Metals and alloys used in food contact materials and articles

A practical guide for manufacturers and regulators

European
Directorate for the
Quality of Medicines
& HealthCare

Committee of
Experts on Packaging
Materials for Food
and Pharmaceutical
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A practical guide for manufacturers and regulators

prepared by

the Committee of Experts on Packaging Materials for Food and Pharmaceutical Products (P-SC-EMB)

European Directorate for the Quality of Medicines & HealthCare

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Foreword

Supplementing **Council of Europe Resolution CM/Res(2013)9**, the Technical guide is intended to ensure the safety and suitable quality of **food contact materials and articles made from metals and alloys**. Chemical elements that constitute metallic food contact articles and that may be present in certain alloys are stated in the current edition and specific release limits (SRLs) have been set for each element, where appropriate. This new set of documents supersedes the previously established Guidelines on Metals and Alloys (first issued on 9 March 2001 and revised on 13 February 2002 under the former Council of Europe Partial Agreement in the Social and Public Health Field).

The revision of the 2002 guidelines was triggered by a series of comments from official inspection services and analytical control laboratories in several European countries. When testing food contact materials and articles, certain metal ions were detected that could pose a health risk for consumers if released into food in relevant amounts. An increasing number of notifications on metal ions from food contact materials was transmitted through the EU-Rapid Alert System for Food and Feed (RASFF) over recent years.

Information presented in this guide

- **Chapter 1**: General provisions and Specific Release Limits (SRL) for metal
- **Chapter 2**: Safety review and recommendations
- **Chapter 3**: Analytical methods for release testing of food contact materials and articles made from metals and alloys
- **Chapter 4**: Declaration of compliance for metals and alloys used in food contact materials and articles

The general provisions and recommendations are intended to assist national policy makers and to enhance the harmonisation of technical standards among the States Parties to the Convention on the Elaboration of a European Pharmacopoeia.

Where relevant, they should be read in conjunction with Article 3 (1) of Regulation (EC) No. 1935/2004 of the European Parliament and the Council of 27 October 2004 on materials and articles intended to come into contact with food.

The documentation was produced by the **Committee of Experts on Packaging Materials for Food and Pharmaceutical Products (P-SC-EMB)**.

Acknowledgements

Special thanks go to the rapporteurs from Belgium who initiated the work project, provided background information and drafted the recommendations.

The delegations of the Council of Europe Committee of Experts on Packaging Materials for Food and Pharmaceutical Products (P-SC-EMB) and national experts from the public and the private sector critically reviewed the documentation and made substantial amendments. This contribution is gratefully recognised and appreciated.

This work was finalised with the support of the national representatives at the Consumer Health Protection Committee (CD-P-SC), leading to the adoption of Resolution CM/Res(2013)9, presented hereafter.

Great appreciation is also due to the EDQM Secretariat for co-ordinating the work, translating relevant contributions and final editing of the document.

Council of Europe Resolution CM/Res(2013)9 on metals and alloys used in food contact materials and articles

Adopted by the Committee of Ministers on 11 June 2013
at the 1173rd meeting of the Ministers' Deputies

The Committee of Ministers, in its composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia[1] ("the Convention"),

Recalling the Declaration and Action Plan adopted by the Third Summit of Heads of State and Government of the Council of Europe (Warsaw, 16-17 May 2005), Chapter III – "Building a more humane and inclusive Europe", Article 1. "Ensuring social cohesion", laying down in particular protection of health as a social human right and an essential condition for social cohesion and economic stability;

Recalling Resolution Res (59) 23 of 16 November 1959 extending the activities of the Council of Europe in the Social and Public Health field on the basis of a Partial Agreement, and Resolutions Res (96) 34 and Res (96) 35 of 2 October 1996 revising the rules of the Partial Agreement;

Having regard to the decisions of the Committee of Ministers of 2 July 2008 (CM/Del/Dec (2008) 1031) to dissolve the Partial Agreement in the Social and Public Health Field and to transfer activities related to cosmetics and food packaging to the European Directorate for the Quality of Medicines & HealthCare (EDQM) as of 1 January 2009, thereby rendering the EDQM responsible for developing harmonised approaches to ensure product quality and safety in the areas of cosmetic products and packaging materials for food and pharmaceutical products;

Having regard to the terms of reference of the Consumer Health Protection Committee (Partial Agreement) (CD P-SC), as approved by the Committee of Ministers on 11 March 2009 (CM/Del/Dec (2009) 1050) and renewed on 21 September 2011 (CM/Del/Dec (2011) 1121);

Considering the efforts made over several years (under the former Council of Europe Partial Agreement in the Social and Public Health Field) to harmonise national provisions in the public health field and, in particular, in the sector of food contact materials;

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[1] Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine and United Kingdom.

Considering the health risk posed to humans by metals and alloys that are used in food contact materials and articles because of the release of metal ions into foodstuffs;

Taking into account 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, Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food and Regulation (EC) No. 852/2004 on the hygiene of foodstuffs, which although not binding for all of the States Parties to the Convention, should nevertheless be applied by all;

Taking into account that the Guidelines on Metals and Alloys first published by the Council of Europe on 3 February 2001 and revised on 13 February 2002 have provided useful information and support to professionals in the food contact material industry, national authorities and other stakeholders that are involved in ensuring compliance with the provisions of the aforementioned Regulation (EC) No. 1935/2004 and in particular, its general requirements laid down in Article 3 (1);

Considering that, in the absence of specific requirements at the European level for metals and alloys used in food contact materials and articles, a Technical guide has been produced by the Committee of Experts on Packaging Materials for Food and Pharmaceutical Products (P-SC-EMB) that supersedes the aforementioned guidelines;

Taking note that this Technical guide will be regularly updated by the P-SC-EMB and approved by the Consumer Health Protection Committee (CD-P-SC, Steering Committee under the responsibility of the Committee of Ministers) and published under the aegis of the European Directorate for the Quality of Medicines & HealthCare (EDQM);

Being of the opinion that each member State, faced with the need for provisions in this field, will benefit from harmonised provisions at the European level,

Recommends to the governments of member States Parties to the Convention that they adopt legislative and other measures aimed at reducing the health risks arising from consumer exposure to certain metal ions released into food from the contact with metals and alloys during manufacture, storage, distribution and use according to the principles and guidelines set out in the Technical guide on Metals and Alloys used in food contact materials and articles. These recommendations shall not prevent governments from maintaining or adopting national measures that implement stricter rules and regulations.

Technical guide on metals and alloys used in food contact materials and articles

Abbreviations used in the Technical guide

ADI	Acceptable Daily Intake
AFNOR	Association Française de Normalisation
AFSSAPS	French Agency for the Safety of Health Products
Anses/AFSSA	French Agency for Food, Environmental and Occupational Health& Safety (AFSSA former acronym)
ALARA	As Low As Reasonably Achievable
BMD	Benchmark dose
CoE	Council of Europe
COT	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment
DGCCRF	Directorate for Competition policy, Consumers affairs and Fraud control (Ministry of Economy and Finances, France)
EFSA	European Food Safety Authority
EMA /EMEA	European Medicines Agency (EMEA previous acronym)
EPA	Environmental Protection Agency (USA)
EVM	UK Expert Group on Vitamins and Minerals
FAO	United Nations Food and Agriculture Organisation
FCM	Food Contact Material(s)
FSA	Food Standards Agency (UK)

GMP	Good Manufacturing Practice
IPCS INCHEM	International Programme on Chemical Safety – Chemical Safety Information from Intergovernmental Organisations
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOAEL	Lowest Observed Adverse Effect Level
NOAEL	No Observed Adverse Effect Level
PDE	Permitted Daily Exposure (as used in the Pharmaceutical EMEA/CHMP/SWP/4446/2000 guideline)
PMTDI	Provisional Maximum Tolerable Daily Intake
P-SC-EMB	Committee of Experts on Packaging Materials for Food and Pharmaceutical Products
PTMI	Provisional Tolerable Monthly Intake
PTWI	Provisional Tolerable Weekly Intake
QM	Maximum permitted Quantity of a substance in a food contact material
RASFF	Rapid Alert System for Food and Feed
RDI	Recommended Daily Intake
RfD	Reference Dose (established by EPA – maximum acceptable oral dose of a toxic substance derived from the NOAEL)
RIVM	National Institute for Public Health and the Environment (Netherlands)
SCF	EU Scientific Committee on Food
SR	Specific Release
SRL	Specific Release Limit
SML	Specific Migration Limit
SML (T)	Specific Migration Limit (expressed as total of moiety or substances indicated)

TDI	Tolerable Daily Intake
TWI	Tolerable Weekly Intake
WHO	World Health Organisation

Chapter 1 – General provisions and specific release limits (SRLs) for metals

Introduction

Metals and alloys are used in food contact materials and articles in food-processing equipment, containers and household utensils as well as in foil used to wrap food. These materials are frequently used as a safety barrier between the food and the environment. They are often covered by a coating to reduce ion release into foods.

Metal ions can be released from these materials, into foods and, if the release exceeds the toxicological reference values, it may endanger the health of the consumer or unacceptably alter the composition of the food or its organoleptic characteristics. As a consequence, it was decided to establish technical guidance in this area.

Objectives

The Technical guide on metals and alloys used in food contact materials and articles is intended to assist national policy-makers. Furthermore, its general provisions should be taken into account in national regulations and enforcement activities on food contact materials made from metals and alloys with a view to harmonising regulations and their implementation at the European level.

The general provisions define the scope, specifications and restrictions concerning metals and alloys used in food contact materials and articles.

Safety review and recommendations are intended to provide guidance on metals and alloys used in food contact materials and articles. They will be regularly updated to keep up with scientific and technical progress.

Due to their technical nature, these documents are not submitted to the Committee of Ministers for approval.

Elaboration procedure and stakeholders

Governments of Council of Europe member states[1] participated actively in the elaboration of the documents. Their representatives in the Committee of Experts on Packaging Materials for Food and Pharmaceutical Products (P-SC-EMB) and the Consumer Health Protection Committee (Steering Committee, CD-P-SC) are experts in the area of food contact materials as well as being responsible for the implementation of government policies in their national ministries.

The Committee of Experts on Packaging Materials for Food and Pharmaceutical Products (P-SC-EMB) prepared Resolution CM/Res(2013)9 on metals and alloys used in food contact materials and articles and the Technical guide. Following approval by the Consumer Health Protection Committee (CD-P-SC), the Committee of Ministers adopted the resolution.

The European Commission participated in the work of the Committee of Experts and the Steering Committee.

An ad hoc group on release testing was created to assist the Committee of Experts. Ad hoc groups are not authorised to make official decisions.

During its elaboration, the Technical guide was subject to consultations with relevant professional associations and industry representatives.

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1 States concerned: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, the Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, Ukraine and the United Kingdom.

Legal status of the resolution and link with the European Union

Resolution CM/Res(2013)9, based on the experience and participation of national ministries, health authorities and enforcement agencies, provides an interpretation of the provisions for materials and articles in relevant EU regulations.

The Council of Europe resolution is not legally binding for member states, but serves as a reference for the implementation of Article 3 paragraph 1 of Regulation (EC) No. 1935/2004.

General provisions

Article 1. Definitions

1.1. Metals

Metals are characterised by their chemical and physical properties in the solid state:

- reflectivity, which is responsible for the characteristic metallic lustre;
- electrical conductivity, which decreases with increasing temperature;
- thermal conductivity;
- mechanical properties, such as strength and ductility.

Metals are the class of materials linked, on an atomic scale, by metallic bonds. They can be considered an array of positive metallic ions forming long-range crystal lattices in which valency electrons are commonly shared throughout the structure.

1.2. Alloys

An alloy is a metallic material composed of two or more elements. Alloys are homogeneous at a macroscopic scale and their components cannot be separated by mechanical means.

1.3. Release

Release is defined herein as the unintentional transfer to food of metal ions from food contact materials and articles made of metal or alloy.

1.4. Specific release limit

A “specific release limit” (SRL) describes the maximum permitted amount of a given metal ion or metalloid ion (in mg) when released from a material or article of a defined surface area into food (in kg) or food simulants.

Article 2. Scope

2.1. Included in the scope

The provisions laid down in this chapter apply to the unintentional release of certain metal ions from materials and articles at the end-use level, coated or uncoated, made completely or partially of metals and alloys, manufactured or imported into Europe, which in their finished state:

a. are intended to be brought into contact with food; or
b. are already in contact with food and were intended for that purpose; or
c. can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

   Examples: *household utensils and processing equipment such as food processors, wrapping, containers, pots, blenders, knives, forks, spoons, etc.*

2.2. Excluded from the scope

These provisions do not apply to:

a. metals and alloys used in food contact materials and articles that are covered by an organic surface coating that has been demonstrated to restrict release of metal ions to less than the applicable specific release limit (SRL);

b. ceramics, crystal glass, printing inks, polymerisation aids and other types of food contact materials, which are either covered by specific legislation in the EU or at national level or by Council of Europe resolutions;
c. food contact materials that were designed to release certain substances into the food (so-called "active food contact materials"); such materials have been addressed in EU legislation on active food contact materials (Regulation (EC) No. 1935/2004 and Regulation (EC) No. 450/2009).
d. pipelines for drinking water which are covered by separate international legislation;
e. toys, even though they are often found in direct contact with food (e.g. in breakfast cereals).

Contribution to the total intake of metal ions due to other sources of exposure than metals and alloys used in food contact materials and articles are taken into consideration by applying allocation factors, where appropriate, when deriving specific release limits (SRLs).

Article 3. General requirements

3.1. Quality and safety requirements

Metals and alloys used in food contact materials and articles shall be manufactured in accordance with Article 3, paragraph, 1 of Regulation (EC) No. 1935/2004 so that, under normal and foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

a. endanger human health; or
b. bring about an unacceptable change in the composition of the food; or
c. bring about a deterioration in the organoleptic characteristics thereof.

The release of a substance should be reduced as much as reasonably achievable, not only for health reasons, but also to maintain the integrity of the foodstuffs it is in contact with.

Metallic food contact materials and articles shall be manufactured in accordance with Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

They should also comply with Chapter 5 of Annex II, §1 of Regulation (EC) No. 852/2004 on the hygiene of foodstuffs:

> *"All articles, fittings and equipment with which food comes into contact are to:*
>
> *(a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination;*
>
> *(b) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination;*
>
> *(c) with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept clean and, where necessary, to be disinfected; and*
>
> *(d) be installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area."*

The technical specifications for metals and alloys defined in European standards (EN ISO) should also be taken into account, as well as national legislation on the composition of metals and alloys.

3.2. Declaration of compliance and documentation

Food contact materials and articles made of metals and alloys shall be accompanied by a declaration of compliance with the provisions of Article 3 of Regulation (EC) No. 1935/2004.

Appropriate documentation shall be available to demonstrate such compliance, taking into account, where applicable, Article 16 of Regulation (EC) No. 1935/2004 and Regulation (EC) No. 2023/2006 and may be requested by competent authorities.

The information to be presented in a declaration of compliance for food contact materials and articles made of metals and alloys is presented in Chapter 4.

3.3. Labelling

Metallic food contact materials and articles should be accompanied by special instructions for safe and appropriate use, where necessary, as stipulated by Article 15, paragraph 1, point b, of Regulation (EC) No. 1935/2004.

Where necessary, manufacturers of metallic food contact materials and articles should provide information on their composition and use to reduce the risk for unintentional release. Temperature and storage time are known to influence the release of certain metal ions from metals and alloys used in food contact materials and articles into certain types of foodstuff. Thus, labelling could be used to mention restrictions for the storage and processing of strongly acidic, alkaline or salted foodstuffs to minimise the phenomenon of corrosion. The labelling could also include guidance on the storage temperature of foods in order to minimise release.

The labelling could, for example, state:

- "User information: do not use this equipment with acidic or alkaline or salted foodstuffs"; or
- "Exclusively for use with non-acidic foodstuffs stored in refrigerators"; or
- "Keep below 5° C if the food is to be stored for longer than 24 hours".

If users must initially wash the material, then the labelling should provide appropriate cleaning instructions.

> **Remark:** *It should be recognised that industrial use and household use of food contact materials may vary extensively.*
>
> *An industrial environment usually implies:*
> - *in-process controls;*
> - *repeated use of the same equipment according to standard conditions;*
> - *selection and qualification of the food contact material (equipment or packaging) for a given range of foodstuffs and its use;*
> - *possible liability of the manufacturer in case of harm to consumers.*
>
> *Household use usually implies:*
> - *a wide range of foodstuffs and contact conditions;*
> - *uncontrolled use of utensils limited only by concepts such as "current practice" or reasonably foreseeable use conditions.*

Article 4. Specific release limits (SRLs)

Metals and alloys used in food contact materials and articles shall comply with the specific release limits (SRLs) set out below in Table 1 and Table 2. SRLs are expressed in mg/kg.

Table 1 – *SRLs for metals and alloy components*

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

*except in field of application under Regulation (EC) No. 1881/2006

Table 2 – *SRLs for metals as 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
Pb	Lead	0.010
Li	Lithium	0.048
Hg	Mercury	0.003
Tl	Thallium	0.0001

Remarks:

In the cases of antimony, cobalt, chromium, molybdenum, nickel, vanadium as well as the contaminants arsenic, beryllium, mercury and thallium, deviation from the SRL is tolerated due to analytical limitations, subject to the approval by the competent authority.

In the case of cadmium and lead, deviation from the SRL may be tolerated for certain applications, subject to the approval by the competent authority. However, the ALARA[1] *principle should be applied.*

Establishing an SRL:

The P-SC-EMB considered toxicological information, the ALARA principle where appropriate or relevant legislation. Each metal ion required a specific approach for setting an SRL, avoiding either over-conservative specific release limits or limits where compliance would not be possible.

The following criteria must be considered when defining a specific release limit:

- appropriate toxicological reference values, (e.g. JECFA, EFSA or national risk assessment bodies);
- appropriate exposure assessments, based on oral intake data from food, drinking water and other sources from several European countries;
- allowances for food contact materials as one possible source for the human exposure (next to food and dietary supplements): expressed as percentage of the toxicological reference value;
- actual release data: rather than setting an SRL on the basis of toxicological reference values, actual release data may serve to define technically feasible levels (ALARA);
- any regulations governing the presence of metal ions in foodstuffs must be taken into consideration to avoid conflicts between standards.

Based on the above criteria, the following model approach was used to set SRL for metals used in food contact materials:

---

[1] ALARA is an acronym for "As Low As Reasonably Achievable". The term "ALARA principle" is used in reference to chemical or radiation exposure levels where social, technical, economic, practical, or public policy considerations seek to achieve a small but acceptable level of risk.

Criterion 1: appropriate toxicological reference values exist and oral intake data of sufficient quality are available.

Calculation of the SRL:

(i) For oral intake data of sufficient quality not exceeding the toxicological limit: based on the toxicological reference value and a variable, justified allowance in the case of a gap between worst-case oral intake (95th percentile) and the toxicological reference value;

Examples in this guide: *Cu, Mo, Zn.*

(ii) For oral intake data of sufficient quality exceeding the toxicological limit: based on the ALARA principle;

Example in this guide: *Al.*

Criterion 2: appropriate toxicological reference values exist, but insufficient or no oral intake data are available.

Calculation of the SRL: based on the toxicological reference value and a fixed allowance of 20%, which is in agreement with the WHO "Drinking Water Guidelines" (WHO, 1993, 2008 and 2011).

Examples in this guide: *Co, Mn and Ni.*

Criterion 3: appropriate toxicological reference values do not exist, but oral intake data are available.

Calculation of the SRL:

(i) based solely on appropriate oral intake data; as no toxicologically derived limit exists, no allowance can be applied.

Examples in this guide: *Ag, Cr and V.*

(ii) for varying oral intake data; as no toxicologically derived limit exists, based on the ALARA principle;

Example in this guide: *Fe.*

Criterion 4: Metals without an SRL.

The P-SC-EMB concluded that setting SRL was not necessary for Mg and Ti.

Criterion 5: metals and metalloids considered as impurities.

Calculation of the SRL: based on a fixed allowance of 10% of the toxicological reference values is applied independently of oral intake data with the exception of Cd (25% allowance) and Pb (26% allowance).

Examples in this guide: *As, Ba, Be, Cd, Hg, Li, Pb and Tl.*

Article 5. Compliance with the SRLs and release testing

Compliance of the material or article with the SRLs shall be verified by experimental release testing.

a. Testing of release from the material or article into foodstuffs shall be carried out under the reasonable worst-case conditions that promote metal release for the contact during manufacture, storage, distribution and normal or foreseeable use, with respect to time, temperature and composition of the foodstuff (in particular, pH and nature of any salts and acids that are present).
b. When it is not possible to test release into foodstuffs, food simulants as described in Chapter 3 should be used.

Article 6. Updating of the general provisions

This Technical guide will be regularly updated in collaboration with the Committee of Experts on Packaging Materials for Food and Pharmaceutical Products (P-SC-EMB), approved by the Consumer Health Protection Committee (CD-P-SC) of the Council of Europe and published under the aegis of the European Directorate for the Quality of Medicines & HealthCare (EDQM), a Directorate of the Council of Europe.

Chapter 2 – Safety review and recommendations

Metals and alloy components

The following metals are relevant metals and alloy components used in food contact materials and articles

Al	Aluminium
Sb	Antimony
Cr	Chromium
Co	Cobalt
Cu	Copper
Fe	Iron
Mg	Magnesium
Mn	Manganese
Mo	Molybdenum
Ni	Nickel
Ag	Silver
Sn	Tin
Ti	Titanium
V	Vanadium
Zn	Zinc

Aluminium (Al)

Aluminium is the third most abundant element in the Earth's crust and is widespread in minerals. Aluminium does not occur in nature in a free element state because of its reactive nature (Beliles, 1994). Many of its naturally occurring compounds are insoluble at neutral pH and thus concentrations of the element in both fresh and sea water are usually low, less than 0.1 mg/L. Inorganic compounds of aluminium normally contain Al(III). Pure aluminium has good working and forming properties and high ductility, its mechanical strength being low. Therefore, aluminium is often used in alloys (Beliles, 1994).

Sources and levels of intake

The main source of aluminium is the naturally occurring content in foodstuffs. The measured levels of aluminium in unprocessed foodstuffs range from less than 0.1 mg/kg in eggs, apples, raw cabbage, corn and cucumbers to 4.5 mg/kg in tea (Pennington and Jones, 1989; Pennington and Schoen, 1995; MAFF, 1993). Much higher values are found in some industrially processed foods where aluminium salts have been added as a food additive. However, in the EU the use of aluminium salts as a food additive is limited to certain products, such as scones, and aluminium itself is accepted as a decoration in confectionery (Directive 95/2/EC).

Mean dietary exposure from water and food in non-occupational exposed adults showed large variations between the different countries and, within a country, between different surveys. It ranges from 0.2 to 1.5 mg/kg body weight/week. In children, estimated exposure at the 97.5th percentile ranges from 0.7 and 1.7 mg/kg body weight/week. Cereals and cereal products, vegetables and beverages appear to be the main contributors (>10%) to the dietary aluminium exposure in the general population (EFSA, 2008).

Significant *non-dietary* sources of exposure to aluminium are medicines (e.g. antacids or buffered aspirins) (Krewski, 2007) and cosmetics via dermal route (e.g. antiperspirants) (AFSSAPS, 2011).

Metallic food contact materials

Aluminium is widely used in food contact materials such as saucepans, aluminium-lined cooking utensils, coffee pots, and in packaging products such as food trays, cans and can closures (Elinder and Sjögren, 1986). Aluminium food contact materials are often coated with a resin-based coating. Aluminium alloys for food contact materials may contain alloying elements such as magnesium, silicon, iron, manganese, copper and zinc (European Standard EN 601; European Standard EN 602).

Other food contact materials

Certain aluminium compounds are used in pigments (Elinder and Sjögren, 1986).

Release

Aluminium and its various alloys are highly resistant to corrosion (Beliles, 1994). When exposed to air, the metal almost immediately develops a thin film of AL_2O_3. The reaction then slows because this film seals off oxygen, preventing further oxidation or chemical reaction. The film is colourless, tough and non-flaking. Few chemicals can dissolve it (Beliles, 1994).

Aluminium reacts with acids. Pure aluminium is attacked by most dilute mineral acids. At neutral pH, aluminium hydroxide has limited solubility. However, solubility increases markedly at pH below 4.5 and above 8.5 (Elinder and Sjögren, 1986). Alkalis rapidly attack both pure and impure aluminium and dissolve the metal (Hughes, 1992). Therefore, aluminium can be released from uncoated surfaces in contact with foodstuffs.

Furthermore, aluminium can be released from coated food contact materials if the coating does not act as a functional barrier. Release of aluminium from food contact materials depends to a large extent on the pH of the foodstuffs. High salt concentrations (over 3.5% NaCl) can also increase ion release. Use of aluminium saucepans and aluminium-lined cooking utensils and containers may increase the content of aluminium in certain types of foodstuffs, especially during long-term storage of strongly acidic, alkaline or salty foodstuffs. In general, cooking in aluminium vessels increased the content in the foodstuffs by less than 1 mg/kg for about half of foodstuffs, and less than 10 mg/kg for 85% of the foodstuffs examined by Pennington and Jones (1989). Boiling tap water in an aluminium pan for 10 or 15 minutes can result in aluminium release of up to 1.5 mg/L, depending on the acidity of the water and the chemical composition of the aluminium utensils (Gramiccioni *et al.*, 1996; Müller *et al.*, 1993; Mei *et al.*, 1993; Nagy *et al.*, 1994) but values up to 5 mg/L have been reported in one study (Liukkonen-Lilja and Piepponen, 1992). Acidic foodstuffs such as tomatoes, cabbage, rhubarb and many soft fruits most frequently take up more aluminium from containers (Hughes, 1992). While acids give the highest figures, alkaline foodstuffs (less common) and foodstuffs with much added salt also increase aluminium uptake (Hughes, 1992; Gramiccioni *et al.*, 1996).

Temperature and storage time are known to influence the release of aluminium into foodstuffs. In a release study using 3% acetic acid, the release was approximately 10-fold higher at 40° C compared to 5° C after 24 hours (Gramiccioni *et al.*, 1989). Typical values for release of aluminium from foil was <0.05 mg/dm^2 at 5° C and, correspondingly, 6 mg/dm^2 at 40° C. However, after 10 days, the release was considerably higher: 0.5 mg/dm^2 at 5° C compared to 96 mg/dm^2 at 40° C (Gramiccioni *et al.*, 1989). Baking different types of meat wrapped in aluminium foil showed an increased aluminium release compared to raw meat up to 5-fold depending on the temperature (up to 17.2 mg Al/kg wet weight) (Turhan, 2006).

Combined effects of high temperatures during baking or grilling and salt/low pH (addition of vinegar) on aluminium release were demonstrated by baking fish in aluminium foil. Baking the fish without any addition of salt and vinegar led to increased aluminium content up to 4-fold (up to 0.4 mg Al/kg wet weight) compared to the raw fish. When salt and vinegar were added, the aluminium content was increased up to 68-fold (up to 5 mg Al/kg wet weight) (Ranau *et al.*, 2001).

Safety aspects

- In 1988, the JECFA established a PTWI at 7 mg/kg body weight/week for total aluminium intake, including food additive uses of aluminium salts, which was subsequently lowered to 1 mg/kg body weight/week in 2006 (JECFA, 1989 & 2006). In the light of new data, JECFA reassessed aluminium in 2011 and introduced a new PTWI of 2 mg/kg body weight/week based on a NOAEL of 30 mg/kg body weight/day and an uncertainty factor of 100 (JECFA, 2011).
- According to the WHO, no health-based guideline value is recommended in drinking water (WHO, 1993, 2008 & 2011). However, in the latest 2011 (fourth) edition, WHO states that "a health-based value of 0.9 mg/L could be derived from the JECFA PTWI (2006), but this value exceeds practicable levels based on optimisation of the coagulation process in drinking-water plants using aluminium-based coagulants" (WHO 2011).
- Directive 98/83/EC on the quality of water intended for human consumption gives a standard value of 0.2 mg/L for water for human consumption as a compromise between the practical use of aluminium salts in drinking water treatment and discolouration of distributed water.
- Aluminium is excreted by the kidneys, and only a small amount of aluminium is absorbed (JECFA, 1989). However, soluble aluminium salts are more easily absorbed. Patients with impaired renal function treated by dialysis could show a higher aluminium blood level. In the past, some of these dialysis patients have shown neurological symptoms of aluminium intoxication due to an inappropriate treatment that is no longer used; these symptoms were sometimes mistaken for those of Alzheimer's disease. The WHO (IPCS 1997) has concluded that aluminium is not the origin of Alzheimer's disease.
- In 2008, the EFSA (2008) confirmed the PTWI of 1 mg/kg body weight/week previously established by the JECFA in 2006.

Conclusions and recommendations

“the SRL of 5 mg/kg is reasonably achievable”

In the case of aluminium, exposure of certain groups of the population is close to or exceeds the PTWI of 2 mg/kg body weight/week (JECFA, 2011). Certain food contact materials and articles contribute to the dietary intake of aluminium. Therefore, the P-SC-EMB decided that the specific release limit for aluminium should be set at a level that is as low as reasonably achievable (ALARA). Such an approach ensures that the manufacturer apply measures to prevent and reduce the release of aluminium from food contact materials and articles as far as possible in order to protect public health.

Data provided by industry and member states show that the SRL of 5 mg/kg is reasonably achievable at present.

This specific release limit should be subject to a review at the latest three years after the adoption of this Technical guide to take account of the advance of scientific and technical knowledge and improvements in good manufacturing practice.

It should be noted that food contact materials and articles made from aluminium coming into contact with food must comply with the following additional recommendations:

- Storage of acidic (e.g. fruit juices), alkaline (e.g. lye dough products) or salty, liquid foodstuffs in uncoated aluminium utensils should be limited in order to minimise release.
- The producer should provide specific labelling of uncoated aluminium for users. With regard to retail packs, the suppliers must ensure that these are labelled with appropriate information for the end consumer. Examples of such labels could be: “User information: do not use this utensil for storage and processing of acidic, alkaline or salty food” or “To be used for storing food in refrigerator only”.
- Guidance should be available from producers of uncoated aluminium utensils regarding the use of their product with strongly acidic, alkaline or salty foodstuffs.

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Antimony (Sb)

Antimony is naturally present in the Earth's crust and it is discharged into the air from both natural and human-induced sources.
Of the Sb discharged into the air, 41% comes from natural sources, i.e. soil particles transported by the wind, volcanoes, marine aerosols, forest fires and biogenic sources (ATSDR, 1992).
Human-induced sources of atmospheric discharge include the non-ferrous metals industry (mines, foundries and refineries) and coal and waste combustion. Sb is discharged into water from industries producing and exploiting antimony and its compounds (ATSDR, 1992).

Sources and levels of intake

Antimony is detected in most foods, except oils, fats, milk and eggs. Highest concentrations were measured in sugar (8.8 µg/kg), chocolate (4.2 µg/kg), cakes (3.8 µg/kg), meat products (9.9 µg/kg) and fish (2.6 µg/kg) (Anses, 2011; FSA, 2009).

In the 2006 British total diet study mean and high level adult dietary exposures to antimony were 0.03 µg/kg body weight/day and 0.06 µg/kg body weight/day, respectively (FSA, 2009). Anses (2011) estimated mean daily intake at 0.03 µg/kg bw/day in adults and 0.04 µg/kg bw/day in children.

Metallic food contact materials

Antimony is used in the manufacture of lead, tin and copper alloys (it hardens lead). With tin, it is used to manufacture “white metal”. With lead and tin, it is used to treat metal surfaces and to blacken iron.

European Standard EN 610/1995 applies to tin and tin alloys items coated exclusively with tin or tin alloy, or partly tin-plated materials that, as finished products, recurrently come into direct contact with food. It also defines a specific migration limit for antimony (0, 01 mg/kg).

Antimony can be found as an impurity in aluminium alloys and tin.

In France, a maximum permissible antimony content of 2.5% is specified in Information Notice No. 2004-64 on materials in contact with foodstuffs.

Other food contact materials

Antimony is used as a fire-proofing agent in textiles and plastic materials, as an opacifying agent in glass, ceramics and enamels, as a pigment in paintings and as a chemical catalyst.

Release

During storage of mineral water in PET bottles, the catalyst antimony trioxide (Sb203, which exists in dimerised form) migrates and concentrates in proportion to the time spent in the mineral water (Shotyk, 2006). Concentrations (<1 ppb) are always below the recommended maximum rates, and there would appear to be no immediate health hazard.

Safety aspects

- WHO (2008 & 2011) set a guideline value of 0.02 mg/L derived from a TDI of 0.006 mg/kg body weight/day (0.36 mg/day). This value was based on a NOAEL of 6 mg/kg body weight/day from a sub-chronic, drinking-water study in rats, presenting decreased body weight gain and reduced food and water intake. An uncertainty factor of 1,000 (100 for intra-species and inter-species variation and 10 for the use of a sub-chronic study was applied to the NOAEL, resulting in the TDI of 0.006 mg/kg body weight/day (WHO, 2003).

- EFSA (2004) set a SML of 0.04 mg/kg for antimony based on the TDI derived by the WHO. This value was also adopted by EU Directive 2002/72.

Conclusions and recommendations

"the SRL for antimony is set at 0.04 mg/kg"

The SRL was derived from the WHO (2003) assessment of 0.36 mg/day. As antimony is considered an impurity in the metallic material, the P-SC-EMB concluded that an allowance of 10% of the toxicological reference value was reasonable. Therefore, assuming that a person of 60 kg body weight consumes 1 kg of foodstuffs per day that is packaged and/or prepared with food contact materials made from metals and alloys, the SRL for antimony is set at 0.04 mg/kg.

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Chromium (Cr)

Chromium is found mainly in the trivalent form in the environment. Hexavalent chromium, or chromate, may also be found in very small amounts, usually arising from anthropogenic sources (Beliles, 1994). Cr(III) has the ability to form strong, inert complexes with a wide range of naturally-occurring organic and inorganic ligands (Florence and Batley, 1980). In most soils and bedrocks, chromium is immobilised in the trivalent state (Florence and Batley, 1980). Chromium is an essential element to man. Chromium is found at low levels in most biological materials.

Sources and levels of intake

The main sources of chromium are cereals, meat, vegetables, white fish and vegetable oil, while fruits contain smaller amounts (EVM, 2002). Most foodstuffs contain less than 0.1 mg/kg of chromium (EVM, 2002; Nordic Council of Ministers, 1995). Chromium is present in the diet mainly as Cr(III) (EVM, 2002). According to EVM, most of the chromium in food originates from food processing using stainless steel food processors and containers (EVM, 2002).

Dietary intake of chromium from food sources in multiple European countries ranges between 61-160 µg/day for adults, with an upper intake of 580 µg/person/day (EFSA, 2010).

Anses (2011) estimated mean daily intake of total chromium at 277 µg/person/day in adults and 223 µg/person/day in children.

Metallic food contact materials

Chromium is found in some types of cans and utensils. In cans, it serves to passivate tinplate surfaces. Chromium is used in the production of stainless steel of various kinds and in alloys with iron, nickel and cobalt. Ferro-chromium and chromium metal are the most important classes of chromium used in the alloy industry (Langaard and Norseth, 1986). All stainless steels contain chromium (minimum 10.5% – see guideline on stainless steel) and they are important food contact materials used for transportation e.g. in milk trucks, for processing equipment e.g. in the dairy and chocolate industry, in processing of fruit such as apples, grapes, oranges and tomatoes, for containers such as wine tanks, for brew kettles and beer kegs, for processing of dry food such as cereals, flour and sugar, for utensils such as blenders and bread-dough mixers, in slaughter-houses, in the processing of fish, for nearly all of the equipment in professional kitchens such as restaurants and hospitals, in electric kettles, cookware and kitchen appliances of all kinds such as sinks and drains, for bowls, knives, spoons and forks. Chromium is also used to coat other metals, which are then protected from corrosion because of the passive film that forms on the surface of chromium.

Other food contact materials

Chromium compounds are found in pottery, glazes, paper and dyes (Langaard and Norseth, 1986).

Release

Since chromium does not readily oxidise to the hexavalent state, release from food contact materials and articles is expected to occur as Cr(III) and not as Cr(VI) (Guglhofer and Bianchi, 1991).

There is only limited information on the release of chromium from metals and alloys used in food contact materials and articles. In one study a comparison was performed between meals prepared in different stainless steel and glass pans. The amount of chromium measured in stainless steel cooked meals was higher for some, but not for others when compared to glass cooked meals (Accominotti, 1998).

Another study investigated the release of chromium from different stainless steel pots using cold and boiling 5% acetic acid. While, with one exception, no chromium was measured when cold acetic acid was used, release into boiling acetic acid after 5 min. ranged between 0.010-0.315 mg/kg (Kuligowski, 1992).

Further, in a market survey of stainless steel cutlery, conducted by the German surveillance authorities, elevated levels of chromium up to 43 mg/L were detected. The release was tested with 3% acetic acid for 2 hours at 70° C. It was noted by the authorities that in particular cheap, low quality cutlery showed the highest release (CVUA-OWL, 2009).

Chromium plated objects should also be tested for nickel release.

Safety aspects

- The JECFA has not evaluated chromium.
- In the first edition of the WHO "Guidelines for drinking-water quality", published in 1984, a guideline value of 0.05 mg/L for total chromium was set (WHO, 1984). However, the second edition of the guidelines (1993) questioned this value because of uncertainties in the toxicological database (WHO, 1993). Consequently, the guideline value of 0.05 mg/L total chromium was designated as "provisional" and maintained in the third and fourth editions of the guidelines (WHO, 2008 & 2011).
- The speciation of chromium is of great importance for toxicity. Cr(III), the most stable oxidation state in biological materials, is an essential element for normal glucose metabolism, whereas Cr(VI) is highly toxic (Beliles, 1994; Costa, 1997; Nordic Council of Ministers, 1995). Cr(III) has low toxicity due to low absorption (about 0.5%) (Nordic Council of Ministers, 1995). Toxic aspects of chromium are related to Cr(VI) (Nordic Council of Ministers, 1995), due to its high absorption, easy penetration of the cell membranes and its genotoxicity and oxidising properties (Codex, 1995).

- SCF (2003) concluded in its opinion on the tolerable upper level of trivalent chromium for foods for particular nutritional uses and for food supplements, that there was no evidence of adverse effects associated with supplementary intake of chromium up to a dose of 1 mg chromium/day.
- WHO (1996) considers that chromium supplementation should not exceed 250 μg/day.
- The EVM (COT EVM, 2003) assessed chromium but were unable to establish a safe upper level for intake. However, 0.15 mg Cr(III)/kg body weight/day was not expected to result in adverse effects. This is based on a dose of 15 mg Cr/kg body weight/day, administered to rats as chromium chloride that did not show adverse effects. An uncertainty factor of 100 was used (10 for inter-species and 10 for intra-species variation). This guidance applies to Cr(III) compounds only and excludes chromium picolinate (a synthetic chromium compound with higher solubility and lipophilicity than other Cr(III) compounds, which has been shown to cause DNA damage in mammalian cells *in vitro*).
- In 2010, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) stated that "a Tolerable Upper limit for chromium is not available. The Panel also noted that both the limit of 1 mg chromium/day proposed by the SCF, and of 250 μg chromium/day for supplementation proposed by the WHO are based on studies that were not designed to test the safety of chromium The Panel also noted that an intake of 250 μg chromium/day from supplementation would be in the range of intake of chromium from the regular diet. Therefore, the Panel concluded that until more is known about chromium, the value set by the WHO seems most adequate to limit the intake of chromium from foods for particular nutritional uses and foods intended for the general population (including food supplements)."
- Chromium is used in the synthesis of pharmaceutical substances and is included in the EMA Guideline on the specification limits for residues of metal catalysts or metal reagents. According to this EMA Guideline, chromium residues in pharmaceuticals are typically measured as total Cr. Intake of chromium from pharmaceuticals is more likely to be in the form of Cr(III) than Cr(VI). That Guideline classifies chromium in Class 1C, metals of significant safety concern, which also includes

molybdenum, nickel and vanadium. That Guideline proposes a conservative approach to deriving an oral PDE employing the TDI for Cr(VI) of 0.005 mg/kg/day derived by the Dutch RIVM. Therefore, an oral PDE of 0.250 mg/day for a 50 kg individual is proposed.

Conclusions and recommendations

"the SRL for chromium is set at 0.250 mg/kg"

Intake of chromium (as trivalent chromium) should not exceed 250 µg/day. Since this limit had not been derived toxicologically, a fractional allowance for exposure through food contact materials and articles made from metals and alloys cannot be applied.

The P-SC-EMB recommends establishing an SRL based on the EFSA opinion. Consequently, assuming that a person of 60 kg body weight consumes 1 kg of foodstuffs per day that is packaged and/or prepared using food contact materials made from metals and alloys, the SRL for chromium is set at 0.250 mg/kg.

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Cobalt (Co)

Cobalt is a rare element, composing about 0.001% of the Earth's crust (Beliles, 1994). Cobalt often occurs in association with nickel, silver, lead, copper and iron ores (Elinder and Friberg, 1986). Cobalt is present in the vitamin cobalamin or vitamin B12 (Elinder and Friberg, 1986).

Sources and levels of intake

Cobalt is normally found in very low concentrations in foodstuffs (approximately 0.01-0.05 mg/kg) (Beliles, 1986), mainly in green leafy vegetables. Common plants such as lettuce, beets, cabbage, spinach, and sweet potatoes act as sources of dietary cobalt, with spinach containing between 0.1-0.7 mg/kg on a moisture-free basis (Beliles, 1994).

Anses (2011) estimated mean daily intake at 0.18 µg/kg body weight/day in adults and 0.31 µg/kg body weight/day in children.

Metallic food contact materials

Cobalt is used for the production of high-strength alloys (Elinder and Friberg, 1986). It can account for between 0.05% and 0.1% of the composition of certain steels.

Other food contact materials

In the glass and ceramic industries small quantities of cobalt oxide are used to neutralise the yellow tint resulting from the presence of iron in glass, pottery and enamels. Larger quantities are used to impart a blue colour to these products (Beliles, 1994). Cobalt oxide is used in enamel coatings on steel to improve the adherence of the enamel to the metal (Beliles, 1994).

Release

Cobalt is a relatively non-reactive metal; it does not oxidise in dry or moist air (Beliles, 1994). Cobalt reacts with most acids, but becomes passive in concentrated nitric acid. Cobalt is not attacked by alkalis, either in solution or when fused, but it combines with halogens when heated (Beliles, 1994).

Safety aspects

- Cobalt is an essential element. An amount of 5 mg in the body is required for vitamin B12 in order to avoid pernicious anaemia, a fatal illness. Generally cobalt has a low toxicity. Gastrointestinal absorption of soluble cobalt compounds can be estimated to be about 25% (Elinder and Friberg, 1986). Cobalt is used in fertilisers, since a low cobalt concentration in soil may cause cobalt deficiency in sheep and cattle. Cobalt is also used in human medicine in the treatment of certain iron-resistant anaemia (Elinder and Friberg, 1986). Even though cobalt is essential to humans and animals, a few cases of poisoning have been recorded. An effect on the heart, blood pressure, abdominal pain, breathing difficulties and, in the worst cases, death were seen after intakes of cobalt via large amounts of contami¬nated beer (cobalt is used to prevent fermentation) (Elinder and Friberg, 1986).
- SCF (1993) scientific opinion on vitamin B12 recommends that daily intake should not exceed 0.2 mg/day.
- EFSA (2003) confirmed, in an opinion on oleic acid cobalt salts, the classification of cobalt in SCF-List 3 with a restriction of 0.05 mg/kg. This value has also been adopted by Directive 2002/72/EC and was derived by the Dutch RIVM in 1991 based on estimates of total daily intakes.
- In 2003, cobalt was assessed by the UK Expert Group on Vitamins and Minerals (EVM). While there was insufficient data to establish a

safe upper level, they suggested an intake of 0.023 mg/kg body weight/day would not be expected to produce adverse effects. This was based on animal data showing minor testicular effects at 23 mg Co/kg body weight/day with a total uncertainty factor of 1,000 (10 for extrapolation from a LOAEL to a NOAEL and 10 for inter-species and 10 for intra-species variation) (COT EVM, 2003).

- RIVM (2001) derived a TDI of 0.0014 mg/kg body weight/day (0.08 mg/person/day) from human data, in which an additional effect from alcohol consumption in the study population was possible.

Conclusions and recommendations

"the SRL for cobalt is set at 0.02 mg/kg"

The TDI established by the RIVM in 2001 was derived from human data. Since European intake data are scarce, the default allowance of 20% for exposure through food contact materials and articles made from metals and alloys was applied to the TDI of 0.0014 mg/kg body weight/day. Assuming that a person of 60 kg body weight consumes 1 kg of foodstuffs per day that is packaged and/or prepared with food contact materials made from metals and alloys, the SRL for cobalt is set at 0.02 mg/kg.

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Copper (Cu)

Copper is found at a concentration of 70 mg/kg in the Earth's crust (Beliles, 1994). Copper exists in two oxidation states: Cu(I) (cuprous) and Cu(II) (cupric). Copper can also occur in a trivalent state due to certain chemical reactions. Copper is amongst the most effective of metal biochemical oxidising agents. Copper is an essential element to man (Aaseth and Norseth, 1986). Copper also has the ability to restrict bacterial growth, e.g. Legionella in drinking water systems (Rogers *et al.*, 1994).

Sources and levels of intake

Copper is naturally present in most foodstuffs in the form of copper ions or copper salts. Generally, the concentration of copper in foodstuffs is about 2 mg/kg or less, the main sources being meat, offal, fish, pecans, milk chocolate and green vegetables (Aaseth and Norseth, 1986). However, levels of up to 39 mg/kg have been reported for liver and cocoa.

In the European Union Risk Assessment Report (EU-RAR, 2008), copper exposure from food and beverages, estimated from a wide range of duplicate diet studies and market basket analysis consistently show copper intakes <2 mg/day. An overall median copper intake of 1.25 mg Cu/day was derived (EU-RAR, 2008).

Anses (2011) estimated mean daily intake at 1.94 mg/person/day in adults and the 95th percentile at 4.1 mg/person/day.

Additionally, exposure to copper via dietary supplements can contribute up to 2 mg/day to the total intake (EU-RAR, 2008).

Metallic food contact materials

Copper vessels are traditionally used in many specialised food processing activities, such as in breweries and distilleries, for cheese-making, chocolate, dry vegetables, jam and sweets production. In general, copper is used unalloyed for food utensils, for example in saucepans, which are usually lined inside with tin or stainless steel. Copper is used in alloys, particularly brass, bronze, and nickel silver.

Other food contact materials

No information is available.

Release

Copper is slowly attacked by dilute hydrochloric acid or dilute sulphuric acid and is soluble in ammonia water (Beliles, 1994). Acidic foodstuffs can attack copper in utensils. Therefore, copper may be present in foodstuffs due to release from food contact materials, e.g. copper utensils, copper pipes, etc., or from using drinking water from copper pipes for food preparation. In some cases, high copper release may induce some discolouration.

Safety aspects

- JECFA (1982) has established a PMTDI of 0.5 mg/kg body weight/day.
- The daily requirement is 0.05 mg/kg body weight/day, set by the JECFA in 1982.
- WHO (1993) has set a provisional health-based guideline value for copper at 2 mg/L in drinking water as a result of uncertainties in the dose-response relationship between copper in drinking water and acute gastrointestinal effects in humans. This value was also taken forward to the latest fourth edition (WHO, 2011).
- There is greater health risk from a copper deficiency than from excess copper intake. Acute toxicity due to ingestion of copper is infrequent

in humans. However, when it occurs it is usually a consequence of the release of copper into beverages (including drinking water) or from accidental or deliberate ingestion of high quantities of copper salts. Symptoms include vomiting, lethargy, acute haemolytic anaemia, renal and liver damage, neurotoxicity, increased blood pressure and respiratory rates. In some cases, coma and death ensued (Environmental Health Criteria for Copper, 1996). Chronic copper poisoning has not been described in the general population (Aaseth and Norseth, 1986).

- SCF (2003) and EFSA (2006) derived an upper limit for adults of 5 mg/person/day from a dietary supplementation study. This value arose from a copper dose of 10 mg/day, where no adverse effects were detected, and an uncertainty factor of 2 for population variability. However, this study was characterised by a limited number of participants (n=7) and did not establish a dose-response-relationship. For children aged 1-3 years, an upper limit of 1 mg/day was derived, taking into consideration their lower body weight.
- The UK Expert Group on Vitamins and Minerals assessed copper and derived a safe upper level of 0.16 mg/kg body weight/day based on a NOAEL of 16 mg/kg body weight/day in a sub-chronic rat toxicity study and using an uncertainty factor of 100 (COT EVM, 2003).
- Copper is used in the synthesis of pharmaceutical substances and is included in the EMA Guideline on the specification limits for residues of metal catalysts or metal reagents. That Guideline classifies copper in Class 2, metals with low safety concern, which also includes manganese. In that Guideline, an oral PDE of 2500 µg/day or 50 µg Cu/kg/day in a 50 kg subject is considered to be suitable for both sub-chronic and chronic ingestion based on a sub-chronic oral NOEL of 5 mg Cu/kg/day in rats and dogs with a safety factor of 100 (2 x 10 x 5 x 1 x 1).
- In 2008, the copper industry submitted a voluntary risk assessment report to the European Commission, which was evaluated by the "Technical Committee for New and Existing Substances" (TCNES) and the "Scientific Committee for Health and Environmental Risk" (SCHER). A NOAEL of 16.3 mg/kg body weight/day was derived from a 90 day sub-chronic rat study, which was also confirmed by a two-generation rat reproductive toxicity study. After applying an uncertainty

factor of 100, 0.16 mg/kg body weight/day was set, corresponding to 9.8 mg/day (EU-RAR, 2008).

Conclusions and recommendations

“the SRL for copper is set at 4 mg/kg”

Since the upper limit derived by SCF (2003) and EFSA (2006) was based on a supplementation study performed with only seven adults and showing no adverse effects, the P-SC-EMB concluded to establish an SRL based on the EU-RAR assessment with a human derived value of 9.8 mg/day.

The intake data were used to estimate a worst-case oral exposure to copper. Assuming a worst-case intake from food/drinking water at the 95th percentile of 4 mg/day and an additional intake from copper supplements of 2 mg/day, a total intake of 6 mg/day can be calculated. Since this worst-case intake is below the toxicologically derived limit of 9.8 mg/day, the difference can be allocated to exposure from food contact materials made from metals and alloys.

Consequently, assuming that a person of 60 kg body weight consumes 1 kg of foodstuffs per day that is packaged and/or prepared with food contact materials made from metals and alloys, the SRL for copper is set at 4 mg/kg.

Children were not considered as a vulnerable sub-population as done by SCF (2003) and EFSA (2006) because of the negligible exposure of children to food contact materials and articles made out of copper (Foster, 2010).

Release due to traditional use, as referred to in Regulation (EC) No. 1935/2004, falls outside the scope of this SRL.

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Iron (Fe)

Iron is the fourth most abundant element (5%) in the Earth's crust (Beliles, 1994). Iron is used for the production of steel. The principal compounds of iron are ferrous Fe(II) and ferric Fe(III) (Beliles, 1994). Iron is essential for the synthesis of blood pigments. Under normal conditions the body contains about 4 g of iron (Beliles, 1994). Haemoglobin contains the greatest amount of iron in the body (67%), and this is largely in the red blood cells (Beliles, 1994).

Sources and levels of intake

Iron is present in most foods and beverages. In general, liver, kidney, beef, ham, egg yolk, and soybeans have iron concentrations in the order of 30-150 mg/kg (Elinder, 1986). In several countries the cereal most commonly eaten, e.g. wheat flour, is fortified with iron in order to provide the necessary amount of iron in the diet (Nordic Council of Ministers, 1995).

Mean dietary intakes from various European countries range from 10-22 mg/day and the 97.5th percentile from 16-72 mg/day (SCF, 2003 and EFSA, 2006).

Anses (2011) estimated mean daily intake at 7.71 mg/person/day in adults and 6.57 mg/person/day in children.

Metallic food contact materials

Iron is used in a great variety of kitchen utensils. Iron is found in steel cans and in lids and closures for glass bottles and jars. Cast iron is also used for pots and pans. Iron is the major constituent of steel, which also contains small quantities of certain other metals, such as chromium, manganese, molybdenum and nickel (Elinder, 1986).

Other food contact materials

Several forms of iron oxide are used as paint pigments (Beliles, 1994), of which some are also permitted as food colourings. The soluble salts are variously used as pigments in food contact materials (Beliles, 1994).

Release

Food contamination by iron may originate from food processing equipment, containers and other utensils used for foodstuffs. Tests performed on various stainless steel sauce pans using boiling 5% acidic acid as a simulant and a contact time of 5 minutes resulted in iron release between 0.22-2.85 mg/kg (Kuligowski, 1992). Similarly, a survey of teapots showed iron release between 0.1 mg/L and 4.7 mg/L using a citric acid solution (1 g/L) as a simulant and a contact time of 30 min. (Bolle, 2011). Rare cases of release of very high quantities of iron from food contact materials such as iron kitchen utensils have been observed. For example, the release of 2500 mg/kg iron from a wok and a cast iron skillet were observed under the conditions mentioned above (Kuligowski, 1992).

Safety aspects

- JECFA (1983) has established a PMTDI at 0.8 mg/kg body weight/day. The value applies to iron from all sources except for iron oxides used as colouring agents, supplemental iron taken during pregnancy and lactation and supplemental iron for specific clinical requirements. The value is eight times lower than the acute toxic dose.

- SCF (1993) has evaluated iron mainly to be a deficiency problem.
- The WHO proposed that no health-based guideline value be set for iron in drinking water (WHO, 1993). This was also maintained in their latest fourth edition (WHO, 2011).
- The recommended intake is 10-15 mg/day (Nordic Council of Ministers, 1995).
- Iron is an essential trace metal (JECFA, 1983). Iron is mainly a deficiency problem and not a toxicological problem. Iron deficiency is generally acknowledged to be the single most common nutritional deficiency in both developing and developed countries (Nordic Council of Ministers, 1995). Certain iron salts, mainly ferrous sulphate and ferrous succinate, are frequently used for the treatment and prevention of iron deficiency in humans (Beliles, 1994). Under normal conditions, about 5-15% of the iron is absorbed (Elinder, 1986). Ingestion of soluble iron salts by children in doses exceeding 0.5 g of iron can give rise to severe lesions in the gastrointestinal tract, followed by metabolic acidosis, shock and toxic hepatitis (Elinder, 1986).
- Iron supplementation of more than 30 mg/day could be associated with iron accumulation indicators in older adults (Fleming, 2002).
- The Belgian Royal Decree of 03 March 1992 on marketing of nutriments and foodstuffs with added nutriments sets the maximum authorised intake via food supplements at 28 mg/day.
- In 2006, the EFSA Scientific Panel on Dietetic Products, Nutrition and Allergies were unable to establish a tolerable upper intake level as the data available were insufficient. The risk of adverse effects from current dietary iron intakes, including fortified foods in some countries but excluding supplements, was considered to be low for the population as a whole, except those homozygous for hereditary haemochromatosis. Mean dietary iron intake across the EU was in the range of 10-22 mg/person/day and the 97.5th percentile ranged from 16-72 mg/person/day (EFSA, 2006).
- The EVM did not consider there to be sufficient data to derive a safe upper level of iron intake, but they suggested that a supplemental intake of 0.28 mg/kg body weight/day (17 mg/day) would not be expected to produce adverse effects in the majority of people (COT EVM, 2003).

This is based on data showing that doses between 50 and 220 mg/day cause effects in humans, and using the lower end of this range and an uncertainty factor of 3 to extrapolate from a LOAEL to a NOAEL. No factor for inter-species variation was required and, as the data had been collected in large numbers of people, it was not deemed necessary to use an uncertainty factor for inter-individual variation.

- Iron (Fe) is used in the synthesis of pharmaceutical substances and is included in the EMA Guideline on the specification limits for residues of metal catalysts or metal reagents. That Guideline classifies iron in Class 3, metals with minimal safety concern, which also includes zinc. In that Guideline, an oral PDE for Fe is set at 13 mg/day (260 µg Fe/kg/day in a 50 kg patient), based on the US RDA and the UK guidance value for supplementary intake. This is also supported by the fact that the 97.5 percentile dietary intake in UK is 26 mg/day. In addition, a significant proportion of dietary Fe is in the form of haem Fe that is well-absorbed compared to non-haem Fe (the form likely to be encountered as a catalyst residue in pharmaceuticals).

Conclusions and recommendations

"an SRL of 40 mg/kg is reasonably achievable"

Since no toxicologically derived upper limit could be set, the P-SC-EMB decided that a specific release limit for iron should be set at levels that are as low as reasonably achievable (ALARA). Such an approach ensures that the manufacturer apply measures to prevent and reduce the release of iron from food contact materials and articles as far as possible in order to protect public health.

Data provided by industry and member states show that an SRL of 40 mg/kg is reasonably achievable at present.

This specific release limit should be subject to a review at the latest three years after the adoption of this Technical guide to take account of the advance of scientific and technical knowledge and improvements in good manufacturing practice.

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Magnesium (Mg)

Magnesium is an alkaline earth metal. It is the eighth most abundant element in the Earth's crust and the third most common metal after aluminium and iron. It is also the third most important component of salts dissolved in seawater.

Magnesium is a metal that has few useful mechanical characteristics but is very light (one-third lighter than aluminium), is silvery-white in colour and tarnishes slightly on exposure to air.

Sources and levels of intake

Magnesium is widely used in medicine and pharmacology. It plays a very important role in the human diet. Many disorders can result from lack of magnesium: depression and anxiety, diabetes, muscle spasms, cramps, cardiovascular disorders, high blood pressure and osteoporosis. It plays an active role in inter-neuronal data transmission (Giannini, 1997; Giannini, 2000).

Excess consumption is naturally eliminated. Intake of large quantities of magnesium causes diarrhoea. Magnesium is effectively filtered by the kidneys in adults, but poisoning by excessive magnesium can occur in children and in cases of renal insufficiency (Kontani, 2005).

Magnesium hydroxide $Mg(OH)_2$, which is obtained by a reaction between sodium hydroxide and magnesium salt, is used in medicine as an antacid and also as a laxative (milk of magnesia) and in sugar refining.

Seafood (apart from winkles) contains 410 mg/100 g, and there is no doubt that this is the food source richest in magnesium, followed by molasses (from 197 to 242 mg/100 g), cocoa (from 150 to 400 mg/100 g) and whole grains (from 100 to 150 mg/100 g). However, the polysaccharides and phytic acids that the latter contain impede magnesium absorption, especially in the case of yeasted wholemeal bread. Spinach contains between 50 and 100 mg/100 g, but it also contains oxalic acid that can inhibit magnesium assimilation. Fish, offal and bolted cereals contain between 25 and 50 mg/100 g of magnesium. A few other foodstuffs also contain magnesium, e.g. greens, buckwheat, broad beans, almonds, Nigari (magnesium chloride) and bananas.

Anses (2011) estimated mean daily intake at 304 mg/person/day in adults and 227 mg/person/day in children. Highest concentrations in the French TDS were measured in tofu (1340 mg/kg), chocolate (1143 mg/kg), molluscs and crustaceans (811 mg/kg) and cookies (514 mg/kg).

Metallic food contact materials

Magnesium is mainly used in aluminium-magnesium alloys. It is also used in the iron and steel industry to eliminate sulphur. It can be used in the manufacturing of spheroidal graphite cast iron, in which the graphite takes the form of nodules (spheroids) or cast iron (iron and steel industry).

Magnesium is widely used in aluminium-based alloys for permanent set yielding, facilitating the manufacturing of profiles or beverage cans, which consume large quantities of the metal (Luo, 2001).

Other food contact materials

No information available.

Release

No information available.

Safety aspects

- SCF (2001) has established a tolerable upper limit of 250 mg Mg per day for readily dissociable magnesium salts and compounds like MgO in nutritional supplements, water, or added to food and beverages. This upper limit does not include Mg normally present in foods and beverages.
- Magnesium is used in the production of many alloys, particularly aluminium alloys. It may constitute 11% of some alloys. SCF (2001) and AFSSA (France) (2001) recommended that daily intake should not exceed 700 mg/day. The Belgian Royal Decree of 3 March 1992 on the marketing of nutriments and foods with added nutriments sets the maximum authorised intake via food supplements at 450 mg/day (Recommended Daily Intake).
- The UK EVM assessed magnesium and considered there to be insufficient data to derive a safe upper level (COT EVM, 2003). On the basis of the available data from one study showing only mild reversible diarrhoea in a small percentage of people supplementing magnesium at around 400 mg/person/day, this level of magnesium supplementation was considered to be without significant adverse effects. This corresponds to 6.7 mg/kg body weight/day for a 60 kg adult.

Conclusions and recommendations

"deriving an SRL was unnecessary"

With regard to the safety aspects mentioned above, it can be assumed that release of magnesium from food contact materials made from metals and alloys at a level where adverse effects occur is not likely. Therefore, the P-SC-EMB concluded that deriving an SRL was unnecessary.

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Manganese (Mn)

Manganese is an essential element, widely distributed in the environment, comprising approximately 0.1% of the Earth's crust (Florence and Batley, 1980). About 90% of total manganese production is used in steel manufacture as a deoxidising and desulphurising additive and as an alloying constituent (Beliles, 1994; Saric, 1986). Manganese exists in two common oxidation states, as manganese (II) and manganese (IV) (Florence and Batley, 1980).

Sources and levels of intake

Manganese is present in most foodstuffs. The main contributors of manganese to the diet are cereals (10-30 mg/kg) as well as vegetables and fruits (0.5-5 mg/kg) (Beliles, 1994). Nuts may also have a high content of manganese. In some countries, manganese has replaced organic lead as an additive in petrol. This may result in increasing concentrations of manganese in the environment and in foodstuffs in the future.

The average intake is 2-3 mg/day (SCF, 1993). More recent intake data from the British total diet study (2006) estimated the mean and high-level intake for adults at 4.02 mg/person/day and 7.44 mg/person/day, respectively (FSA, 2009).

Anses (2011) estimated the mean daily intake at 2.16 mg/person/day in adults and 1.46 mg/person/day in children.

Metallic food contact materials

Manganese is used in steel and other alloys (Saric, 1986).

Other food contact materials

Manganese is used in the manufacture of glass to bleach out the colour of any iron present (Saric, 1986). Manganese is used in pigments, glazes, and other products.

Release

Release of manganese from six types of stainless steels containing 0.21-2.0 wt % manganese was examined in drinking water and in waters with 500 mg/L chloride or 3 mg/L "free" chlorine. The release of manganese was below 0.002 mg/L in all tests (Lewus *et al.*, 1998).

Safety aspects

- The JECFA has not evaluated manganese.
- WHO (1993) recommends a daily intake of 2-3 mg/day.
- SCF (1993) recommends 1-10 mg/day as the acceptable range of intake.
- SCF (1996) recommends a maximum limit of 0.5 mg/L for manganese in natural mineral waters.
- In its 2001 recommendation, the AFSSA (France) set a safety limit of 10 mg/day (AFSSA-CNERNA-CNRS, 2001).
- The Belgian Royal Decree of 3 March 1992 sets the maximum authorised intake via food supplements at 5.25 mg/day (RDI – Recommended Daily Intake).
- WHO (2003) derived a limit of 0.06 mg/kg body weight/day (3.6 mg/day) within the drinking-aater guidelines. This limit was derived from the average nutritional intake of manganese for an adult of 11 mg/day and an uncertainty factor of 3 (for the possible higher bio-availability of manganese in water) and resulted in a guidance value of 0.4 mg/L.

However, in the 2011 revision of the guidelines, the WHO stated that this "health-based value is well above concentrations of manganese normally found in drinking-water, it is not considered necessary to derive a formal guideline value" (WHO, 2011).

- Both SCF (2000) and EFSA (2006) concluded that an upper level of manganese cannot be set due to the limitations of the human data and the non-availability of NOAELs for critical endpoints from animal studies, thereby producing a considerable degree of uncertainty. To date, the lowest-adverse-effect-levels (LOAELs) following oral administration observed are 0.28 mg/kg body weight/day in growing male rats and 0.36 mg/kg body weight/day in adult female rats (SCF, 2000; EFSA, 2006).
- Manganese is an essential trace element that plays a role in bone mineralisation, protein and energy metabolism, metabolic regulation, cellular protection from damaging free radicals, and the formation of glycosaminoglycans (ATSDR, 2008). Although manganese is an essential nutrient, exposure to high levels via inhalation or ingestion may cause some adverse health effects (ATSDR, 2008). Excess manganese affects the central nervous system and neurological effects have been observed in cases of occupational exposure. No problems have been reported in connection with dietary intake of manganese, since manganese is considered one of the least toxic metals. Consistent with its role as an essential element, manganese and its inorganic compounds have a relatively low order of acute toxicity (Beliles, 1994). However, absorption is increased in individuals with iron deficiency (Beliles, 1994). In humans, the degree of manganese absorption from the gastrointestinal system is generally low, in the order of 3% (Beliles, 1994).
- The EVM could not derive an upper intake limit (COT EVM, 2003). However, guidance levels where no adverse effects are expected were derived using two retrospective studies. In these studies, the cohorts were exposed to either two or three different concentrations, respectively, of manganese in drinking water. The study using three different manganese concentrations found significant neurological effects and symptoms in the highest exposure group. Based on the NOAEL for these effects, the EVM derived a guidance level for older people of 0.15 mg/kg body weight/day (9 mg/day). No significant effects

were observed at either concentration in the second study. Hence, the EVM derived a guidance level for the general population of 0.2 mg/kg body weight/day (12 mg/day) using the higher concentration.

- Manganese is used in the synthesis of pharmaceutical substances and is included in the EMA Guideline on the specification limits for residues of metal catalysts or metal reagents. That Guideline classifies manganese in Class 2, metals with low safety concern, which also includes copper. In that Guideline, a conservative oral PDE for non-dietary intake of manganese of 2.5 mg Mn/day is considered to be appropriate.

Conclusions and recommendations

"the SRL for manganese is set at 1.8 mg/kg"

Since the WHO limit was **derived** from dietary intake data, the P-SC-EMB decided to use the EVM assessment. Therefore, following the concept of protecting vulnerable sub-populations, the guidance level of 9 mg/day for older people was used as a starting point. In this case, because oral intake data from multiple European countries was not available, applying an allowance of 20% for food contact materials is appropriate. Assuming that a person of 60 kg body weight consumes 1 kg of foodstuffs per day that is packaged and/or prepared with food contact materials made from metals and alloys, the SRL for manganese is set at 1.8 mg/kg.

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Molybdenum (Mo)

Molybdenum is a hard white metal with a density of 10.2 g/cm^3 (at room temperature). It is found ubiquitously in animals and plants. The human body contains approximately 6 mg of Mo (Winter, 2007).

Sources and levels of intake

The main natural sources of molybdenum are liver, peas, beans, spinach, wheat germ, tomatoes and lemons.

The EFSA estimated oral intake for adults from food up to 500 µg/day. In children age 1-3 years old up to 89 µg/day (EFSA, 2009). The 2006 British total diet study estimated the mean and high-level intake for adults at 96.6-98.4 µg/person/day and 181.8-184.8 µg/person/day, respectively (FSA, 2009).

Anses (2011) estimated mean daily intake at 93.9 µg/person/day in adults and the 95th percentile at 155 mg/person/day.

Metallic food contact materials

Adding a small amount of molybdenum helps to harden steel. Over two-thirds of all molybdenum production is used for alloys. Molybdenum is used in the production of many iron alloys (some stainless steels contain over 4% Mo).

Molybdenum is used in high-resistance alloys and high-temperature steels. Special alloys containing molybdenum, such as Hastelloy®, are highly resistant and do not corrode, even at high temperatures.

Other food contact materials

Molybdenum oxides are a constituent of pigments commonly used in ceramics.

Release

No information.

Safety aspects

- SCF (2000) and EFSA (2006) laid down an upper limit for molybdenum of 0.6 mg/day. This limit was based on an uncertainty factor of 100 using a NOAEL of 0.9 mg/kg body weight/day from a 9-week study in rats (incorporating an uncertainty factor of 10 for the additive effect of Cu deficiency in metabolism and an uncertainty factor of 10 for the effects on human reproduction). Furthermore, for children aged 1-3 years an upper limit of 0.1 mg/day was extrapolated from the adult upper limit due to adverse effects on growth seen in young rats. EFSA (2009) confirmed these derived upper limits in an opinion of the ANS Panel.
- The EVM assessed molybdenum and determined that there was insufficient data to derive a safe upper level (COT EVM, 2003). Studies had shown that intakes of 1 mg/person/day and above could be associated with gout-like symptoms. However, the intake of molybdenum in the UK diet (maximum 0.23 mg/person/day) was not expected to present a risk.
- Molybdenum is used in the synthesis of pharmaceutical substances and is included in the EMA Guideline on the specification limits for residues of metal catalysts or metal reagents. That Guideline classifies molybdenum in Class 1C, metals of significant safety concern, which also includes nickel, chromium and vanadium. That Guideline sets an oral PDE of 300 µg Mo/day for a 50 kg individual (following the RIVM approach – Tolerable Daily Intake of 10 µg Mo/kg/day; bodyweight of 50 kg and a safety factor of 0.6).

Conclusions and recommendations

"the SRL for molybdenum is set at 0.12 mg/kg"

Since the EVM could not derive an upper limit for molybdenum and only estimated the maximum dietary intake, the P-SC-EMB has decided to follow the opinion presented by the EFSA (2006, 2009) with a derived upper limit of 0.6 mg/day.

Intake data from multiple European countries was provided by the EFSA (2009). However, the data used by the EFSA in 2009 was brought forward from earlier SCF opinions and contained data originating from the 1980s. Since newer intake data was only available from two European countries, the default allowance of 20% for exposure to food contact materials and articles made from metals and alloys was applied to the upper limit of 0.6 mg/day. Consequently, assuming that a person of 60 kg body weight consumes 1 kg of foodstuffs per day that is packaged and/or prepared with food contact materials made from metals and alloys, the SRL for molybdenum is set at 0.12 mg/kg.

Children are not considered as a vulnerable sub-population because of the negligible exposure of children to food contact materials and articles containing molybdenum (Foster, 2010).

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Nickel (Ni)

Nickel, combined with other elements, occurs naturally in the Earth's crust, is found in all soils, and is also emitted from volcanoes. Nickel is the 24th most abundant element and, in the environment, nickel is found primarily as oxides or sulphides (ATSDR, 2005). There has been a growing interest in the possible effects of nickel in foodstuffs, i.e. a possible worsening of nickel-related dermatitis. Nickel is probably an essential element in animals, but not in humans (ATSDR, 2005).

Sources and levels of intake

Nickel is found in small quantities in many foodstuffs (0.001-0.01 mg/kg) and in higher concentrations in foodstuffs such as grains, nuts, cocoa products and seeds (up to 0.8 mg/kg) (National Food Agency of Denmark, 1995).

In the diet it is found as complex bound Ni2+-ions. Recently, the British total diet study (2006) estimated mean and high nickel intake levels for adults to be 0.09-0.1 mg/day (1.49-1.63 µg/kg body weight/day) and 0.18-0.19 mg/day (3.01-3.08 µg/kg body weight/day), respectively (FSA, 2009).

Anses (2011) estimated mean daily intake at 2.33 µg/kg body weight/day in adults and 3.83 µg/kg body weight/day in children.

Metallic food contact materials

85% of the world-wide production of nickel is used for the manufacturing of alloys, 9% for plating and 6% for other uses (e.g. batteries) (Nickel Institute, 2011). There are at least 3,000 different alloys containing nickel. The major use of nickel is in the production of high-quality, corrosion resistant alloys with iron, copper, aluminium, chromium, zinc and molybdenum.

Nickel-containing stainless steel is strongly corrosion-resistant. Most nickel-containing food contact materials are stainless steels. Nickel-containing stainless steels (see guideline on stainless steel) are important food contact materials used for transport e.g. in milk trucks, for processing equipment e.g. in the dairy and chocolate industry, in processing of fruit such as apples, grapes, oranges and tomatoes, for containers such as wine tanks, for brew kettles and beer kegs, for processing of dry foods such as cereals, flour and sugar, for utensils such as blenders and bread-dough mixers, in slaughterhouses, in fish processing, for nearly all of the equipment in professional kitchens such as restaurants and hospitals, for electric kettles, cookware and kitchen appliances of all kinds such as sinks and drains, for bowls, knives, spoons and forks.

Nickel-plated items are less durable, less corrosion-resistant than stainless steel and are therefore not commonly used for articles in contact with food and drink. For chromium-plated objects, the materials are consecutively given a copper, nickel and then a chromium layer. Typical food contact materials and articles are kitchen utensils and nickel-plated heating coils in electric kettles.

Other food contact materials

Nickelous oxide, NiO, is used in the production of enamel frits and ceramic glazes, and in glass manufacture (Beliles, 1994). Basic nickel carbonate is used in colouring ceramics and glazes (Beliles, 1994).

Release

A study comparing foods prepared in different stainless steel and glass pans found a higher nickel content in the stainless-steel-cooked foods. However, the additional contribution from the stainless steel represented only a minor fraction of the nickel content in the foods (Accominotti, 1998). In a similar study, acidic foods such as rhubarb cooked in new stainless steel pans only showed significant pick-up of nickel during the first cooking operation (Flint, 1997). Using boiling 5% acidic acid as a stimulant for 5 minutes in stainless steel pans, nickel release ranged between 0.08 and 0.21 mg/kg (Kuligowski, 1992). A survey of teapots showed nickel release between 1.2 mg/L and 35 mg/L using a citric acid solution (1 g/L) as a simulant and a contact time of 30 min. (Bolle, 2011). Further, for the years 2009 to 2011, RASFF shows 17 notifications for nickel release from stainless steel products up to 49 mg/kg (RASFF, 2011).

Safety aspects

- The JECFA has not evaluated nickel.
- In 2008, AFSSA set a tolerable daily intake at 22 µg/kg bw/d, according to WHO (2005), based on a 2-generations rat study.
- EFSA (2005) could not derive a tolerable upper intake level for nickel in the evaluation of safety of fortified foods and food supplements due to the absence of adequate dose-response data for dermal reactions in nickel-sensitised subjects.
- The absorption and retention of nickel in the gastrointestinal tract is influenced by fasting and food intake. Food intake and gastric emptying are of substantial significance for the bio-availability of nickel from aqueous solutions. The absorption of free nickel ions released in the gastrointestinal tract may be 40 times higher than that of complex-bound nickel from foodstuffs (Sunderman *et al.*, 1989). The absorption of nickel from drinking-water is increased by fasting (Nielsen *et al.*, 1999). Up to 10% of inorganic nickel compounds are absorbed from the gastrointestinal tract (Norseth, 1986). Nickel intake via foodstuffs does not cause hazards for the majority of consumers. A subgroup of the population (approximately 10%, mainly women) has contact allergies to nickel. Nickel allergies are only caused by absorption of nickel through the skin. However, some patients with certain types of nickel dermatitis may get a flare-up of eczema through oral ingestion of even small amounts of nickel, e.g. from foodstuffs rich in nickel or foodstuffs or drinks contaminated by nickel-containing materials (Veien, 1989; Veien and Menné, 1990).

- WHO (2008 & 2011) has derived a TDI of 0.012 mg/kg body weight/day (0.7 mg/day) from human data. This value was derived from the LOAEL of 0.012 mg/kg body weight/day from an oral provocation study using fasting individuals with an allergy against nickel (Nielsen, 1999). Because the LOAEL was based on a highly susceptible population, the WHO stated that no additional uncertainty factor was necessary.
- The EVM also assessed nickel; and. while they could not derive a safe upper level, they determined that intakes of 0.0043 mg/kg body weight/day would not be expected to affect non-sensitised individuals (COT EVM, 2003). This guidance is based on a LOAEL for increased perinatal mortality in a multi-generation rat study of 1.3 mg/kg body weight/day and using uncertainty factors of 10 for inter-species variation, 10 for intra-species variation and 3 for extrapolation of a LOAEL to a NOAEL.
- In their 2008 statement, the COT considered that UK dietary exposures above the EVM guidance level but within the WHO TDI of 0.012 mg/kg body weight/day were unlikely to be of toxicological concern, though they noted that nickel may exacerbate contact dermatitis/eczema in pre-sensitised individuals (COT, 2008). The COT had previously concluded that pre-school children (who have the highest exposures) are less likely than adults to be sensitised and would therefore not be considered to be a sensitive sub-group.
- Nickel is used in the synthesis of pharmaceutical substances and is included in the EMA Guideline on the specification limits for residues of metal catalysts or metal reagents. That Guideline classifies nickel in Class 1C, metals of significant safety concern, which also includes molybdenum, chromium and vanadium. That Guideline proposes an oral PDE of 300 µg Ni/day (6 µg Ni/kg/day in a 50 kg person), based on a NOEL of 5 mg/kg/day (from a 2 year rat study, Ambrose *et al,* 1976) and a safety factor of well over 800. This recommended PDE is equivalent to 30% the RfD for Ni proposed by the EPA.

Conclusions and recommendations

"the SRL is set at 0.14 mg/kg"

The P-SC-EMB has decided to use the WHO TDI of 0.012 mg/kg body weight/day (0.7 mg/day), which is based on human data from nickel-sensitised individuals, rather than that from the EVM, which is based on animal data.

Since recent European intake data are scarce, the default allowance of 20% for exposure through food contact materials and articles made from metals and alloys was applied to the TDI. Assuming that a person of 60 kg body weight consumes 1 kg of foodstuffs per day that is packaged and/or prepared with food contact materials made from metals and alloys, the SRL is set at 0.14 mg/kg. This SRL also protects nickel-sensitised individuals.

Independently of the release limit, it should be noted that nickel-plated objects are not suitable for direct contact with foodstuffs.

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Silver (Ag)

Pure silver has the highest thermal and electrical conductivity of all metals. Silver alloyed with 7.5% copper is known as sterling silver (Beliles, 1994).

Sources and levels of intake

Silver may be ingested via consumption of marine organisms containing low concentrations, and in small amounts released from dental fillings (Fowler and Nordberg, 1986). Silver salts are used in some countries to disinfect drinking water because of their germicidal properties (Beliles, 1994; Fowler and Nordberg, 1986). Silver is also used as a colouring agent for decorations in confectionery and in alcoholic beverages.

Based on actual levels of silver in drinking water that were generally below 0.005 mg/L (WHO, 1993), the WHO estimated an intake of about 0.007 mg/day (0.12 µg/kg body weight/day).

Anses (2011) estimated mean daily intake between 1.29 and 2.65 µg/kg body weight/day (according to lower bound or upper bound assumptions) for adults and between 1.60 and 3.47 µg/kg body weight/day for children.

Metallic food contact materials

Silver is used in the production of cutlery and tableware (Fowler and Nordberg, 1986).

Attention should be paid to the European standards EN ISO 8442-2 (AFNOR, 1997) and EN ISO 8442-3 (AFNOR, 1997) that apply to silver-plated nickel silver, or silver-plated stainless steel cutlery and to silver-coated brass, copper, nickel-silver, pewter and stainless steel hollow-ware and attachments thereto, respectively.

Other food contact materials

No information is available.

Release

The information on release of silver is limited. Pure silver is a moderately soft metal (Beliles, 1994). Chemically, silver is the most reactive of the noble metals, but it does not readily oxidise; instead it "tarnishes" by combining with sulphur or H2S. Nitric or sulphuric acids can oxidise silver to the unipositive ion, the form in which it exists in most of its compounds (Beliles, 1994).

Safety aspects

- The JECFA has not evaluated silver.
- Up to 10-20% of silver salts may be absorbed following ingestion (Fowler and Nordberg, 1986). The biological half-life of silver ranges from a few days for animals up to about 50 days in the human liver (Fowler and Nordberg, 1986). Water-soluble silver compounds, such as silver nitrate, have a local corrosive effect and may cause fatal poisoning if ingested accidentally. Repeated exposure to silver may produce anaemia, cardiac enlargement, growth retardation and degenerative changes in the liver (Fowler and Nordberg, 1986).
- Acute human toxicity from silver is unknown, but some silver compounds such as silver oxide and silver nitrate are irritating, and exposure is associated with nose-bleeds and abdominal cramps (Beliles, 1994).
- In 1980, the EPA analysed and described a series of experiments, concluding that silver ion concentrations > 0.2 mg/L in drinking water had no harmful effect on laboratory animals that had been continuously ingesting them for 11 months (EPA, 1980).

- The WHO did not set any value for silver in the 4th edition of the "Guidelines for drinking-water quality", which is coherent with previous editions (WHO, 1993, 2008 & 2011). Using argyria (silver overload) (Gaul, 1935) as an endpoint, they derived a total lifetime oral intake where no effects are expected of about 10 g of silver (equal to 0.39 mg/person/day).
- The EFSA has established a group restriction for substances containing silver at 0.05 mg/kg food. In their decision the EFSA considered the WHO "Guidelines for drinking-water quality" limit of 0.39 mg/person/day and concluded that a restriction of 0.05 mg Ag/kg food would contribute about 12.5% of the human NOAEL (EFSA, 2005).
- Remark: food contact materials containing nanoscale silver have not been considered and need to be evaluated separately on a case-by-case basis.

Conclusions and recommendations

"the SRL is set at 0.08 mg/kg"

Given the lack of data and the lack of clarity associated with the WHO derived total lifetime oral intake of about 10 g, the P-SC-EMB decided to use the intake data from Anses (2011). Using the lower value of 1.29 µg/kg body weight/day (0.08 mg/day) and assuming that a person of 60 kg body weight consumes 1 kg of foodstuffs per day that is packaged and/or prepared with food contact materials made from metals and alloys, the SRL is set at 0.08 mg/kg. Because the limit was derived from intake data no allowance for metallic food contact materials was applied.

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Tin (Sn)

Tin occurs in the Earth's crust with an average abundance of 2 mg/kg and is concentrated in areas of tin-bearing minerals, mainly as cassiterite or tinstone (SnO_2), which is the main source of tin production (Beliles, 1994). Combustion of fossil fuels releases small quantities of tin into the air (CICAD, 2005). Secondary tin sources are general tin-, lead- and copper-based alloys and, in particular, solder from electrical and electronic devices. Tin is recovered from tinplate manufacture and from cans (Magos, 1986).

Sources and levels of intake

Inorganic tin is found in most foodstuffs; it may occur in a cationic form (stannous and stannic compounds) or as inorganic anions (stannites or stannates). Levels are generally less than 1 mg/kg in unprocessed foodstuffs. Higher concentrations are found in canned foodstuffs due to dissolution of the tinplate to form inorganic tin compounds or complexes (WHO, 2005).

A normal diet without canned foodstuffs or beverages contains approximately 0.2 mg tin/day (WHO, 2005). The total average dietary intake of tin is 4 mg/day (Beliles, 1994). More recently, the 2006 British total diet study mean and high level adult dietary exposures to nickel were 1.4 mg/day (23 µg/kg body weight/day) and 4.9 mg/day (82 µg/kg body weight/day), respectively (FSA, 2009).

Anses (2011) estimated mean daily intake as total tin at 3.9 µg/person/day in adults and 7.3 µg/person/day in children. Highest concentrations were measured in stewed fruits (8.55 mg/kg) and cheese (1.94 mg/kg).

Metallic food contact materials

At present, the major source of tin in the diet is from food contact materials; especially the release from tin cans to acidic foodstuffs (WHO, 2005). Tin cans are actually steel cans with a thin coating of metallic tin (tinplate) (Beliles, 1994). There is often an internal resin-based coating on the tinplate. Tinplate is mainly used in cans and closures and lids for glass bottles and jars. Tin is also found in pewter. Tin is used in alloys, e.g. with copper for conversion into bronze and with zinc for galvanisation (Beliles, 1994). Tin is also used to coat kitchen utensils.

While the use of tin in cans has decreased somewhat in recent years in the USA, tinplate remains the largest tin use sector in the EU, where quantities employed have been stable for several years. There is significant growth in tinplate use in other regions.

Other food contact materials

Inorganic tin compounds are used as pigments in the ceramic industry (Magos, 1986).

Tin(IV) oxide is used both as an opacifier and as a constituent of coloured pigments in high-quality tableware, e.g. bone china and porcelain products. Thin tin(IV) oxide films on glass can also be used to strengthen and provide scratch-resistance to beer glasses, milk bottles, etc.

Release

Tin is amphoteric, reacting with both strong acids and bases, but is relatively non-reactive with nearly neutral solutions (Beliles, 1994). The presence of oxygen greatly accelerates reactivity in solution (Beliles, 1994).

Tinplate used in food containers is only slowly oxidised. The tin content in foodstuffs depends on:

- whether the tin cans are lacquered;

- the presence of any oxidising agents or corrosion accelerators (e.g. nitrate);
- the acidity of the product in the tin can;
- how long, and at what temperature, the tin cans are stored before being opened;
- the length of time the product is kept in the tin can after it has been opened.

Oxidation of tinplate, followed by the release of tin ions into the foodstuff is known as a “sacrificial anode effect”, a physiochemical mechanism that protects the underlying steel from corrosion. The dissolution of tin protects the can from possible perforation and protects the contents from degradation (changes in colour and flavour) during heat sterilisation and storage.

The concentration of tin in foodstuffs stored in unlacquered cans may exceed 100 mg/kg, whereas foodstuffs stored in lacquered cans show tin levels generally below 25 mg/kg (WHO, 2005). Storing foodstuffs in opened unlacquered cans results in substantial increases in the tin concentration in the foodstuffs (WHO, 2005). Fruits and vegetables consumed from unlacquered cans make up only a small percentage of dietary intake (by weight of total food intake), but their contribution to dietary tin intake amounts to 85%. The thickness of the lacquer coating greatly influences the performance of the lacquered food can (WHO, 2005).

An oxide film forms on metallic tin on exposure to air, whether in the pure form or as an alloy, and not just on dipped and electroplated tin. The film is fairly stable and provides a barrier to further oxidation. At pH values between 3 and 10 and in the absence of complexing agents, the oxide barrier protects the metal from the food. Outside this pH range, however, corrosion of the tin occurs (Murphy and Amberg-Muller, 1996).

Pewter may contain lead as a contaminant, which can also be released. Antique pewter may have been manufactured using lead-containing alloys, but this is not the case with modern pewter. Today, maximum levels of lead are specified for lead-containing pewter.

Safety aspects

- JECFA (1989) established in 1988 a PTWI at 14 mg/kg body weight/week including tin from food additives. The JECFA also states, that "tin levels should be as low as practicable because of possibility of gastric irritation". In 2005, the JECFA maintained the PTWI of 14 mg/kg/week (JECFA 2005).
- WHO (1993 & 2011) has concluded that, because of the low toxicity of inorganic tin, a tentative guideline value could be derived three orders of magnitude higher than the normal tin concentration in drinking-water. For this reason the establishment of a numerical guideline value for inorganic tin was deemed not necessary.
- Codex Standard 193-1995 fixed a maximum limit of 250 mg/kg for tin in canned foods and a maximum level of 150 mg/kg for tin in canned beverages.
- According to Directive 2003/114/EC on food additives other than colours and sweeteners, stannous chloride is authorised as a food additive for canned and bottled asparagus up to 25 mg/kg (as tin).
- There are no indications of chronic tin toxicity in humans (WHO, 2005). Inorganic tin compounds, especially the environmentally dominant tetravalent tins, are poorly absorbed from the gastrointestinal tract (Magos, 1986). Tin compounds act as an irritant for the gastrointestinal tract mucosa, causing nausea, vomiting, diarrhoea, fatigue and headache (WHO, 2005). There is only a limited number of cases indicating possible gastrointestinal irritation which have been reported following the consumption of canned fruit juices, tomatoes, cherries, asparagus, herrings and apricots. The exact concentrations of tin were unknown in these cases of assumed acute poisoning, but were probably in the range of 300-500 mg/kg (WHO, 1980). Earlier studies suggest that tin might interfere with iron absorption and haemoglobin formation. Tin also has an inhibitory effect on copper, zinc and calcium absorption (WHO, 2005). Chronic exposure to high levels of tin may result in growth depression and altered immune function, possibly due to interactions between tin and zinc or selenium (WHO, 2005).
- EFSA (2006) quoted a study recording a decrease in zinc assimilation following absorption of 50 mg/day of $SnCl_2$. The EFSA assessed tin in

2005, but considered the available data insufficient to derive a tolerable upper intake level (EFSA, 2005). They noted that current daily intakes in the EU, ranging up to 6 mg/day in the UK, appears to be well below levels associated with adverse effects.

- In their assessment, the EVM could not establish a safe upper level, but considered that 0.22 mg/kg body weight/day (13.2 mg/day) would not be expected to produce adverse effects in humans (COT EVM, 2003). This was based on a NOAEL for liver cell changes and anaemia of 22-33 mg/kg body weight/day from a sub-chronic study in rats with uncertainty factors of 10 for inter-species and 10 for intra-species variation.
- The COT, in their 2008 statement, considered that the PTWI is not directly applicable to long-term dietary exposure as it appears to be based on acute toxicity (COT, 2008). They used the EVMs assessment as a guidance level.
- In 2010, the “REACH Tin Metal Consortium” conducted a 28-day, repeated dose, oral toxicity study in rats with tin as powder. Multiple endpoints were investigated and no adverse effects have been detected even at the highest dose (1,000 mg/kg body weight/day). However, the P-SC-EMB reviewed the study and considered it inadequate because tin was administered in a powder form, which is not representative of human dietary exposure.
- According to Regulation (EC) No. 1881/2006 setting maximum levels for certain contaminants in foodstuffs, the maximum levels of tin (inorganic) have been set to:
  - 50 mg/kg for certain canned foods for babies and young children
  - 50 mg/kg canned dietary foods for special medical purposes for infants
  - 100 mg/kg for canned beverages, including fruit juices and vegetable juices
  - 200 mg/kg for canned foods other than beverages

Conclusions and recommendations

> ***"the SRL for tin is set, in approximation with Regulation (EC) No. 1881/2006, at 100 mg/kg"***

Food contact with tin materials exposed to air should be avoided at low pH and high temperatures as the "sacrificial effect" afforded by sealed tin-plated cans is lost and the underlying steel is no longer protected.

Consumers should be advised against storing food in opened tin-plated cans.

In view of the observed acute effects (gastric irritation) the SRL for tin is set, in approximation with Regulation (EC) No. 1881/2006, at 100 mg/kg. This limit does not apply to food contact applications that are covered by Regulation (EC) No. 1881/2006.

The lower limit for babies and young children was not considered because exposure of children to tin from food contact applications that are not covered by Regulation (EC) No. 1881/2006 is negligible (Foster, 2010).

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Titanium (Ti)

Titanium is the ninth most common element in the Earth's crust and occurs in a number of minerals (Beliles, 1994). Titanium is a silvery-grey metal resembling polished steel (Beliles, 1994). There is no evidence indicating that titanium is an essential element for man (Nordman and Berlin, 1986).

Sources and levels of intake

Titanium is used in the form of titanium dioxide as a colour additive in confectionary, dairy products and soft drinks, etc. (Directive 95/2/EC). Titanium is also used as additives to edible inks, toothpaste, and pharmaceuticals (Whitehead, 1991).

Metallic food contact materials

Titanium is often used in the form of alloys, which are stronger and more resistant to corrosion than the metal itself (Nordman and Berlin, 1986). However, its use in food contact materials is unknown. Titanium has been suggested for use with corrosive or delicate liquids such as dairy products, fruit juices and in the wine industry (Feliciani *et al.*, 1998). Titanium is also used in certain so-called "stabilised" forms of stainless steels, which in general contain less than 1% titanium.

Other food contact materials

The extreme whiteness and brightness of titanium dioxide has led to its extensive use as a white pigment in paints, lacquers, enamels, paper-coatings and plastics (Beliles, 1994; Nordman and Berlin, 1986). Titanium compounds are also used as catalysts in the manufacture of plastics.

Release

Titanium seems to be practically inert, due to the phenomenon of passivation of the titanium surface by the formation of a molecular layer of TiO_2. This layer, which is very adherent to the metallic substrate, is hardly removed even by aggressive 3% V/V acetic acid solution saturated with 18-20% sodium chloride (Feliciani *et al.*, 1998).

Safety aspects

- Titanium dioxide was assessed by the JECFA in 1969 and an unlimited ADI was determined (JECFA, 1970).
- The estimated intake of titanium is 0.3-1 mg/day (Beliles, 1994; Whitehead, 1991).
- Titanium compounds are generally considered to be poorly absorbed upon ingestion (Nordman and Berlin, 1986). Studies on titanium alloys used in implants and titanium compounds used in cosmetics and pharmaceuticals do not indicate any localised tissue effects (Nordman and Berlin, 1986). A distinct toxicological dichotomy exists between TiO_2, the insoluble, unreactive non-metabolised form that is devoid of toxicity, and the soluble, inorganic salts that metabolise normally with absorption, distribution, and excretion (Beliles, 1994). However, little information exists on how titanium acts as a toxic agent, and what does exist is of little or no value in understanding the toxic actions of titanium (Beliles, 1994).
- EFSA (2005) concurred with JECFA (1970) assessment of titanium dioxide and considered it supported by more recent chronic toxicity and carcinogenicity studies.

Conclusions and recommendations

"it is appropriate not to set any SRL for titanium"

There is no known biological role for titanium. There is a detectable amount of titanium in the human body and, while most passes through the human body, it has been estimated that about 0.8 mg/day is absorbed. The human body can tolerate titanium in large doses. Titanium (titanium dioxide) has been evaluated as a food additive.

Therefore, it is appropriate not to set any SRL for titanium.

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Vanadium (V)

Vanadium is a white, shiny, soft, ductile metal. It is highly resistant to corrosion by alkali compounds as well as hydrochloric and sulphuric acids. It is to be found in some ores and it is mainly used in alloys.

Sources and levels of intake

Vanadium is mainly found in seafood and mushrooms, but also in many fruits and vegetables, albeit in very low quantities.

In the USA, dietary intake was estimated in the range of 6-18 µg/day for adults (Pennington and Jones, 1987). Results from a duplicate diet study in Spain estimated the dietary intake of vanadium equal to 156 µg/day (Domingo, 2011).

Anses (2011) estimated mean daily intake at 52 µg/day (0.86 µg/kg body weight/day) in adults and 1.06 µg/kg body weight/day in children.

Metallic food contact materials

Vanadium can be used in alloys to manufacture tools such as knife blades. Vanadium steel is extremely well suited to the manufacture of tools, axes and knives, as well as spare parts for rotating machines. Adding vanadium to steel in proportions of approx. 1% produces a highly shock-resistant alloy.

French Information Notice No. 2004-64 on materials in contact with foodstuffs specifies limits for vanadium, as follows:

- Steel (apart from packaging) in % mass: 0.30;
- Uncoated steel for packaging (black plate) in % mass: 0.10.

Other food contact materials

Vanadium oxide is used in ceramic pigments.

Release

No information available.

Safety aspects

- The EVM (COT EVM, 2003) has assessed vanadium but could not derive an upper limit.
- The American Food and Nutrition Board (FNB, 2001) derived an upper limit (UL) of 1.8 mg/day for vanadium. This value was derived from a LOAEL of 7.7 mg/kg body weight/day (460 mg/day) from a rat study, an average body weight of 68.5 kg and an uncertainty factor of 300. This upper limit was also adopted by Health Canada. However, Health Canada has stated that: "Although vanadium in food has not been shown to cause adverse effects in humans, there is no justification for adding vanadium to food and vanadium supplements should be used with caution. The UL is based on adverse effects in laboratory animals and this data could be used to set a UL for adults but not children and adolescents." (Health Canada, 2004)
- EFSA (2004; 2009) reviewed the findings of FNB (2001). The absence of a NOAEL and limited dose-response data prevented the EFSA from deriving an upper limit. Furthermore, the EFSA noted that vanadium has been observed as having adverse effects on kidneys, spleen, lungs and blood pressure in animals. In addition, developmental toxicity has also been seen in the offspring of rats. However, it was noted that an exposure of 0.01 to 0.02 mg/day is at least three orders of magnitude below the dose which causes gastrointestinal effects in body-builders taking vanadium as supplements (EFSA, 2004; 2009).
- Vanadium is used in the synthesis of pharmaceutical substances and is included in the EMA Guideline on the specification limits for residues of metal catalysts or metal reagents. That Guideline classifies vanadium

in Class 1C, metals of significant safety concern, which also includes molybdenum, nickel and chromium. It proposes an oral PDE of 300 µg/day (6 µg V/kg/day in a 50 kg person), based on a human NOEL of 0.5 mg/kg/day (from a 6-week human study, Dimond *et al,* 1963) and a safety factor of 80. This recommended PDE is equivalent to 50% of the sub-chronic RfD for NaVO3 proposed by the EPA and 20% of the chronic RfD for VOSO4.

Conclusions and recommendations

"the SRL for vanadium is set at 0.01 mg/kg"

The P-SC-EMB decided to follow the opinion issued by the EFSA. Given the toxicity data and potential for adverse health effects, an SRL determined using the FNB/Health Canada upper limit cannot be supported. Therefore, the P-SC-EMB has agreed to base the SRL on the EFSA exposure data. Using the lower estimated intake of 0.01 mg/day and assuming that a person of 60 kg body weight consumes 1 kg of foodstuffs per day that is packaged and/or prepared with food contact materials made from metals and alloys, the SRL for vanadium is set at 0.01 mg/kg. Since the SRL has been derived from exposure data, the use of an allocation factor is not deemed necessary.

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Zinc (Zn)

Zinc is an essential trace metal (Elinder, 1986). Zinc is the 25th most abundant element and is widely found in nature (Beliles, 1994). Zinc appears in the form of zinc ions or zinc salts. Galvanising, a process involving the coating of iron and steel with zinc to prevent corrosion, is the most important use of zinc (Beliles, 1994). Zinc protects iron from rusting because it is a stronger reducing agent (Beliles, 1994). Zinc is also used in fertilisers.

Sources and levels of intake

Zinc occurs in most foodstuffs and beverages (ATSDR, 2005). The main contributors to zinc intake are meats, especially organs, whole grain cereals and milk products including cheese. Oysters and peanuts may contain up to 100 mg/kg and 30 mg/kg zinc, respectively.

The 2006 British total diet study mean and high level adult dietary exposures to zinc were 8.5 mg/day (141 µg/kg body weight/day) and 16.1 mg/day (268 µg/kg body weight/day), respectively (FSA, 2009). More recently results from a duplicate diet study in Spain estimated the dietary intake of zinc equal to 6.8 mg/day (Domingo, 2011). In Ireland the mean and 95th percentile intake from all sources including supplements were equal to 10.4 mg/day and 19.4 mg/day, respectively (IUNA, 2011). Anses (2011) estimated for adults the mean daily intake at 7.9 mg/day and for the 95th percentile at 13.3 mg/day.

Metallic food contact materials

Major uses of zinc are in the production of non-corrosive alloys, brass and in galvanised steel and iron products (Elinder, 1986). A common use of metallic zinc is to coat iron or other metals so that they do not rust or corrode (ATSDR, 2005). Metallic zinc is also mixed with other metals to form alloys such as brass and bronze (ATSDR, 2005). Galvanised products are widely used as household appliances (Elinder, 1986). Zinc may contain small amounts of more toxic metals, e.g. cadmium (0.01-0.04%) and lead, as impurities (Elinder, 1986). The use of food contact materials made of zinc, zinc alloys or galvanised zinc is limited.

Zinc-coated steels are used in silos for storing foodstuffs.

Other food contact materials

Zinc sulfide is grey-white or yellow-white, and zinc oxide is white. Both of these salts are used to make white paints, ceramics, and several other products (ATSDR, 2005).

Release

Zinc is a relatively soft metal and has a strong tendency to react with inorganic compounds, e.g. to form oxides, as well as organic compounds (Elinder, 1986). Galvanised iron containers holding acidic drinks such as orange juice or alcoholic beverages have resulted in a number of reports of poisoning. Zinc is easily dissolved in dilute acids and by bases (Beliles, 1994). Zinc galvanised utensils may release zinc and cadmium. They can also release zinc hydrocarbonate in confined spaces when exposed to air and humidity.

Data on the release of zinc from food contact materials and articles are scarce. One study, a survey of teapots, showed zinc release between 0.9 mg/L and 40 mg/L using a citric acid solution (1 g/L) as simulant and a contact time of 30 min. (Bolle, 2011).

Safety aspects

- JECFA (1982) has established a PMTDI of 0.3-1 mg/kg body weight/day.
- The required daily intake for adults is about 15 mg/day. However, the requirement varies with age (JECFA, 1982).
- WHO (1993, 2008, 2011) stated that derivation of a health-based guideline value for drinking water was not required. However, drinking water containing levels above 3 mg/L may not be acceptable to consumers.
- Zinc is one of the most ubiquitous of the essential trace metals (Florence and Batley, 1980). The absorption of ingested zinc is highly variable (10-90%) (Elinder, 1986). Zinc is an essential element necessary for the functioning of a large number of metallo-enzymes (ATSDR, 2005; Beliles, 1994). Zinc acts to reduce the toxicity of cadmium and copper (Florence and Batley, 1980). Zinc may be a modifier of the carcinogenic response; zinc deficiency or excessively high levels of zinc may enhance susceptibility to carcinogenesis (Beliles, 1994).
- In their assessment, the EVM (COT EVM, 2003) derived a safe upper level of 0.42 mg/kg body weight/day (25 mg/day) for supplemental zinc. This is based on a LOAEL of 50 mg/person/day for the inhibition of erythrocyte superoxide dismutase (eSOD) by zinc, associated with a mild copper deficiency. An uncertainty factor of 2 was used for LOAEL to NOAEL extrapolation as the effect is a small inconsistent change in a biochemical parameter. Assuming a maximum intake of 17 mg/person/day from food a total intake of 0.7 mg/kg body weight/day would not be expected to result in any adverse effect.
- Based on more recent studies, the SCF (2003) and EFSA (2006) interpreted, for the same endpoint (inhibition of eSOD), the value of 50 mg/day as the NOAEL. Using an uncertainty factor of 2 to account for the small number of subjects surveyed, the upper limit was set to 25 mg/day. Furthermore, for children aged 1-3 years, an upper limit of 7 mg/day was extrapolated from the adult upper limit.
- In the 2008 European Risk Assessment Report, the overall oral NOAEL of 50 mg/day was confirmed, using the same studies as SCF (2003). However, no additional uncertainty factor was used. (JRC, 2008)

- Zinc is used in the synthesis of pharmaceutical substances and it is included in the EMA Guideline on the specification limits for residues of metal catalysts or metal reagents. Zn forms a range of covalent organo-compounds such as Zn(0) alkyls that are useful as reagents in organic synthesis. That Guideline classifies zinc in Class 3, metals with minimal safety concern, which also includes iron. In the Guideline, an oral PDE for Zn is set at 13,000 µg/day (260 µg Zn/kg/day in a 50 kg patient), based on the human LOEL (US EPA, 2001) of 50 mg/day, i.e. 1 mg/kg/day, and considering the data on dietary intakes (up to 0.2 mg Zn/kg/day) and the use of Zn supplements. This allows for an uncertainty factor of 4, which is more than sufficient to extrapolate the LOEL to the NOAEL. This recommended PDE is equivalent to 87% of the RFD for Zn proposed by the EPA.

Conclusions and recommendations

"the SRL for zinc is set at 5 mg/kg"

The P-SC-EMB decided to follow the opinion issued by the SCF (2003) and EFSA (2006) with a derived upper limit of 25 mg/day.

Furthermore, intake data from multiple European countries to estimate worst-case oral exposure from zinc were provided. The calculated worst-case intake from food and supplements at the 95th percentile resulted in a daily intake of 20 mg/day. Since this value is below the toxicologically derived limit of 25 mg/day the difference of 5 mg/day can be allocated to exposure from food contact materials made from metals and alloys.

Consequently, assuming that a person of 60 kg body weight consumes 1 kg of foodstuffs per day that is packaged and/or prepared with food contact materials made from metals and alloys, the SRL for zinc is set at 5 mg/kg.

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Metal contaminants and impurities

The following metals are relevant contaminants and impurities that may occur in food contact materials and articles.

As	Arsenic
Ba	Barium
Be	Beryllium
Cd	Cadmium
Pb	Lead
Li	Lithium
Hg	Mercury
Tl	Thallium

Arsenic (As)

Arsenic is the 54th most abundant element in the Earth's crust, which contains 1.8 mg/kg of arsenic down to a depth of 16 km.
It is a notoriously toxic metalloid that has numerous allotropic forms:

- yellow (non-metallic allotrope)
- several black and grey (metalloids).

Several hundreds of these mineral species are known.
Arsenic and its compounds are used as pesticides, herbicides and insecticides.
The arsenic content of some iron ores is similar to their phosphorus content. Both substances enter the steel production as impurities from raw materials and/or processing contaminants and may adversely affect steel quality. The presence of arsenic reduces impact strength of steel.

Sources and levels of intake

Seafood and fish are foodstuffs rich in arsenic. Many types of vegetable also contain arsenic (e.g. cabbage and spinach) (Schoof, 1999; Guéguen, 2011; Arnich, 2012). It is also found in some sources of drinking-water.

Making a number of assumptions for the contribution of inorganic arsenic to total arsenic, the inorganic arsenic exposure from food and water across 19 European countries, using lower bound and upper bound concentrations, has been estimated to range from 0.13 to 0.56 µg/kg body weight/day for average consumers, and from 0.37 to 1.22 µg/kg body weight/day for 95th percentile consumers. Dietary exposure to inorganic arsenic for children under three years of age is in general estimated to be from 2 to 3-fold that of adults (EFSA, 2009). Anses (2011) estimated mean daily intake of inorganic arsenic at 0.28 µg/kg bw/day in adults and 0.39 µg/kg bw/day in children (according to upper bound concentrations).

Metallic food contact materials

Some of the less common food contact alloys can contain arsenic. Special types of brass are obtained by incorporating one or more additional elements such as tin, aluminium, manganese, nickel, iron, silicon or even arsenic, which improves some of their properties, particularly their mechanical characteristics, mostly to increase their resistance to corrosion.

In France, tin or tin alloys and articles exclusively coated with tin or tin alloy or partly tin-plated, which as finished products are designed to come into direct, recurrent contact with foodstuffs, must not exceed a maximum arsenic content of 0.030% (French Decree of 28 June 1912).

Other food contact materials

Arsenic is used in the processing of the following products: glass, pigments, textiles, paper, metal adhesives, ceramics and wood conservation agents.

Orpiment is an arsenic sulphide mineral found naturally or produced artificially. It is also known in French as jaune d'arsenic. It has a fine, golden yellow colour and has been known since the second millennium BC. Its use as a pigment was abandoned after the arrival of cadmium pigments in the 19th century.

Release

No information available.

Safety Aspects

- WHO (1993) established a guideline value for arsenic in drinking-water of 0.01 mg/L. This value was also brought forward in the following editions (WHO 2008 & 2011).
- The JECFA PTWI 15 µg/kg body weight/week (2.1 µg/kg body weight/day) for arsenic was set in 1988 (JECFA, 1989). In 2010, at the recent 72nd JECFA meeting, arsenic was reassessed and a benchmark dose approach was used to assess the epidemiological data available. The inorganic arsenic lower limit of the benchmark dose for a 0.5% increased incidence of lung cancer (BMDL0.5) was determined from epidemiological studies to be 3.0 µg/kg body weight/day (2-7 µg/kg body weight/day based on the range of estimated total dietary exposure) using a range of assumptions to estimate total dietary exposure to inorganic arsenic from drinking-water and food. As the previous PTWI (JECFA1989) is within this range, it was no longer considered appropriate and it has since been withdrawn (JECFA, 2010).
- In their 2008 statement the COT considered that inorganic arsenic is genotoxic and a known human carcinogen and, therefore, exposure should be as low as reasonably practicable (COT 2008).
- EFSA (2009) used a benchmark dose (BMD) approach to assess arsenic, using data from key epidemiological studies and noting other modelling results. A benchmark response of 1% extra risk was selected and the range of the 95% lower confidence interval of the dose (BMDL01) causing this response was considered. Lung cancer had the lowest BMDL01, with an overall range of 0.3-8.0 µg/kg body weight/day. There is little or no margin of exposure between estimated dietary exposure and this range and therefore the possibility of a risk to consumers cannot be excluded.

Conclusions and recommendations

"the SRL for arsenic is set at 0.002 mg/kg"

Arsenic can be found in the form of impurities in many metals and alloys. Efforts are therefore needed to prevent its possible release.

In light of the recent COT, EFSA and JECFA assessments (COT, 2008; EFSA, 2009; JECFA, 2010), using JECFA (1989) PTWI as a basis for deriving a specific release limit was not considered appropriate. Instead, the lower end of the BMDL01 from the EFSA (2009) assessment was used, resulting in a limit of 0.0003 mg/kg body weight/day (0.018 mg/day). As arsenic is considered an impurity in the metallic material, the P-SC-EMB concluded that an allowance of 10% of the toxicological reference values was reasonable. Therefore, assuming a person of 60 kg body weight consumes 1 kg of foodstuffs per day that is packaged and/or prepared with food contact materials made from metals and alloys, the SRL for arsenic is set at 0.002 mg/kg.

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Barium (Ba)

The mineral Barytine is the raw material from which virtually all barium compounds are derived. World production of barite in 1985 was estimated at 5.7 million tonnes (WHO, 1990). Barium and its compounds are used in various industrial products, ranging from ceramics to lubricants. It is also used in the manufacture of alloys, as a weighting element for paper, soap, rubber and linoleum, and in the manufacture of valves (WHO, 1990).

Sources and levels of intake

The main sources of barium in the human diet are milk, potatoes and flour. Some cereal products and nuts tend to have high barium content, e.g. groundnuts, bran flakes and Brazil nuts (WHO, 1990). Some plant species accumulate barium when they grow in a soil rich in this element (WHO, 1990).

The British total diet study (2006) mean and high-level adult dietary exposures to barium were 0.56 mg/day (9.4 µg/kg body weight/day) and 2.72 mg/day (45.3 µg/kg body weight/day), respectively (FSA, 2009).

Anses (2011) estimated mean daily intake at 0.38 mg/day (6.4 µg/kg body weight/day) in adults and 10.2 µg/kg body weight/day in children.

Metallic food contact materials

Barium is to be found in certain metals and alloys in the form of impurities. Barium reacts strongly with metals to form metal alloys. Iron is the most resistant metal to barium. Barium forms inter-metal compounds and alloys with lead, potassium, platinum, magnesium, silicon, zinc, aluminium and mercury (Hansen, 1958). Metallic barium reduces oxides, halides, sulphides and most of the less reactive metals, resulting in their elemental state. It is therefore used in molten salt baths for thermal treatment of metals. Metal bromates [$Ba(BrO_3)_2$] are used for preparing rare-earth bromates and inhibiting corrosion in low-carbon steels. It is used in aluminium refining and leather tanning. The chromate ($BaCrO_4$) is an anti-corrosion pigment for metals. It is used in alloys with aluminium, magnesium and nickel for specific applications.

Other food contact materials

Barium and barium compounds are used in ceramics and as a weighting element for paper, rubber and valve manufacture.

The chloride, $BaCl_2$, is used in the pigment, lacquer and glass industries. In the dyeing industry, it is used as a mordent and load, as well as in dyeing textile fibres. The chromate, $BaCrO_4$, is also used to colour glass, ceramics and porcelain.

Release

No information available.

Safety aspects

– EPA (1985) derived a Reference Dose (RfD) of 0.2 mg/kg/day. In 2005 the EPA reassessed barium and confirmed the RfD for barium of 0.2 mg/kg body weight/day. However, new studies were taken into consideration and a benchmark dose lower confidence limit (BMDL) approach was chosen. Consequently, the RfD was derived from a $BMDL_5$ of 63 mg/kg body weight/day for a 5% increased risk of nephropathy in mice with an uncertainty factor of 300 (100 for intra- and inter-species variability and 3 for database deficiencies).

- Health Canada (Federal Ministry) (1990) recommendations on drinking water estimate the average intake of barium at 1 mg/day.
- WHO (2001) specified a TDI of 0.02 mg/kg body weight/day (1.2 mg/day) from an epidemiological study. In that study, populations from two cities having a 70-fold difference in drinking water concentrations of barium were investigated. Significant differences in cardiovascular effects, however, could not be detected. Using the higher barium drinking water concentration of the two cities compared, a TDI of 0.21 mg/kg body weight/day was derived and divided by an uncertainty factor of 10 to account for database deficiencies and possible differences between adults and children.
- WHO (1993) established a guideline value for barium in drinking water of 0.7 mg/L from an epidemiological study with no effects observed. This value was also brought forward in the following editions (WHO 2008 & 2011)
- In their 2008 statement, the UK COT considered that since the WHO TDI was based on studies that did not show statistically significant effects, it was possible that the LOAEL could be much higher than the NOAEL and, therefore, the TDI could be overly conservative (COT, 2008). The COT concluded that exposures of up to 4-fold above the TDI were not necessarily a toxicological concern.

Conclusions and recommendations

"the SRL for barium is set at 1.2 mg/kg"

The P-SC-EMB decided to use the EPA RfD of 0.2 mg/kg body weight/day (12 mg/day) to derive the SRL. As barium is considered an impurity in the metallic material, the P-SC-EMB concluded that an allowance of 10% of the toxicological reference value was reasonable. Therefore, assuming that a person of 60 kg body weight consumes 1 kg of foodstuffs per day that is packaged and/or prepared with food contact materials made from metals and alloys, the SRL for barium is set at 1.2 mg/kg.

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Beryllium (Be)

Beryllium has the highest melting point of all the light metals. It is lighter and six times more resilient than aluminium. It is approximately 1⅓ times more ductile than steel. It is an excellent heat conductor, is non-magnetic and is resistant to concentrated nitric acid. Under normal conditions of temperature and pressure beryllium is oxidation-resistant when exposed to air. A thin layer of oxide is formed, making it hard enough to scratch glass.

In nature, it is mainly found in the form of oxides or complex beryllium-aluminium-silicates known as beryls, the best-known gemstone variants of which are emeralds and aquamarines.

In view of the scarcity of beryllium in nature (3 mg/kg), it raises no particular environmental concerns, but its industrial use in coal mining, aeronautics and the nuclear arms industry leads to its dispersal in the air and its deposition in the environment, contaminating water, soil, air and the human body (Mroz, 2001). There is also controversy about its use in dentistry, for dental prostheses (Mroz, 2001).

It is mainly used as a hardening agent in alloys such as moldamax, a copper-beryllium alloy used for manufacturing moulds for plastics.

Its alloys are light, rigid, heat-resistant and have a low dilation coefficient. It is incorporated into some special alloys, e.g. materials used for friction.

Sources and levels of intake

The intake in the USA, as estimated by the EPA (1998), is 0.42 μg/day via water and food (0.12 μg/day from food and 0.3 μg/day from water). Much of the intake is, therefore, deemed to come from drinking-water. On the other hand the WHO (2008 and 2011) states that beryllium is unlikely to occur in drinking-water and consequently, it has been "excluded from guideline value derivation". Results from a duplicate diet study in Spain estimated the dietary intake of beryllium equal to 19 μg/day (Domingo, 2011).

Metallic food contact materials

Beryllium can be found in the form of impurities in some metals and alloys, though seldom as an alloy component. Although beryllium is theoretically highly unlikely to come into contact with food, its use in plumbing, boiler-making and piping cannot be precluded.

Other food contact materials

Beryllium oxide can potentially be used in the ceramics industry, but there is no evidence of it being used for ceramics coming into contact with food.

Release

No information available.

Safety aspects

- The EPA (EPA, 1998) recommended a Reference Dose (RfD) of 0.002 mg/kg body weight/day (i.e. 0.12 mg/day for a person weighing 60 kg) for beryllium. EPA (1987) estimated beryllium intake in the USA at 0.423 μg/day via water and food, which is negligible compared to the RfD.
- The WHO Environmental Health Criteria document (WHO, 1990) and more recently, the Concise International Chemical Assessment

Document (IPCS INCHEM, 2001) show that there is little data available on oral toxicity of beryllium and the bulk of the information available pertains to inhalation toxicity and, in particular, the effects of inhalation in occupationally-exposed workers. The CICAD derived an oral tolerable intake of 0.002 mg/kg body weight/day (CICAD, 2001). This value was estimated using the BMD10 of 0.46 mg/kg body weight/day at the lower 95% confidence limit for a 10% incidence of small intestinal lesions in dogs chronically exposed to beryllium sulphate tetrahydrate and considered equal to the NOAEL. In addition, an uncertainty factor of 300 (10 for inter-species, 10 for intra-species variation and 3 for database deficiencies due to a lack of data on developmental effects or mechanistic data, suggesting this may be an issue) was applied.

Conclusions and recommendations

"the SRL for beryllium is set at 0.01 mg/kg"

The proven high toxicity of beryllium means that any potential release must be limited.

The SRL for beryllium was derived on the basis of the 2001 CICAD oral tolerable intake of 0.002 mg/kg body weight/day (0.12 mg/day) (IPCS INCHEM, 2001). As beryllium is considered an impurity in the metallic material, the P-SC-EMB concluded that an allowance of 10% of the toxicological reference value was reasonable. Therefore, assuming that a person of 60 kg body weight consumes 1 kg of foodstuffs per day that is packaged and/or prepared with food contact materials made from metals and alloys, the SRL for beryllium is set at 0.01 mg/kg.

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Cadmium (Cd)

Cadmium is one of the metallic elements of most concern in the food and environment of man. Cadmium is widely distributed, occurring in all soils and rocks, including coal, in very low concentrations (<0.1 mg/kg) (ATSDR, 2008; Lind, 1997). Also, zinc ores contain cadmium, which is emitted during the melting of zinc (Friberg *et al.*, 1986). Cadmium is a relatively rare element (Codex Standard 193-1995) and current analytical procedures indicate much lower concentrations of the metal in environmental media than previous measurements had shown due to improved sampling and analytical techniques (WHO, 1992). Phosphate fertilisers and sewage sludge used on agricultural land may be significant sources of cadmium (Friberg *et al.*, 1986).

Cadmium metal was previously used as an anti-corrosive, electroplate on steel (Friberg *et al.*, 1986). Cadmium can be replaced by other less toxic materials, for instance in batteries.

Sources and levels of intake

Cadmium is found in most foodstuffs in the range of 0.005-0.1 mg/kg (Friberg *et al.*, 1986). Certain foodstuffs, e.g. mushrooms, kidneys and oysters, may contain much higher concentrations (Friberg *et al.*, 1986). The lowest levels of cadmium are found in dairy products and beverages (European Commission, 2004). Vegetables, cereals and cereal products contribute most to cadmium intakes.

The mean dietary exposure across European countries was calculated to be 2.3 µg/kg body weight/week and the high exposure was calculated to be 3.0 µg/kg body weight/week. Due to their high consumption of cereals, nuts, oilseeds and pulses, vegetarians have a greater dietary exposure of up to 5.4 µg/kg body weight/week. Regular consumers of bivalve molluscs and wild mushrooms were also found to have higher dietary exposures of 4.6 and 4.3 µg/kg body weight/week, respectively. Anses (2011) estimated mean daily intake at 1.12 µg/kg body weight/week in adults and 1.68 µg/kg body weight/week in children.

Tobacco smoking can contribute to a similar internal exposure as that from the diet. House dust can be an important source of exposure for children (EFSA, 2009).

Metallic food contact materials

The use of cadmium-plated utensils in food processing and preparation is forbidden according to Regulation (EC) No. 1907/2006. Cadmium can occur as impurity in zinc galvanised pipes and in solders (Friberg *et al.*, 1986).

Other food contact materials

Cadmium sulphide and cadmium selenide have been used as red, yellow and orange colour pigments in plastics and various types of paint (Friberg *et al.*, 1986). Cadmium stearate was previously used as a stabiliser in plastics (Friberg *et al.*, 1986). Cadmium can also be used as a pigment in certain enamels in food contact materials. Leachable cadmium in enamel pottery and glazes may be a source of contamination.

Release

The release information on cadmium is limited. Cadmium, like zinc, loses its lustre in moist air and is rapidly corroded by moist NH_3 and SO_2. It is readily attacked by most acids, but more slowly than zinc (Beliles, 1994). One study could be identified where the release of cadmium from pewter cups was investigated. Using different beverages (e.g. wine, beer) and simulants (e. g. vinegar, 3% acetic acid), a release of cadmium ranging from < LOD (beer) to 8.2 µg/L (3% acetic acid) was measured (Dessuy, 2011).

Safety aspects

- JECFA (1993) established a PTWI at 0.007 mg/kg body weight/week, stating that "the PTWI does not include a safety factor" and that "there is only a relatively small safety margin between exposure in the normal diet and exposure that produces deleterious effects". This value was confirmed by the JECFA in 2003. During their 73rd meeting in 2010, the JECFA withdrew the PTWI of 0.007 mg/kg body weight/week and replaced it by a provisional tolerable monthly intake (PTMI) of 0.025 mg/kg body weight/month, due to the exceptional long half-life of cadmium (JECFA, 2010).
- WHO (1993) established a guideline value for cadmium in drinking-water of 0.003 mg/L. This value was also brought forward in the following editions (WHO 2008 & 2011).
- In the EU the limit for cadmium in drinking-water has been set to 0.005 mg/L (Council Directive 98/83/EC).
- Cadmium is unique among the metals because of its combination of toxicity in low dosages, long biologic half-life (about 30 years in humans), its low rate of excretion from the body, and the fact that it is stored predominantly in the soft tissues (liver and kidney) (Beliles, 1994). The PTWI is based upon kidney damage and the long half-life of cadmium. The effects of cadmium on humans are nephrotoxicity, osteotoxicity, cardiovascular-toxicity, genotoxicity and effects on reproduction and development (European Community, 1996). Kidney damage also occurs as a result of cadmium exposure (Beliles, 1994). Occasional peaks in cadmium intake may cause a drastic increase in fractional absorption of cadmium (Lind, 1997). Ingestion of highly contaminated foodstuffs or drinks results in acute gastrointestinal effects in the form of diarrhoea and vomiting (Friberg *et al.*, 1986). About 5% of ingested cadmium is absorbed (Friberg *et al.*, 1986). The speciation of cadmium in foodstuffs may be of importance for the evaluation of the health hazards associated with areas of cadmium contamination or high

cadmium intake (WHO, 1992). The bioavailability of cadmium differs depending on the form of cadmium present. For instance, cadmium of animal origin has been shown to have a lower bioavailability in mice than cadmium of vegetable origin (Lind, 1997). Cooking does not seem to alter the bioavailability of cadmium of animal origin.

- EFSA (2009) has derived a TWI for cadmium of 0.0025 mg/kg body weight/week. This TWI was derived from dose-response data between urinary cadmium concentrations and urinary beta-2-microglobulin (B2M), a marker for tubular effects in kidneys. Using the benchmark dose lower confidence limit for a 5% increase in the prevalence of elevated B2M ($BMDL_5$) resulted in a limit of 1 µg Cd/g creatinine. Subsequently, the dietary cadmium intake that corresponds to a concentration below 1 µg Cd/g creatinine in the urine was estimated from exposure data, resulting in the above TWI.

Conclusions and recommendations

"the P-SC-EMB decided to set the SRL at 0.005 mg/kg"

The use of cadmium in metals and alloys in materials in contact with foodstuffs is unacceptable due to its long biological half-life (about 30 years in humans) and its high toxicity.

Electroplated equipment should be coated.

The SRL was derived from the EFSA (2009) assessment, rather than from that of JECFA (2010), because it resulted in a more conservative limit. Using the EFSA (2009) TWI of 0.0025 mg/kg body weight/week as a starting-point resulted in a TDI of 0.00036 mg/kg body weight/day (0.02 mg/person/day). Using an allowance of 10% of the toxicological reference value and assuming that a person of 60 kg body weight consumes 1 kg of foodstuffs per day that is packaged and/or prepared with food contact materials made from metals and alloys, the calculated limit for cadmium would be at 0.002 mg/kg.

However, the P-SC-EMB decided to set the SRL at 0.005 mg/kg, which is consistent with the limit for cadmium stated in Council Directive 98/83/

EC (European Commission, 1998). This equals an allowance of 25% of the toxicological reference value.

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Lead (Pb)

Lead is found as a contaminant in air, water and soils. The Earth's crust contains about 15 mg/kg of lead (Beliles, 1994). Lead is present in the environment in the form of metallic lead, inorganic ions and salts and organo-metallic compounds (CE, 1994). There are numerous sources of contamination including accumulators, petrol, recycling of lead batteries and combustion of industrial and household waste. Lead pollution is decreasing in most parts of the world, as lead-containing chemicals, such as tetraethyl lead and tetramethyl lead that are used as gasoline additives to increase octane rating, are replaced by other additives (ATSDR, 2007) and due to recycling of accumulators and batteries. Exposure through drinking-water, where lead or lead soldered pipes are still used, may contribute significantly to lead intake. WHO Air Quality Guidelines for Europe indicate that airborne lead contributes about 1-2% of human intake. The greatest single use of lead metal today is in batteries for automobiles (Beliles, 1994). Most of the lead in the environment is present as complex bound lead ions in solution or as slightly soluble Pb(II) salts.

Sources and levels of intake

Lead in the soil is only poorly taken up by plant roots and is not transported away from the roots to the rest of the plant. Therefore, lead levels in plants are, to a large extent, governed by air-borne lead contamination, which makes leaves and leafy vegetables most vulnerable to air-borne deposition

(EFSA, 2010). Cereal grains have also been shown to absorb substantial amounts of lead via the air (CCFAC, 1995). The main sources of lead intake are foodstuffs such as vegetables, cereals and cereal products and drinking-water (EFSA, 2010). Game and shellfish may also contain rather high amounts of lead (EFSA, 2010).

In Europe, lead dietary exposure ranges from 0.36 to 1.24 µg/kg body weight/day in average adult consumers and up to 2.43 µg/kg body weight/day in high-end consumers. Exposure of infants ranges from 0.21 to 0.94 µg/kg body weight/day and of children from 0.80 to 3.10 µg/kg body weight/day (average consumers) and up to 5.51 µg/kg body weight/day (high consumers) (EFSA, 2010). Anses (2011) estimated mean daily intake at 0.20 µg/kg body weight/day in adults and 0.27 µg/kg body weight/day in children.

Additionally, dust and soil can be significant non-dietary sources in children (EFSA, 2010).

Metallic food contact materials

Canned foodstuffs previously contained markedly higher lead levels than fresh foodstuffs and this was most evident in fruits (Tsuchiya, 1986). However, modern canning techniques without lead soldering are now typically used (Tsuchiya, 1986), which has caused a decrease in lead intake from this source. Metallic lead in food is likely to arise from the presence of lead from shot or partially-jacketed bullets in game (CE, 1994). Lead is also found in the lead solder used to repair equipment. Manufacturing equipment and household utensils may contain parts made wholly or partly of lead, and such parts may release lead if they come into contact with food. Lead pipes or lead solder used to repair equipment have also caused contamination problems. The lead that may be found as a contaminant in pewter may also be released. Tin is also liable to release lead due to its presence in the metal as an impurity; the standard specification of tin (according to European Standard EN610:1995) specifies a maximum permissible lead content of 0.050%. The EU Packaging Directive (94/62/EC) limits the Pb content of tin cans to less than 100 ppm.

Other food contact materials

Previously, lead pigments were often used in ceramic glazes (Beliles, 1994). However, because lead pigments are toxic, their use is now restricted. In the EU, lead release is now regulated by Directive 84/500/EEC that sets limits for the release of lead from materials and articles made of ceramics. Imported products from some countries and handicrafts still need particular attention. White lead is the most important lead pigment (Beliles, 1994). Also, crystal glass typically contains 24% lead.

Release

The information on release of lead from metallic food contact materials is limited. One study investigated the release of lead from pewter cups. Using different beverages (e.g. wine, beer) and simulants (e.g. vinegar, 3% acetic acid), the lead release ranged from < LOD (beer) to 1.1 mg/L (3% acetic acid) after 24 h contact time (Dessuy, 2011). Further, a survey with teapots made out of brass found lead release between 1.1 mg/L and 62 mg/L, using citric acid solution (1 g/L) as a simulant and a contact time of 30 minutes (Bolle, 2011).

Safety aspects

- JECFA (1993) established a PTWI at 0.025 mg/kg body weight/week or 0.214 mg/day/person (average body weight ~60 kg). This limit was confirmed by the JECFA in 2000. During their 73rd meeting in 2010, the JECFA withdrew the PTWI, concluding that the PTWI could no longer be considered protective of health (JECFA, 2010). In children, the level of 1.9 µg/kg body weight per day was associated with a decrease of 3 intelligence quotient (IQ) points, which is deemed by the Committee to be of concern.
- WHO (1993) set a health-based guideline value for lead in drinking-water at 0.01 mg/L based on the PTWI established by the JECFA in 1993. In the third and fourth editions of the WHO (2008 and 2011) Guidelines for drinking-water quality the health-based guideline value for lead in drinking-water remains the same. However, in the 4th edition the

value was made provisional on the basis of treatment performance and analytical achievability (WHO, 2011).

- In the EU, the limit for lead in drinking-water has been set to 0.01 mg/L (Council Directive 98/83/EC).
- For the general population, exposure to lead occurs primarily via the oral route, with some contribution through inhalation (EFSA, 2010). In adults, approximately 15-20% of the ingested lead is absorbed in the gastrointestinal tract (EFSA, 2010). Children however seem to show a higher absorption rates (EFSA, 2010). Lead has a half-life in the blood of about a month, whereas it may have a half-life as long as 30 years in bones (EFSA, 2010). The toxicity of lead is based on its ability to bind biologically important molecules and thus to interfere with their function (EFSA, 2010). The most common form of acute lead poisoning is gastrointestinal colic (Beliles, 1994). Dietary lead exposure is unlikely to represent a significant cancer risk (EFSA, 2010).
- It should be noted that the most critical effect of lead on children has been identified as reduced cognitive development and intellectual performance. There is no evidence of a threshold for this effect. This issue was discussed in a JECFA paper on maximum levels for lead in fish (JECFA 2006).
- In their 2008 statement, the COT considered that the JECFA PTWI could not be considered fully protective for all age groups and that, since it is not possible to identify a threshold for the association between lead exposure and decrements in intelligence quotient, efforts should continue to reduce lead exposure from all sources (COT, 2008).
- In 2010, the EFSA published an opinion on lead using a benchmark dose BMD approach (EFSA, 2010). Developmental neurotoxicity in young children and cardiovascular effects and nephrotoxicity in adults were identified as the relevant endpoints for lead. As a result, the EFSA found that neuro-development effects at current exposure levels are a concern for infants, children and pregnant women. Consequently, since no threshold of effects for the critical endpoints could be identified, the EFSA concluded that the JECFA PTWI is no longer appropriate and that further efforts to derive a PTWI would not be appropriate. The EFSA derived the following 3 benchmark dose lower confidence limits (BMDL):

- developmental neurotoxicity $BMDL_{01}$: 0.50 µg/kg body weight/day
- effects on systolic blood pressure $BMDL_{01}$: 1.50 µg/kg body weight/day (90 µg/day)
- effects on prevalence of chronic kidney disease $BMDL_{10}$: 0.63 µg/kg body weight/day (38 µg/day).

Conclusions and recommendations

"the P-SC-EMB decided to set the SRL at 0.01 mg/kg"

Since dietary intake of lead in certain populations exceeds levels where adverse health effects are caused, its release from food contact materials made from metal and alloys into food should be reduced as much as possible.

In order to set an SRL for lead, the P-SC-EMB decided to use the $BMDL_{10}$ of 0.63 µg/kg body weight/day (38 µg/day) for chronic kidney disease. As lead is considered an impurity in the metallic material and intake can be higher than the $BMDL_{10}$, the allowance for lead release from food contact materials and articles should not exceed 10% of the toxicological reference value. Therefore, assuming that a person of 60 kg body weight consumes 1 kg of foodstuffs per day that is packaged and/or prepared with food contact materials made from metals and alloys, the calculated limit for lead would be at 0.004 mg/kg.

However, the P-SC-EMB decided to set the SRL at 0.01 mg/kg, which is consistent with the limit for lead stated in Council Directive 98/83/EC. This equals an allowance of 26% of the toxicological reference value.

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Lithium (Li)

Lithium is a soft, silvery-white metal which tarnishes and oxidises very quickly on contact with air and water (Winter, 2007).

Lithium is widely distributed across the globe, but it is not found in metallic form because of its high reactivity (Beliles, 1994). It is mainly encountered as an impurity in the salts of other alkali metals.

Lithium is the lightest solid element. It is mainly used in the manufacture of certain high-performance alloys used in aeronautics. Lithium is the metal with the lowest molecular mass and also the lightest metal, with a density half that of water. In accordance with the Dulong-Petit law, it is the solid with the highest specific heat (Winter, 2007).

Lithium salts such as lithium carbonate, citrate and orotate are used as mood regulators for the treatment of bipolar and sleep disorders (Winter, 2007).

Sources and levels of intake

Lithium is found in foodstuffs at concentrations ranging from 0.012-3.4 mg/kg. As the main contributors grains and vegetables were identified (Schrauzer, 2002).

Mean daily intake through food from multiple countries was estimated between 350 and 1500 µg/day (Schrauzer, 2002). Anses (2011) estimated mean daily intake at 48.2 µg/person/day in adults and 19.8 µg/person/day in children. Main contributors are water (35%), coffee and other hot beverages in adults.

Metallic food contact materials

High-performance lithium-aluminium, -cadmium, -copper and –manganese alloys are used in the manufacture of high-quality mechanical parts, although there is no evidence of such alloys coming into contact with food.

Other food contact materials

Lithium is sometimes used in low thermal-expansion glasses and ceramics.

Release

No information available.

Safety aspects

- RIVM (1991) derived a TDI of 0.008 mg/kg body weight/day (0.48 mg/day). This limit was derived from 90-day oral rat studies, mutagenicity data, and therapeutic uses of Li salts.

Conclusions and recommendations

"the SRL for lithium is set at 0.048 mg/kg"

Based on the limited information available, the SRL was derived from the TDI of 0.008 mg/kg body weight/day (0.48 mg/day) established by the RIVM (1991). As lithium is considered an impurity in the metallic material, the P-SC-EMB concluded that an allowance of 10% of the toxicological reference value was reasonable. Therefore, assuming that a person of 60 kg body weight consumes 1 kg of foodstuffs per day that is packaged and/or prepared with food contact materials made from metals and alloys, the SRL for lithium is set at 0.048 mg/kg.

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Mercury (Hg)

Mercury is among the metals of most concern for human health, especially organic mercury. Mercury in ambient air originates mainly from volcanic and industrial activity (Codex Standard 193-1995). About 100 tonnes of mercury are released into the global atmosphere each year by the burning of fossil fuels, melting of sulfide ores, cement manufacture and the heating of other materials containing mercury (Florence and Batley, 1980). Methyl mercury is biosynthesised from inorganic mercury as a consequence of microbial activity (ATSDR, 1999). Methyl mercury is found in foodstuffs and, in particular, in fish and seafood. Much has been done in the last decade to eliminate or reduce mercury contamination of foodstuffs.

Sources and levels of intake

Mercury is found in concentrations ranging from 0.005-0.05 mg/kg in foodstuffs. The main contributor is methyl mercury in fish, which contains between 2 and 4 mg/kg. The average level of mercury in fish is 0-0.08 mg/kg (National Food Agency of Denmark, 1995). The major source of mercury from fish is methyl mercury (Beliles, 1994; Berlin, 1986). In Regulation (EC) No. 1881/2006, maximum levels for mercury in fish and food supplements have been specified.

The European Commission, DG-SANCO (2004), estimated a mean dietary intake of mercury among 13 European states equal to 0.006 mg/day (0.1 µg/kg body weight/day). In the British total diet study (2006), mean and high level adult dietary exposures to mercury were 0.02-0.05 µg/kg body weight/day and 0.1-0.13 µg/kg body weight/day, respectively (FSA, 2009).

Anses (2011) estimated the mean daily intake of inorganic mercury between 0.006 and 0.18 µg/kg body weight/day in adults and between 0.014 and 0.26 µg/kg body weight/day in children (according to lower bound or upper bound concentrations). Mean daily intake of organic mercury via fish and seafood products were estimated at 0.017µg/kg body weight/day in adults and 0.022 µg/kg body weight/day in children.

Other sources of mercury may be the chloro-alkali industry, the electrical industry, manufacture of paints, instruments, agrochemicals and other specialist items.

Mercury has a propensity to form alloys (amalgams) with almost all other metals, except iron (Beliles, 1994). Dental amalgam contains tin and silver (and sometimes gold) dissolved in mercury (Beliles, 1994).

The safety of the use of dental amalgam and its substitutes is subject to specific risk assessment by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). The use of dental amalgam has been banned in Denmark, Norway and Sweden and has also been discouraged in other EU countries (Norwegian Ministry of the Environment, 2007; Swedish Ministry of the Environment, 2009; European Commission, 2008).

Metallic food contact materials

Due to its physico-chemical properties and, in particular its known toxicity, mercury is not used in food contact materials.

Release

No information is available.

Safety aspects

- JECFA (1978; 1988) established a PTWI of 0.005 mg/kg body weight/week for mercury, but with a maximum of 0.0033 mg/kg body weight/week for methyl mercury. However, it was stated that this PTWI might not adequately protect foetuses. In 2010, a new PTWI of 0.004 mg/kg body weight/week for inorganic mercury in foods other than fish and shellfish was established (JECFA, 2010). The previous PTWI for total mercury was withdrawn. The new PTWI of 0.004 mg/kg body weight/week was based on the benchmark dose lower limit (BMDL10=0.06 mg/kg body weight/day) for a 10% increase in relative kidney weight in male rats, the application of an uncertainty factor of 100 and extrapolation to a weekly limit.
- The WHO (1993) set a guideline value for total mercury in drinking-water of 0.001 mg/L; however, in the third edition of the Guideline for drinking-water quality, a guideline value of 0.006 mg/L only for inorganic mercury in drinking-water was set (WHO, 2008).This value was also brought forward to the fourth edition (WHO, 2011).
- Mercury, in its metallic form, is unlikely to cause poisoning by ingestion, whereas the vapour is toxic. Methyl mercury is the most toxic form of organic mercury (Codex Standard 193-1995). The oral absorption of elemental mercury is limited and may be approximately 0.1% (Beliles, 1994). Some inorganic mercury salts and organic mercury compounds may be more readily absorbed, e.g. methyl mercury which is absorbed completely (Beliles 1994). The toxic properties of mercury vapour are due to mercury accumulation in the brain, causing an unspecific psychoasthenic and vegetative neurological syndrome (micromercurialism) (Berlin, 1986). At high exposure levels, mercurial tremor is seen, accompanied by severe behavioural and personality changes, increased excitability, loss of memory and insomnia (Berlin, 1986). Low concentrations of methyl mercury cause cell death and inhibition of cell proliferation in cell cultures, whereas mercury chloride primarily disrupts the plasma membrane (Braeckman *et al.*, 1997). Methyl mercury is listed as one of the six most dangerous chemicals in the environment. Inorganic mercury is classified as a carcinogen. However, there is a lack of data on risks to humans (Beliles, 1994).

Mercury and silver interferes with copper distribution. The general population is exposed to methyl mercury primarily through their diet (organic mercury) and dental amalgam "fillings" (inorganic mercury) (ATSDR, 1999).

- An IPCS Working Group (IPCS, 2003) recommended a TDI of 0.002 mg/kg body weight/day for inorganic Hg based on the NOAEL of 0.23 mg/kg body weight/day for kidney effects from a 26-week study in rats (NTP, 1993) and applying an uncertainty factor of 100 (for inter-species and intra-species variation) after adjusting for dosages 5 days/week. A similar TDI was obtained by applying an uncertainty factor of 1,000 (an additional uncertainty factor of 10 for adjustment from a LOAEL to a NOAEL) to the LOAEL for renal effects of 1.9 mg/kg body weight/day from a 2-year study in rats (NTP, 1993).

Conclusions and recommendations

"the SRL for mercury is set at 0.003 mg/kg"

Mercury is one of the most dangerous metals for human health.

The SRL was derived from the JECFA (2010) assessment. Using the TWI of 0.004 mg/kg body weight/week as a starting point resulted in a TDI of 0.0006 mg/kg body weight/day (0.03 mg/day). As mercury is considered an impurity in the metallic material, the P-SC-EMB concluded that an allowance of 10% of the toxicological reference value was reasonable. Therefore, assuming that a person of 60 kg body weight consumes 1 kg per of foodstuffs day that is packaged and/or prepared with food contact materials made from metals and alloys, the SRL for mercury is set at 0.003 mg/kg.

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Thallium (Tl)

The Earth's crust comprises some 0.7% of thallium (USGS, 2010). Thallium is found in zinc, copper, iron and lead ores (John Peter, 2005). Only very rare minerals (lorandite, crookesite, etc.) contain thallium (Shaw, 1952). Pyrite ash used to manufacture cement may contain considerable quantities of thallium (John Peter, 2005).

Sources and levels of intake

According to currently available data, the risk of excessive public exposure to Tl is low. To date, only a few studies investigating the human health risks associated with dust deposits from certain industries (e.g. cement works) have been conducted (Brockhaus *et al.*, 1981). Thallium can be found in vegetables, potatoes and fish at concentrations around 0.001 mg/kg (FSA, 2009).

Dietary intake was estimated at < 5 µg/day (Sherlock, 1986). More recently, the 2006 British total diet study mean and high level adult dietary exposures to antimony were 0.01 µg/kg body weight/day (0.6 µg/day) and 0.02 µg/kg body weight/day, respectively (FSA, 2009).

Metallic food contact materials

This highly toxic metal can be found as an impurity in alloys. The French Decree of 27/8/1987 lays down a QM of thallium in aluminium of 0.05%. Furthermore, the addition of thallium to certain metals apparently increases their resistance to deformation and corrosion. However, there is no evidence of any thallium use in a food-related context, although neither has its absence (as a component or impurity) from metals or alloys been demonstrated.

Other food contact materials

No information available.

Release

No information available.

Safety aspects

- EPA (2009) specified a RfD of 0.00001 mg/kg body weight/day (0.001 mg/day). This was based on a NOAEL of 0.04 mg/kg body weight from a sub-chronic rat study and an uncertainty factor of 3,000 (10 to extrapolate from sub-chronic to chronic data, 10 to account for intra-species variability, 10 for interspecies variability, and 3 to account for the lack of reproductive and chronic toxicity data).
- In a 2008 COT statement, no health-based guidance values for thallium were expressed, but the current UK dietary exposures were considered unlikely to be of toxicological concern (COT, 2008).
- The WHO (1996) considered that exposures resulting in urinary thallium levels of 5 µg/L are unlikely to cause adverse health effects. This level corresponds to an oral intake of 0.17 µg/kg body weight/day for a 60 kg adult.

Conclusions and recommendations

"the SRL for thallium is set at 0.0001 mg/kg"

The SRL was derived from the EPA (2009) RfD of 0.001 mg/day. As thallium is considered an impurity in the metallic material, the P-SC-EMB concluded that an allowance of 10% of the toxicological reference value was reasonable. Therefore, assuming that a person of 60 kg body weight consumes 1 kg of foodstuffs per day that is packaged and/or prepared with food contact materials made from metals and alloys, the SRL for thallium is set at 0.0001 mg/kg.

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Stainless steel and other alloys

An alloy is a metallic material composed of two or more elements. Alloys are homogeneous at a macroscopic scale and their components cannot be separated by mechanical means. Alloying elements are incorporated into the metallic matrix to form a new metallurgical structure that enhances specific properties of the metal (e.g. tensile strength, corrosion resistance, electrical or thermal conductivity). The metallurgical structure depends on the alloy composition, but also on the different thermal and mechanical processes applied during production of the material.

Steel is an alloy made of iron and carbon (less than 2% carbon). Other elements are added (e.g. up to 3% nickel, chromium and/or molybdenum). Stainless steels comprise a group of special steels with high corrosion resistance that renders them “stainless”.

Main types of alloys

Most metals are mainly used in alloy form. Among the commonest alloys are:

- Stainless steels are iron-chromium alloys which contain a minimum of 10.5% chromium (usually 17-18%) and less than 2% carbon, and which are often also alloyed with other elements such as nickel, molybdenum, etc., to provide desired properties (see chapter on stainless steels).
- Bronze consists of 80-95% copper and 5-20% tin.
- Brass consists of 60-70% copper and 30-40% zinc.
- German silver is an alloy based on copper, nickel and zinc with a composition of e.g. 60% copper, 20% nickel and 20% zinc.
- Pewter alloy is made up of tin, antimony and copper in the following percentages: tin 91-95%, antimony 2.5-8%, copper 0.05-2.5%.
- Other alloys are used in small quantities, for example nickel-titanium, nickel-copper, and quasi-crystal.

The composition of an alloy is usually presented as a concentration range for each individual element. This is because national and international standards specify permissible concentration ranges. Within the ranges given in these standards, the properties of the alloy will be the same. Besides the principal alloying elements that define the alloy type, other “minor” alloying elements can be added to enhance a specific property of the material (e.g. the addition of 1-6% Pb in brass to improve the machinability of the material). Alloys may also contain metallic impurities from the production process. Maximum permissible impurity concentrations are set in the alloy specification and are generally less than 0.5%, depending on the alloy type.

Release

When in contact with a given foodstuff, release of metallic ions from alloys is reduced compared with pure metals, while also increasing the chemical stability of the products.

Measurable amounts of metallic elements in the alloy may be released into foodstuffs from food preparation and cooking, leading to human ingestion. Whether such releases can cause adverse health effects needs to be addressed.

Release tests have been carried out on coffee-pots (mocha-type pots) with different compositions of aluminium alloys. The coffee pots consisted of alloys containing 0.09-0.77% zinc, 0.19-5.5% copper, 0.02-0.5% lead, as well as other metallic elements. The release of copper, zinc and lead was determined. The results showed that increasing amounts of copper in the starting alloy did not correspond to increased copper release. Also, repeated use gave irregular, but decreasing, release of all the tested metals (Gramiccioni *et al.*, 1996).

Safety aspects

- When assessing the risk of the use of one or more substances incorporated into a special preparation (for instance alloys), the way the constituent substances are bonded in the chemical matrix shall be taken into account (Regulation (EC) No. 1907/2006).

- There are no specific toxicological evaluations for the individual alloys used for direct food contact and, therefore, any safety assessment is usually based on the information available for individual elements.
- The constituent elements of an alloy are released from the alloy as individual elements.
- There is usually less release of elements from alloys than from non-alloyed metals due to the microstructure and surface properties of the alloys. In most alloys, the constituent elements are chemically bound together, essentially forming solid solutions and new compounds; for this reason, these elements are not free to migrate independently to the surface or from the surface.

Conclusions and recommendations

- Any metallic element released from an alloy should comply with the corresponding specific release limit (SRL, chapter 1).
- In the absence of a specific safety evaluation of an alloy, the safety of any released amounts of the individual elements should be evaluated.
- Cadmium must not be added intentionally.

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Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as amended. Chapter 0.11.

Stainless steels

Stainless steels are widely used in food contact applications due to their resistance to corrosion under conditions that would corrode or lead to rusting of iron or “non-stainless” steels, their durability, their ability to be readily cleaned and sterilised without deterioration. They impart neither colour nor flavour to foodstuffs and beverages.

Corrosion resistance in stainless steels results from a very thin, naturally-formed protective surface layer often called a passive film. The film is formed in the presence of chromium. Increasing the chromium content from a minimum of 10.5% to 17 or 20% also increases the stability of the passive film. This film, only a few Å thick, forms almost instantaneously on contact with the oxygen in air or water. Agitation or abrasion does not easily lead to film break-down and, if damaged, the film rapidly reforms. Nickel promotes repassivation and molybdenum is very effective in stabilising the film in the presence of chlorides. Hence, these two alloying elements are used in many of the stainless steels used in food contact applications.

Main types of stainless steel

Stainless steels vary in composition, but always contain a high percentage of chromium (a minimum of 10.5%). The majority of stainless steels used in food contact applications contain 16-18% of chromium (except martensitic stainless steel for cutlery), as this has been found to be the optimum chromium concentration for corrosion resistance in a wide range of food and beverage media.

Stainless steels are sub-divided into families according to their metallurgical structure. The stainless steel grades commonly used for food contact applications are defined by European Standard EN 10088:

- Martensitic stainless steels: 11.5-19% chromium, with low (0-2%) or medium (4-7%) nickel. They may contain molybdenum (up to 2.8%) and vanadium (up to 0.2%). Sub-families with varying amounts of carbon, with or without molybdenum, are used for particular applications. Some typical compositions and applications are:

  - 13% chromium, 0.2% carbon, no nickel or molybdenum, used for medium-price cutlery.
  - 13% chromium, 0.4% carbon, plus molybdenum, used for high-quality cutlery.
  - 14-15% chromium, >0.4% carbon, 0.5-0.8% molybdenum, 0.1-0.2% vanadium, no nickel, used for professional cooks' knives.

- Ferritic stainless steels: minimum 10.5-30% chromium and maximum 1% nickel. Some grades may contain up to 4% molybdenum, and aluminium may be used as an alloying element. 16-21% chromium is used in cutlery, hollow-ware, table surfaces, panels and worktops.
- Austenitic stainless steels: for food contact applications, typically contain a minimum of 16% chromium and 6% nickel. Austenitic grades with varying amounts of chromium and nickel, sometimes with other elements (e.g. molybdenum, copper), are used for particular applications.

  Austenitic stainless steel grades are used in a very wide range of food contact applications, both domestic and industrial (cutlery, hollow-ware and kitchen utensils typically have 18% chromium and 8-10% nickel; whereas higher alloy grades used for food processing, storage and transport equipment, pipe-work, etc., have 17% chromium, 11% nickel and 2% molybdenum). Grades containing molybdenum (approximately 2% or 4.5%) are particularly resistant to the corrosion caused by salt-containing foods.

  Recent years have seen an increasing use of the so-called 200 series stainless steels, where manganese (up to 8%) is substituted for nickel, for food contact applications. These steel grades also contain nitrogen and copper to further stabilise the austenitic phase as well as additional strength (N) and improved cold forming properties (Cu). However, although the 200 series are austenitic stainless steels, their corrosion resistance is generally not equal to that of the 300 series stainless steels.

  According to EN ISO 8442-1 austenitic stainless steels for cutlery are divided into two groups:

  - CrNi – minimum 17% Cr, 8% Ni
  - CrMn – minimum 17% Cr, 4% Ni, 7.5% Mn

  Super-austenitic grades are used in similar applications and also for steam-heating systems, boilers, etc.

- Austeno-ferritic steels, also known as Duplex steels, contain 21-28% chromium, 0-4.5% molybdenum, 1.35-8% nickel, 0.05-0.3% nitrogen and up to 1% tungsten. These stainless steels may be used in contact with corrosive foodstuffs as they have a very high resistance to corrosion caused by, for example, saline solutions at high temperatures.

Composition limits

There are no universal composition limits for stainless steels used in food contact applications, although there are legislative requirements in France and Italy. In France, stainless steels for food contact products must contain at least 13% of chromium and can contain nickel and manganese. Maximum limits are imposed for certain other alloying elements (4% for Mo, Ti, Al and Cu; 1% for Ta, Nb and Zr). In Italy, there is a list of stainless steel grades for food contact materials. These grades must pass tests for corrosion in distilled water, olive oil, an aqueous solution of ethanol and 3% acetic acid in water, under specified conditions. New grades can be added to the list following appropriate testing. In the UK, there are numerous specifications for a wide range of food contact applications for stainless steels. Other countries also have similar regulations. References to some of the Italian, French, UK and German legislation/standards (e.g. DIN 18 865 and DIN 18 866) are given below.

In addition, there are European standards for certain types of application of stainless steels. The composition limits for stainless steel for table cutlery are specified in EN ISO 8442-2. The composition depends on the application of the table cutlery.

Compositional information on some other grades of stainless steels used in food contact applications can be found in Outukumpu Stainless Corrosion Handbook (Outokumpu Stainless Corrosion Handbook 10th edition 2009).

Stainless steels used in contact with food

The following food contact applications often use stainless steels:

i. Containers for storage and transportation e.g. milk trucks, wine tanks.

ii. Processing equipment used in industrial plants e.g. processing of fruit and vegetables, dry foods such as cereals, flour, sugar; fish processing; brew kettles and beer kegs, utensils such as blenders and bread-dough mixers.

iii. Processing equipment, as well as many fittings in catering facilities such as restaurants, hospitals and in industrial kitchens.

iv. Slaughterhouse equipment.

v. Household equipment e.g. electric kettles, cookware, kitchen fittings (sinks, counters and drains) as well as bowls, knives, spoons and forks.

A wide range of stainless steels are highly resistant to corrosion in acetic acid (concentration range 1-20%) at temperatures up to boiling point (Outukumpu Stainless Corrosion Handbook, 10th edition 2009). Similar corrosion resistance is seen for beer, citric acid (up to 5%), coffee, fruit juices, wines, lactic acid, milk and various detergents. It is well known that molybdenum improves the corrosion resistance of stainless steels in contact with foods or fluids that contain chloride ions. In Italy, stainless steels must meet certain release criteria in a variety of media before they can be approved for food contact applications. The list of approved stainless steels includes the standard austenitic grades 304 (18% Cr, 10% Ni) and 316 (17% Cr, 12% Ni+Mo). In addition, some European Standards (e.g. EN ISO 8442-2) specify the finish quality of the products and their ability to meet test criteria, which minimises the likelihood of pitting or crevice corrosion occurring during the normal lifetime of the product.

Release

Metal ion release from stainless steel is generally assumed to be a time-dependent measure of metal transition. However, tests have shown that the release of nickel from stainless steel decreases time-dependently to a minimum value, which is below 0.1 mg/m2 (usually below 0.1 mg/kg foodstuff) for all the new pots examined (Vrochte *et al.*, 1991).

Preparation of foodstuffs such as rhubarb, sauerkraut and red wine sauce in brand new stainless steel cooking pots may cause chemical changes of the stainless steel surface. These changes can be regarded as the development of a protective layer that reduces further nickel release (Vrochte *et al.*, 1991). The amount of nickel derived from food contact utensils in standard portions of various corrosive foodstuffs is 0-0.008 mg (Flint and Packirisamy, 1995).

The highest rates of chromium and nickel release from saucepans were observed in new saucepans at first use (Flint and Packirisamy, 1997). Nickel and chromium release was tested with rhubarb, apricots, lemon marmalade, tomato chutney and boiled potatoes. The release of nickel was approx. 0.2 mg/kg for apricots and rhubarb after the first cooking operation. After the first two cooking operations, the highest nickel release for apricots and rhubarb were reduced to approximately 0.07 mg/kg and 0.01 mg/kg, respectively. Correspondingly, the release of chromium was 0.05 mg/kg and 0.01 mg/kg, respectively.

Studies on the release of chromium and nickel using cooking utensils made of ferritic and austenitic stainless steel and glass have shown that the release of nickel and chromium into an average daily diet is negligible compared with the natural contents of these elements in foodstuffs. Furthermore, no significant differences in ion release have been noted between these steels and glass.

Safety aspects

- No particular health concerns have been raised, in terms of excessive intakes of nickel or chromium, by several studies of corrosion in various media and of uptake of metals by foods cooked in stainless steel pans.
- Special grades of stainless steels are available for use in applications (e.g. those involving contact with relatively high levels of chloride ions) where particular corrosion resistance characteristics are required.

Compliance with specific release limits, as presented in these guidelines, will help to reduce health risks that may arise from the use of certain stainless steels that are not well known or that have not been individually tested.

References

DIN 10528 Food hygiene – Guideline for the selection of materials used in contact with foodstuffs – General principles.

EN ISO 8442-2. European Standard. Materials and articles in contact with foodstuffs – cutlery and table hollow-ware – Part 2. Requirements for stainless steel and silver-plated cutlery, May 1997.

European Standard EN 10088-1:2005 (CEN – European Committee for Standardization, June 2005).

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Flint, G.N., Packirisamy, S. (1997). Purity of food cooked in stainless steel utensils. Food Additives and Contaminants. 14(2), p. 115-126.

French Decree of 13 January 1976 related to stainless steels in contact with foodstuffs.

French standard NF A 36-711. Stainless steel intended for use in contact with foodstuffs, products and beverages for human and animal consumption – 1/4/2002.

Germany: Technical regulations for large-scale kitchen equipment DIN 18 865 and DIN 18 866.

Hygiene control of packaging, containers, tools, intended to come into contact with foodstuffs or with substances for personal use. Official Gazette of the Italian Republic, 20 April 1973.

Outukumpu Stainless Corrosion Handbook, 10th edition 2009.

UK standards:

- Specification for domestic pressure cookers BS 1746: 1987 (1987-02-27).
- Specification stainless steel catering containers and lids BS 5312: 1996 (1976-02-27).
- Stainless steel tubes and fittings for the food industry and other hygienic applications (1992-01-31)
  - BS 4825-1 (1992-01-31) – Specification for tubes;
  - BS 4825-2 – Specification for bends and tees;
  - BS 4825-3 – Specification for clamp type couplings;
  - BS 4825-4 – Specification for threaded (IDF type) coupling;

  - BS 4825-5 – Specification for recessed ring joint type couplings.
- Specification for table cutlery BS 5577: 1984 (1984-02-29).

Vrochte, H. *et al.* (1991). Studies on the question of nickel release from stainless steel saucepans. Journal of Food Science. 30 p. 181-191.

Chapter 3 – Analytical methods for release testing of food contact materials and articles made from metals and alloys

Requirements established under the general provisions

Specific release limits (SRL) – Article 4

Article 4 states:

> *Metals and alloys used in food contact materials and articles shall comply with the specific release limits (SRLs) set out below in Table 1 and Table 2. SRLs are expressed in mg/kg.*

Compliance with the SRL and release testing – Article 5

Article 5 states:

> *Compliance of the material or article with the SRLs should be verified by experimental release testing.*
>
> *(a) Testing of release from the material or article into foodstuffs should be carried out under the reasonable worst-case conditions that promote metal release for the contact during manufacture, storage, distribution and normal or foreseeable use, with respect to time, temperature and composition of the foodstuff (in particular, pH and nature of any salts and acids that are present).*

(b) When it is not possible to test release into foodstuffs, food simulants should be used.

Criteria for the choice of test procedure

To assess compliance, the material or article must be tested for the relevant specific release (i.e. of those metals and impurities likely to be present in significant amounts), either into foodstuffs or in food simulants, according to the following criteria.

Testing release from materials and articles into foodstuffs

Release from metallic food packaging into foodstuffs is influenced by the properties of the packaging material, the chemical and physical properties of the foodstuff, and ambient conditions such as thermal processing of filled containers, storage time and temperature and residual oxygen after sealing.

To verify the compliance of materials or articles with the relevant SRLs, actual foodstuffs should be tested or used in testing under actual conditions of application in the following cases:

- when the material or article placed on the market is already in contact with food (e.g. canned food, beer kegs, etc.) or is intended for packaging applications (e.g. empty cans destined for the food industry) and as far as possible at end of shelf life.
- when the material or article is not yet in contact with food (i.e. non-packaging applications, for example, food processing utensils), but the intended use for specified foodstuff(s) or group(s) of foodstuffs is clearly indicated by the manufacturer or is undoubtedly recognised (e.g. garlic presses, tea infusers, etc.).
- when harsh physical conditions or abrasion are expected to be encountered under normal use that cannot be reproduced when using liquid simulants (e.g. pepper mills, coffee grinders or other mills for nuts, cereals etc.).
- when the natural metal content of the foodstuffs is capable of significantly influencing the analytical result. In this case, the choice of alternative representative foodstuffs must be scientifically justified.

Testing release from materials and articles into simulants

Food simulants should be used for release testing when:

- the material or article may come into contact with foodstuffs whose diversity cannot be included in a particular category of food (e.g. kitchen utensils or other articles at end-use level).
- the intended use for specified foodstuff(s) or group(s) of foodstuffs is not clearly indicated or known.
- it is not feasible to test release from food contact materials and articles directly into foodstuffs either for technical [e.g. when analysis is not technically possible in specified foodstuff(s) or group(s) of foodstuffs] or practical reasons [e.g. when the specified foodstuff(s) or group(s) of foodstuffs are not available].

Articles for repeated use

For materials or articles not yet in contact with food (i.e. non-packaging applications) but intended to come into repeated contact with foodstuffs, the release test(s) shall be carried out three times in succession. Between tests, samples should be treated as described under "Pre-treatment of materials and articles". Where these instructions apply only to the first use or where the instructions indicate that no washing is required before or between uses, this must be taken into account.

Compliance is established on the findings from the third test. This takes account of the passivation process that some alloys or metals undergo.

However, the sum of the results of the first and second tests should not exceed an exposure equivalent to daily use for one week (i.e. seven times the SRL) according to the formula:

$$\text{RESULT1}^{st}\text{ test} + \text{RESULT2}^{nd}\text{ test} < 7 \text{ x SRL.}$$

This takes into account the overall acceptability of a food contact article.

Articles for repeated use, like hot beverage appliances (e.g. coffee machines), should be tested after decalcification and any other cleaning steps stated within the corresponding instruction manual. The release test must be performed according to DIN 10531.

Remark:
Where physical changes occur in the test specimen under the specified test conditions, the test must be adapted with conditions that do not lead to the physical changes but still reflect the worst foreseeable conditions of use.

Sampling of materials and articles

Sampling for analysis means taking an article, a material or an already packed food item in order to verify its compliance with the established requirements, such as relevant SRLs.

Sampling should be performed at all stages of the supply chain for food contact materials.

A sampling strategy should be defined, which allows an appropriate and representative sample of the production batch. The type, amount, size and characteristic properties of the sample should, as a minimum, be specified.

The number of test specimens sampled and the sample size must be sufficient to perform repeat analyses and to confirm results in case of dispute.

For each sampling effort, an appropriate sampling protocol form should be prepared, which must be completed during the sampling exercise.

In case of sampling for enforcement purposes replicate samples should be taken for primary analysis, disputes (in which case, analyses should be repeated) and confirmatory analyses (if results are challenged, analyses should be performed by different laboratories), unless such a procedure conflicts with the rules of member states as regards the rights of the food manufacturer.

Packaging materials (e.g. canned foodstuffs)

An effective sampling scheme should be developed in order to check batch compliance for packaging materials at the manufacturing or distribution stage, which should be reflected in the supporting documentation of any declaration of compliance. A suitable sampling plan for this purpose is given in Table 1 and may be applied.

Table 1 *Number of packages or units to be sampled, depending on the batch size.*

Number of packages or units in the batch	Number of packages or units to be sampled
≤ 25	at least three
26 to 100	about 5%, at least three
> 100	about 5%, a maximum of 10

Materials and articles other than packaging materials (e.g. kitchen utensils)

At least three samples of materials or articles other than packaging materials should be sampled.

Competent authorities/inspectorates

For market surveillance purposes (e.g. as part of a campaign), the number of samples and the sample size may differ from the sampling schemes referred to above.

Pre-treatment of materials and articles

Any instructions provided by the manufacturer with regard to pre-treatment of the test specimens, such as cleaning, must be followed before release testing is performed.

When washing is required and no detailed instructions are provided, test specimens should be washed with household liquid detergent in water (pH 6-8.5, at a temperature of approximately 40 ° C), then rinsed with tap-water and finally with distilled water or water of similar quality. They should be left to drain and dry. Any staining should be avoided. The surface to be tested must not be handled after cleaning.

During the sample preparation, modification of the physical properties of the surface of the food contact material or article should be avoided, especially for metal-plated products.

Release testing into foodstuffs

Pre-treatment of materials and articles and handling between, where appropriate, is described under “Pre-treatment of materials and articles”.

If appropriate, test conditions may be selected using the times and temperatures set out under “Release testing into food simulants”.

Selection of foodstuffs

The material or article to be tested shall be brought into contact with the intended foodstuff, if available.

If no particular foodstuff has been indicated, a representative foodstuff should be selected, especially one having an equivalent pH value and organic acid, salt, fat and alcohol content. The principle of reasonable worst-case circumstances of use shall be applied. For example, testing should be carried out with known corrosion accelerators, such as sulphur dioxide or nitrate, at levels close to the typical upper limits.

Where applicable, the representative foodstuff will be specified in the supporting documentation for the declaration of compliance and, if necessary, the initial concentration of the metal(s) or alloy(s) before release testing. This is to ensure that the tests can be reproduced, if necessary.

> NOTE: Souci (2008)[1] provides Food Composition and Nutrition Tables that the reader may find helpful. For example, this reference identifies foodstuffs with the highest concentrations of typical organic acids.

Natural metal content of the foodstuff

There should be prior knowledge of the natural concentration of the metal(s) in the foodstuff to be tested. Therefore, the metal concentration in the foodstuff needs to be measured before and after contact with the metallic material or article. If available, information about the expected natural metal concentration and its variability in the foodstuff should be

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[1] **Food Composition and Nutrition Tables** SW Souci, W Fachmann, H Kraut. Wissenschaftliche Verlagsgesellschaft mbH, Stuttgart 7th edition 2008.

mentioned by the food producer in the supporting documentation for declarations of compliance.

Testing of packaging materials

When testing a representative foodstuff and where physical changes occur in the test specimen under the specified test conditions, the test must be adapted with conditions that do not lead to the physical changes but should still reflect the worst realistic conditions of use.

During sample preparation, modification of the physical properties of the surface of the food contact material or article should be avoided, especially in the case of electro-plated products.

Processing and packaging conditions[1]

When checking compliance, test conditions should be as close as possible to actual processing and packaging conditions to avoid an over- or under-estimation of metal release. The presence of oxygen during the test, for example, may increase the release of iron and tin from tinplate cans or of aluminium from aluminium containers. Metal containers must be hermetically sealed (i.e. closed in such a way that air is prevented from entering or leaving the enclosure).

If a vacuum is created in the container after sealing under actual packaging conditions, an equivalent vacuum should also be created in the test packaging.

If hot foodstuffs are packed into containers under industrial packaging conditions, then this should also be carried out for testing purposes.

Storage conditions[1]

Most hermetically closed metal containers for foodstuffs are used for products with long shelf-lives that may, in some cases, extend up to 5 years.

It is likely that the release of metals due to interactions between foodstuffs and the food contact surface of metal containers will continue throughout

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[1] These conditions may be suitable for manufacturers, while competent authorities may not be able to replicate industrial conditions. Thus, comparison of their respective results may not be possible.

the shelf-life of the product. The increase in the concentration of metals in packed foodstuffs may not be linear in all cases. Therefore, it is not possible to accurately predict the concentration of the metal at the end of the shelf-life based on measurements taken only after storage for a short time.

Thus, for declarations of compliance, it is advisable to store the test specimen under actual storage conditions for its entire shelf-life.

If rapid test results are needed, metal release can be accelerated by using more challenging storage conditions, for example, higher temperatures, regular shaking of the container, or alternating between hot and cold storage. The extrapolation of these data must be justified by comparison with data obtained under normal conditions. For example, after verification of their applicability (scientifically validated), the contact time and temperature tables reported in Regulation CE 10/2011, Annex V, could be used.

In order to establish compliance, this information must be mentioned in the declaration of compliance.

Determination of metals in the foodstuff

The metal concentration in the foodstuff can usually be determined using the same analytical methods as for the determination of metal concentrations in food simulants (see 8.7). Individual digestion conditions and particular measures to avoid matrix interferences may be required. In the case of any special sample treatment, a thorough description of instrumental conditions must be included in the test report.

Test results and conclusions

The release of a particular metal from a metallic food contact material or article (MR) into foodstuffs can be determined by subtracting the natural metal concentration of the foodstuff (MF) from the total metal concentration in the foodstuff after contact with the material or

$$MR = MT - MF$$

Release testing into food simulants

Food simulants

As it is not always possible to test release from food contact materials and articles into actual foodstuffs, food simulants have been introduced that share certain characteristics with one or more food types. In practice, various mixtures of food types are possible, for instance fatty and aqueous foods.

Taking into account sound scientific knowledge, tests conducted in the context of this Technical Document and the principle of reasonable worst-case conditions of use, testing on the following food simulants is recommended:

Table 2 *Food types and food simulants.*

Type of food	Simulant
Aqueous or alcoholic or fatty food	Artificial tap water DIN 10531*
Acidic foods (pH ≤ 4.5)	Citric acid 5 g/L

* DIN 10531 (2011-06) Food hygiene – Production and dispense 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.

Any other simulant, considered more suitable for testing, can be used provided that its use is either based on scientific data or verified by appropriate experimentation.

Where appropriate, see JRC Guideline[1] on testing conditions for articles in contact with foodstuffs.

Distilled water at the same temperature as the test material should be added regularly during testing to replace the quantity of simulant lost by evaporation.

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[1] JRC Guidelines on testing conditions for articles in contact with foodstuffs (with a focus on kitchenware). A CRL-NRL-FCM Publication, 1st Edition 2009. Office for Official Publications of the European Communities EUR 23814, 2009). Available at: http://publications.jrc.ec.europa.eu/repository/handle/111111111/8793.

To cover (close) a receptacle when it has no lid, an appropriate covering (e.g. fluoroplastic film) may be placed on top. Containers that have a cover should be closed as under actual conditions.

Articles that can be filled

Where appropriate, this applies to articles such as mixing bowls, pots, pans, flasks, kettles, bakeware and food trays.

Test conditions:

The article should be filled with the simulant to approximately ⅔ total capacity and then suitably covered to reduce evaporation.

A distinction should be made between use at ambient temperature (e.g. for salads) and uses that include hot fills or boiling liquids.

Articles should be tested under actual conditions of use or, if not applicable, by applying the following conditions where appropriate:

- for use at ambient temperature, the article should be tested over a period of 10 days at 40 ° C.
- for use with hot fills and short-term storage at room temperature, the article should be tested for 2 hours at 70 ° C followed by 24 hours at 40 ° C.
- for use with boiling contents, the article should be tested for 2 hours at the respective boiling temperature of the simulant.

For other uses, see JRC Guidelines on testing conditions.[1]

Articles that cannot be filled and for which it is impractical to estimate the ratio of surface area to the amount of foodstuff in contact with it

This applies to articles such as tableware, cooking utensils, colanders, potato mashers and cheese graters.

Test conditions:

The articles should be tested, intact, by immersion to a reasonable depth reflecting normal use of the article (see Annex II for a detailed procedure).

For the purpose of the test, contact times and temperatures should reproduce the intended and worst foreseeable conditions of use of the material or article (see JRC Guidelines on testing conditions[1]).

Materials and articles at the end-use level that cannot be filled such as baking sheets, foils

This applies to materials and articles such as aluminium foil, cutting boards, kitchen sinks with draining boards and kitchen countertops.

> "End-use" may be defined as the food contact application or function for which a material or article has been designed or for which it is ultimately used, e.g. mincers or meat slicers.

Either the entire article or a sample of it can be tested. In the latter case, the total area of the sample should be 1 dm^2. The tolerance on these measurements is ± 1 mm. Only the food contact surface is taken into account when determining the specific release value. The areas of cut edges are taken into account only if the thickness exceeds 2 mm.

Edge preparation for stainless steel articles:

The procedure for preparing the edges of stainless steel articles involves appropriate polishing. For example, the stainless steel surface may be polished under water using SiC 1200 paper to round off the edges without damaging the adjacent surface. After polishing, the article must be washed with special care so that no contaminants (such as metal particles) are left on the surface of the sample. Finally, the sample should be left for at least 24 hours in a clean and dry area so that the passive layer can re-form naturally.

Test conditions:

The articles should be tested, where appropriate, by immersion of the relevant surfaces intended for contact with food.

- For cutting boards, short-term contact with hot foodstuffs is assumed. Therefore, the test should be performed for 2 hours at 70 ° C.

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[1] JRC Guidelines on testing conditions for articles in contact with foodstuffs (with a focus on kitchenware). A CRL-NRL-FCM Publication, 1st Edition 2009. Office for Official Publications of the European Communities EUR 23814, 2009). Available at: http://publications.jrc.ec.europa.eu/repository/handle/111111111/8793.

- For articles such as counter-tops, where ambient long-term storage is assumed, testing conditions should be 10 days at 40 ° C.
- For articles such as baking foil, the testing conditions should be 2 hours at 100 ° C.

Food processing appliances

This applies to articles such as coffee makers, juicers, dispensing equipment, electric kettles and meat mincers, as well as accessories.

Test conditions:

The articles (or their component parts reasonably likely to be in contact with food) should be tested under conditions of use according to the instructions of the manufacturers.

For hot beverage appliances, testing should be performed in accordance with DIN 10531.[1]

Methods of analysis

Methods of analysis used for release testing of food contact materials and articles must comply with the provisions of Annex III (Characterisation of methods of analysis) of Regulation (EC) No. 882/2004. Laboratories performing analysis must use validated methods for the determination of metals and other elements according to the guidelines and criteria specifically set out by the EURL-NRL FCM Network (EUR 24105, 2009).

For example, an analytical procedure from a national authority, for the determination of aluminium, is given in Annex I of this Technical Document for information.

Scope

The methods for the determination of metallic elements released from metals and alloys into foodstuffs and simulants.

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[1] DIN 10531 (2011-06) Food hygiene – Production and dispense of hot beverages from hot beverage appliances – Hygiene requirements, migration test.

Principle

The concentration of a metallic element in a foodstuff or simulant is determined by an instrumental method of analysis that fulfils the performance criteria described below.

Homogenisation and digestion of food samples

Food samples should be homogenised and digested with mineral acid using an appropriate method, while avoiding any contamination or loss of material.

When removing foodstuff from articles, abrasion of the surfaces to be tested must be avoided.

Preparation of test specimens of materials or articles

See under "Pre-treatment of materials and articles".

Quality of reagents

All reagents and solvents must be of analytical quality, unless otherwise specified.

Water must be distilled or demineralised or water of similar quality such as Ph. Eur. 008 Water, purified.[1]

Quality and preparation of analytical equipment

Test vessels and storage containers made of low-density polyethylene disposable material or quartz shall be used. High-density polyethylene (HDPE) is also acceptable, while polypropylene (PP) is acceptable after verification.

Fluoroplastics are recommended where necessary, except for polytetrafluoroethylene (PTFE).

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[1] Water, purified, monograph 0008. Ph. Eur. 8th Edition. Strasbourg, France: Council of Europe; 2013.

> NOTE: Quartz containers should always be used in preference to glass. If the use of glassware cannot be avoided, it should be carefully decontaminated before use.

All equipment used for the preparation and execution of immersion experiments should be acid cleaned with 10% HNO_3 for a minimum of 24 h and then carefully rinsed with ultra-pure water before use to minimise the risk of contamination of metals.

Instruments

> NOTE: Analytical instruments and equipment are specified only when necessary; otherwise, standard laboratory equipment may be used.

Appropriate analytical methods should be employed, using instruments such as:

- Flame Atomic Absorption Spectrophotometer (FAAS)
- Graphite Furnace Atomic Absorption Spectrophotometer (GF-AAS)
- Inductively coupled plasma atomic emission spectrometer (ICP-AES, ICP-OES)
- Inductively Coupled Plasma Mass Spectrometer (ICP MS)

Other methods may be used, such as polarography, specific electrodes, etc.

Blank tests

A blank test must be performed to determine the initial concentration of the metallic element in the homogenised/digested foodstuff or simulant prior to contact with the material or article under study. A blank test should be carried out for each series of tests.

Analytical performance requirements

For the determination of metallic elements in foodstuffs or simulants, laboratories must use a validated analytical method that fulfils the performance criteria indicated below, whenever possible.

The detection limit is defined as the concentration of the element in the blank sample that gives a signal equal to three times the background noise of the instrument.

The quantification limit is defined as the concentration of the element in the foodstuff or simulant that gives a signal equal to six times the background noise of the instrument.

As far as possible:

1. Limit of detection (LOD) < 1/10 SRL
2. Limit of quantification (LOQ) < 1/5 SRL
3. Recovery rate from 80% to 120%
4. The within-laboratory standard deviation (sWR) for repeated analysis of a reference or fortified material, under conditions of reproducibility, should not exceed the level calculated by the Horwitz Equation[1] (see Table 3).

Table 3 *Predicted value for within-laboratory standard deviation (sWR), depending on concentration. Based on the Horwitz Equation.*

Analyte %	Analyte ratio	Unit	RSD (%) predicted
0.01	10-4	100 ppm	8.0
0.001	10-5	10 ppm	11.3
0.0001	10-6	1 ppm	16.0
0.00001	10-7	100 ppb	22.6

5. Specificity: as far as possible free from matrix and spectral interferences. Spectral interferences can be excluded by measuring different lines.

The *Guidelines for performance criteria and validation procedures of analytical methods used in controls of food contact materials*[2] should be taken into account.

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[1] The Certainty of Uncertainty J. AOAC International, 86, 109 (2003).

[2] Guidelines for performance criteria and validation procedures of analytical methods used in controls of food contact materials EUR 24105 EN – 1st edition 2009. European Commission, Joint Research Centre, Institute for Health and Consumer Protection.

Measurements and reporting

Three independent measurements should be performed and results should be corrected for recovery and reported in mg/kg. The mean concentration of a metal in a foodstuff or simulant should be reported together with the analytical method and any uncertainty surrounding the measurements.

When articles consist of separate parts (including accessories) and the ratio of surface area to volume or amount of foodstuff in contact is known for individual parts, but not for the assembled article, the total mass of any given released element must be calculated for all parts in contact with food of the end-use article.

This total mass of released elements is converted in mg/kg by taking into account the highest amount of foodstuff coming in contact with the individual parts of the article.

In cases where the amount of foodstuff is unknown, the reference weight for individual parts is applied accordingly.

For articles with a capacity greater than 10 kg of food, the actual surface/mass ratio has to be taken into account.

Examples: *mincer / meat slicer / espresso machine*

Calculation of specific release (SR)

The SR is the average result of the different replicates (at least 3).

When SR is measured in mg/kg:

$$\text{SR [mg Me/kg]} = c_1 \text{ Me [mg Me/kg]} - c_o \text{ Me [mg Me/kg]}$$

where, SR [mg Me/kg] is the concentration of the element that is released from the metal or alloy into the foodstuff/simulant,

C_1 Me [mg Me/kg] is the concentration of the element in the foodstuff/simulant after contact with the metal/alloy, and

C_o Me [mg Me/kg] is the concentration of the element in the foodstuff/simulant before contact with the metal/alloy.

SR < SRL = compliant

SR > SRL = non-compliant

Taking into consideration measurement uncertainty,[1] non-compliance can be established on the basis of the standard deviation, i.e. the lower bound for C1 Me [Me mg/kg] and the upper bound for Co Me [Me mg/kg].

Example: *given a measurement uncertainty of 20%:*

C_o Me: 2 ± 0.4 mg/kg → upper bound: 2.4 mg/kg
C_1 Me: 8 ± 1.6 mg/kg → lower bound: 6.4 mg/kg
SR [mg Me/kg] = C_1 Me [Me mg / kg] – C_o Me [Me mg/kg]
SR = 6.4-2.4 = 4 mg/kg

Calculating the SR for articles as defined in Annex II

The results are expressed in mg/kg according to the following procedure:

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[1] Guidelines for performance criteria and validation procedures of analytical methods used in controls of food contact materials EUR 24105 EN – 1st edition 2009. European Commission, Joint Research Centre, Institute for Health and Consumer Protection.

1. The article dimensions are measured using a gauge (e.g. Vernier calipers).
2. The largest dimensions for length, width and height (X, Y and Z, respectively) are recorded as one of the following 6 fixed values: 5, 10, 15, 20, 25 and 30 cm (the maximum value that can be attributed is 30 cm).

Measurement in cm	Attributable Value
< 5 cm	5 cm
5 cm < X, Y or Z < 10 cm	10 cm
10 cm < X, Y or Z < 15 cm	15 cm
15 cm < X, Y or Z < 20 cm	20 cm
20 cm < X, Y or Z < 25 cm	25 cm
X, Y or Z > 25 cm	30 cm

3. The envelope volume is calculated as X × Y × Z.
4. The reference weight (RW) is determined with respect to the envelope volume (V) using the following formula:
   Reference weight (kg) = Envelope volume (cm^3)/1000.
5. The SR is obtained by dividing the mass of the element released by the article (M) by the determined reference weight (RW).
   a) $M = C \times V$
      V = volume of simulant used.
      C = concentration of the element to be examined in the simulant.
   b) $SR = M / RW$
      M = mass of the element released by the article
      RW = reference weight

When SR is measured in mg/dm² (SRs):[1]

$$SR\ [\text{mg Me/kg}] = SRs\ [\text{mg Me/dm}^2] \times 6 = (c_1\ \text{Me}[\text{mg Me/dm}^2] - c_0\ \text{Me}\ [\text{mg Me/dm}^2]) \times 6$$

SRs: Specific release expressed as mg/dm^2

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[1] Applicable for articles described in "Materials and articles at the end-use level that cannot be filled such as baking sheets, foils".

Annex I (Informative): Experimental protocol of a national authority for the determination of aluminium in foodstuffs or food simulants

Table of contents

1 Aim and scope

This procedure describes the analysis of aluminium by inductively-coupled argon plasma atomic emission spectrometry (ICP-AES).

The aim of the analyses is to check the conformity of foodstuffs such as acidic foods or ingredients that have been cooked in aluminium foil containers. These containers have a tendency to release aluminium into the food.

2 Definitions and abbreviations

Aluminium foil container: a form of semi-rigid aluminium packaging for storage and cooking of prepared foods.

Ingredient: a cooking ingredient is a substance, excluding food additives, used in the manufacture or preparation of a food and present in the finished product (Codex alimentarius).

Acidic food: any food with an acid pH (<4.5) such as lemon juice and tomato purée. Such foods contain natural acids such as citric acid, ascorbic acid or acetic acid.

SOP: Standard Operating Procedure.

3 Principle of the method

A sample of the food is weighed using an analytical balance and is introduced into a digestion tube. It is then subjected to nitric acid digestion with heating, and the resulting solution is evaporated until a defined volume is obtained followed by treatment with hydrogen peroxide. The digest is made up to volume using milli-Q water.

The solution is then analysed using ICP-AES.

The software calculates the concentration of aluminium in the sample based on a (previously determined) calibration curve.

4 Safety

Gloves should be worn when washing laboratory glassware using solutions with a pH <3.

Heat-resistant gloves should be worn to avoid burns when removing hot samples from the oven.

In addition to carrying out digestion under a fume hood with the extraction system activated, the premises should be well ventilated to avoid the inhalation of nitrous vapour.

During the analyses, operators should avoid spending too much time in the presence of the apparatus because of the impact of noise.

5 Sample collection

Samples are collected from the local market (large supermarket).

6 Receipt, distribution, storage and disposal of samples

- The SOP for sample management is followed when the samples are received, distributed and registered
- Storage of samples: samples are stored in a cupboard before analysis. Since the analysis is destructive there is no storage of samples afterwards. In this case, it is not necessary to mention this in the sample record.

7 Experimental method

7.1 Consumables

- Milli-Q Water: > 18 MΩ
- Nitric acid: 69-70%, Baker instra-analysed, product No. 9598-34 or equivalent (for analysis of trace elements), stored under a fume hood.
- Hydrogen peroxide 30% min., Baker instra-analysed, product No. 9598-34 or equivalent (for analysis of trace elements).
- Single-element standard solutions: Al. Concentration of 1 g/L, Perkin-Elmer or C.P.A. (ACSD group) or equivalent, stored protected from light and at room temperature.
- Argon gas for analysis: 99.99%, Liquid air, stored in a reservoir outside the building.
- Detergent and decontaminant: Rbs 35, Chemical Products R. Borghgraefs.a.

7.2 Laboratory equipment and apparatus

- Analytical balance: maximum weighing capacity of 220 g with an uncertainty of ± 0.1 mg.
- Volumetric flasks: volumes ranging from 50 mL to 10 L, glass or plastic.
- Pipettes and micropipettes: various volumes, 20 µL to 25 mL.
- Tubes: disposable, 15 and 50 mL, used for storage of solutions after release and for the sampler.
- 20 mL PFA (Perfluoroalkoxy) tubes for digestion.

- Ovens: Binder, for digestion with heating.
- Inductively-coupled argon plasma atomic emission spectrometry: ICP-AES.

7.3 Environmental conditions

The incoming air is filtered and continually renewed in order to keep the equipment rooms clean.

Dust control mats are placed at the entrances of the premises in order to limit any dust being brought into the premises.

> NOTE: Ensure that the air-conditioning is working in order to maintain the required environment.

7.4 Preparation of the solutions

- Intermediate solution: 100 mg/L aluminium solution, obtained by tenfold dilution of the 1 g/L stock solution. Dilution in 2% nitric acid (V/V).
- Standard solutions: The standard solutions are obtained by diluting the intermediate solution in 2% HNO_3 (V/V). Place 1 mL of concentrated HNO_3 in 50 mL Falcon tubes and then prepare the standards:

  For the 100 µg/L standard: place 50 µL of the intermediate aluminium solution (100 mg/L) in a 50 mL volumetric flask and make up to volume with milli-Q water.

  For the 200 µg/L standard: place 100 µL of the intermediate aluminium solution (100 mg/L) in a 50 mL volumetric flask and make up to volume with milli-Q water.

  For the 300 µg/L standard: place 150 µL of the intermediate aluminium solution (100 mg/L) in a 50 mL volumetric flask and make up to volume with milli-Q water.

  For the 500 µg/L standard: place 250 µL of the intermediate aluminium solution (100 mg/L) in a 50 mL volumetric flask and make up to volume with milli-Q water.

These solutions are stable in 2% nitric acid for a few weeks but it is advisable to check for any significant variation in the calibration curve, which might indicate contamination or some other problem; if this happens, the solutions should be renewed as soon as the change in the curve is observed.

7.5 Operating procedure

7.5.1 Preparation of the samples

- *Release during cooking*:

  Remove the food from its packaging, which should not be made of aluminium. Blend and homogenise the food.

  After blending/homogenisation and just prior to placing the food into the aluminium foil container, remove 0.5 ± 0.1 g (weighed with a balance with a precision of ± 0.1 mg) and place it in a digestion tube that will be used to determine the Al content of the food before cooking.

  Cook the blended food in the aluminium foil container in an oven at 200 ° C for 30 min. After cooling, remove a sample of 0.5 ± 0.1 g (weighed with a balance with a precision of ± 0.1 mg) and place it in a digestion tube that will be used to determine the Al content of the food after cooking.

  The digestion tubes are numbered using the section No. for each sample.

- *Digestion*:

  Add 3 mL of suprapur (69-70%) nitric acid to the weight of the previously weighed sample. The digestion tubes are capped, but not tightly (to allow the vapours to escape), and are placed in an oven at 180 ° C. Continue the digestion until the volume of liquid in the tubes reaches the level of the hemispherical bottom.

  After digestion, carry out a final oxidation using 3 mL of hydrogen peroxide per tube and heat in an oven at 180 ° C until the volume is reduced to 1 mL.

- *Making up to volume and storage*:

  The solution obtained after evaporation is placed in a 15 mL Falcon tube and made up to volume with milli-Q water. The solutions are now ready for analysis.

  All the data concerning the preparation of the sample is entered into an Excel sheet (weighing sheet). This data consists of the weighing date, the matrix, the elements to be determined, the volumes of reagents used for the digestion, sample Nos. and tube Nos.

The samples or standards are stable in nitric acid and can be stored for several months.

7.5.2 Operating procedure

- Turn on the plasma torch at least half an hour before the analysis.
- Check the wavelength settings every month (or if there is a change in the torch).
- Check the tubing of the peristaltic pump.
- Clean the sampler every month using a 2% solution of nitric acid (V/V).
- Filter the solutions, before analysis, if you see a precipitate or suspended matter.

7.5.3 Calibration

The apparatus is calibrated under the following conditions:

- Generator power: 1500 W
- Viewing: axial
- Injection flow rate: 2.0 mL/min.
- Ar flow rate: Plasma = 15 L/min.; Aux = 0.2 L/min.; Nebulisation = 0.5 L/min.
- Nebuliser: GemCone or meinhard
- Read out time: 5 to 10 seconds and read delay of at least 45 seconds
- 3 tests (replicates) per sample.

The apparatus is calibrated by external calibration using a calibration blank similar to the solvent used to make the solution up to volume (2% nitric acid (V/V)) and 5 standards.

The intensity is determined from the area of the peak, and the equation of the calibration curve is given by linear regression with calculation of the Y-intercept.

7.5.4 Measurement programme

- Analysis of the calibration blank (2% nitric acid (V/V))
- Analysis of the 50 µg/L standard (Al)
- Analysis of the 100 µg/L standard
- Analysis of the 200 µg/L standard
- Analysis of the 300 µg/L standard
- Analysis of the 500 µg/L standard

Verification of the calibration results: intensity of the calibration blank, value of the slope and value of R^2. If the values are suitable, continue the analysis:

- Analysis of the blank (that was used for the calibration)
- Analysis of the standard: 50 µg/L
- Analysis of the blank
- Analysis of the samples (maximum 10 including the 2 procedural blanks)
- Analysis of the blank
- Analysis of the standard: 50 µg/L
- Analysis of the blank
- Analysis of the samples (maximum 10)
- Analysis of the blank
- Analysis of the standard: 50 µg/L
- Analysis of the blank

Repeat the cycles: Analysis of the blank, analysis of the 50 µg/L standard, analysis of the blank between each series of 10 samples.

Remark: after analysis, all the raw data are classified in the folder that is added to the file.

7.6 Decontamination and rinsing of laboratory equipment

The solutions may be prepared either in glassware or in plastic containers.

Before making up any preparations, glassware must be decontaminated using 10% nitric acid (V/V), for at least 12 h, and then rinsed three times with milli-Q water.

Use the solution itself for rinsing if possible.

The disposable Falcon tubes used to store the samples are unwrapped and/or opened only when they are needed.

Decontaminate the PFA digestion tubes with 10% nitric acid (V/V) and heating and keep them filled until they are used.

If suspended matter (or precipitate) is present in the solution of the sample to be examined, do not use filters with a syringe since they contain a significant amount of aluminium that will contaminate the solution. It is advisable to centrifuge the solution or use filter paper after checking that it is free of aluminium.

As the apparatus performs a rinse cycle after each analysis to prevent any contamination, do not forget to fill the rinse reservoir with 2% nitric acid (V/V).

8 Validation of the results

The results are obtained by calculating the areas of the emission peaks at a wavelength of 396.153.927 for aluminium, after optimisation.

Before analysing the samples found and after calibrating the apparatus, check the acceptance criteria for the calibration curve:

Element	Slope is greater than	R^2 is greater than
Al	100	0.995

After carrying out a series of analyses of 10 samples, the 50 µg/L standard should not exceed ± 10% on average.

During analysis, the blanks should not exceed: 5 µg/L.

The LOQ to be reported will be: 200 µg/kg.

9 Calculations

The equipment results may be corrected if dilutions were prepared or if the blank in the procedure gave significant concentrations compared with the measured concentration Co.

$Ce = (Co - CBLpr) * FD$

Ce: Effective concentration (mg/L)

Co: Concentration measured by the apparatus (mg/L)

CBLpr: Concentration of the procedural blank (mg/L)

FD: Dilution factor

The aluminium content per kg of product (mg/kg) or per litre of sample (mg/L) is calculated as follows:

$W = Ce * V/m$

Ce: Effective concentration (mg/L)

V: Volume of the digestion solution (in mL)

m: the mass of the sample (in g)

The quantity of aluminium that was released from the aluminium foil container during cooking is obtained by the difference between the Al content in the food after cooking and the Al content in the food before cooking.

10 Method validation

Internal procedure.

11 Test reports

Internal procedure.

12 Quality control testing

First line of control:

After the apparatus has been calibrated, check that the slopes and coefficients of correlation fall within the acceptance range.

During the analysis, make sure that there has been no deviation in the calibration by analysing the 50 µg/L standard and the blank used for the calibration.

A control chart will be established to be able to monitor these parameters over time.

Second line of control:

A sample that has already been analysed previously may be analysed on a blind basis twice a year; it is also possible to use a certified reference material (CRM) whose aluminium content is already known with certainty.

Third line of control:

The laboratory participates in inter-laboratory studies organised either by CRL or by FAPAS or by other official organisations, if such studies are organised.

Control charts are used (internal procedure).

13 Standards and References

- Manuals: Perkin Elmer; Installation, maintenance and description of the system
- Council Directive 96/23/EC, Commission Decision (2002/657/EC)
- Commission Regulation (EC) No.: 333/2007, of 28 March 2007
- “Drafting an analytical procedure” (internal procedure)

Annex II: Methods for measurement of articles that cannot be filled

This method deviates from the empiric method currently used by the European Regulation (EC) No. 10/2011 on plastic materials since the following method seems, in such cases, more appropriate for a number of utensils where surface area is not correlated with consumer exposure.

The measurement of the surface area of a utensil is complex and it is not objectively linked to the consumer's exposure. The following method provides a direct and simple calculation in mg/kg and relates it to the consumer's exposure. For each three-dimensional object, the three dimensions (X = depth, Y = width, Z = height) are calculated using a few simple conventions. This yields a parallelepiped (simple geometric figure) used as a reference in the method to calculate the conformity of the object.

Measurements for the calculation of the envelope volume of the utensil

The values chosen for this measurement are 5, 10, 15, 20, 25 and 30 cm.

5 cm is the smallest value that can be assigned and 30 cm is the largest value.

Choice of the values of X, Y, or Z

Measurement (cm)	Value to be assigned
< 5 cm	5 cm
5 cm < X, Y or Z < 10 cm	10 cm
10 cm < X, Y or Z < 15 cm	15 cm

Measurement (cm)	Value to be assigned
15 cm < X, Y or Z < 20 cm	20 cm
20 cm < X, Y or Z < 25 cm	25 cm
X, Y or Z > 25 cm	30cm

Measurement along the axes X, Y and Z

Measure the values of X, Y and Z for the metal part of the utensil (excluding handle*) using a gauge (e.g. Vernier calipers).

Prerequisite: measurement of Z

For articles whose functional part (the part that is necessarily in contact with the foodstuff) is somewhat distant from the handle, a value of 2/3 of the height excluding the handle is assigned for the total height (e.g., skimmer, potato masher).

Legend for scheme of defining height of utensils next pages:

↕ Hn = Part necessarily in contact with the foodstuff

↕ Hp = Part possibly in contact with the foodstuff

↕ Z = height for defining envelope volume

↕ Handle

↕ *Handle defined by default

① If $Hp \leq 0.5\ Hn$ → $Z = Hr$

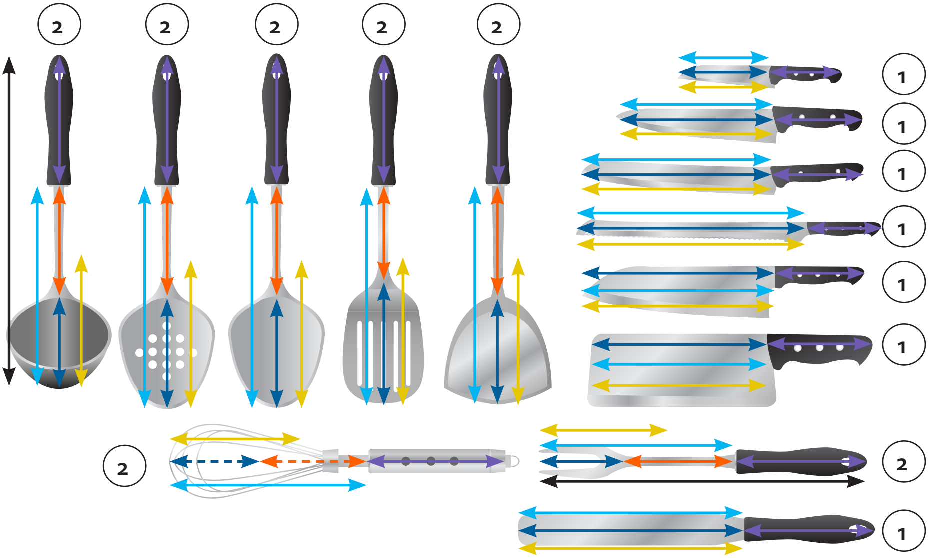
② If $Hp > 0.5\ Hn$ → $Z = 2/3$ of Hr

↕ Htotal = Handle + Hr

↕ Hr = Hn + Hp = Height reasonably in contact with the foodstuff

* If the handle is made of metal and it is not clearly separate from the rest of the article, it is assigned a default length of 1/3 of total height.

Scheme of defining height of utensils


2
2
2
2
2
1
1
1
1
1
1
2
2
1

Measurement process

A parallelepiped (a geometric figure) based on the 3 axes (X, Y and Z) is used to calculate the envelope volume.

Diagram 3 illustrates the dimensions X, Y and Z in the three-dimensional diagram that define the envelope volume.

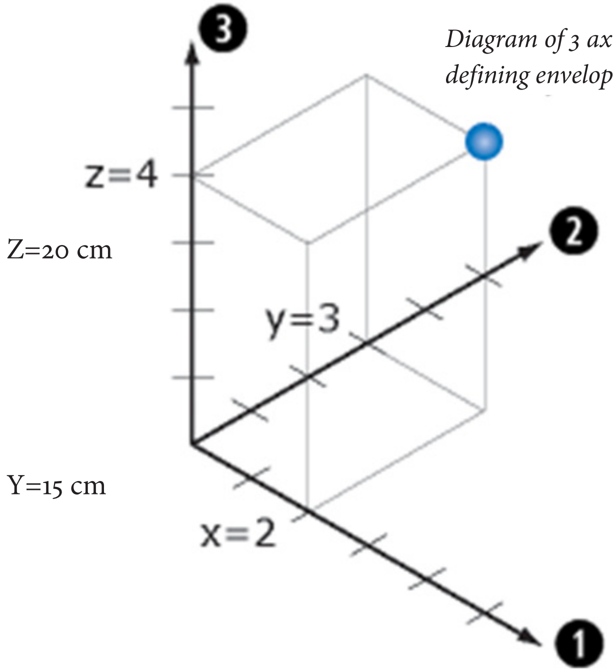
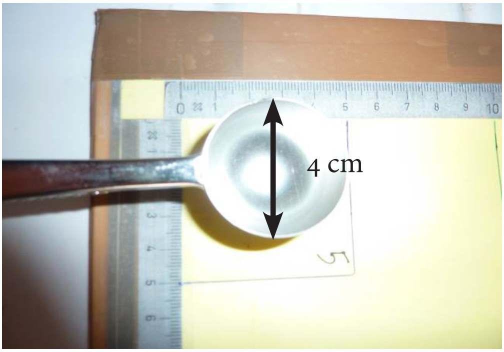


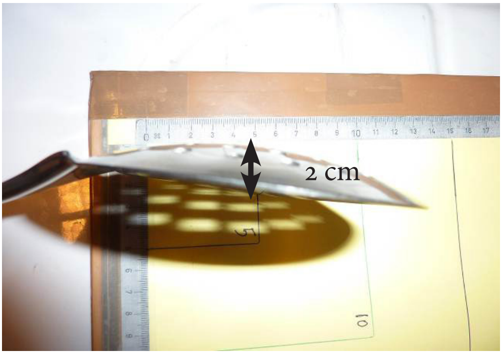
Diagram of 3 axes for defining envelope volume

Practical examples of the measurement of utensils

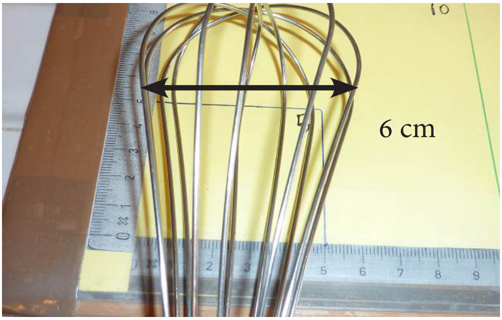
Measurement of X:



X = 4 cm: 5 cm is therefore attributed



X = 2 cm: 5 cm is therefore attributed



X = 6 cm: 10 cm is therefore attributed

X = 10.5 cm: 15 cm is therefore attributed

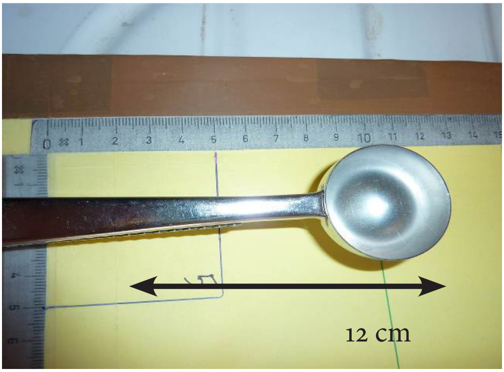
Measurement of Y:

Y = 3.5 cm: 5 cm is therefore attributed

Y = 7 cm: 10 cm is therefore attributed

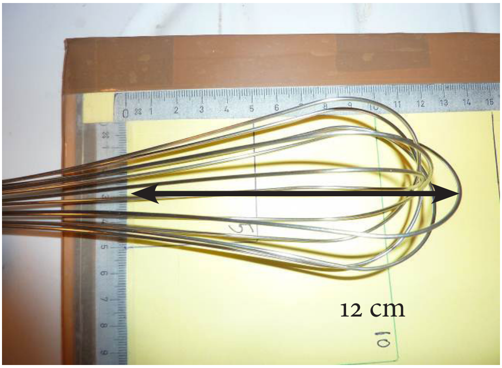
Y = 12 cm: 15 cm is therefore attributed

Measurement of Y:

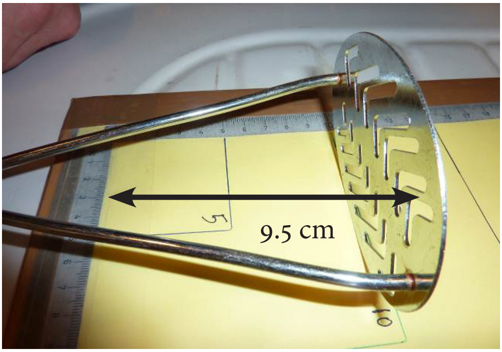


Z = 12 cm: 15 cm is therefore attributed

Z = 16 cm: 20 cm is therefore attributed



Z = 12 cm: 15 cm is therefore attributed



Z = 9.5 cm: 10 cm is therefore attributed

Calculation of the envelope volume

Once the parallelepiped has been constructed, calculate the envelope volume as follows:

Envelope volume = X × Y × Z (in cm^3)

Determination of the reference weight (RW)

Determine the reference weight with respect to the envelope volume using the following formula: RW (kg) = Envelope volume (cm^3) /1000

Examples:

- potato masher: 15 × 10 × 10 = 1500 ⟶ reference weight = 1.5 kg
- skimmer: 5 × 15 × 20 = 1500 ⟶ reference weight = 1.5 kg
- small ice cream scoop: 5 × 5 × 15 = 375 ⟶ reference weight = 0.375 kg

Determination of the released mass of a specific element

Immerse the article in a known volume of simulant at the temperature and for the duration recommended in Chapter 3.

This volume is not necessarily the same as the envelope volume. It may be larger (depending on availability of glassware sizes) or smaller (to maximise the concentration and therefore reduce the practical limit of detection) for reasons of laboratory practice.

Once the specific element has been released and its concentration in the simulant has been measured, calculate the released mass of the specific element.

Released mass (M) = V × C

V: volume of simulant used

C: Concentration of the element to be examined in the simulant

Determination of the specific release

As a general rule: SR = M/RW

Chapter 4 – Declaration of compliance for metals and alloys used in food contact materials and articles

General considerations

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/CEE and 89/109/CEE stipulates under Article 16 that materials and articles intended to come into contact with food, when governed by specific measures, shall be accompanied by a written declaration stating that they comply with the rules applicable to them.

Furthermore, it states that appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to the competent authorities on demand.

The Regulation also states that Member States can retain or adopt national provisions for declarations of compliance.

A declaration of compliance for metals and alloys used in food contact materials and articles common to the Member States of the Council of Europe should be drawn up in order to harmonise their position.

This declaration of compliance:

- should be issued by the manufacturer or an importer established within the territory overseen by the Council of Europe,
- should contain the information laid down below and

- should be available at all marketing stages other than at the point of sale to the retail stage.

The declaration of compliance should permit easy identification of the metals and alloys used in food contact materials for which it is issued. It should be renewed when substantial changes in composition or production occur that may alter the release of metal ions from the food contact materials or when new scientific data become available.

This declaration does not concern food contact materials and articles for which there are specific legal requirements for the declaration of compliance, e.g. ceramic articles, plastic materials, recycled plastic materials, active and intelligent materials and regenerated cellulose films.

Appropriate documentation to demonstrate that the metals and alloys used in food contact materials and articles comply with Article 3 of Regulation (EC) 1935/2004 and the requirements of this Resolution should be made available by the manufacturer or importer to the national competent authorities on request.

This documentation shall contain the conditions and results of testing, calculations, other analysis and evidence pertaining to the safety or reasonably demonstrating compliance of food contact materials or articles. Guidance on experimental demonstration of compliance is provided in Chapter 3.

Information to be presented in the declaration of compliance

1. The name and address of the manufacturer or importer of the food contact material established within the territory overseen by the Council of Europe;
2. The identity of the food contact material/article;
3. The date of the declaration;
4. The confirmation that the food contact material/article complies with the legal requirements of the European Union, the resolutions of the Council of Europe and, where applicable, the national legislation, for the

conditions of use e.g. “I, the undersigned (representing the company), declare that the food contact material/article complies with ….” ;

5. In the absence of national or European legislation, any relevant information (standards, reference values, international restrictions) concerning all the substances for which there are specifications;
6. One or more of the following conditions of use are to be mentioned:
   - type of food that the food contact material/article is intended to come into contact with;
   - storage temperature and shelf-life of the food contact material/article;
   - any treatment of the food contact material/article;
   - surface area/volume ratio to establish the compliance of the material or article.

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Metals and alloys used in food contact materials and articles

Committee of Experts on Packaging Materials for Food and Pharmaceutical Products ◆ P-SC-EMB

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