



Preliminary draft Grand-Ducal Regulation on materials and articles made of metal and alloys intended to come into contact with foodstuffs

We, the undersigned, Henri, Grand Duke of Luxembourg, Duke of Nassau,

Having regard to the amended Law of 25 September 1953 on the reorganisation of the control of foodstuffs, beverages and usual products, and in particular Article 2 thereof;

Having regard to the Law of 28 July 2018 establishing a system of control and sanctions relating to foodstuffs.

Having regard to the Law of 8 September 2022 establishing and organising the Luxembourg Veterinary and Food Administration ('ALVA') and amending:

- (1) the amended Law of 21 November 1980 on the organisation of the Directorate of Health;
- (2) the amended Law of 19 May 1983 regulating the manufacture and trade of animal feed;
- (3) the Law of 28 July 2018 establishing a system of control and sanctions relating to foodstuffs;

Having regard to the decision of the Benelux Committee of Ministers of 17 October 2022 M (2022) 12 on materials and articles made of metal and alloy intended to come into contact with foodstuffs;

Having regard to the opinions of the Chamber of Agriculture, the Chamber of Commerce and the Chamber of Trade;

Having heard our Council of State;

On the report submitted by our Minister for Agriculture, Viticulture and Rural Development, and following deliberation by the Government in Council;

Order:

Article 1. Definitions

For the purposes of this Regulation, the following definitions shall apply:

- 1) 'competent administration': the Luxembourg Veterinary and Food Administration, hereinafter referred to as 'ALVA', which is responsible for carrying out official controls and other official activities under this Regulation;
- 2) 'metals': substances characterised by the following physico-chemical properties in a solid state:
 - i. Reflectivity responsible for the characteristic metallic brilliance,
 - ii. Electrical conductivity,
 - iii. Thermal conductivity,



- iv. Mechanical properties such as strength and ductility.

Metals correspond to a category of materials whose cohesion is ensured, at the atom level, by metal bonds. They can be assimilated to a set of positive metal ions forming extended crystalline networks in which valence electrons are shared by the entire structure;

- 3) 'alloy': a metal material, homogeneous at a macroscopic level, consisting of two or more elements combined in such a way that they cannot be easily separated by mechanical means;
- 4) 'undertaking': any undertaking within the meaning of Article 2(2)(c) of 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;
- 5) 'establishment': any unit of a food business, as referred to in Article 2(1)(c), of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, as amended;
- 6) 'operator': business operator within the meaning of Article 2(2)(d) of 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 foodstuffs and repealing Directives 80/590/EEC and 89/109/EEC;
- 7) 'release': the unintentional transfer of metals to foodstuffs from materials or articles made of metals or alloys;
- 8) 'specific release limit (SRL)': the maximum permitted quantity of a given metal or metalloid ion, in milligrams, released by a material or article into foodstuffs or food simulants, in kilograms;
- 9) 'Minister': the Minister responsible for food safety.

Article 2. Scope

The provisions of this Regulation shall apply to the unintentional release of metals or impurities thereof by materials and articles in their final state, whether wholly or partially made of metals or alloys or whether or not they are covered with a surface coating, and which:

- a) are intended to come into contact with foodstuffs; or
- b) are already in contact with foodstuffs and were intended for that purpose; or



- c) - which can reasonably be expected to be brought into contact with foodstuffs or transfer their constituents to foodstuffs under normal or foreseeable conditions of their use.

Article 3. General provision

Materials and articles made of metal and alloy intended to come into contact with foodstuffs shall be manufactured in accordance with:

- a) 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 foodstuffs and repealing Directives 80/590/EEC and 89/109/EEC;
- b) Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with foodstuffs;
- c) The amended law of 28 July 2018 establishing a food control regime.

Article 4. Specific release limit (SRL)

The materials and articles made of metal and alloy referred to in Article 2 shall comply with the specific release limits (SRL) specified in Chapter 1 of the Annex to this Regulation.

Substances made of nanomaterials, as defined in Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterials, require in all cases a specific assessment of their properties, the intended use and the exposure measurement in the event of release in foodstuffs.

Article 5. Verification of specific release limits

1. The conformity of finished materials and articles is checked by release tests or examination methods.

The competent administration and undertakings shall apply testing and examination methods in accordance with Article 34 of Regulation (EU) 2017/625 to establish the compliance of materials and articles with the specific release limits set out in Chapter 1 of the Annex to this Grand-Ducal Regulation.

Tests for the release of materials and articles are carried out under the worst foreseeable conditions of use.



The results of specific release testing obtained in foodstuffs shall prevail over the results obtained in food simulants. The results of specific release testing obtained in food simulants shall prevail over those obtained by examination methods.

2. For the purpose of verifying compliance, the specific release values of a finished product shall be expressed in mg/kg, on the basis of the true area-to-volume ratio under actual or expected conditions of use.

By way of derogation from this provision, for sheets, films and flat surfaces not yet in contact with foodstuffs, the migration value shall be expressed in mg/kg, on the basis of an area-to-volume ratio of 6 dm² per kg of foodstuff.

Article 6. Specific labelling particulars

1. Producers of aluminium materials and articles without protective coating shall affix a label indicating to users that the aluminium does not have a protective coating.

In the case of packaging for retail sale, suppliers shall ensure that such packaging includes information labels for the final consumer that specify not to use the materials and articles to store or process acidic, alkaline or salty foodstuffs or to use them only to store foodstuffs in the refrigerator.

2. Producers of aluminium materials and articles without protective coating shall provide advice on the use of their products with highly acidic, alkaline or salty foodstuffs.

Article 7. Declaration of conformity

1. The conformity of the materials and articles shall be attested by means of a declaration of conformity following the template set out in Chapter 2 of the Annex to this Regulation.

2. The declaration of conformity referred to in paragraph 1 shall be drawn up by the operator.

3. By way of derogation from paragraph 1, for all materials and articles made of metal and alloy intended to come into contact with foodstuffs not yet considered as finished products, at least points 1, 2, 3, 4 and 6 of the declaration of conformity following the template set out in Chapter 2 of the Annex to this Regulation are to be completed.

4. By way of derogation from paragraph 1, a risk-based approach shall be applied for components used for the assembly of a production process and for a complete production process in the same food industry establishment, in case a declaration of conformity is lacking. This risk assessment shall be made available to the competent authority upon request.

Article 8. Mutual recognition



The provisions of this Regulation, except those of Article 7, as well as the corresponding provisions applicable to the Kingdom of Belgium or the Kingdom of the Netherlands as derived from the Decision of the Benelux Committee of Ministers of 17 October 2022 M (2022) 12 on materials and articles made of metal and alloy intended to come into contact with foodstuffs, shall not apply to products lawfully manufactured or marketed in a Member State of the European Union not belonging to the Benelux or Turkey, or lawfully manufactured in an EFTA State party to the Agreement on the European Economic Area, unless mutual recognition cannot be applied pursuant to Articles 34 to 36 of the Treaty on the European Union.

Article 9. Enforceable form

Our Minister responsible for Food Safety is responsible for the implementation of this Regulation, which shall be published in the Official Journal of the Grand Duchy of Luxembourg.



ANNEX

CHAPTER 1: SPECIFIC RELEASE LIMIT (SRL)

Table 1: SRLs applicable to metals and alloy components.

Symbol	Name	SRL (mg/kg food)
Al	Aluminium	5
Sb	Antimony	0.04
Ag	Silver	0.08
Cr	Chromium	0.250
Co	Cobalt	0.02
Cu	Copper	4
Sn*	Tin	100
Fe	Iron	40
Mg	Magnesium	-
Mn	Manganese	1.8
Mo	Molybdenum	0.12
Ni	Nickel	0.14
Ti	Titanium	-
V	Vanadium	0.01
Zn	Zinc	5

* Except within the scope of Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs

Table 2: SRLs applicable to metals in the form of contaminants and impurities.

Symbol	Name	SRL (mg/kg food)
As	Arsenic	0.002
Ba	Barium	1.2
Be	Beryllium	0.01
Cd	Cadmium	0.005
Li	Lithium	0.048
Hg	Mercury	0.003
Pb	Lead	0.010
Tl	Thallium	0.0001

CHAPTER 2: INFORMATION THAT MUST BE INCLUDED IN THE DECLARATION OF CONFORMITY.

The written declaration referred to in Article 7(1) shall contain the following information:

- 1) The identity and address of the operator issuing the declaration of conformity;



- 2) The identity and address of the operator who manufactures or imports the materials and articles or substances intended for the manufacture of such materials and articles;
- 3) The identity of metals and alloys intended for the manufacture of materials and articles;
- 4) The date of the declaration;
- 5) Confirmation of the conformity of the materials and articles with the applicable requirements of this Regulation, with the corresponding requirements applicable to the Kingdom of Belgium or the Kingdom of the Netherlands as derived from the Decision of the Benelux Committee of Ministers of 17 October 2022 M (2022) 12 on materials and articles of metal and alloys intended to come into contact with foodstuffs, or other specific legislation concerning metals and alloys published in a Member State of the European Union not belonging to the Benelux or Turkey or an EFTA State party to the Agreement on the European Economic Area, and with the applicable requirements of Regulation (EC) No 1935/2004;
- 6) Adequate information to enable downstream operators to ensure compliance with restrictions or specifications;
- 7) Adequate information on restricted metals in foodstuffs obtained by experimental data or the theoretical calculation of their specific level of release;
- 8) Specifications for the use of the material or article such as:
 - i. the type(s) of foodstuff(s) intended to be brought into contact with them;
 - ii. the time and temperature of treatment and storage in contact with the foodstuff;
 - iii. the area-to-volume ratio in contact with the foodstuff used to establish conformity of the material or article.

The written declaration makes it easy to identify the materials, articles or substances for which it is established and is renewed when substantial changes in production lead to changes in the release of metals or where new scientific data are available. If no changes apply to the raw materials, regarding their processing or usage or the production process etc., a declaration of conformity may remain valid for a maximum period of five years. This remains without prejudice to the possibility that the product manager may always decide to renew the declaration of conformity even if the status quo is maintained.



I. Comments on the articles

Article 1. Definitions

Article 1 contains the necessary definitions, which are essentially derived from the decision of the Benelux Committee of Ministers of 17 October 2022 M (2022) 12 on materials and articles made of metal and alloy intended to come into contact with foodstuffs, and which correspond to those of the resolution and the related technical guide.

In addition to these definitions in the above Decision, Article 2(2)(d) of Regulation (EC) No 1935/2004 describes the business operator as: *'the natural or legal person(s) responsible for ensuring compliance with the requirements of this Regulation in the undertaking under their control'*.

Furthermore, the establishment within the meaning of Article 2(1)(c) of Regulation (EC) No 852/2004 and the undertaking within the meaning of Article 2(2)(c) of Regulation (EC) No 1935/2004 also have an almost identical definition in the two normative texts. In order to have a complete definition in the context of market surveillance for the market of food and food contact materials and articles, both concepts have been taken up.

The establishment within the meaning of Article 2(1)(c) of Regulation (EC) No 852/2004 is defined as follows: *'any unit of a food business'*.

In the context of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, Article 2(2)(c) describes the undertaking as: *'any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of manufacture, processing and distribution of materials and articles'*.

Article 2. Scope

Article 2 defines the scope of this Regulation, always in accordance with the relevant resolution, decision and technical guide. For an indication of the specific materials and articles that do not fall within this scope, reference can be made to the guidelines accompanying the decision, the latest version of which shall be available on the website of the competent authority.

Article 3. General provision

The manufacture of the materials in question intended to come into contact with foodstuffs must be carried out in accordance with the provisions of the European regulations, as defined in Regulation (EC) No 1935/2004 and Regulation (EC) No 2023/2006, as well as the provisions of the Law of 28 July 2018 establishing a system of controls and penalties for foodstuffs.

Article 4. Specific release limit (SRL)

The specific release limits for the food contact materials concerned are set out in the Annex to this Regulation.



The values in question are those contained in the resolution, the decision and the accompanying technical guide.

If, in the future, other values are adopted within the framework of the Council of Europe, these new values should replace those currently listed in the Annex to this Regulation. It will then be necessary to amend this Annex to this effect, as provided for in the Decision.

Article 5. Verification of specific release limits

As provided for in the resolution, the decision and the accompanying technical guide, the conformity of finished materials and articles must be verified.

To this end, release tests or examination methods must for the time being be carried out in accordance with the general provisions of Article 34 of Regulation (EU) 2017/625.

Where control rules or guidelines apply specifically to the materials intended to come into contact with the food concerned, it is, however, expected that the competent administration and companies apply these specific testing and examination methods.

Article 6. Specific labelling particulars

Under Article 6, the competent authority shall require the manufacturer to comply with specific labelling requirements. These requirements – including the symbol that can be used – apply only to aluminium materials and articles without a protective coating. An example of such requirements can be found in the Decision Guidelines.

Article 7. Declaration of conformity

The declaration of conformity provided for in Article 7 shall be used to demonstrate the conformity of the food contact materials.

The declaration template is set out in the Annex to this Regulation and corresponds to the usual template used at the EU level.

For materials and articles made of metal and alloy which are not yet considered as finished products, a minimum content shall be indicated in the declaration of conformity in accordance with the third subparagraph. If additional information is available, it shall also be indicated in the declaration of conformity.

In the case referred to in the fourth subparagraph, a risk-based approach may be used in the absence of a declaration of conformity.

This derogation refers to 'the food industry', as defined in the guidelines of the Decision. In the absence of (a) declaration(s) of conformity demonstrating the conformity of an assembly, a risk



assessment shall be mandatory for users in the food industry in order to ensure that the release limits set out in the Annex to this Regulation are not exceeded. These assessments are mandatory throughout the production chain, with the exception of small and medium-sized enterprises (SMEs).

Article 8. Mutual recognition

As this Regulation imposes requirements that are not required at the EU level, Article 8 includes a mutual recognition clause in order not to create an unjustified obstacle to the free movement of goods within the European Union, the Customs Union with Turkey or the European Economic Area Free Trade Area.

In other words, goods which do not meet the requirements of the Decision (which in addition to the Grand Duchy of Luxembourg also includes the Kingdom of Belgium and the Kingdom of the Netherlands) but which satisfy the requirements of the countries concerned and offer at least an equivalent level of protection are not excluded from the Benelux internal market.

Article 9. Enforceable form

The ministerial responsibilities have been precisely determined, providing information on the competence in which the member of the Government is called upon to intervene.