverages;
- Order of 15 November 1945 establishing a list of materials that may be used without harm to public health for the production of measuring instruments.

3.1.2. Other texts

- Act no. 83-558 of 1 July 1983 amending certain provisions of the General Tax Code (CGI) on the guarantee of fineness of gold, silver and platinum;
- Decree no. 84-623 of 16 July 1984 on regulations for the guarantee of fineness of materials and pieces in platinum, gold or silver;
- Standards of the NF EN ISO 8442 series Materials and articles in contact with foodstuffs -Cutlery and table holloware (cutlery in white metal/silver-plated metal);



 Standard NF D 29-00 - Cutlery and table holloware - features of the electrolyte deposit (January 1984).

3.2. Criteria

3.1.2. Maximum content (medium + coating where applicable)

In particular, verification of the content in nickel, silver, copper, tin, chromium, zinc and in undesirable elements: lead, arsenic and cadmium.

3.2.2 Specific Release Limits

In particular, release limits of nickel, silver, copper, tin, chromium, zinc, lead, arsenic and cadmium according to the composition of the articles.

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 Release Limits

Refer to the release limits set in Appendix I and, in particular, the release limits of nickel, silver, copper, tin, chromium, zinc, lead, arsenic and cadmium according to the composition of the articles.

5. Rules for checking the criteria defined in Paragraph 3

5.1 Support

The manufacturer of the support and/or coating provides the manufacturer of the finished material or article with a report analysing the chemical composition.

5.2 Final product

On the final product, inertia is checked on the ready-for-use article (specific release).

The manufacturer of the final product checks this inertia by means of release tests on the basis of the specifications set out in Appendix II (uncoated metals and alloys or those with a metallic coating).



APPENDIX I: Specific Release Limits (SRLs)

Criteria update date: 01/04/2017

Metals and alloy components

Symbol	Chemical name	Specific Release Limit* (SRL) [mg/kg]
Ag	Silver	0.08
Al	Aluminium	5**
Со	Cobalt	0.02
Cr	Chromium (total)	0.250
Cu	Copper	4
Fe	Iron	40
Mg	Magnesium	-
Mn	Manganese	1.8
Мо	Molybdenum	0.12
Ni	Nickel	0.14
Sn***	Tin	100
Ti	Titanium	-
V	Vanadium	0.01
Zn	Zinc	5

* Details on the toxicological data used to draw up these SRLs are available in the Technical Guide to Resolution CM/Res(2013)9 on metals and alloys.

** Value established temporarily using the ALARA principle.

*** For tin, with the exception of the cases covered by Regulation (EC) No 1881/2006 of 19 December 2006.

Contaminants and impurities

Symbol	Chemical name	Specific Release Limit* (SRL) [mg/kg]
As	Arsenic	0.002
Ва	Barium	1.2
Be	Beryllium	0.01
Cd	Cadmium	0.005
Hg	Mercury	0.003
Li	Lithium	0.048
Pb	Lead	0.010
Sb	Antimony	0.04
TI	Thallium	0.0001



APPENDIX II: Test conditions

Criteria update date: 01/04/2017

Verification of the compliance of metals and alloys with Article 3 of Regulation (EC) No 1935/2004 of 27 October 2004 is carried out on foodstuffs or food simulants and according to the test criteria and conditions set out in parts I and II below:

I Foodstuffs and/or food simulants

Prevalence of test results**: migration/release tests in foodstuffs > migration/release tests in food simulants > composition specifications of materials and articles*.

* The composition specifications of materials and articles are in particular of interest when it is impossible to conduct migration/release tests.

** This is not applicable to materials and articles composed exclusively of stainless steel or aluminium or aluminium alloy, covered by a specific regulation.

> <u>Tests on foodstuffs</u>

As regards the choice of foodstuffs, taking account of the natural metal content in the foodstuffs and the tests on the packaging of foodstuffs, reference should be made to the Technical Guide to Resolution CM/Res(2013)9.

Test are conducted as a priority on foodstuffs in the following cases:

- When the article is already in contact with the foodstuff, for instance tinned food, beer kegs, etc. or is specifically intended for packaging (i.e. tins destined for the agri-food industry). Insofar as possible, tests are conducted on the foodstuffs' sell-by-date ;
- When the material or article is not in contact with a foodstuff (uses excluding packaging, for instance utensils used for food processing) but where the planned use of the foodstuffs or groups of foodstuffs is clearly indicated or is in no doubt (i.e. garlic crusher, tea infuser, etc.);
- When extreme physical conditions or abrasion takes place as part of normal use and cannot be reproduced under laboratory test conditions (i.e. pepper mills, coffee grinders or other devices for grinding nuts, grains, etc.).

If the "natural" metal content in the foodstuffs can have a substantial impact on the outcome of the analysis, it may be necessary to use a food simulant or another foodstuff, the choice of which, in this case, must be justified from a scientific standpoint.

In foodstuffs, release from packaging is affected by the properties of the packaging material, the physical and chemical properties of the foodstuffs and the atmospheric conditions (heat treatment of filled recipients, duration and temperature of preservation and the presence of residual oxygen after sealing, etc.). As a result, analyses are carried out in conditions representing the worst case scenario that is reasonably foreseeable and that encourages the release of metals as part of normal or reasonably foreseeable use factoring in, in particular, the contact time and temperature, and composition of the foodstuffs (especially pH and the nature of any salt or acid present).

Where applicable, checks are conducted on the foodstuff after it is put into contact with the industrial equipment by taking account of its life cycle (storage, transport, use, etc.) or on the packaged foodstuff until its use by date (UBD) or at least until its minimum durability date (MDD).



> Tests on food simulants

Food simulants are used:

- When the material or article may enter into contact with a wide range of foodstuffs that cannot be classified in a specific food category, such as kitchen utensils;
- When use with specific foodstuffs or groups of foodstuffs is not known or clearly indicated ;
- When it is not possible to test release using materials or articles directly in the foodstuffs either for technical reasons (for instance, when laboratory analysis is technically impossible) or for practical reasons (for instance, when the foodstuffs are unavailable).

The simulants used are those:

- of table 1 below for specific release tests of the constituent elements of uncoated metals and alloys or those with a metallic coating:

Type of foodstuff	Simulant
Contact with all foodstuffs, including	Citric acid 5 g/L*
acidic foodstuffs	
Contact with non-acidic foodstuffs	Artificial tap water**
(including dry foodstuffs)	

Table 1.

* Monoanhydride ** Standard NF EN 16889 July 2016 - Food hygiene - Production and distribution of hot beverages from hot beverage appliances - Hygiene requirements, migration test.

Approximate ion concentrations: calcium 16.4 mg/L, magnesium 3.3 mg/L, sodium 16 mg/L, hydrogen carbonate 44 mg/L, chloride 28.4 mg/L, sulphate 13 mg/L.

The pH value must be corrected to 7.5.

In the event of technical impossibility, distilled water should be used.

- of table 2 below for specific migration/release tests of the constituent elements of metals or alloys with an organic coating:

Type of foodstuff	Simulant
Contact with all non-acidic foodstuffs (including dry foodstuffs)	Simulants A, C, D1, D2 and E of table 1 of Annex III to Regulation (EU) No 10/2011, selected according to the relevant foodstuffs
Acidic foodstuffs (pH \leq 4.5)	Citric acid 5 g/L*

Table 2.

- of table 3 below for overall migration tests for metals and alloys with an organic coating:

Type of foodstuff	Simulant
Contact with all non-acidic foodstuffs***	Simulants A, C, D1, and D2 of table 1 of Annex III to Regulation (EU) No 10/2011,
	selected according to the relevant foodstuffs
Acidic foodstuffs (pH ≤ 4.5)	Ethanol 10%* for light foodstuff packaging (beverage cans, food tins, aerosols, yogurt lids, etc.)
	Acetic acid 3%** for other uses such as household utensils and articles (frying pans, saucepans, dishes, etc.) and equipment



* Tests are ongoing to confirm the use of citric acid 5 g/L for the overall migration for foodstuff packaging (beverage cans, food tins) with a method under which overall migration represents the loss of mass of the can/tin after contact with the simulant.

** Should the overall migration limit be exceeded with the acetic acid 3% simulant, it is possible to estimate, if applicable, the contribution of the metallic medium's attack to overall migration, by quantifying the metallic fraction of the extract. If this fraction is significant and higher than the overall migration limit, an extraction of chloroform from the organic part of the migration residue may be carried out. The mass of this extract is then compared with the 10 mg/dm² overall migration limit.

*** Dry foodstuffs are not concerned by overall migration tests.

Il Migration/release test conditions in the laboratory

The contact time and temperature of the tests constitute the worst case scenario foreseen or reasonably foreseeable. These conditions are based on the rules for specific migration testing set out in Regulation (EU) No 10/2011 of 14 January 2011.

First, reference should be made to table 4 below for the choice of these conditions:

Type of articles	Test conditions		
1) Testing for overall migration/release			
a) Articles than can be filled			
Long-term use at room temperature (without hot-fill)	10 days at 40°C		
Hot-fill* then, where applicable, short-term preservation at room temperature Examples: foodstuff packaging, bowls, dishes, etc.	2 hours at 70°C then, if applicable, 24 hours at 40°C		
Boiled liquids (articles and utensils used for cooking, flasks, etc.)	24 hours after hot-filling (simulant's reflux temperature) Storage at room temperature		
Any other use	Refer to the specific migration testing conditions set out in Annex V to Regulation (EU) No 10/2011.		
Articles for cold service (champagne or wine tumbler, ice cream bowl or spoon, etc.) with T<20°C	2 hours at 22°C(+/-2°C)		
b) Articles that cannot be filled, with the S/V ratio impossible to estimate			
Utensils for preparing and serving food, tableware, cutlery, etc.	2 hours at 70°C		
Articles with short-term contact such as scissors, stirrers, etc.	30 minutes at 70°C		
Table knives and forks	30 minutes at 70°C		
Tea or table spoons	Work/discussions are ongoing at the Council of Europe concerning the test conditions for these types of articles		
Utensils for preparing food at room temperature for a short period of time	30 minutes at 40°C		



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Examples: garlic crusher, cheese grater,		
nutcracker, vegetable peeler, tin opener, etc.		
Articles such as kitchen utensils, colander,	Full test by immersion in a depth of simulant	
potato masher, etc.	representing actual use. Test conditions	
	are chosen on the basis of specific use.	
Flat articles (chopping sheet, board, etc.)	Test by immersing the entire article or part of the article with surface area of approximatively 1 dm ² For chopping boards, it is assumed that contact with hot food is of short duration. The test is conducted for 2 hours at 70°C.	
Work surfaces	Long-term contact is assumed. The testing conditions are 10 days at 40°C.	
Baking sheets: cooking followed by long-term preservation at room temperature	2 hours at 100°C then 10 days at 40°C	
Any other use	Specific migration testing conditions set out in Annex V to Regulation (EU) No 10/2011	
2) Overall migration tests to be carried out on metals and alloys with an organic coating		

All articles and uses	Overall migration testing conditions set out	
	in Annex V to Regulation (EU) No 10/2011	
Table 4.		

* Contact for less than 30 minutes at a temperature of under 100°C.

III Conducting migration/release tests

For articles used repeatedly, if the tests are carried out on food simulants, contact is made three times in each tested sample, using a new portion of the simulant each time. The article should be rinsed with distilled water between each migration.

For uncoated metals or those with a metallic coating that are used repeatedly, compliance with the specific release limit of each element is verified from the simulant used during the third contact with the material. Nevertheless, the total outcomes for the first and second test must not exceed exposure equivalent to daily use for a week, i.e. seven times the specific release limit.

When **labelling information** is provided and recommends treatment of the materials and articles prior to their use (i.e. cleaning), such recommendations shall be complied with provided, nevertheless, that they do not depart from the conditions for use that may be reasonably foreseeable by the final consumer (refer also to chapter 3 of Resolution CM/Res(2013)9).

This labelling must be suitable, be connected with use that may be reasonably foreseeable by the consumer having regard to the nature of the article, as well as being sufficiently clear for the consumer.

> Method of analysing for uncoated metals and alloys or those with a metallic coating To measure specific release, the **determination method** put forward in chapter 3 of the Technical Guide to Resolution CM/Res(2013)9 should be used.

This method should be aligned with the analytical technique (ICP or ICP-MS) and according to the limit of detection (LOD) and limit of quantification (LOQ) for each element to be determined.

Method of analysing metals and alloys with an organic coating

Overall migration methods: Refer to standards of the series NF EN 1186.



Specific migration methods: Refer to standards of the series EN 13130 for certain methods for measuring specific migration. Also refer to standard XP CEN/TS 14234 of March 2003 (Polymer coverings on paper and board).

> Calculating the results of release tests

For kitchen articles whose surface area is difficult to calculate, the "envelope volume" method (Annex II to the Technical Guide on metals and alloys to Resolution Res(2013)9) should be used. This method enables a migration result in mg/kg to be obtained by using a basic calculation.

For all articles that cannot be filled and for which the S/V ratio is impossible to estimate, the conventional surface area/volume ratio of 6 dm² for 1 kg of food or 1L of simulant applies by default.

For materials and articles subject to dynamic contact (such as certain implements and equipment used in the agri-food industry), verification of compliance is carried out according to the results of the migration/release in static contact, on the basis of actual conditions of use that are known (volume of mass of foodstuffs, integrated contact time, temperature, etc.) or are the most detrimental (instance of multi-use).

Where applicable, dynamic contact may be factored in following the results of the static test, by calculation, on the basis of the flow rate of the foodstuff in the article or, where applicable, if the flow rate can be variable, a minimum flow rate may be calculated enabling the specific limit to be complied with.



APPENDIX III

Update date: 01/04/2017

The following table lists the materials (in solid state and/or in the form of a thick coating (stellite)) which are not covered by a specific sheet and for which the test specifications and specific release limits set out in Appendices I and II may be used as a reference to check compliance with Article 3 of the Framework regulation.

The compliance of these metals and alloys with Article 3 of the Framework regulation must be verified before they are marketed.

Metals and alloys	Comments	
Copper alloys	Phosphorous-copper, silver-copper, low alloyed copper alloys (less than 5% alloying elements), copper-aluminium alloys (aluminium bronzes), copper-nickel alloys (cupro-nickel), copper-nickel-zinc alloys (nickel silver or mailleshort), copper-tin alloys (bronzes), binary copper-zinc alloys (binary brass), copper-zinc-lead alloys (lead brass) and complex copper-zinc alloys (complex brass). (definitions in standard XP CEN/TS 13388)	
Titanium and titanium alloys	 Titanium is usually graded according to its structure: Alpha alloys (compact hexagonal structure) which include unalloyed titanium (for instance, ASTM grades 1 to 4) and titanium alloyed with palladium (for instance, ASTM grades 7 and 11). Near-alpha alloys which contain a small amount of beta phase (body-centred cubic structure) such as ASTM grade 12 (Ti-0.3%Mo0.8Ni), Ti-3%Al-2.5%V, etc. Alpha and beta alloys that enable high mechanical properties to be obtained, such as Ti-6%Al-4%V, the most-produced titanium alloy. Beta alloys such as Ti-3%Al-8%V-6%Cr-4%Zr-4%Mo, Ti-15%V-3%Cr-3%Sn-3%Al, etc. 	
Nickel alloys	 Although there are different systems for describing nickel alloys, they are mainly referred to by their commercial names. There are four main groups of nickel and nickel alloys: Commercially pure nickel with at least 99% nickel content. A three-figure number (2xx, 3xx) is used for the commercial reference. Nickel-copper alloys with around 30% copper content. NB: These are called "Monel". Those with added titanium and aluminium that are precipitation hardenable. Nickel-chromium-iron alloys that are not hardenable by heat treatment. They contain between 15% to 22% of chromium and up to 46% of iron. NB: They are referenced under the names "Inconel (Inconel 600)", "Incoloy" or "Hasteloy". But, alloys containing more iron than nickel are stainless steels. Nickel-chromium-iron alloys that are hardenable by heat treatment. 	

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	There are also cast nickel alloys whose composition is similar to that of the ASTM A-494 GR CY5SnBiM grade (around 13% of chromium, 4% of tin, 4% of bismuth and 3% of molybdenum).		
	NB: Cobalt alloys that may be used are principally stellites, "Tribaloys" or "Haynes 25".		
Cobalt alloys The matrix is a cobalt and chromium solid solution (around 30% chromium for stellite 6B, 8.5% for "Tribaloy T-400" and 17.5% for "Tribaloy") or cobalt-chromium-nickel (20% chromium and 10% nickel) "Haynes 25" with carbides dispersed in the matrix (essentially tungs carbides for the stellites or "Haynes 25" and molybdenum for "Tribaloys".			
Stellites are used either in solid state or as a coating.			
Magnesium alloys	Unalloyed magnesium is defined by standard NF EN 12421. The chemical composition of magnesium alloy ingots and casti		
	Wrought magnesium alloys are defined by standard ISC alloys by standard ISO 16220.	0 3116 and cast	
Cast unalloyed magnesium is defined by standard ISO 8287.			
The main alloy elements used are aluminium, zinc, mangan and sometimes copper, silver, silicon and rare-earth metal cerium).			
	Metal matrix composites containing carbides and, most of		
Carbides	NB: The metal bond is usually cobalt but a nickel bond is for food contact.	s generally used	
High-alloy steels	These are high-alloy steels (often classified amongst "to carbon content of over 1.20% which can therefore not stainless steels. They contain carburigen elements (W, N variable chromium content.	be classified as	

Table of Appendix III



APPENDIX IV

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

Description of t	he steel								% in ma	ISS			
Name	Number	С	Si	Mn	P max.	S	N max.	Cr	Мо	Nb	Ni	Ti	Other
		max.	max.	max.									
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					
X6CrAl13	1.4002	0.08	1.00	1.00	0.040	<u><</u> 0.015 ^b		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				4(C+N)+0.15≤0.80 ^c	
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≤0.80 ^c	
X3CrNb17	1.4511	0.05	1.00	1.00	0.040	< 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	< 0.015	0.020	16.00 to 18.00	0.80 to 1.40			4(C+N)+0.15≤Ti≤0.80 °	
X2CrMoTi18-2	1.4521	0.025	1.00	1.00	0.040	< 0.015	0.030	17.00 to 20.00	1.80 to 2.50			4(C+N)+0.15≤Ti≤0.80 °	
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	< 0.015	0.040	16.00 to 18.00	0.80 to 1.40	7(C+N)+0.10≤Nb≤1.00			
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≤0.80 ^c	Al: 1.70 to 2.10
X2CrNbTi20	1.4607	0.030	1.00	1.00	0.040	<u><</u> 0.015	0.030	18.50 to 20.50		1.00		4(C+N)+0.15≤Ti≤0.80 ^c	
X2CrTiNb18	1.4509	0.030	1.00	1.00	0.040	<u><</u> 0.015		17.50 to 18.50		3C+0.3≤ Nb ≤ 1.00		0.10 to 0.60	
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≤Ti≤1.00 ^c	
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≤0.80 ^c	
X2CrMnNiTi12	1.4600	0.030	1.00	1.00 to 2.50	0.040	<u><</u> 0.015	0.025	12.00 to 13.00			0.30 to 1.00	6C ≤ Ti ≤ 0.35	
X2CrTi21	1.4611	0.030	1.00	1.00	0.050	0.050		19.00 to 22.00	0.50			4(C+N)+0.20≤Ti≤1.00 ^c	Cu: 0.50 Al: 0.05
X2CrTi24*)	1.4613*)	0.030	1.00	1.00	0.050	0.050		22.00 to 25.00	0.50		0.50	4(C+N)+0.20≤Ti≤1.00 °	Cu: 0.50 Al: 0.05
X2CrNbCu21	1.4621	0.030	1.00	1.00	0.040	0.015	0.03	20.00 to 21.50		0.2≤ Nb ≤ 1.00			0.1 ≤ Cu ≤ 1.00
X2CrSiTi15	1.4630	0.030	0.20 to	1.00	0.050	0.050		13.00 to 16.00	0.50	0.50	0.50	4(C+N)+0.15≤Ti≤0.80 °	Cu: 0.50 Al: 1.50
X2CrCuNb18-2	1.4608	0.030	1.50 1.50	1.00	0.040	< 0.030		17.00 to 19.00		≤ 0.50			Cu: 1.50 to 2.50
72010UIND 10-2	1.4000	0.030	1.50	1.00	0.040	<u>< 0.030</u>		17.00 10 19.00		≥ 0.50			Nb>7x(C+N)
X2CrAlSiNb18	1.4634	0.030	0.20 to	1.00	0.050	0.050		17.50 to 18.50	0.50	3C+0.30≤Nb≤1.00 ^c	0.50		Cu: 0.50 Al: 0.20 to
		1	1.50										1.50

^a Elements not appearing in this table shall not be voluntarily added to the composition of the steel without the buyer's agreement, with the exception of those intended to produce the casting. All precautions must be taken to avoid addition from scrap and raw materials used to produce elements that could affect the mechanical properties and the steel's capacity for use.

^b For the relevant bars, wire rods, sections and semi-finished products, a maximum sulphur content of 0.030% applies.

For all products destined to be processed, a controlled sulphur content of between 0.015% and 0.030% is recommended and authorised.

^c Stabilisation can be carried out using titanium and/or niobium and/or zirconium. Owing to the atomic mass of these elements and the carbon and nitrogen content, the equivalence should be as follows:

 $\begin{array}{ccc} {\sf Ti} \simeq & {\sf 7} \ {\sf Nb} \sim & & {\textstyle \frac{7}{4}} \ {\sf Zr} \\ {\sf 4} \end{array}$

*) Patented steel grade



Table 2 - Chemical composition (casting analysis)^a of martensitic and precipitation hardenable stainless steels

Description of the	e steel						%	in mass				
Name	Number	Сь	Si	Mn	P max.	S	Cr	Cu	Мо	Nb	Ni	Other
			max.	max.								
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 ^c	13.00 to 14.00					
X30Cr13	1.4028	0.26 to 0.35	1.00	1.50	0.040	<u><</u> 0.015 ^c	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 ^c	13.00 to 14.50					
X46Cr13	1.4034	0.43 to 0.50	1.00	1.00	0.040	< 0.015 ^c	13.00 to 14.50					
X50CrMoV15	1.4116	0.45 to 0.55	1.00	1.00	0.040	<u><</u> 0.015 ^c	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	< 0.015 ^c	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 ^c	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 ^c	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 ^c	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 ^c	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	< 0.015 ^c	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	< 0.015 ^c	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 to	0.025	≤ 0.015	13.50 to 16.00		1.00 to 1.50		24.0 to 27.00	B: 0.0030 to 27.00
				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	< 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	< 0.07	0.70	1.00	0.040	< 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	

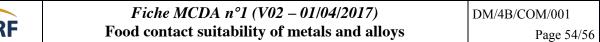
^a Elements not appearing in this table shall not be voluntarily added to the composition of the steel without the buyer's agreement, with the exception of those intended to produce the casting. All precautions must be taken to avoid addition from scrap and raw materials used to produce elements that could affect the mechanical properties and the steel's capacity for use.

^b Narrower carbon content brackets can be decided upon at the time of the invitation to tender and the order.

^c For the relevant bars, wire rods, sections and semi-finished products, a maximum sulphur content of 0.030% applies.

For all products destined to be processed, a controlled sulphur content of between 0.015% and 0.030% is recommended and authorised.

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



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

Description of the	e steel							% in mass		1		l	l
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 ^c	
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	
X5CrNiCu19-6-2	1.4640	0.030 to 0.08	0.50	1.50 to 4.0	0.045	≤0.015 ^b	0.03 to 0.11	18.0 to 19.0	1.30 to 2.00			5.5 to 6.9	
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 ^c	5xC to 0.7
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 ^c	
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 ^c	
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 ^c	
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 0.7
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 ^c	
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 9.00	0.040	≤ 0.030	0.10 to 0.30	15.00 to 18.00	2.00 to 3.50	≤ 1.00		≤ 3.00	
X8Cr MnNi19-6-3 X11CrNiMnN19-8-6	1.4376 1.4369	0.01 0.07 to 0.15	1.00 0.50 to 1.00	5.00 to 8.00 5.0 to 7.5	0.045 0.030	≤0.015 ≤ 0.015	0.30 0.20 to 0.30	17.0 to 20.5 17.50 to 19.50				2.00 to 4.50 6.50 to 8.50	

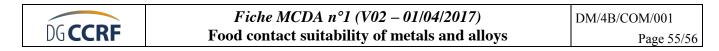


Table 3 - Chemical composition (casting analysis) ^a of austenitic stainless steels (contin

	Number	С	Si	Mn	Р	S	N	Cr	Cu	Mo	Nb	Ni	Ti
(3CrNiMo17 13 3					max.								
NOCITATIVIO 17 - 10-0	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 ^c	
K2CrNiMo18-14-3	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	
CCrNiMoN18-12-4	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 °	
K2CrNiMo18-15-4	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 °	
(1CrNiSi18-15-4	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	
(12CrMnNiN17-7-5	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	
K2CrMnNiN17-7-5	1.4371	≤0.030	≤1.00	6.00 to 8.00	0.045	≤0.015	0.15 to 0.25	16.00 to 17.50				3.50 to 5.50	
K12CrMnNiN18-9-5	1.4373	≤0.15	≤1.00	7.50 to 10.50	0.045	≤0.015	0.05 to 0.25	17.00 to 19.00				4.00 to 6.00	
K3CrNiCu19.9.2	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	
K3CrNiCu18-9-4	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	
K3CrNiCuMo17-11-3-2	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	
(13CrMnNiN18-13-2	1.4020	0.15	1.00	11.0 to 14.0	0.045	≤0.030	0.20 to 0.45	16.5 to 19.0				0.5 to 2.5	
K6CrMnNiN18-13-3	1.4378	0.08	1.00	11.5 to 14.5	0.060	≤0.030	0.20 to 0.40	17.0 to 19.0				2.3 to 3.7	
K6CrMnNiCuN18-12-4-2	1.4646	0.02 to 0.10	1.00	10.5 to 12.5	0.050	≤0.015 ^b	0.20 to 0.30	17.0 to 19.0	1.50 to 3.00	0.50		3.5 to 4.5	
K9CrMnNiCu17-8-5-2	1.4563 1.4618 1.4615	≤0.020 0.100	≤0.70 1.00	≤2.00 5.5 to 9.5 7.00 to 9.00	0.030 0.070 <0.040	≤0.010 0.010 <0.010	<u>≤</u> 0.11 0.15 0.02 to 0.06	26.00 to 28.00 16.5 to 18.5 14.00 to 16.00	0.70 to 1.50 1.00 to 2.50 2.00 to 4.00	< 4.00		30.00 to 32.00 4.5 to 5.5 4.5 to 6.0	

^a Elements not appearing in this table shall not be voluntarily added to the composition of the steel without the buyer's agreement, with the exception of those intended to produce the casting. All precautions must be taken to avoid addition from scrap and raw materials used to produce elements that could affect the mechanical properties and the steel's capacity for use.

^b For the relevant bars, wire rods, sections and semi-finished products, a maximum sulphur content of 0.030% applies. For all products destined to be processed, a controlled sulphur content of between 0.015% and 0.030% is recommended and authorised.

^c When for special reasons, for instance forgeability for manufacturing tubes without welding or low magnetic permeability, it is necessary to limit the delta ferrite content, the maximum Ni content may be increased by 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

*) Patented steel grade. The boron content is: B: 0.0005 to 0.0050

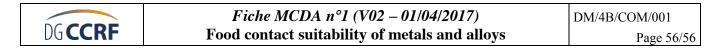


Table 4 -Chemical composition (casting analysis)^a of austenitic-ferritic stainless steels

Description of steel								% in mass				
Name	Number	C max	Si max	Mn max	P max	S max	Ν	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 24.5	0.10 to 0.60	0.10 to 0.60	3.50 to 5.50	
X2CrMnNiN21-5-1*)	1.4162*)	0.04	1.00	4.0 to 6.0	0.040	0.015	0.20 to 0.25	21.0 to 22.0	0.10 to 0.80	0.10 to 0.80	1.35 to 1.90	
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 ^b	0.05 to 0.20	25.00 to 28.00		1.30 to 2.00	4.50 to 6.50	
X2CrMnNiMoN21-5-3	1.4482	0.030	1.00	4.0 to 6.0	0.035	0.030	0.05 to 0.20	19.5 to 21.5	≤ 1 .00	0.10 to 0.60	1.5 to 3.5	
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	
X2CrNiMnMoCuN24-4-3-2*)	1.4662*)	0.03	0.70	2.50 to 4.00	0.035	0.005	0.20 to 0.30	23.0 to 25.0	0.10 to 0.80	1.00 to 2.00	3.0 to 4.5	
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
X2CrNiN22-2*)	1.4062*)	0.030	1.00	2.00	0.040	0.010	0.16 to 0.28	21.5 to 24.00		<u><</u> 0.45	1.00 to 2.90	
X2CrCuNiN23-2-2*)	1.4669*)	0.045	1.00	1.0 to 3.0	0.040	0.030	0.12 to 0.20	21.5 to 24.0	1.60 to 3.00	<u>0.50</u>	1.00 to 3.00	

^a Elements not appearing in this table shall not be voluntarily added to the composition of the steel without the buyer's agreement, with the exception of those intended to produce the casting. All precautions must be taken to avoid addition from scrap and raw materials used to produce elements that could affect the mechanical properties and the steel's capacity for use.

^b For the relevant bars, wire rods, sections and semi-final products, a maximum sulphur content of 0.030% applies.

For all products destined to be processed, a controlled sulphur content of between 0.015% and 0.030% is recommended and authorised.

*) Patented steel grade.



1- GENERAL INTRODUCTION

Article 3 of **Regulation** (EC) No 1935/2004 of 27 October 2004 foresees that food contact materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health, bring about an unacceptable change in the composition of the food or bring about a deterioration in the organoleptic characteristics thereof.

For certain categories of materials, the implementing legislation for this Regulation defines rules (composition, purity standards, etc.) for ensuring compliance with this inertness. In this way, specific directives, such as those concerning ceramic articles and regenerated cellulose films, or regulations, including ones dealing with plastic materials or active and intelligent materials, were adopted.

Moreover, in the absence of specific legislation that is applicable EU-wide for a given type of material, national regulations shall apply, such as those in France relating to stainless steel, aluminium and its alloys, rubbers and silicone elastomers.

Nevertheless, a certain number of materials have not yet been the subject of specific regulations, either at EU or national level, or are regulated in an incomplete fashion.

Amongst inorganic materials, only so-called "traditional" ceramic articles are currently subject to partial European Union regulation with Directive 84/500/EEC of 15 October 1984, transposed into French legislation by the Order of 7 November 1985.

In the absence of a specific regulatory text, the DGCCRF has drafted sheets for various types of materials. They are primarily intended for official control departments and laboratories. These sheets specify the means for verifying the food contact suitability of metals and alloys, and more specifically the means for verifying the principle of inertia set out in Article 3 of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004.

They have been the subject of a prior consultation with stakeholders representatives (competent laboratories in the area of FCMs, manufacturers and processors of such materials, agrifood industries, distributors, etc.).

They are available on the DGCCRF website so that operators can, in complete transparency, become informed about certain criteria and means used by the departments as part of official inspections.

The criteria listed in these sheets are not exhaustive. Other relevant criteria may be taken into account, depending on the nature, origin and composition of the materials, as well as treatments to which they are subjected.

2- SCOPE OF APPLICATION

The following inorganic materials are the subject of a specific sheet within this document: **Glass – Crystal – Ceramics – Glass ceramics – Enamelled articles**.

Metals and alloys are the subject of another specific sheet and do not fall within the scope of this document.

3- SPECIFIC DEFINITIONS AND ABBREVIATIONS

<u>Framework regulation</u>: Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004.

FCM: Food contact materials.



<u>Inorganic materials</u>: Materials made from non-metallic mineral elements, which include in particular ceramics, glass, crystal, glass ceramics, slate, concrete, stone, "technical" ceramics (obtained by sintering a dry powder without passing through a liquid state), etc.



GLASS – CRYSTAL – CERAMICS – GLASS CERAMICS – ENAMELLED ARTICLES

Last update of regulatory texts and reference documents referred to in these sheets: 1 May 2016

Last update of criteria referred to in these sheets: 1 May 2016

1. Scope of application

This sheet deals with materials made from glass, crystal, ceramics, glass ceramics and enamelled articles that, as finished products, are intended to be in contact with food.

The term **"glass**" refers to 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 may be decorated or not.

The term "**ceramic**" refers to a mixture of inorganic materials with a generally high clay or silicate content to which small quantities of organic materials may be added. Ceramic articles are first shaped, and the shape is then fixed permanently by firing. Ceramics can be glazed, enamelled and/or decorated.

This description refers to the so-called "traditional" (feldspathic) ceramics obtained through the high-temperature solidification of a moist plastic material (pottery, earthenware, stoneware, porcelain).

The term **"crystal"** refers to inorganic non-metallic materials as described in Council Directive 69/493/EEC of 15 December 1969.

The term **"glass ceramic"** refers to an inorganic non-metallic material obtained by melting raw materials that are primarily mineral at a high temperature. The homogeneous liquid is gradually cooled after being shaped, and then crystallised to a certain extent by heat treatment. Glass ceramic articles may be decorated or not.

The term **"enamelled articles"** refers to articles having a coating consisting of one more layers created by melting or sintering of non-organic constituents.

2. Specific limitations on the use of materials

No specific limitations within the context of this sheet.

3. Definition of food contact suitability criteria

3.1 Reference texts

3.1.1. Regulatory texts

- <u>Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27</u> <u>October 2004</u> on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.
- <u>Commission Regulation (EC) No 2023/2006 of 22 December 2006</u> on good manufacturing practice for materials and articles intended to come into contact with food.



 Order of 7 November 1985 (transposing Directive 84/500/EEC of 15 October 1984 into French law) establishing limits for the extractable quantities of lead and cadmium in ceramic articles.

3.1.2 Other texts

- Standard ISO 6486/1 and 2: Ceramic ware in contact with food. Release of lead and cadmium. Test methods, Permissible limits (6 January 1981).
- Standard ISO 7086/1: Glassware and glass ceramic ware in contact with food. Release of lead and cadmium. Test methods, Permissible limits (15 November 1982).
- Standard NF EN 1388-1 and 2 (classification index D 25 501): Materials and articles in contact with foodstuffs. Silicate surfaces. Determination of the release of lead and cadmium (January 1996).
- B.O.C.C.R.F. Notification of 13 February 1996: Transfer of chromium 6 from materials in contact with foodstuffs.

3.2 Criteria

At the stage of the final product, the person responsible for first placing the product on the market checks that inertia criteria are met, i.e.:

- Migration* of lead, cadmium, aluminium, cobalt and arsenic for materials and articles made from ceramic, crystal, glass, glass ceramic and enamelled articles.
- Migration of hexavalent chromium for enamelled and/or decorated articles (except for ceramics).
- Migration of lead and cadmium by oral contact for materials and articles made from ceramic, crystal, glass, glass ceramic and enamelled articles.
- Migration of hexavalent chromium by oral contact for enamelled and/or decorated articles.

In the case of internal surface treatments, the treatments shall be carried out using products suitable for food contact.

*In the case of inorganic materials, the term "release" is generally more suitable. However, for the sake of clarity, only the term "migration" is used in this document.



4. Limits of acceptability

4.1 Ceramics and enamelled or decorated ceramics

4.1.1 Lead and Cadmium (Order of 7 November 1985)

	Lead	Cadmium
Category 1 : Articles which cannot be filled and articles which can be filled, the internal depth of which, measured from the lowest point to the horizontal plane passing through the upper rim, does not exceed 25 mm	0.8	0.07
Specific migration limits in mg/dm²		
<u>Category 2</u> : articles that can be filled other than those covered by Categories 1 and 3.		
Specific migration limits in mg/l	4.0	0.3
<u>Category 3*</u>: cooking ware, packaging and storage vessels with a capacity of more than 3 liters.		
Specific migration limits in mg/l	1.5	0.1
Oral contact (for all articles with 20mm of external decoration measured from the outer edge).		
Specific migration limits in mg/article	2	0.2

Table 1.

*The following articles must comply with the requirements of Category 3:

- Articles intended to be use in ovens, including microwave ovens, whose labelling information (logo or instructions for the consumer) provides for their use in conventional or microwave ovens.
- Articles for which it can be reasonably assumed that consumers will use them in microwave ovens: these include in particular mugs (large cups), bowls and plates.

4.1.2 Aluminium, cobalt and arsenic (Article 3 of the Framework Regulation)

	Specific migration limits (in mg/kg of food simulant)
Aluminium	1 mg/kg*
Cobalt	0.02 mg/kg**
Arsenic	Not detectable (detection limit does not
	exceed 0.002 mg/kg***)
	T-1-1-0

Table 2.

*Limit established on the basis of a risk analysis, based on an PTWI of 1 mg Al/kg body weight per week established by the EFSA (2008), conventional assumptions used for food contact materials and a toxicity reference value (TRV) allocation factor of 10% for food contact materials.



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per day (RIVM, 2001), conventional assumptions used for food contact materials and a toxicity reference value (TRV) allocation factor of 20% for food contact materials.

***Limit established on the basis of a risk analysis, based on an limit of 0.0003 mg As/kg body weight per day (EFSA, 2009), conventional assumptions used for food contact materials and a toxicity reference value (TRV) allocation factor of 10% for food contact materials, as arsenic is considered to be an impurity.

4.2 Glass - crystal - glass ceramic - enamelled articles (other than ceramics)

4.2.1 Lead, cadmium and Chromium 6 (Article 3 of the Framework Regulation)

	Lead	Cadmium	Chromium 6**
Category 1: Articles which cannot be filled and articles which can be filled, the internal depth of which, measured from the lowest point to the horizontal plane passing through the upper rim, does not exceed 25 mm.	0.8	0.07	0.005
Specific migration limits in mg/dm ²			
Category 2 : articles that can be filled other than those covered by Categories 1 and 3.			
Specific migration limits in mg/l	4.0	0.3	0.03
Category 3*: cooking ware, packaging and storage vessels with a capacity more than 3 liters			
Specific migration limits in mg/l	1.5	0.1	0.03
Oral contact (for all articles with 20mm of external decoration measured from the outer edge).			
Specific migration limits in mg/article	2	0.2	0.015

Table 3.

*The following articles must comply with the requirements of Category 3:

- Articles intended for use in ovens, including microwave ovens, whose labelling information (logo or instructions for the consumer) provides for their use in conventional or microwave ovens.
- Articles for which it can be reasonably assumed that consumers will use them in microwave ovens: these include mugs (large cups), bowls and plates.

** Concerns only enamelled and/or decorated articles, whatever the nature of the materials, other than ceramics.

<u>4.2.2 Aluminium, cobalt and arsenic (Article 3 of the Framework Regulation)</u> See paragraph 4.1.2



5. Rules for checking the criteria defined in Paragraph 3

5.1 Lead and cadmium

5.1.1 Test conditions

- Washing of the samples according to the standards applicable to the material under consideration.
- Simulant: 4% acetic acid solution
- Temperature: 22°C ± 2°C
- Contact time: 24 hours ±30 minutes
- Contact conditions:
 - Categories 1-2-3: Fill up to 1mm from the overflow point,
 - Carafes: Fill the carafe up to the overflow point and gently insert the cap, letting the excess acetic acid flow away,
 - Oral contact: Immersion of the top 20 mm of a recipient used for drinking, as measured down the recipient's wall.

5.1.2 Test methods

- Determination of the specific migration of lead and cadmium by atomic absorption spectrophotometry or any other method having (if possible) a detection limit equal at most to one tenth of the limits indicated in paragraphs 4.1 and 4.2.
- Determination of chromium 6 by diphenylcarbazide colorimetry according to NF T 90 043 or any other method having (if possible) a detection limit at most equal to one tenth of the limits indicated in paragraphs 4.1 and 4.2.

5.1.3 Results

If, during testing of an article, the migrations of lead, cadmium, and chromium, or one of these three, exceed the limits indicated in paragraph 4, but not by more than 50%, the article shall nevertheless be considered to be in compliance if the quantities of lead, cadmium and chromium taken from at least three other articles that are similar in shape, dimensions, decoration and glaze, and that are subjected to a test carried out under the conditions set out in paragraph 5, do not exceed, on average, the established limits, and if the limits for each article are not exceeded by more than 50%.

5.2 Aluminium, cobalt and arsenic

5.2.1 Test conditions

See paragraph 5.1.1 (excluding oral contact)

For repeated use articles, three successive migration tests shall be carried out, taking into account the results obtained at the 3rd migration. The article should be rinsed with distilled water between each migration.

5.2.2 Test methods

For aluminium and cobalt, any method having (if possible) a detection limit equal at most to one tenth of the limits indicated in paragraph 4.1.2. In the case of arsenic, the detection limit shall be 0.002 mg/kg or less.



5.2.3 Results See paragraph 5.1.3.

In the case of articles which cannot be filled, if it can be determined, the actual surface/volume ratio should be used to express the results. Alternatively the standard ratio of 1 kg/6dm² should be used.