

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

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

FCM: Food contact materials.

Inorganic materials: 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

- [Regulation \(EC\) No 1935/2004 of the European Parliament and of the Council of 27 October 2004](#) on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.
- [Commission Regulation \(EC\) No 2023/2006 of 22 December 2006](#) 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 |
|---|------|---------|
| <p>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</p> <p>Specific migration limits in mg/dm²</p> | 0.8 | 0.07 |
| <p>Category 2: articles that can be filled other than those covered by Categories 1 and 3.</p> <p>Specific migration limits in mg/l</p> | 4.0 | 0.3 |
| <p>Category 3*: cooking ware, packaging and storage vessels with a capacity of more than 3 liters.</p> <p>Specific migration limits in mg/l</p> | 1.5 | 0.1 |
| <p>Oral contact (for all articles with 20mm of external decoration measured from the outer edge).</p> <p>Specific migration limits in mg/article</p> | 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***) |

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.

***Limit established on the basis of a risk analysis, based on an TDI of 0.0014 mg Co/kg body weight 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** |
|--|------|---------|--------------|
| <p>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.</p> <p>Specific migration limits in mg/dm²</p> | 0.8 | 0.07 | 0.005 |
| <p>Category 2: articles that can be filled other than those covered by Categories 1 and 3.</p> <p>Specific migration limits in mg/l</p> | 4.0 | 0.3 | 0.03 |
| <p>Category 3*: cooking ware, packaging and storage vessels with a capacity more than 3 liters</p> <p>Specific migration limits in mg/l</p> | 1.5 | 0.1 | 0.03 |
| <p>Oral contact (for all articles with 20mm of external decoration measured from the outer edge).</p> <p>Specific migration limits in mg/article</p> | 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.*

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

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.