



### **Note for the attention of Members of the Government**

In June 2013, the Member States of the Council of Europe adopted Resolution CM/Res(2013)9 of the Committee of Ministers of the Council of Europe of 11 June 2013 on metals and alloys used in materials or articles intended to come into contact with foodstuffs (hereinafter referred to as the Resolution), which aims to harmonise national requirements for such materials that come into contact with foodstuffs, in order to achieve a high level of protection of public health.

To this end, the resolution invites the Member States of the Council of Europe to take legislative or other measures, in accordance with the principles and guidelines set out in the technical guide accompanying the resolution.

By Decision M (2022) 12 of the Benelux Committee of Ministers of 17 October 2022 on materials or articles made of metals and alloys intended to come into contact with foodstuffs, the Benelux countries seek to implement the resolution jointly, in accordance with the European legal framework for the placing on the market of materials that come into contact with foodstuffs within the European Union. In this way, the rules to be applied in the three countries will be harmonised.

The purpose of these draft governmental amendments is to implement in national law Decision M (2022) 12 of the Benelux Committee of Ministers of 17 October 2022 on materials or articles made of metals and alloys intended to come into contact with foodstuffs in order to guarantee the same high level of protection of public health throughout the Benelux countries.

At the national level, Article 2 of the amended Act of 25 September 1953 concerning the reorganisation of the control of foodstuffs, beverages and commodities, in conjunction with Article 6 of the Act of xxyyooo on official controls of foodstuffs and materials and articles intended to come into contact with foodstuffs, constitutes the legal basis for the present draft government amendments.

In addition, the operative part of the present draft governmental amendments has been amended by adding a new Article 8a which contains criminal offences which are to be penalised either by administrative fines or by criminal penalties by the Act of xxyyooo on official controls of foodstuffs and materials and articles intended to come into contact with foodstuffs, as requested by the Council of State in its opinion of 25 June 2024.



## TEXT AND COMMENTARY OF GOVERNMENT AMENDMENTS

### Article 1

The preamble to the draft Grand-Ducal Regulation is amended as follows:

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

Having regard to the amended Act 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 Act of 28 July 2018 establishing a system of control and sanctions relating to foodstuffs, as amended;~~

**Having regard to the Act xxxxxxxx on official controls of foodstuffs and on materials and objects intended to come into contact with foodstuffs, and in particular 6;**

Having regard to the Act of 8 September 2022 establishing and organising the Luxembourg Veterinary and Food Administration (« ALVA »);

~~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;~~

The opinions of the Chamber of Agriculture, the Chamber of Commerce and the Chamber of Trade having been requested;

Having heard our Council of State;

On the report of ~~Our~~**the** Minister for Agriculture, ~~Viticulture and Rural Development~~**Food and Viticulture** and after deliberation of the Government in Council; ”.

### Amendment 2

Article 1 of the draft amended Grand-Ducal Regulation is amended as follows:

~~' For the purposes of this~~**For the** application, the following definitions shall apply:

1° 'competent administration': the Luxembourg Veterinary and Food Administration, hereinafter 'ALVA';

2° 'metals': substances characterised by the following physico-chemical properties in a solid state:

- a) Reflectivity responsible for the characteristic metallic brilliance;
- b) Electrical conductivity;
- c) Thermal conductivity;
- d) 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~~ responsible for agriculture. '

### **Amendment 3**

Article 2 of the draft amended Grand-Ducal Regulation is amended as follows:

'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~~:

1° which are intended to come into contact with food; or

2° which are already in contact with foodstuffs and are intended for that purpose, or

3° 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'.



#### **Amendment 4**

Article 4 of the draft amended Grand-Ducal Regulation is amended as follows:

##### **'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 the Annex**, Chapter 1 of 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. '

#### **Amendment 5**

A new Article 5a is added to read as follows:

**"The generic limit of 60 mg/kg is applicable to substances without a specific release limit or specific migration limit or other restriction, unless otherwise specified. "**

#### **Amendment 6**

Article 5 of the draft amended Grand-Ducal Regulation is amended as follows:

##### **'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 companies shall apply testing and examination methods in accordance with the provisions of Article 34 of Regulation (EU) No. 2017/625 **of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities to ensure the verification of compliance with food law, feed law, animal health and animal welfare rules, plant health and plant protection products, amending Regulations (EC) No. 999/2001, (EC) No. 396/2005, (EC) No. 1069/2009, (EC) No. 1107/2009, (EU) No. 1151/2012, (EU) No. 652/2014, (EU) 2016/429 and (EU) 2016/2031, Council Regulations (EC) No. 1/2005 and (EC) No. 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations of the European Parliament and of the Council (EC) No. 854/2004 and (EC) No. 882/2004, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Regulation on official controls), as**



**amended**, 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 purposes of compliance verification, the specific release values of a finished product shall be expressed in ~~mg/kg~~ **milligrams per kilogram**, based on the true ~~surface area/volume~~ ratio **between surface and volume** under actual or intended 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~~ **milligrams per kilogram**, on the basis of a ~~area-to-volume~~ ratio **between surface area and volume** 6 dm<sup>2</sup> per kg of foodstuff. '

#### **Amendment 7**

Article 6 of the draft amended Grand-Ducal Regulation is amended as follows:

« (1) Operators 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, operators 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) Operators of aluminium materials and articles without protective coating shall provide advice on the use of their products with highly acidic, alkaline or salty foodstuffs'.

#### **Amendment 8**

Article 7 of the draft amended Grand-Ducal Regulation is amended as follows:

'(1) The conformity of the materials and articles shall be attested by means of a declaration of conformity following the template set out **in the annex**, 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 subparagraph~~ **in paragraph** 1, for all metal and alloy materials and articles intended to come into contact with foodstuffs which are not yet considered as finished



products, at least points 1°, 2°, 3°, 4° and 6° of the declaration of conformity following the model set out in in the Annex, Chapter 2, ~~of the Annex to this Regulation~~ shall be completed.

(4) By way of derogation ~~from subparagraph~~ 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'.

#### **Amendment 9**

Article 8 of the draft amended Grand-Ducal Regulation is amended as follows:

*"Goods lawfully marketed in another Member State of the European Union or in Turkey, or originating and lawfully marketed in the Contracting Parties to the EEA Agreement are presumed to be compatible with these rules. The application of these regulations is subject to Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No. 764/2008".*

#### **Amendment 10**

An Article 8a, is inserted in the amended draft Grand-Ducal Regulation:

« **Art. 8a. Administrative fines and criminal sanctions**

**(1) The Minister may impose an administrative fine against the operator acting in breach of the following articles of this Regulation in accordance with Article 13(1) of the Act of xxyyoooo on official controls of foodstuffs and materials and articles intended to come into contact with food:**

**1° Article 3;**

**2° Article 6;**

**3° Article 7.**

**(2) Infringements of Article 4 of this Regulation shall be punishable by the penalties laid down in Article 16(2) of the Act of xxyyoooo on official controls of food and on materials and articles intended to come into contact with food'.**

#### **Amendment 11**

Article 9 of the draft amended Grand-Ducal Regulation is amended as follows:

'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.



## **Amendment 12**

The Annex to the amended draft Grand-Ducal Regulation is amended as follows:

### **CHAPTER 1: SPECIFIC RELEASE LIMIT (SRL)**

#### **Chapter 1 - Specific release limits (SRLs)**

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	<del>0.250</del> <b>1*</b>
Co	Cobalt	0.02
Cu	Copper	4
<del>Sn</del>	<del>Tin</del>	<del>100</del> <b>**</b>
Fe	Iron	40
Mg	Magnesium	<del>100</del> <b>***</b>
Mn	Manganese	<del>1.80</del> <b>55***</b>
Mo	Molybdenum	0.12
Ni	Nickel	0.14
<del>Sn*</del>	<del>Tin</del>	<del>100</del>
Ti	Titanium	<del>100</del> <b>***</b>
V	Vanadium	0.01
Zn	Zinc	5
Zr	Zirconium	2

**\* For chromium (VI).**

**\*\*** Except in the field of application of Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No. 1881/2006.

**\*\*\* An LLS of 0.07 mg/kg applies to foods intended for infants and young children conforming to Regulation (EU) No. 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No. 41/2009 and (EC) No. 953/2009.**

**\*\*\*\* the generic limit of 60 mg/kg does not apply.**

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	Thalium	<del>0.0001</del> <u>0.001</u>

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

### **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 **M (2022) 12** 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 **cited above**;
- 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:
  - a) the type(s) of foodstuff(s) intended to be brought into contact with them;
  - b) the time and temperature of treatment and storage in contact with the foodstuff;
  - c) 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 operator may always decide to renew the declaration of conformity even if the **status quo** is maintained. '



## COMMENTS ON GOVERNMENT AMENDMENTS\_

### **Ad Article 1**

The legislative observations of the Council of State have been taken into account.

The 1953 Act is still the legal basis for a multitude of legal texts. In addition, this act remains the legal basis for the control of customary products and cosmetics that have remained under the competence of the Ministry of Health.

The repeal of the 1953 Act would entail the adaptation of all existing Grand-Ducal Regulations adopted in implementation of the previous act in order to supplement these Grand-Ducal Regulations with the article specifying the provisions criminalised in relation to draft Act 8156, as requested by the Council of State.

It is therefore proposed to amend the 1953 Act in a second stage in consultation with the Ministry of Health and following the entry into force of Act 8156, in order to be able to prepare the articles requested by the Council of State.

Thus, Article 2 of the 1953 Act in conjunction with Article 6 of the Act of xxyyooo on official controls of foodstuffs and materials and articles intended to come into contact with food constitutes the legal basis for this *Regulation*.

### **Ad Amendment 2**

The legislative observations of the Council of State have been taken into account.

### **Ad Amendment 3**

The legislative observations of the Council of State have been taken into account.

### **Ad Amendment 4**

The legislative observations of the Council of State have been taken into account.

### **Ad Amendment 5**

As specified in the Benelux Decision, the LLS referred to therein are automatically replaced by any other value established within the framework of the Council of Europe, and accordingly each Benelux country shall take the necessary measures in its internal legal order to give effect to this replacement.



Thus, the generic limit has been added in this new article in accordance with the new EDQM guidelines.

#### **Ad Amendment 6**

The legislative observations of the Council of State have been taken into account.

#### **Ad Amendment 7**

The legislative observations of the Council of State have been taken into account.

#### **Ad Amendment 8**

The legislative observations of the Council of State have been taken into account.

#### **Ad Amendment 9**

The legislative observations of the Council of State have been taken into account.

#### **Ad Amendment 10**

*In its Opinion No. 61.359, the Council of State states that 'Article 16(1) of Draft Act 8156 provides for a penalty in the event of failure to comply with the provisions of the Grand-Ducal Regulations adopted on the basis of Article 1(7). In the absence of an article specifying the provisions criminalised, any provision of the draft Grand-Ducal Regulation made in implementation of the draft Foodstuffs Act would be subject to the penalty provided for in the draft act, even those articles which do not contain wrongdoing, which would not be in line with the principle of specification of offences.'*

Thus, the operative part of this Regulation adopted in implementation of the draft Food Act has been amended by adding to it such an article which carries criminal offences.

Act 8156 aims to introduce administrative fines through government amendments, as is already the case in Act 8300 and Act 8177. That uniform approach would thus ensure fair treatment for all the operators concerned.

Thus, the reprehensible acts are to be sanctioned either by administrative fines or by criminal sanctions.

Conduct referred to in paragraph 2 which may constitute a risk to human health shall be punishable by criminal penalties in light of its seriousness in accordance with the requirement of deterrence and proportionality of penalties required by European Union law.

#### **Ad Amendment 11**



The purpose of the amendment under consideration is to confer powers on the Minister responsible for Food.

In its opinion of 25 June 2024 on the draft Grand-Ducal Regulation on processed cereal-based foods and baby foods for infants and young children, the Council of State proposes that the enforcement order be adopted in accordance with the Government's internal regulations as follows:

The Minister responsible for Food Policy shall be responsible for implementing this Regulation, which shall be published in the Official Journal of the Grand Duchy of Luxembourg.'

The designation of governmental powers in the enforcement order is made in accordance with Annex B to the Government's internal regulations, approved by the Grand-Ducal Decree of 27 November 2023 approving and publishing the Government's internal regulations.

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

In Annex B to the Government's internal regulations, the Ministry of Agriculture, Food and Viticulture has the following governmental powers/competences: Agriculture, Food and Viticulture. These are then the subject of detailed information under points 1 to 12. Although food policy is one of several elements, it does concern food.

In order to respond to this remark by the Council of State and to ensure consistency, it is proposed to adopt the following alternative wording:

*'The Minister responsible for Food'.*

## **Ad Amendment 12**

The legislative observations of the Council of State have been taken into account.

In addition, the values in Tables 1 and 2 reflect the specific release limits of the Technical Guide for Manufacturers and Regulatory Authorities of the European Directorate for the Quality of Medicines and Health Care (EDQM) in relation to the metals and alloys making up food contact materials and articles.



## COORDINATED TEXT OF THE

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

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

Having regard to the amended Act 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 Act of 28 July 2018 establishing a system of control and sanctions relating to foodstuffs, as amended;~~

#### Having regard to the Act xxxxyoooo on official controls of foodstuffs and on materials and objects intended to come into contact with foodstuffs, and in particular 6;

Having regard to the Act of 8 September 2022 establishing and organising the Luxembourg Veterinary and Food Administration («ALVA»);

~~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;~~

The opinions of the Chamber of Agriculture, the Chamber of Commerce and the Chamber of Trade having been requested;

Having heard our Council of State;

On the report of ~~Our~~ the Minister of Agriculture, Viticulture and Rural Development Food and Viticulture and after deliberation of 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 'ALVA';

2° 'metals': substances characterised by the following physico-chemical properties in a solid state:

- a) Reflectivity responsible for the characteristic metallic brilliance;
- b) Electrical conductivity;
- c) Thermal conductivity;
- d) 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~~ responsible for agriculture.

## Article 2. Scope of application

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~~:

1° which are intended to come into contact with food; or

2° which are already in contact with foodstuffs and are intended for that purpose, or

3° 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:

1° 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; and

2° 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.

#### **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 the Annex, Chapter 1 of 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 5a. Generic limit**

**The generic limit of 60 mg/kg is applicable to substances without a specific release limit or specific migration limit or other restriction, unless otherwise specified.**

#### **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 companies shall apply testing and examination methods in accordance with the provisions of Article 34 of Regulation (EU) No. 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities to ensure the verification of compliance with food law, feed law, animal health and animal welfare rules, plant health and plant protection products, amending Regulations (EC) No. 999/2001, (EC) No. 396/2005, (EC) No. 1069/2009, (EC) No. 1107/2009, (EU) No. 1151/2012, (EU) No. 652/2014, (EU) 2016/429 and (EU) 2016/2031, Council Regulations (EC) No. 1/2005 and (EC) No. 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations of the European Parliament and of the Council (EC) No. 854/2004 and (EC) No. 882/2004, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Regulation on official controls), as amended, 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 purposes of compliance verification, the specific release values of a finished product shall be expressed in ~~mg/kg~~ **milligrams per kilogram**, based on the true ~~surface area/volume~~ ratio **between surface and volume** under actual or intended 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~~ **milligrams per kilogram**, on the basis of a ~~area-to-volume~~ ratio **between surface area and volume** 6 dm<sup>2</sup> per kg of foodstuff.

#### Article 6. Specific labelling particulars

(1) Operators 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, operators 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 compliance

(1) The conformity of the materials and articles shall be attested by means of a declaration of conformity following the template set out **in the annex**, 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 subparagraph~~ **in paragraph 1**, for all metal and alloy materials and articles intended to come into contact with foodstuffs which are not yet considered as finished products, at least points 1°, 2°, 3°, 4° and 6° of the declaration of conformity following the model set out ~~in the Annex~~, Chapter 2, ~~of the Annex to this Regulation~~ shall be completed.

(4) By way of derogation ~~from subparagraph~~ **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.





LE GOUVERNEMENT  
DU GRAND-DUCHÉ DE LUXEMBOURG  
Ministère de l'Agriculture,  
de l'Alimentation et de la Viticulture



## Article 8. Mutual recognition

Goods lawfully marketed in another Member State of the European Union or in Turkey, or originating and lawfully marketed in the Contracting Parties to the EEA Agreement are presumed to be compatible with these rules. The application of these regulations is subject to Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No. 764/2008.

### Art. 8a. Administrative fines and criminal sanctions

(1) The Minister may impose an administrative fine against the operator acting in breach of the following articles of this Regulation in accordance with Article 13(1) of the Act of xxyyoooo on official controls of foodstuffs and materials and articles intended to come into contact with food:

1° Article 3;

2° Article 6;

3° Article 7.

(2) Infringements of Article 4 of this Regulation shall be punishable by the penalties laid down in Article 16(2) of the Act of xxyyoooo on official controls of food and on materials and articles intended to come into contact with food.

## Article 9. Executory clause

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)**

#### **Chapter 1 - Specific release limits (SRLs)**

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	<del>0.25</del> <b>1*</b>
Co	Cobalt	0.02
Cu	Copper	4
<b>Sn</b>	<b>Tin</b>	<b>100 **</b>
Fe	Iron	40
Mg	Magnesium	<del>-</del> ****
Mn	Manganese	<del>1.80</del> <b>0.55***</b>
Mo	Molybdenum	0.12
Ni	Nickel	0.14
<del>Sn*</del>	<del>Tin</del>	<del>100</del>
Ti	Titanium	<del>-</del> ****
V	Vanadium	0.01
Zn	Zinc	5
Zr	Zirconium	2

**\* For chromium (VI).**

**\*\*** Except in the field of application of Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No. 1881/2006.

**\*\*\*** **An LLS of 0.07 mg/kg applies to foods intended for infants and young children conforming to Regulation (EU) No. 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No. 41/2009 and (EC) No. 953/2009.**

**\*\*\*\*** **the generic limit of 60 mg/kg does not apply.**



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	Thalium	<del>0.0001</del> <b>0.001</b>

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

### 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 **M (2022) 12** 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 **cited above**;
- 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:



- a) the type(s) of foodstuff(s) intended to be brought into contact with them;
- b) the time and temperature of treatment and storage in contact with the foodstuff;
- c) 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 operator may always decide to renew the declaration of conformity even if the status quo is maintained.

## FINANCIAL STATEMENT

### **Draft Grand-Ducal Regulation on materials and articles made of metal and alloys intended to come into contact with foodstuffs**

The present draft Grand-Ducal Regulation has a neutral impact, since it does not provide for any additional measures charged to the State budget.