European Committee for Food Contact Materials and Articles (Partial Agreement) (CD-P-MCA)

Technical Guide on Metals and Alloys used in food contact materials and articles,

2nd edition

Draft for public consultation of stakeholders

Consultation period: 21 March – 29 April 2022

Feedback and comments further to revisions made to the draft second edition are welcome for the duration of the consultation.

How to participate:

1. Download the **Excel submission form here** and save a local copy.
2. Fill in contact details, as needed.
3. Select section range/line numbers, where applicable; enter comments and suggested texts.
4. Save the completed Excel file.
5. Send as attachment by e-mail to: fcm.metals_alloys@edqm.eu.
6. Deadline for comments by e-mail: 29 April 2022.
   Please note: comments submitted in any other format will not be treated.

EDQM will not publish all comments received but reserves the right to publish or otherwise make public the conclusions of this consultation. Name and affiliation details submitted may be disclosed to mandated reviewers. Submissions without name or other details will be treated anonymously. Personal data will be stored for 2 years by the EDQM.

Consultation assessment

The EDQM Secretariat shall support the CD-P-MCA in the review of consultation feedback and recommendations of due follow-up, with a view to the release of a completely revised 2nd edition.

Outcome

Follow the work programme of the CD-P-MCA for further information.

European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe
Department of Biological Standardisation, OMCL Network & HealthCare (DBO)
Address: 7, Allée Kastner | Cs 30026 | F-67081 Strasbourg (FRANCE)
Internet address: www.edqm.eu

Technical Guide on Metals and Alloys used in food contact materials and articles, a practical guide for manufacturers and regulators, *second edition*

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Foreword

Supplementing Council of Europe Resolution CM/Res(2020)9, this technical guide is intended to ensure the safety and suitable quality of food contact materials and articles made from metals and alloys. Chemical elements are described that constitute metallic food contact articles or may be present as impurities and specific release limits (SRLs) have been set for those elements, where appropriate.

Information presented in this guide

– Resolution CM/Res(2020)9 on food contact materials and articles, defining Guiding Principles applicable to food contact materials not yet harmonised by European material-specific measures, such as coatings, paper and board and metals

– Chapter 1: Definitions, scope and Specific Release Limits (SRL) for metals

– Chapter 2: Safety review and recommendations

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

The guiding principles and technical recommendations are intended to assist national policy makers and to enhance the harmonisation of technical standards across Europe.

The European Committee for Food Contact Materials and Articles (CD-P-MCA) entirely reviewed the 1st edition of this Technical Guide and prepared the present document.

This revision was triggered by the adoption of Resolution CM/Res(2020)9 and takes into account scientific opinions of the European Food Safety Authority (EFSA) issued since 2013 as well as relevant publications by national risk assessment bodies (such as BfR, ANSES). The review of safety data has resulted in the following changes:

- Chromium: the Specific Release Limit (SRL) is set at 1 mg/kg (former limit: 0.250 mg/kg)
- Manganese: the SRL is set at 0.55 mg/kg (former limit: 1.8 mg/kg)
- Thallium: the SRL was corrected to 0.001 mg/kg (former limit: 0.0001 mg/kg)

A new section on zirconium has been added and the SRL is set at 2 mg/kg.

Guidance on release testing has been updated to ensure coherence with the 2020 Guidelines for testing conditions for kitchenware made from metals and alloys.

The chapter on the declaration of compliance of the 1st edition was omitted in the 2nd edition in view of the corresponding guiding principles stated in the annex of Resolution CM/Res(2020)9, section 8.2.

Acknowledgements *[text to follow on publication]*

Council of Europe Resolution CM/Res(2020)9 on food contact materials and articles *[texts closed for consultation]*

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

BfR Federal Institute for Risk Assessment (Germany)

BMD Benchmark dose

CD-P-MCA European Committee for Food Contact Materials and Articles

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

ICH, international conference on harmonisation of technical requirements for registration of pharmaceuticals for human use

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 ICH Guideline on elemental impurities, ICH Q3D)

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

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 materials into food and may endager the health of the consumer if the intake exceeds the toxicological reference value, or may unacceptably alter the composition of the food or its organoleptic characteristics. Consequently, 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 supplements the guiding principles stated in Resolution CM/Res(2020)9. It is not legally binding and is intended to assist national regulators when preparing or updating legal provisions on food contact materials made from metals and alloys, with a view to harmonising regulations and enforcement activities at the European level.

Safety reviews of single metals and the restrictions defined for metals and alloys used in food contact materials and articles are updated regularly to keep up with scientific and technical progress.

Practical recommendations for release testing and checking compliance with the applicable restrictions provide support to manufacturers, importers and control laboratories.

Involvement of national experts and stakeholders

Governments of Council of Europe member states[1] participated actively in the elaboration of the updated documentation. Their representatives in the European Committee for Food Contact Materials and Articles (CD-P-MCA) are experts in the area of food contact materials or responsible for the implementation of government policies in their national ministries.

Whereas Resolution CM/Res(2020)9 was approved by the Council of Europe's Committee of Ministers, the technical guide has not been submitted for approval in view of its technical nature and the need for timely updates.

[1] Albania, 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, Republic of Moldova, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, North Macedonia, Turkey, Ukraine and United Kingdom.

The European Commission (EC), the EC’s Joint Research Centre (JRC) and the European Food Safety Authority (EFSA) participate in the work of the CD-P-MCA.

Experts from national authorities, the JRC, industry, private testing laboratories and other stakeholders share their knowledge and expertise and contribute in the updating of this technical guide as members of the ad hoc groups in the field of metals and alloys.

The draft revised Technical guide was subject to further consultations with relevant professional associations and industry representatives.

Legal status of the technical guide and link with the European Union

The Council of Europe technical guides are not legally binding for member states, but serve as a reference for the implementation of Article 3 paragraph 1 of Regulation (EC) No. 1935/2004, where applicable. The member states may include reference to these guides in national provisions or transpose the text into national law.

Definitions, scope and Specific Release Limits (SRL)

1. Definitions

The definitions of the resolution apply in the context of this Technical Guide.

In addition, the following definitions apply:

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.

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, kitchen appliances and industrial 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, enamels, 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].

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).

3. Labelling

In addition to the requirements in Article 5 of Resolution CM/Res(2020)9, manufacturers of metallic food contact materials and articles should provide information on the composition as applicable (e.g. when the content of impurities has been restricted) and their use to reduce the risk for unintentional release.

Temperature and storage time are known to influence the release of metal ions from metals and alloys used in food contact materials and articles into certain types of foodstuff. Thus, labelling could be used to highlight 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. However, producers shall take the foreseeable use by consumers into account and therefore they should consult the guidelines on *Testing conditions for kitchenware articles in contact with food stuffs: Plastics, Metals, Silicone & Rubber*[2] or its revisions.

The labelling could, for example, states:

– “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 and care instructions.

Remarks: *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.*

4. Specific release limits (SRLs)

Food contact materials and articles within the scope of this Technical Guide comply with the specific release limits (SRLs) set out below in Table 1 and Table 2. SRLs are expressed in mg/kg food.

Table 1 – *SRLs for metals and alloy components*

Symbol	Name	SRL [mg/kg food]
Al	Aluminium	5
Sb	Antimony	0.04
Cr	Chromium (III)	1*

[2] Beldi G., Senaldi C., Robouch P. and Hoekstra E. (2021), Testing conditions for kitchenware articles in contact with foodstuffs: Plastics, Metals, Silicone and Rubber. European Commission, Ispra, JRC125894.

Co	Cobalt	0.02
Cu	Copper	4
Fe	Iron	40
Mg	Magnesium	–
Mn	Manganese	0.55
Mo	Molybdenum	0.12
Ni	Nickel	0.14
Ag	Silver	0.08**
Sn	Tin	100***
Ti	Titanium	–****
V	Vanadium	0.01
Zn	Zinc	5
Zr	Zirconium	2

* For chromium (VI), check Chapter 2, section on chromium.

** Check also Chapter 3, Annex II for the possibility of applying a reduction factor assessing compliance of cutlery made from silver and silver-plated cutlery.

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

**** The generic specific release limit of 60 mg/kg food is not applicable.

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	0.001

* Not applicable to tinplate steel sheet used as packaging for foodstuffs for which a maximum level of lead is set in Regulation (EC) No. 1881/2006, provided that the tin that is used meets the following specification: lead content: not more than 0.01%.

Remarks:

In the cases of antimony, cobalt, chromium, molybdenum, nickel, vanadium as well as the contaminants arsenic, beryllium, mercury and thalliumn, 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[3] principle should be applied.

Establishing an SRL:

Toxicological information, the ALARA principle where appropriate or relevant legislation is considered. Each metal ion requires 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 are also 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 lowest feasible levels (ALARA) and levels usually achieved with GMP;

– 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:

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.

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[3] 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.

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, 2017)[4].

Examples in this guide: *Co 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 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.

Setting SRLs for Mg and Ti was not considered necessary.

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.*

Criterion 6: appropriate toxicological reference values exist, actual release data show much lower release when using good manufacturing practice.

In order to ensure the use of GMP a lower release limit was chosen.

Example in this guide: *Cr.*

Updating of the Technical Guide and further provisions or guidance

When updating this Technical Guide the technical specifications for metals and alloys defined in International (ISO) and European standards (CEN) should also be taken into account, as well as national legislation on the composition of metals and alloys.

[4] Guidelines for drinking-water quality: fourth edition incorporating the first addendum. ISBN 978-92-4-154995-0, © World Health Organization 2017. Available at http://apps.who.int/iris/bitstream/10665/254637/1/9789241549950-eng.pdf.

CHAPTER 2

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.

Aluminium (Al)

Antimony (Sb)

Chromium (Cr)

Cobalt (Co)

Copper (Cu)

Iron (Fe)

Magnesium (Mg)

Manganese (Mn)

Molybdenum (Mo)

Nickel (Ni)

Silver (Ag)

Tin (Sn)

Titanium (Ti)

Vanadium (V)

Zinc (Zn)

Zirconium (Zr)

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. Mean aluminium content in unprocessed foodstuffs ranges from around or less than 1 mg/kg in eggs, fats and oils, fruits, vegetables or juices to around 5 mg/kg in tea (Kolbaum et al., 2019; Tietz et al., 2019; AGES, 2017;

EFSA, 2008). Exceptionally high aluminium content was found in spices, mussels, nuts, legumes and oilseeds (around 30 – 244 mg/kg with highest content in spices). Due to procession or usage of aluminium-containing food additives, aluminium content of processed foodstuffs can be higher than for the respective raw products (e.g for bitter chocolate, sugar, confectionary coffee, cocoa and tea infusions (Kolbaum et al., 2019; Tietz et al., 2019). It should be noted, that in the EU the use of aluminium and its salts as a food additive is regulated in Regulation (EC) No 1333/2008 and strictly related to a limited number of applications such as scones and aluminium decoration in confectionery.

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. In studies from the late 1990s and early 2000s as summarised in EFSA (2008), it ranged from 0.2 to 1.5 mg/kg body weight/week. In children, estimated exposure at the 97.5th percentile ranged from 0.7 and 1.7 mg/kg body weight/week. In recent studies the estimated weekly intake was lower: ANSES (2011) estimated a weekly aluminium intake for adults from food of 0.28 – 0.49 mg/kg body weight/week (mean – 95th percentile), and for children (3 – 14 years) of 0.44 – 0.83 mg/kg body weight/week. ANSES (2016) estimated a weekly intake for infants (0 – 3 years) from food of 0.21 – 0.62 mg/kg body weight/week (mean – 90th percentile). Estimated exposure of Austrian infants (0 – 6 months) fed with infant formula was in the same range (AGES, 2017). Kolbaum et al. (2019) and Tietz et al. (2019) estimated the weekly aluminium intake of German adults from food to 0.18 – 0.44 mg/kg body weight/week (mean – 95th percentile). Food groups with the highest impact on overall aluminium uptake were instant tea and tea beverages, vegetables and salads, bitter chocolate, cereals and cereal products like bread and rolls (Kolbaum et al., 2019; Tietz et al., 2019; ANSES, 2011). However, the main food groups accounted for only ca. one third of the overall aluminium intake. Contributors to the remaining two thirds of the overall intake are diversely distributed among food groups and cannot be assigned to a specific consumption pattern (Kolbaum et al., 2019; Tietz et al., 2019).

Significant non-dietary sources of exposure to aluminium can be medicines (e.g. antacids or buffered aspirins) (Krewski et al., 2007) and cosmetics via oral and dermal route (e.g. antiperspirants) (AFSSAPS, 2011; Tietz et al. 2019). However, recent studies showed, that the dermal uptake of aluminium and its salts may be significantly lower than estimated from earlier studies (SCCS, 2020)

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/dm2 at 40 °C. However, after 10 days, the release was considerably higher: 0.5 mg/dm2 at 5 °C compared to 96 mg/dm2 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).

Sander et al. (2018) showed aluminium release of up to 20 mg/kg from uncoated aluminium menu trays into sauerkraut juice, tomato puree and applesauce, during cook & chill process.

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, 2012).

The Scientific Committee on Consumer Safety (SCCS) agreed on the NOAEL of 30 mg/kg bw/day used by JECFA for risk assessment (SCCS, 2020)

In 2017, the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER, 2017) published an opinion on tolerable intake of aluminium with regard to adapting the migration limits for aluminium in toys. SCHEER established a TDI of 0.3 mg/kg body weight based on the same NOAEL of 30 mg/kg body weight per day.

– 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, 2017).

– Directive 2020/2184/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.

– Only a small amount of ingested aluminium is absorbed (mean 0.1% according to EFSA 2008). After absorption, aluminium is mainly (80 - 90%) (Priest, 1995) excreeted via urine. Unexcreeted aluminium is distributed into all tissues, accumulation takes place especially in the bones, muscels, kidney and brain (COT, 2013; EFSA, 2008; JECFA, 2012). 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) concluded that a causal relationship between aluminium intake and Alzheimer’s disease could not be inferred by these studies.

– In 2008, EFSA (2008) confirmed the PTWI of 1 mg/kg body weight/week previously established by JECFA in 2006. In 2018, EFSA reviewed new toxicological evidence but not with the aim of revising the healthbased guidance value for aluminium set by EFSA in 2008 (EFSA, 2018).

Conclusions and recommendations

“the SRL for aluminium 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 derived by JECFA (2012) of 2 mg/kg body weight/week (Tietz et al., 2019) and the TDI of 0.3 mg/kg body weight per day accepted by SCHEER (SCHEER, 2017). Certain food contact materials and articles contribute to the dietary intake of aluminium. Therefore, it is recommended that the specific release limit for aluminium 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 regular review to take account of the advance of scientific and technical knowledge and improvements in good manufacturing practice.

Based on the current state of the art and available release data from uncoated aluminium FCM (Milana et al., 2019), it is considered necessary to limit the categories of food that may be in contact with uncoated aluminium articles and to introduce adequate labelling for users (Regulation (EC) No 1935/2004, Art.15)

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:

– Contact with 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 for users of aluminium materials or articles not coated with a protective coating. With regard to retail packs, the suppliers must ensure that these are labelled with appropriate information for the end consumer. The labelling should include the following (or equivalent) icon

and the following statement: **DO NOT USE WITH**: ACIDIC FOOD (e.g. pealed fruit, tomatoes, pickles, salad dressing) - SALTY FOOD (e.g. pretzel, white herring, cured meat)

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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 2014 British total diet study the highest total mean and 97.5th percentile exposures were in the age class 1.5 to 3 years and were 0.031 – 0.073 µg/kg bw/day and 0.065 – 0.12 µg/kg bw/day, respectively. The highest contributing food group to total mean exposure was the 'Milk' group with a total mean exposure of 0.0098 µg/kg bw/day (FSA, 2014). 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 tin alloys (it hardens the alloy) to produce Pewter alloy and Britannia metal (regarded as specific type of Pewter alloy).

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 MCDA n°1 (V02 – 01/04/2017) on food contact suitability of metals and alloys.

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 (2017) 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 is also adopted by Regulation (EU) No 10/2011.

Conclusions and recommendations

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

The SRL was derived from the TDI of 0.006 mg/kg body weight/day (0.36 mg/day) assessed by WHO (2003, 2017). Depending on the metallic material, antimony can be considered either as alloying constituent or as impurity. To not weaken consumer protection, it was 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), or present in minerals and rocks in some countries as Greece and Italy (Kazakis et al., 2015). 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 (III) is an essential element to human. 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, 2003). 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, 2003). According to EVM, most of the chromium in food originates from food processing using stainless steel food processors and containers (EVM, 2003). The EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) decided to consider all the reported analytical results of chromium in food as Cr(III). This assumption was based on the outcome of recent speciation work, the fact that food is by-and large a reducing medium, and that oxidation of Cr(III) to Cr(VI) would not be favoured in such a medium. (EFSA 2014).

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).

Chronic dietary exposure to Cr(III) was estimated combining the food mean occurrence data with the food consumption data at the individual level. Overall mean human chronic dietary exposure ranged from a minimum lower bound (LB) of 0.6 to a maximum upper bound (UB) of 5.9 µg/kg b.w. per day. The 95th percentile dietary exposure values ranged from 1.1 (minimum LB) to 9.0 (maximum UB) µg/kg b.w. per day. The adult populations showed lower exposure to Cr(III) than the younger populations (EFSA, 2014).

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 section on stainless steel and alloy) 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

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).

Nickel-chromium electroplated articles should also be tested for nickel release. (Whittington et al., 2015).

Safety aspects

– JECFA has not evaluated chromium.

– WHO established a provisional guideline of 0.05 mg/L for total chromium (WHO, 2017).

– 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), due to its high absorption, easy penetration of the cell membranes and its genotoxicity and oxidising properties (Nordic Council of Ministers, 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 (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).”

– According to ICH Q3D, the oral Chromium PDE is 10700 µg/day. Sources of chromium in pharmaceuticals may include colorants, leaching from equipment or container closure systems, and catalysts. Except when it is used as a catalyst, intake of chromium from pharmaceuticals will be in the form of metallic chromium (Cr(0)) or Cr(3+) rather than the more toxic Cr(6+); therefore, for drug products, this safety assessment is based on the known toxicity of Cr(3+) and Cr(6+) is excluded from this assessment. In 2014, the EFSA Panel on Contaminants in the Food Chain (CONTAM) derived a TDI of 0.3 mg/kg body weight per day for Cr(III) from the lowest NOAEL identified in an NTP chronic oral toxicity study in rats. Under the assumption that all chromium in food is Cr(III), the mean and 95th percentile of dietary exposure across all age groups were well below the TDI and therefore do not raise concerns for public health. In the case of drinking water, the Panel considered all chromium in water as Cr(VI) and a BMDL10 of 1 mg/kg bw/day from a carcinogenicity study in mice as adequate starting point for MOE-calculation.The calculated MOEs are mainly above 10,000 and hence indicate low concern regarding Cr(VI) intake via drinking water (water intended for human consumption and natural mineral waters) for all age groups.

Conclusions and recommendations

“the SRL for chromium is set at 1 mg/kg”

Considerations for Cr (VI):

In water: Data from the literature (Mazinanian et al., 2016) and member state official control laboratories indicate that release of total chromium [sum of Cr(III) and Cr(VI)] in water is negligible. Therefore, release of Cr(VI) from stainless steel FCMs in water, can be considered negligible.

In food: EFSA considered as a reasonable assumption that all chromium in food is in the form of Cr(III). Therefore, any released chromium in food can be assumed to be released as Cr(III) and not further oxidise to Cr(VI). Summarising, based on the current state of the art, the adoption of an SRL for Cr(VI) is not necessary. However, EFSA (2014) recommends that further data for the characterisation of Cr(VI) reduction in the gastrointestinal tract at doses relevant for human exposure should be generated.

Considerations for Cr (III)

Taking into account the TDI of 0.3 mg/kg b.w. per day for Cr(III) which was derived by EFSA (EFSA, 2014), a 20% allocation factor and the conventional assumption 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 Cr(III) could be set at up to 3.6 mg/kg food. However,since several RASFF alerts exceeding 3.6 mg/kg have been reported, to prevent and reduce the release of Cr from food contact materials and articles as far as possible in order to protect public health, it was decided that a specific release limit for total Cr should be set at 1 mg/kg. Based on the current state--of-art, this value is reasonably achievable.

Following the above-mentioned considerations, the SRL for total chromium is set at 1 mg/kg.

Release of Cr into water should be monitored for FCMs intended to be used in contact with water. To ensure a MOE above 10,000, the release of Cr(VI) should not exceed 0.006 mg/L (BMDL10 of 1 mg/kg bw/day, a MOE of 10,000, a person of 60 kg bw consuming 1 liter water per day). Therefore, if the concentration of total chromium released in water exceeds 0.006 mg/kg, further investigation of Cr (VI) release is recommended.

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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 and 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 contaminated 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 been adopted Regulation 10/2011 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) (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) established a PMTDI of 0.5 mg/kg body weight per day from all sources and set a dietary requirement is 0.05 mg/kg body weight per day.

– WHO (2017) set a guideline value for copper at 2 mg/L in drinking water.

– 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 (EVM, 2003).

– According to ICH Q3D, the oral PDE for copper is 3400 µg/day. Copper compounds (e.g., copper chromite) are being used as catalysts in hydrogenolysis and decarboxylation reactions.

– 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, it was 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 saucepans using boiling 5% acetic 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) 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) evaluated iron mainly to be a deficiency problem.

–WHO proposed that no health-based guideline value be set for iron in drinking water (WHO, 2017).

– 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 (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.

– ICH Q3D: Iron is one of some elemental impurities for which PDEs have not been established due to their low inherent toxicity and/or differences in regional regulations are not addressed in this guideline. If these elemental impurities are present or included in the drug product they are addressed by other guidelines and/or regional regulations and practices that may be applicable for particular elements.

Conclusions and recommendations

"the SRL for iron of 40 mg/kg is reasonably achievable"

Since no toxicologically derived upper limit could be set, it was 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 et al., 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 and Powell, 2001).

Other food contact materials

No information available.

Release

No information available.

Safety aspects

– SCF (2001) 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 30 May 2021relating to the placing on the market of nutrients and food products with added nutrients 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 (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 the SRL for magnesium 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, it was concluded that deriving an SRL was unnecessary.

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Manganese (Mn)

Manganese is an essential element as a micronutrient involved in different enzymatic activities (carbohydrates and lipids metabolism, bones formation, healing process, antioxidants protection, etc.). It is 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). The British total diet study reported that the highest total mean and 97.5th percentile exposures were in the 1.5 to 3 years age class and were 160 µg/kg bw/day and 270 µg/kg bw/day, respectively. The highest contributing food group to total mean exposure was the 'non-alcoholic beverages' group with a mean exposure of 43 µg/kg bw/day (FSA, 2014).

In the French total diet study (ANSES, 2011), the highest manganese concentrations were measured in dry fruits and oil seeds (11.9 mg/kg), chocolate (8.87 mg/kg) and bread and bakery products (7.19 mg/kg). The main contributors to manganese exposure were bread (29%) and bakery products (20%). It was established that the manganese mean exposures were 2.16 mg/day for adults and 1.46 mg/day for children. Considering the 95th percentile, the manganese mean exposures were 3.55 mg/day and 2.56 mg /day for adults and children respectively.

The EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) (EFSA, 2013) proposed as Adequate Intake (AI) of 3 mg/day for adults including pregnant and lactating women (equal to the mean intake in EU). For infants aged from 7 to 11 months, an AI of 0.02–0.5 mg/day was proposed, which reflects the wide range of manganese intakes that appear to be adequate for this age group.

In the infant diet study (ANSES, 2016) focusing on the 0 to 3 years old population, the highest manganese concentrations were measured in sweet and salty biscuits (6.26 mg/kg), bread and bakery product (5.17 mg/kg) and pastry (3.64 mg/kg). For children between 1 and 4 months, the main contributors to manganese exposures were first infant formulae (74%) and infant cereals (14%). Between 5 and 6 months, main contributors were follow-on formulae (21%) and infant cereals (15%). Between 7 and 12 months, main contributors were meat/vegetables and fish/vegetables jars (16%), infant cereals (13%) and fruits (11%). Between 13 and 36 months, main contributors were vegetables (14%), fruits (12%) and pasta (10%). It was estimated that the manganese mean exposures varied from 0.126 to 0.653 mg/day according to the age group. Considering the 90th percentile, the manganese mean exposures varied from 0.348 to 1.26 mg /day according to the age group.

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.

– 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). In the total infant study, a security upper limit of 2 mg/day (fixed by the institute of medicine) was retained by ANSES for the 1-3 years old infant (ANSES, 2016).

– The Belgian Royal Decree of 30 May 2021 sets the maximum authorised intake via food supplements at 1 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-water 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, 2017).

– 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 of 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 (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.

– ICH Q3D: Manganese is one of some elemental impurities for which PDEs have not been established due to their low inherent toxicity and/or differences in regional regulations are not addressed in this ICH guideline. If these elemental impurities are present or included in the drug product they are addressed by other guidelines and/or regional regulations and practices that may be applicable for particular elements.

– In the ANSES opinion (2018) related to the maximal safety value of manganese in drinking water, the toxicological reference value (TRV) of 55 µg/kg body weight./day established by the national public health institute of Québec was selected (Valcke et al. 2018). This TRV was derived using a LOAEL of 25 mg/kg b.w./day based on neurological effects observed in rats during development after post-natal exposure (Kern et al., 2010 and 2011, Beaudin et al., 2013 and 2015).

Conclusions and recommendations

“the SRL for manganese is set at 0.55 mg/kg”

The SRL is based on the toxicological reference value of 55 µg/kg b.w. /day established by the national public health institute of Québec and since oral intake data from multiple European countries are not available, an allowance of 20% for food contact materials is applied. Since the endpoint for the calculation of this reference value was based on neurological effects observed during development after post-natal exposure, the recommended SRL is calculated considering toddlers as target population. Based on the food consumption values adopted by EFSA (2016), a toddler consumes 20 g of foodstuffs (other than drinks and food specially intended for infants and toddlers) per kg body weight per day. Consequently, the SRL for manganese is set at 0.55 mg/kg.

Particularly for materials and articles intended for contact with milk, milk products and other non-alcoholic drinks as well as any food especially intended for infants and toddlers the most conservative consumption of 150 mg/kg body weight per day should be used and an SRL of 0.07 mg/kg food applies.

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Molybdenum (Mo)

Molybdenum does not occur naturally as a free metal on earth; it is found only in various oxidation states in minerals. As free element, it is a hard silvery-grey metal with a density of 10.2 g/cm3 (at room temperature). Molybdenum is a trace element essential for nearly all organisms and forms the catalytic centre of a large variety of enzymes such as nitrogenase, nitrate reductases, sulphite oxidase and xanthine oxidoreductases (Schwarz et al., 2009). It is found ubiquitously in animals and plants. The human body contains approximately 9 mg of Mo (Lide, 2006).

Sources and levels of intake

Some of the main natural sources of molybdenum are liver, peas, beans, spinach, wheat germ (Emsley, 2001), and dark leafy greens such as spinach and kale.

The EFSA estimated oral intake for adults from food up to 500 µg/day, andfor 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, as calculated using a bodyweight of 60 kg and from the mean (1.61–1.64 µg/kg bw/day) and high (3.03–3.08 µg/kg bw/day) level exposures, respectively (Rose et al., 2010). 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

Molybdenum is used as an alloying addition in stainless steels that increases resistance to both uniform and local (pitting and crevice) corrosion. The use of molybdenum-containing steel may be required where contact is expected with highly corrosive liquids, like fruit juice, vinegar, wine and carbonated beverages (Mason, 1948). The most commonly used molybdenum-containing material for food contact applications is stainless steel 316 (2-2.5% Mo in an iron-alloy) and its derivatives, but steels with higher or lower molybdenum percentages are used as well (Euro Inox, 2006). Hastelloy C-276 (a highly corrosion resistant Ni-Cr-Mo-Fe alloy) has been used for coffee flash driers. While Inconel and Hastelloy B & C have been used for the following food applications: fruit juice and syrups, pectin, gelatin, salad dressings, vinegar, monosodium glutinate, baker's yeast and carbonated beverages (Mason, 1948), stainless steel grade 316 (2-2.5% Mo) articles are also used for these food contact applications, as they are highly resistant and do not corrode, even at high temperatures.. Molybdenum is also an alloying element in nickel-based alloys used in food contact materials.

Other food contact materials

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

Release

Stainless steel grade 316L exposed to 5g/L citric acid for 2 hour at 70 °C followed by 10 days at 40 °C released 0.02 µg/cm^2 of molybdenum (i.e. 0.012 mg/6 dm^2) (Hedburg et al, 2014). Stainless steel grade 316L exposed to 1% lactic acid or 0.01% HCl for 1 week at 37 °C released 0.2 µg/cm^2 or 0.06 µg/cm^2 of molybdenum, respectively (Okazaki and Gotoh, 2005). The pH of 1% lactic acid and 0.01% HCl solutions is comparable to that of 5 g/L citric acid (i.e. pH of 2.4).

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 (EVM, 2003). One study reported 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 (Mo combinations such as Bi-Mo, Fe-Mo, molybdenum oxide and Mo-complexes, are being used as catalysts in organic synthesis) and is included in the ICH Q3D. That Guideline classifies molybdenum in Class 3, metals of relatively low toxicity. That Guideline sets an oral Permitted Daily Exposure (PDE) of 3400 µg Mo/day for a 50 kg individual, based on a NOAEL of 17 mg Mo/kg/day from a 90-day toxicity study in the rat with dietary sodium molybdate dehydrate (Murray et al., 2014); bodyweight of 50 kg and a safety factor of 250.

Conclusions and recommendations

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

The SRL is calculated from the upper limit derived by EFSA (2006, 2009) of 0.6 mg/day, which agrees with the tolerable daily intake (oral exposure) of 10 µg/kg bw/day reported by RIVM (2001).

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 et al., 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 an essential micronutrient for higher plants and some animal species but there are no data proving that it is essential for humans (EFSA 2015).

Sources and levels of intake

In a monitoring program initiated in 1990 in Denmark, nickel was 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). At FoodEx level 1, high mean levels of Ni were reported for 'Legumes, nuts and oilseeds' (c.a. 2 mg/kg), certain types of chocolate (cocoa) products (3.8 mg/kg), and 'Cocoa beans and cocoa products' (9.5 mg/kg) (EFSA, 2015).

In the diet it is found as complex bound Ni^{2+}-ions. 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 mg/day (3.01-3.08 µg/kg body weight/day), respectively (FSA, 2009). In the 2014 UK Total Diet Study (FSA, 2019) the highest total mean and 97.5th percentile nickel exposures were in the 1.5 to 3 years age class and were 4.4-5.2 µg/kg bw/day and 7.1-8.1 µg/kg bw/day, respectively. For elder children, adolescents and adults the 97.5th percentile nickel exposures were in the range of 3.2-7.3 µg/kg bw/day.

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. In the total infant study, these mean exposures were used (ANSES, 2016). Exposure at the 95th percentile were 3.76 and 7.44 µg/kg bw/d for adults and children, respectively. For these populations, nickel exceedance in food (naturally occurring in food) was observed (Sirot et al., 2018).

EFSA (2015) estimated chronic dietary exposure to Ni combining food mean occurrence data with food consumption data at the individual level. Mean chronic dietary exposure to nickel, across the different dietary surveys and age classes, ranged from 2.0 (minimum lower bound (LB), 'Elderly') to 13.1 µg/kg body weight (b.w.) per day (maximum upper bound (UB), 'Toddlers'). The 95th percentile dietary exposure ranged from 3.6 (minimum LB, 'Elderly') to 20.1 µg/kg b.w. per day (maximum UB, 'Toddlers'). In the update of its risk assessment EFSA (2020) confirmed these values on a slightly higher level. The exposure in the update ranged from 1.57 (minimum mean lower bound (LB), 'Elderly') to 14.6 µg/kg body weight (b.w.) per day (maximum mean upper bound (UB), 'Toddlers'). The 95th percentile dietary exposure ranged from 3.55 (minimum LB, 'Elderly') to 24.8 µg/kg b.w. per day (maximum UB, 'Toddlers'). The highest exposure was found for toddlers and other 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. Most nickel-containing food contact materials are stainless steels.

Nickel-containing stainless steels (see Chapter 2, Stainless steels) 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).

Other nickel-containing food contact materials include German silver (also known as nickel silver and Maillechort), which is used for cutlery and as a base for silverware; and nickel bronze (also known as Dairy bronze and Thai bronze), which is used for cutlery and dairy equipment (see Chapter 2, Alloys).

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.The latter are now rare; concealed (stainless steel) heating coils make de-scaling of kettles much easier.

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% acetic acid as a simulant 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). For the years 2012 to 2018, RASFF shows 145 notifications for nickel release. Release value up to 1634.9 mg/kg was reported in 2014 for a bottle stopper[5].

Safety aspects

— JECFA has not evaluated nickel.

— In 2008, AFSSA set a tolerable daily intake at 22 µg/kg bw/d, 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.

— EFSA (2015) (updated in 2018): The CONTAM Panel identified reproductive and developmental toxicity as the critical effect for the risk characterization of chronic oral exposure to Ni. The Panel derived a tolerable daily intake (TDI) of 2.8 µg Ni/kg b.w. /day from a BMDL10 of 0.28 mg Ni/kg b.w. /day as calculated from the dose response analysis of the incidence of post-implantation fetal loss in rats, applying the default uncertainty factor of 100 to allow for interspecies differences and human variability.

— The BfR (Tietz et al, 2018) reported a refinement of the modelling performed by EFSA (2015) using a nested data approach, which includes litter effects and outlier treatment. The modelling procedure used was in accordance with the EFSA opinion on BMD Modelling (EFSA, 2017). The TDI of 11 µg/kg bw/day derived was in accordance with conclusions from other studies.

— EFSA (2020) updated the previous Scientific Opinion (EFSA, 2015), taking into account new occurrence data, the updated benchmark dose (BMD) Guidance and any newly available scientific information. The critical effect for chronic exposure was confirmed to be post implantation loss and perinatal death of fetusses (as used in the previous Opinions). The Panel derived a TDI of 13 µg Ni/kg b.w. /day from a BMDL10 of 1.3 mg Ni/kg b.w. /day, applying the default uncertainty factor of 100 to account for interspecies differences and human variability.

— 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. Sensitisation against nickel is caused by exposure through skin or by inhalation (EFSA, 2015). However, some patients with

[5] Report by the Slovenian CD-P-MCA delegation (January 2019) from RASFF Notifications for nickel 2012-2018.

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 (2017) 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 (EVM, 2003). This guidance is based on a LOAEL for increased perinatal mortality in a multi-generation rat study of 1.3 mg/kg b.w. /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 b.w. /day were unlikely to be of toxicological concern, though they noted that nickel may exacerbate contact dermatitis/eczema in presensitised 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.

— According to ICH Q3D, the oral nickel PDE is 220 µg/day. Nickel as Ni-Al alloys is being used as catalyst in hydrogenation reactions.

Conclusions and recommendations

"the SRL for nickel is set at 0.14 mg/kg"

Two very close and conservative TDI values, the EFSA TDI of 0.013 mg/kg body weight/day and the WHO TDI of 0.012 mg/kg body weight/day (0.7 mg/day), which are based on human data from nickel-sensitised individuals, have been reported in literature. The WHO TDI was used to derive the SRL.

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.

Care has to be taken to ensure that nickel-plated articles for direct contact with foodstuffs comply with the SRL for nickel.

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Silver (Ag)

Pure silver has the highest thermal and electrical conductivity of all metals. Silver alloyed containing a minimum of 92.5% by weight of silver and 7.5% by weight of other metals, usually 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.

In a recent study on infants and toddlers (Sirot et al., 2018; ANSES, 2016), the daily intake was estimated to be negligible (0 µg/kg body weight/day) in a lower bound calculation both for mean and 90th percentile. For upper bound, a daily intake of 2.10 – 4.23 µg/kg body weight/day (mean) and 2.97-5.35 µg/kg body weight/day (90th percentile) were calculated.

It has to be noted that though the cited studies are total diet studies, in course of which the samples were prepared ‘as consumed’, usage of silver tableware and cutlery were not covered by the study design. Hence, the actual daily intake for consumers using these articles on a daily basis could be higher.

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 uni-positive ion, the form in which it exists in most of its compounds (Beliles, 1994).

Safety aspects

– JECFA (1978) has reviewed the existing toxicological data (WHO, 1977) and concluded that "no evaluation could be made" due to insufficient data. .

– 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).

– According to EFSA (2016), "ionic silver is non-mutagenic in bacteria but genotoxic and clastogenic in mammalian cells in vitro […]. No information is available on the genotoxic potential of ionic silver in vivo."

– Acute human toxicity from silver seems to be related to stimulation followed by depression of structures in the brain stem (WHO, 1977). Symptoms are rise in blood pressure, haemorrhagic gastroenteritis and shock. 10 g of silver nitrate taken orally are considered to be a lethal dose to man, (WHO, 1977). Some silver compounds such as silver oxide and silver nitrate are irritating, and exposure is associated with nose-bleeds and abdominal cramps (Beliles, 1994). High intake of silver, whether as metal or in ionic form can lead to renal and pulmonary lesions and argyria or argyrosis.

– EFSA (2016) summarised the acute toxicity in animals as follows: According to WHO (1977), the LD50 (mice) is 50 mg/kg body weight as silver nitrate (corresponding to 32 mg ionic silver/kg body weight). According to Tamimi et al. (1998), the LD50 in rats and rabbits is 428 and 1261 mg silver nitrate/kg body weight, respectively, corresponding to 280 and 794 mg ionic silver/kg body weight, respectively)

– There are only few studies on subchronic or chronic exposure towards silver. In these, effects on the liver, body weight, immune system as well as developmental toxicity were observed – though data were not always consistent (especially for immune toxicity). The lowest NOAEL (0.26 mg ionic silver/kg body weight/day) was identified for reproduction toxicity observed in a one generation study, where silver acetate was orally ingested via drinking water (Sprando et al., 2017). The NOAEL is based on reduced body weight gain of the pubs and reduced number of implants and post implantation loss. However, it should be noted, that the selection of the NOAEL is questionable, because the reduced body weight was only observed in one dose group (middle dose: 2.6 mg/kg body weight/day), not dose dependent, and could be explained by a slightly increased number of pups. Reduced number of implants and post implantation loss were only observed in the high dose group (26 mg/kg body weight/day). Hence it would be possible to identify this dose as LOAEL, resulting in a NOAEL of 2.6 mg ionic silver/kg body weight/day. However, in accordance with EFSA (2016) it should be concluded, that the data are not robust enough for derivation of a health based guidance value.

– 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).

– EPA has established a chronic oral reference dose (RfD) for silver ingestion of 5 µg/kg of body weight per day on a review of 70 cases of argyria by oral route, last updated in 1991 (EPA 1991). This value is not adapted for risk assessment in food because of the lack of studies.

– 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 & 2017). Using argyria (silver overload) (Gaul and Staud, 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 for silver 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 intake data from ANSES (2011) were used to derive the SRL. 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.

Silver or silverplated cutlery, manufactured to be used for eating or serving (not for cooking) and not on a daily basis, should be labelled accordingly. When assessing their compliance, a reduction factor of 5 may be applied to the specific release value, when justified (see Annex II of chapter 3).

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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 (WHO, 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, in the 2014 British total diet study the highest total mean and 97.5th percentile exposures were in the 1.5 to 3 years age class and were 95 - 96 µg/kg b.w. /day and 300 µg/kg b.w. /day, respectively. The highest contributing food group to total mean exposure was the 'canned vegetables' group with a mean exposure of 61 µg/kg b.w. /day (FSA, 2014).

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 (2017) 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 Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, stannous chloride is authorised as a food additive for canned and bottled asparagus (only white 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 (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 study was considered 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 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

In the UK, the use of titanium dioxide is permitted, with no indications that it will align with the EU on this issue. The Food Standard Agency has decided to launch their own review of the safety of titanium dioxide as a food additive (COT, 2022).

In EU, the titanium dioxide was used as food additive (E 171) and is still used in toothpastes, sunscreens and pharmaceuticals.

As of 2022, the use of E 171 titanium dioxide as a food additive is banned in Europe. Titanium dioxide is not authorised in the food categories listed in Annex II (Part D and E) of Regulation (EC) No 1333/2008 as amended by Regulation (EC) No 2022/63. Until 7 August 2022, foods produced in accordance with the rules applicable before 7 February 2022 may continue to be placed on the market. After that date, they may remain on the market until their date of minimum durability or 'use by' date (Regulation (EC) No 2022/63).

The European Commission "shall, following consultation on the European Medicines Agency, review the necessity to maintain titanium dioxide (E 171) or to delete it from the Union list of food additives for the exclusive use as colour in medicinal products in Part B of Annex II to Regulation (EC) No 1333/2008 within three years after the date of entering into force" of Regulation (EC) No 2022/63.

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 TiO2. 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 TiO2, 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 (2021) provided an updated safety assessment of the food additive titanium dioxide (E 171) taking into account all new relevant data available to EFSA. Along with all the uncertainties, in particular the fact that genotoxicity concern could not be ruled out, the Panel concluded that E 171 can no longer be considered as safe when used as a food additive.

The 2021 opinion by EFSA applies only to E 171 as described in Commission Regulation (EU) No 231/2012 as well as to E 171 specified in the 2019 opinion; while the titanium in metals and alloys as food contact materials seems to be practically inert, due to the phenomenon of passivation.

Conclusions and recommendations

“it is appropriate not to set any SRL for titanium”

At the moment, it is appropriate not to set any SRL for titanium. However, the definition of appropriate measures related to titanium dioxide used in food contact materials and articles is under study.

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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 et al., 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.

In France, MCDA n°1 (V02 – 01/04/2017) on food contact suitability of metals and alloys specifies limits for vanadium.

Other food contact materials

Vanadium oxide is used in ceramic pigments.

Release

No information available.

Safety aspects

– The 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: "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, 2017).

– EFSA (2006; 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, 2006; 2009).

– According to ICH Q3D, the oral Vanadium PDE is 120 µg/day.

Conclusions and recommendations

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

It was 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, it was 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.

In the 2014 British total diet study, the highest total mean and 97.5th percentile exposures were in the 1.5 to 3 years age class and were 320 µg/kg bw/day and 530 µg/kg bw/day, respectively. The highest contributing food groups to total mean exposure were the ‘miscellaneous cereals’ and ‘dairy products’ groups with a mean exposure of 51 µg/kg bw/day. (FSA, 2014). More recently results from a duplicate diet study in Spain estimated the dietary intake of zinc equal to 6.8 mg/day (Domingo et al., 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 et al., 2011).

Safety aspects

– JECFA (1982) 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 (2017) 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 (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.

–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)

– ICH Q 3D: Zinc is one of some elemental impurities for which PDEs have not been established due to their low inherent toxicity and/or differences in regional regulations are not addressed in this guideline. If these elemental impurities are present or included in the drug product, they are addressed by other guidelines and/or regional regulations and practices that may be applicable for particular elements.

Conclusions and recommendations

“the SRL for zinc is set at 5 mg/kg”

It was 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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Zirconium (Zr)

Zirconium is the 20th most common element in the Earth's crust and is found as compounds in many mineral forms. It does not occur in nature as a free element. Zirconium most commonly occurs as zircon ($ZrSiO_4$) and as baddeleyite (ZrO_2 or zirconia). There is no evidence that zirconium is essential to man. Zirconium is highly resistant to heat and corrosion. It is primarily used in metallic materials within the aviation and aerospace industries, in chemical and surgical instruments and in nuclear reactor technology. Other products that contain zirconium compounds include cosmetics and jewellery. Zirconium is also used for the manufacture of cast iron, steel, ceramics, enamels, paints, pigments, preservatives, coatings, abrasives, refractories, tanning agents and water repellents (HSDB, ILO).

Sources and levels of intake

Zirconium is a naturally occurring and widely distributed element. It is present at concentrations ranging from 150 to 300 mg/kg within the Earth's crust (HSDB) and about 0.026 µg/L in seawater (Peterson et al., 2007). Zirconium compounds can be released into the air and surface or ground water through weathering of rocks and soils and are taken up by plants, including edible fruits and vegetables (Ghosh et al., 1992). Zirconium can be found in all animal tissues, generally below 10 µg/g wet tissue (Health Council of The Netherlands, 2002). In food products, elevated levels of zirconium have been found in lamb, pork, eggs, dairy products, grains and vegetables, with concentrations generally varying between 3 and 10 ppm (HSDB).

Exposure to zirconium can occur through the inhalation of ambient air containing low levels of zirconium, ingestion of certain foods and via dermal contact with consumer products containing zirconium compounds, such as cosmetics. Estimations of the daily oral intake of zirconium in man vary from 3.5 to 4 mg, but have been reported to be as high as 125 mg. The average body burden is 260 mg (HSDB).

Metallic food contact materials

Zirconium is used in a wide variety of materials. Certain applications (i.e. refractories, enamels and coating for casting moulds) make the presence of zirconium in metallic food contact materials more likely. A specific example is the use of zirconium compounds as passivation agents for tin-plated steel.

Other food contact materials

Zirconium (II) is a component of some Ziegler-Natta catalysts, used to produce polypropylene (Shamiri et al., 2014). Because of its mechanical strength and flexibility, zirconium dioxide (ZrO_2) is used for sintering into ceramic knives.

Release

The release of zirconium into foodstuffs will potentially depend on the specific compound and its associated chemical properties, most importantly solubility. Since no data has been published on the concentrations of zirconium in food contact materials, the release of zirconium from these materials into foodstuffs cannot be assessed.

Safety aspects

A maximum limit for zirconium in stainless steel was imposed in France, stating that zirconium can only make up 1% of the alloy (French Decree of 13 January 1976; JRC, 2017).

In the USA, zirconium oxide is permitted for use in conversion coatings on the interior of tin-plated steel containers (cans), with or without a polymeric topcoat. The coating may be applied to the food-contact surface at a maximum coating weight of 9 mg/m2. The finished coating may be in contact with all food types, with the exception of liquid (concentrate and ready to feed) infant formula (NCBI; FDA).

The administrative exposure limit (MAC) for zirconium and zirconium compounds in the Netherlands is 5 mg/m3, 8-hour TWA (time-weighted average) (Health Council of the Netherlands, 2002).

The route of absorption and excretion has not been established for all zirconium compounds and depends on the route and duration of exposure (Ghosh et al., 1992). Most zirconium compounds are poorly absorbed from the gastrointestinal tract into the bloodstream. Following oral absorption, absorption percentages of 0.2 and 0.001% have been reported. The predominant excretion route is via the faeces; very little is excreted in the urine. Tissue levels are generally below 10 µg/g wet tissue (Health Council of The Netherlands, 2002). Milk is a second route of excretion. Significant amounts of zirconium have also been found in foetuses (HSDB).

Regarding the toxicity of zirconium, few animal studies are available and these show non-uniform results among the different zirconium compounds. In humans, few case reports are available, some of which suggest toxic effects after exposure to zirconium compounds via different routes (mostly inhalation); others show no zirconium-related effects (HSDB). Overall, based on the available literature, no definitive conclusion can be drawn on the potential for zirconium to produce toxic effects. The Dutch Health Council concluded in 2012 that the available toxicological database on zirconium and its compounds was too poor to justify recommendation of a health-based occupational limit, including the exposure limit (MAC) stated in the Netherlands (Health Council of the Netherlands, 2002).

A specific migration limit (SML) of 2 mg/kg has been established for zirconium used for passivation of metals and alloys in the Netherlands (Dutch WVG), in combination with the following provisions: “For contact with acidic foods, conformity with this SML is to be tested in the relevant food product, or alternatively with 1.5% citric acid. If the properties of acetic acid predominate in the foodstuffs with which the metal comes into contact, the metal passivated with zirconium must be coated with organic polymers. This provision does not apply to zirconium passivated metal in contact with non-acidic food or in contact with food in which the properties of acids other than acetic acid predominate.”

Conclusions and recommendations

“the SRL for zirconium is set at 2 mg/kg”

Given the lack of data available to derive a TDI, the CD-P-MCA has decided to use the SRL of 2 mg/kg as set for zirconium in the legislation on FCM in the Netherlands. For acidic foods, conformity with the SRL should be tested in the relevant food product, or alternatively with 0.5% citric acid. Zirconium-passivated metals should not be used in direct contact with food with predominantly acetic acidic properties, but it can be used in direct contact with other types of food, including acidic food in which the properties of acids other than acetic acid (e.g. citric acidic) predominate.

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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.

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

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 et al., 1999; Guéguen et al., 2011; Arnich et al., 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 (2017) established a provisional guideline value for arsenic in drinking-water of 0.01 mg/L on the basis of treatment performance and analytical achievability.

– 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 (BMDL05) 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, 2010) 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, it was 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).

In the British total diet study, the highest total mean and 97.5th percentile exposures were in the 1.5 to 3 years age class and were 20 µg/kg bw/day and 33 µg/kg bw/day, respectively (FSA, 2014).

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 BMDL5 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 (2017) established a guideline value for barium in drinking water of 1.3 mg/L.

– 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"

It was 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, it was 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 et al., 2001). There is also controversy about its use in dentistry, for dental prostheses (Mroz et al., 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 (1987, 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 (2017) 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 et al., 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 (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 (1990) and more recently, the WHO (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 WHO (2001) derived an oral tolerable intake of 0.002 mg/kg body weight/day. 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 oral tolerable intake of 0.002 mg/kg body weight/day (0.12 mg/day) (WHO, 2001). As beryllium is considered an impurity in the metallic material, it was 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, 2012; 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 (EFSA, 2009). 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 NH3 and SO2. 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 et al., 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 (2017) established a guideline value for cadmium in drinking-water of 0.003 mg/L.

– In the EU the limit for cadmium in drinking-water has been set to 0.005 mg/L (Directive 2020/2184).

– 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 (EFSA, 2009). 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 (BMDL5) 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 SRL for cadmium is set 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, it was decided to set the SRL at 0.005 mg/kg, which is consistent with the limit for cadmium stated in Directive 2020/2184. 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. 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, 2020) 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. 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/materials in contact with 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. 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 Ingot tin (according to European Standard EN 610:1995) specifies a maximum permissible lead content of 0.050% and the standard specification of tinplate (according to European Standard EN 10333:2005) specifies a maximum permissible lead content of 0.01%. The EU Packaging Waste 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 et al., 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 et al., 2011).

A minor source of lead in food cans exists in the form of small impurity levels in the tin of the coating. Most foodstuffs, those based on citric acid, will dissolve only a small amount of it. Only foodstuffs based on malic acid and in cans without an internal lacquer will show a significant tendency to attack the lead (Bird et al., 1986).

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 (2017) established a provisional guideline value for lead in drinking-water of 0.01 mg/L, on the basis of treatment performance and analytical achievability. As this is no longer a healthbased guideline value, concentrations should be maintained as low as reasonably practical.

– In the EU, the limit for lead in drinking-water has been set to 0.005 mg/L (Directive (EU) 2020/2184). The parametric value of 0.005 mg/L shall be met, at the latest, by 12 January 2036. The parametric value for lead until that date shall be 0.010 mg/L.

– 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 BMDL01: 0.50 µg/kg body weight/day

– effects on systolic blood pressure BMDL01: 1.50 µg/kg body weight/day (90 µg/day)

– effects on prevalence of chronic kidney disease BMDL10: 0.63 µg/kg body weight/day (38 µg/day).

Conclusions and recommendations

"the SRL for lead is set 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, it was decided to use the BMDL10 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 BMDL10, 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, it was decided to set the SRL at 0.01 mg/kg, which is consistent with the limit for lead in drinking water, stated in Directive (EU) 2020/2184 to be applicable until January 2036. This equals an allowance of 26% of the toxicological reference value.

By derogation, the SRL does not apply to tinplated steel sheet used as packaging for foodstuffs for which a maximum level of lead is set in Regulation (EC) No 1881/2006, provided that the tin that is used meets the following specification: Lead content: not more than 0.01%. Due to the restriction on the maximum level of tin in food as set in the same regulation, the co-release of the lead impurity will be restricted to an acceptable level.

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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 from plastic food contact materials is regulated (Regulation (EU) No. 10/2011; SML 0.6 mg/kg).

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, it was 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 (2014), total mercury was measured (sum of inorganic mercury and methylmercury) and mercury was detected at low levels or below the LOD. The highest concentration was 0.0497 mg/kg measured in the fish group (FSA, 2014).

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 of 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.

– In line with JECFA 2010, the CONTAM Panel of EFSA established a tolerable weekly intake (TWI) for inorganic mercury of 4 µg/kg b.w., expressed as mercury (EFSA, 2012).

– WHO (2017) established a guideline value for inorganic mercury in drinking-water of 0.006 mg/L.

– 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 (WHO, 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) and EFSA (2012) assessments. 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 (Peter and Viraraghavan, 2005). Only very rare minerals (lorandite, crookesite, etc.) contain thallium (Shaw, 1952). Pyrite ash used to manufacture cement may contain considerable quantities of thallium (Peter and Viraraghavan, 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, 2014).

Dietary intake was estimated at < 5 µg/day (Sherlock, 1986).In the 2014 British total diet study the highest total mean and 97.5th percentile exposures were in the 1.5 to 3 years age group and were 0.021 – 0.22 µg/kg bw/day and 0.073 – 0.36 µg/kg bw/day (FSA, 2014).

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 maximal quantity 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

– In humans, gastroenteritis, polyneuropathy and alopecia are the classical symptoms of poisoning. Most assessments are based on a sub-chronic 90-days-study on rats (MRI 1988) identifying alopecia as most critical endpoint. The authors of this study derived a NOAEL of 0.2 mg/kg body weight from the highest concentration applied.

– EPA (2009) based their evaluation on the above mentioned study, but considered the highest dose of thallium applied (0.2 mg/kg bw./day) as LOAEL due to hair follicle atrophy and identified the second highest dose as NOAEL (0.04 mg/kg bw./day). Due to uncertainties in the study, EPA chose not to derive an RfD.

– 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). COT considered in its assessment the statement of the WHO (1996).

– 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 10 µg/day of thallium in a soluble form (0.17 µg/kg body weight/day for a 60 kg adult). WHO concluded that due to the uncertainties relating to thallium toxicity, it could not derive a health based exposure limit. Furthermore, in the absence of better dose-response relationship data, it would seem prudent to ensure that intakes should be below 10 µg/day.

– Germany's environmental protection agency – Umweltbundesamt – derived a HBM-I value of 5 µg/L urine (UBA 2011) based on an epidemiological study (Brockhaus et al., 1981). The HBM-I-value represents the concentration of a substance in human biological material below which – according to the knowledge and judgement of the HBM Commission – there is no risk for adverse health effects and, consequently, no need for action. This was done by correlating the thallium exposure and the prevalence of certain symptoms known to be associated with chronic thallium intoxication. This urine concentration corresponded to an oral exposure of 10 µg/person/day (adult of 60 kg body weight).

– The Netherland's RIVM evaluated toxicological data available for thallium in 1998. No carcinogenicity studies had been carried out and the genotoxic potential was examined to a limited extent only. The results of studies on reproductive toxicity indicate that thallium compounds adversely affect the male reproductive system. Due to limitations in the data set, only a provisional TDI (PDTI) could be derived for thallium and its compounds (0.2 µg/kg body weight) (RIVM, 1998).

Conclusions and recommendations

"the SRL for thallium is set at 0.001 mg/kg"

The acceptable oral exposure of 10 µg/person/day (UBA 2011) derived by WHO (1996), UBA (2011) and the PTDI by RIVM are of the same order of magnitude. Therefore, it is recommended to derive the SRL based on these data. As thallium is considered an impurity in the metallic material, an allowance of 10% of the toxicological reference value is applicable. Assuming that a person 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 0.001 mg/kg.

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Stainless steel and other alloys

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.

Main types of alloys

Most metals are mainly used in alloy form. The following alloys are amongst those most commonly used for food contact applications:

— Steel is an alloy made of iron and carbon (less than 2% carbon). Other elements (e.g. nickel, chromium and/or molybdenum) may be alloyed with iron and carbon to provide desired properties.

— Cast iron is an iron alloy containing 2 to 4% carbon and small amounts of manganese, silicon and phosphorus.

— Stainless steels are iron-chromium alloys which contain a minimum of 10.5% chromium (usually 17-18%) and less than 1.2% carbon (Heubner, 2009), and which are often also alloyed with elements such as nickel, molybdenum, etc., to provide desired properties (see chapter 2 on stainless steels). Increasing levels of chromium beyond 10.5% further improves corrosion resistance.

— 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).

— Bronze consists of 80-95% copper and 5-20% tin.

— Brass consists of 60-70% copper and 30-40% zinc.

— German silver (also known as nickel silver and Maillechort) is a range of copper-based alloys with the nickel content ranging from 10-20%. Maillechort has chemical composition of 60-64% copper, 17-19% nickel and the remainder zinc, which is specified in EN 1652 and has the designation CW 409J.

— Nickel bronze (also known as Dairy bronze and Thai bronze) is an alloy consisting of 63-67% Cu, 3.5-4.5 % Sn, 3-5% Pb, 3-9% Zn, 1.5% Fe, 19-21.5% Ni, 1% Mn, and 0.15% Si.

— 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-copper, and non-stick Al-Cu-Fe-Cr quasi-crystal- coatings.

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 raw materials and production processes. Maximum permissible impurity concentrations are set in the alloy specification and are generally less than 0.5%, depending on the alloy type.

Release

Measurable amounts of metallic elements in the alloy may be released into foodstuffs during food preparation and cooking, leading to human ingestion. Studies on a variety of metallic food contact materials have been conducted to assess whether such releases could impair food quality and/or are a cause of concern for human health (Flint and Packirisamy, (1995); Flint and Packirisamy, 1997); Vrochte et al., 1991).

In one such study, release tests were 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 unalloyed metals due to the microstructure and surface properties of the alloys. The constituents of alloys are bound together in a chemical matrix, essentially forming solid solutions and new compounds.

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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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, which is formed when the chromium content of the steel exceeds 10.5%. 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 nanometers thick (Olsson and Landolt, 2003), forms almost instantaneously on contact with the oxygen in air or water. Abrasion or other forms of surface damage do not easily lead to film breakdown 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 and knife blades), as this has been found to be the optimum chromium concentration for corrosion resistance in a wide range of food and beverages.

Stainless steels may be sub-divided into families according to their metallurgical structure. European Standard EN 10088 series specifies the chemical composition of stainless steels; some of which are commonly used for food contact applications:

— 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, no nickel, 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, hollowware, table surfaces, panels and worktops.

— Austenitic stainless steels: for food contact applications, typically contain a minimum of 16% chromium and 6% nickel. Austenitic grades (mainly the so called 300 series stainless steels) with varying amounts of chromium and nickel, sometimes with other elements (e.g. molybdenum, copper), are used in a very wide range of food contact applications: both domestic and industrial cutlery, hollowware and kitchen utensils typically having 18% chromium and 8-10% nickel; higher alloy grades used for food processing, storage and transport equipment, pipe-work, etc., having 17% chromium, 11% nickel and 2% molybdenum). Grades containing molybdenum (approximately 2-3%) are particularly resistant to the corrosion caused by salt-containing foods (Eric Partington 2006).

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 grades also contain nitrogen and copper to further stabilise the austenitic structure of the steel and which, respectively, provide additional strength and improved cold forming properties. 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 (300 series)

— CrMn – minimum 17% Cr, 4% Ni, 7.5% Mn (200 series)

Super-austenitic grades (typically containing 20-25% chromium, 20-25% nickel, 4.5-6.5% molybdenum and sometimes with copper additions) are used in contact with food containing very high levels of salt (e.g. soy sauce; 17% chloride) and also for steam-heating systems, boilers, brines, 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, Italy and Greece. 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 positive list of stainless steel grades for use as food contact materials. These grades must pass metal release 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 positive list following appropriate testing. In Greece, stainless steels for food contact products must contain at least 12% (w/w) of chromium. Maximum limits are imposed for certain other alloying elements (4% for Mo, Ti, Al and Cu; 1% for Ta, Nb and Zr; 0.5% for Pb; 0.05% for Cd and 0.05% for As). 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 and International standards for certain types of application of stainless steels. The composition limits for stainless steel for table cutlery (knives, forks, spoons, carving sets, ladles, children's cutlery and other serving utensils) are specified in EN ISO 8442-2; specified compositions are linked to 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 11th edition 2015).

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, 11th edition 2015). 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 631, 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.

In addition to corrosion resistance, grade selection for food applications must also include consideration of durability, formability (e.g. deep drawing for pots and pans) and mechanical/physical properties (e.g. ferromagnetism for induction heating applications). Users of the Guide are recommended to seek expert advice on the selection of suitable stainless steel grades for their specific food contact applications.

Release

Metal ion release from stainless steel is generally assumed to be a time dependent measure of metal transition. Tests have shown that metal release from stainless steel decreases with time (Mazinanian et al., 2016). Further information on these processes can be obtained from the literature cited below.

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 (Bünig-Pfaue et al., 1999). 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 average release of nickel was 0.21 mg/kg for apricots and 0.14 mg/kg for rhubarb after the first cooking operation. After the fifth cooking operation, the highest nickel release for apricots and rhubarb was reduced to approximately 0.06 mg/kg and 0.03 mg/kg, respectively. Correspondingly, the highest release of chromium after the fifth cooking operation was 0.04 mg/kg and 0.04 mg/kg, respectively.

Using boiling 5% acidic acid as a simulant for 5 minutes in stainless steel pans, nickel release ranged between 0.08 and 0.21 mg/kg (Kuligowski, 1992). A study of the levels of nickel and chromium found in 11 habitual menus cooked in glass and stainless steel saucepans fall within or are close to the range of nickel and chromium contents of these foods reported in the literature (Accominotti, 1998).

A review on the metal release from stainless steel in biological environments including food is available. (Hedberg et al, 2016)

Safety aspects

— No particular health concerns have been raised, in terms of excessive intakes of nickel or chromium, by several studies of metal release in various media and of the 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.

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CHAPTER 3

Chapter 3 - Release testing of food contact materials and articles made from metals and alloys

Resolution CM/Res(2020)9 on the safety and quality of materials and articles for contact with food establishes that compliance of the food contact materials and articles with the relevant provisions and restrictions shall be verified by appropriate scientific methods (including modelling or worst-case calculations) in accordance with Regulation (EU) No. 2017/625 or relevant national legislation.

Furthermore, tests on release from the material or article into foodstuffs are carried out under the conditions of manufacture, storage, distribution and normal/foreseeable use considered to be a "reasonable worst-case" with respect to contact time, temperature and composition of the foodstuff. The results of specific release testing obtained in food shall prevail over the results obtained in food simulants.

Criteria for the choice of test procedure

To assess compliance (see Calculation of specific release), the material or article must be tested for the release of the relevant metals and impurities, either into foodstuffs or into food simulants, according to the following criteria.

Testing release from materials and articles into foodstuffs

Release from metallic materials and articles into foodstuffs is influenced by the properties of the 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 are 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.) and as far as possible at end of shelf life.

– when the material or article is not yet in contact with food, 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. food processing utensils such as 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. The natural metal content of the foodstuff should be considered and reported with the analytical result (see Natural metal content of the foodstuff).

Testing release from materials and articles into food simulants

Following from the guiding principles established by Resolution CM/Res(2020)9, food simulants are used instead of foodstuffs when release testing in food is not feasible or not practical, as described below:

–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.

– the analysis is not technically possible or the specified foodstuff(s) or group(s) of foodstuffs are not available.

The food simulants and conditions of contact are selected in such a way that release is at least as high as into food.

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 are 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:

$$RESULT1^{st}\ test + RESULT2^{nd}\ test \leq 7 \times SRL.$$

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

Care should be taken so that repeated use articles made from plated metals or alloys are produced in such a way that the integrity of the plating is guaranteed throughout their lifetime. Such items should be labeled with a warning that in case of any defect, they may no longer be safe for use.

Articles for repeated use, like hot beverage appliances (e.g. coffee machines), should be tested after any preparatory or cleaning steps (e.g. decalcification) stated within the corresponding instruction manual.

Remark:
Where relevant physical changes occur in the test specimen only under the specified test conditions but not under the worst foreseeable conditions of use of the material or article, the test must be adapted with alternative 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. cans)

A sampling strategy 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. An example of sampling plan for this purpose is given in Table 1 and may be applied. Different sampling plans can be used; however, they should not be seen as substitute for effective process control (Commission Regulation (EC) No 2023/2006).

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**
1-59	at least 3
60-200	at least 5%
> 200	10

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

At least three replicated samples 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 plan 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 dishwashing soap/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". However, these conditions for testing into food simulants could be inappropriate for food (e.g. causing deterioration/alteration of the food). In such cases, the conditions of worst foreseeable real use should be selected.

Selection of foodstuffs

The material or article to be tested shall be brought into contact with the intended foodstuff, if available. Contact surface to volume ratio is important – whenever possible, tests should be performed with the real surface to volume ratio.

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 in the presence of known corrosion accelerators, such as sulphur dioxide or nitrate, if these substances are reasonably foreseeable to be present in the foodstuff and at levels close to their typical upper limits.

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

NOTE: Souci(1) (2016) 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 (at least minimum – maximum values) in the foodstuff should be mentioned in the supporting documentation of any declaration of compliance.

Testing of packaging materials

Processing and packaging conditions*

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*

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 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.

Consequently, it is advisable to store the test specimens 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 (EU) No 10/2011, Annex V, could be used.

The information on any accelerated testing must be mentioned in the supporting documentation of any declarations of compliance.

* 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.

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. 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 (SR) into foodstuffs can be determined by subtracting the concentration of the element in the foodstuff before contact with the metal/alloy (C_0) from the concentration of the element in the foodstuff after contact with the metal/alloy (C_1):

$SR = C_1 – C_0$ expressed in [mg Me/kg food] or in [mg Me/dm^2].

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 EN16889*
Acidic foods (pH ≤ 4.5)	Citric acid 0.5% (m/v)**

* EN 16889:2016 Food hygiene(3) – 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 and pH adjusted to 7.5 using 0.1M NaOH or 0.1M HNO_3.

** Prepared by dissolving 5 g of citric acid monohydrate (CAS No. 5949-29-1) in distilled water and diluting to final volume of 1 L.

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

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

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

Kitchenware articles and other articles that can be filled (e.g. cans) should be filled with the food simulant to approximately ⅔ total capacity and then suitably covered to reduce evaporation. The same volume (or mass) of food or simulant must be used for replicate analysis and this volume (or mass) must be reported.

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

Kitchenware should be tested under actual conditions of use (temperature, time, volume or mass) or by applying the test conditions as specified in the JRC Guidelines on testing conditions for kitchenware articles in contact with foodstuffs(2). The temperature refers to the temperature of the simulant at the surface in contact with the article.

Articles other than kitchenware should be also tested under actual conditions of use; however, if not practical (e.g. 2 years at room temperature for cans or even longer time), other testing conditions can be used after describing the rationale behind the selection of the testing conditions.

Due to practical limitations, these conditions do not apply to large volume equipment such as pipes and tanks.

Articles that cannot be filled

A. 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

Test conditions for articles including cutlery and cooking utensils such as colanders, potato mashers and cheese graters:

The article should be tested, intact, by immersion to a reasonable depth reflecting normal use of the article (see Annex I 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(2)).

B. Materials and articles at the end-use level that cannot be filled other than A such as baking sheets, foils

This applies to materials and articles such as aluminium foil (e.g. chocolate bar wrapped in aluminium foil), cutting boards, kitchen sinks with draining boards and kitchen countertops.

Either the entire article or a test specimen of it can be tested by immersion of the relevant surfaces intended for contact with food. In the latter case, the total area of the test specimen should be at least 1 dm², determined with a measurement precision of 1 mm for each side. 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 their thickness exceeds 2 mm.

As an alternative to testing by immersion, a test cell can be used for samples of flat (non fillable) articles. The sample is mounted to the test cell with the food contact surface facing towards the foodstuff or food simulant.

Testing conditions should be selected as described above for articles that can be filled.

Test cells can be used if the applicable test conditions as described in the JRC guideline are met (2).

Test cells should be as close as possible to being inert with respect to the applied foodstuffs or food simulants. A blank test must be performed in order to measure a potential release of metals caused by the test cell itself. In the blank configuration, an inert sheet that does not release any metals should be used in the place of the sample. The results of the blank test have to be subtracted from the results of release tests with sample material.

Edge preparation for stainless steel articles:

The procedure for preparing the edges of stainless steel test specimens which have been cut from larger surfaces or 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 Guidelines issued by the JRC on testing conditions for kitchenware articles[(2)] specify the testing time and temperature for a wide variety of kitchenware articles. For example:

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

– For articles such as counter-tops, where ambient temperature long-term contact 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.

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 EN 16889(3)

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 (EU) 2017/625. 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(5), 2009), as revised.

Scope

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

Principle

The concentration of an element in a foodstuff or food 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 tested surfaces must be avoided, and only non-metal household utensils (plastic spoon, wooden scraper) should be used.

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 distilled, deionised(4), or water of similar quality.

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, but care should be taken when using polytetrafluoroethylene (PTFE), because of reported interactions with metals. Before using PTFE labware, tests should verify that absorption of metals in their surface at the conditions applied is negligible.

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. Blank measurements should verify effective decontamination.

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. Finally, the equipment must be dry when used.

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. providing that the analytical performance described below are as far as possible achieved.

Blank tests

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

Analytical performance requirements

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

The limit of detection 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 limit of quantification 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 for repeated analysis of a reference or fortified material, under conditions of reproducibility (intermediate precision), should not exceed the level calculated by the Horwitz Equation (see Table 3).

Table 3. *Predicted value for within-laboratory RSD, under conditions of reproducibility, depending on concentration* [5]

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

The Guidelines for performance criteria and validation procedures of analytical methods used in controls of food contact materials [5] should be taken into account.

Measurements and reporting

The analytical results for test specimens sampled (see Sampling of materials and articles) and tested for release in a foodstuff or food simulant, with the measurements corrected for recovery, should be reported in mg Me/kg or mg Me/dm^2, with their expanded uncertainty and the analytical method.

A test specimen can be considered compliant when the concentrations of any released elements (or the average concentration, in the case of replicate instrumental measurements, of the same test specimen solution after the release testing) do not exceed the corresponding SRLs, taking into account the expanded uncertainty of the measurements (see Calculation of specific release).

Usually, more than one specimen of the same sample are tested (see Sampling of materials and articles). Only if all the test specimens of the sample are compliant, the sample is considered compliant.

In case of single use materials or articles, the results after the first migration test are used for compliance statement.

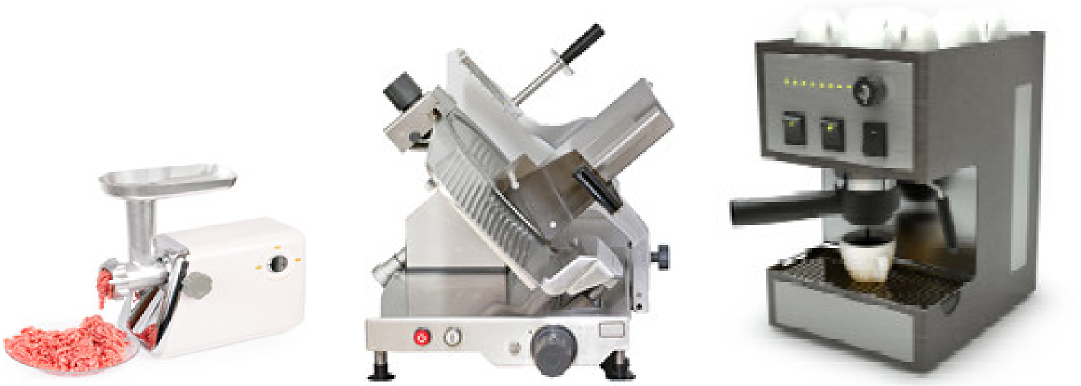
In case of repeated use materials or articles, the results after the third migration test are used for compliance statement. However, the sum of the results of the first and second migration tests should not exceed seven times the SRL (see Articles for repeated use).

For 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, the specific release is calculated according to the rules set in the Annex I. The corresponding envelope volume must be reported.

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

This total mass of released elements must be converted in mg/kg by taking into account the amount of foodstuff coming into contact with the assembled article.

Examples: mincer / meat slicer / espresso machine



For silver or silver-plated cutlery, a reduction factor may be applied to the specific release of silver when justified (see Annex II).

Calculation of specific release (SR)

When the foodstuff or food simulant used for the release test contains amounts of the element under investigation (see "Natural metal content of the food"), the original metal content must be subtracted from the result of the release test.

$$SR = C_1 - C_0$$

where SR is the concentration of the element that is released from the metal or alloy into the foodstuff/food simulant, expressed in [mg Me/kg food] or in [mg Me/dm^2];

C_1 is the concentration of the element in the foodstuff/food simulant after contact with the metal/alloy, expressed in [mg Me/kg food] or in [mg Me/dm^2]; and

C_0 is the concentration of the element in the foodstuff/food simulant before contact with the metal/alloy, expressed in [mg Me/kg food] or in [mg Me/dm^2].

Note: The measurement uncertainty of the release test result must be taken into account to assess compliance.

Example:

Assuming

C_0 = 2.0 mg Me/kg, $u(C_0)$ = 0.4 mg Me/kg

C_1 = 8.0 mg Me/kg, $u(C_1)$ = 1.6 mg Me/kg

where, $u(C_1)$ and $u(C_0)$ are the respective standard measurement uncertainties, one gets:

$SR = C_1 - C_0 = 8 - 2 = 6$ mg Me/kg

$U(SR) = 2 * \sqrt{u(C_1)^2 + u(C_0)^2} = 2 * \sqrt{0.4^2 + 1.6^2} = 3.3$ mg Me/kg

where, U(SR) is the expanded uncertainty, calculated using a coverage factor (k) of 2, and applying the law of uncertainty propagation according to JCGM 100L2008 GUM 1995(a)

The final result should be reported as **SR = 6.0 ± 3.3 (k=2) mg Me/kg**.

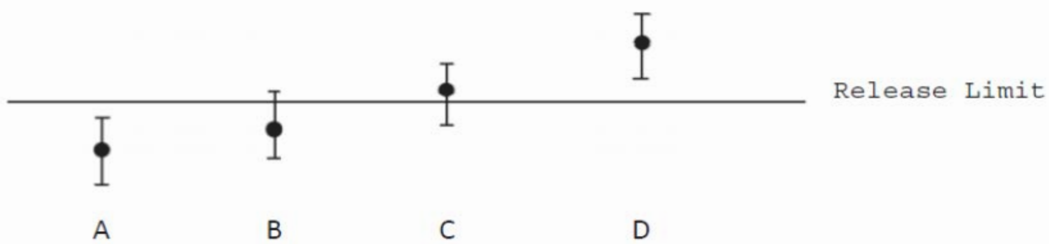
This approach is applicable when C_0 and C_1 are expressed in mg Me/dm^2. The final result should then be multiplied (b) by "6" to obtain a result expressed in mg Me/kg.

(a) BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP, OIML (2008). Guide to the expression of uncertainty in measurement, JCGM100:2008, GUM 1995 with minor corrections. BIPM (First edition September 2008). Available from https://www.bipm.org/

(b) Applicable for articles described in section "Materials and articles at the end-use level that cannot be filled other than A such as baking sheets, foils".

How to check compliance

The Eurachem guide(a) defines the four cases presented in the figure:



(a) A. Williams and B. Magnusson (eds.) Eurachem/CITAC Guide: Use of uncertainty information in compliance assessment (2nd ed. 2021). ISBN 978-0-948926-38-9. Available from www.eurachem.org

Case A represents a result that is beyond any reasonable doubt below the release limit SRL, (SR + U < SRL), hence the results would be considered as "compliant".

Similarly, case D represents a result that is beyond any reasonable doubt above the release limit SRL, (SR - U > SRL), hence the result would be considered as "non-compliant".

A case-by-case assessment is required for cases "B" and "C", in order to judge whether the results comply with the release limit value, taking into account the risks associated with making a wrong decision. The conservative approach, meant to protect the consumer, would consider cases "B" and "C" as "non-compliant".

Calculating the SR for articles as defined in Annex I

The calculation is described in Annex I.

References

(1) Food Composition and Nutrition Tables SW Souci, W Fachmann, H Kraut. Wissenschaftliche Verlagsgesellschaft mbH, Stuttgart 8th edition 2016.

(2) Beldi G., Senaldi C., Robouch P. and Hoekstra E. (2021) Testing conditions for kitchenware articles in contact with foodstuffs: Plastics, Metals, Silicone and Rubber. European Commission, Ispra, JRC125894.

(3) EN 16889 Food hygiene – Production and dispense of hot beverages from hot beverage appliances – Hygiene requirements, migration test.

(4) Deionised water R prepared by distillation with a resistivity of not less than 0.18 MΩ·m determined at 25oC. Ph. Eur. 10th Edition, Strasbourg, France: Council of Europe; 2019.

(5) Bratinova S., Raffael B., Simoneau C. (2009) 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.

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

This annex describes a method for calculating the foreseeable mass of foodstuff in contact with articles of the section "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", such as forks, brushes, etc.

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 conventions to be used for a direct and simple calculation of the specific release in mg/kg as it relates to the consumer's exposure. For each three-dimensional object, the lengths of its three dimensions (X = depth, Y = width, Z = height) are defined using a few simple conventions. This yields a rectangular box parallelepiped (simple geometric figure) enclosing the object called "envelope volume" which is used as a reference in the method for the amount of food that comes into contact with an article.

This method deviates from the method currently described in the European Regulation (EU) No. 10/2011 on plastic materials and it is proposed as more appropriate for a number of utensils whose surface area is not correlated with the amount of food in contact and therefore consumer exposure.

Measurements for the calculation of the envelope volume of the utensil

In order not to drastically underestimate the contact volume for articles with small dimensions along one or more of the axes, the minimum value that can be assigned to each axis (X, Y and Z) is 5 cm. Each value below 5 cm will be rounded to 5 cm.

Beyond the minimum value of 5 cm, the length of each axis shall be measured and expressed in increments of 1 mm.

Determination of dimensions along the axes X, Y and Z

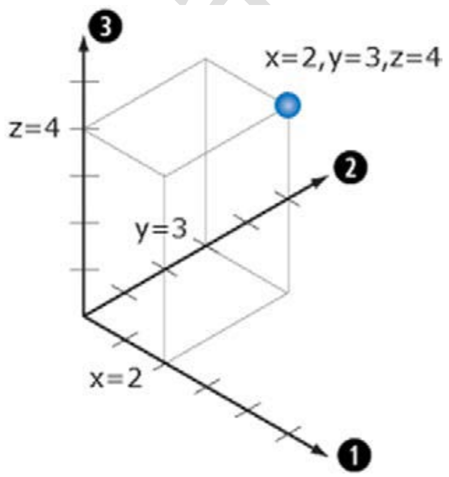


Diagram 1 illustrates the three-dimensional envelop volume, where the Z axis represents the height of the utensil, the X axis its depth and the Y axis its width (Y).

Measure the value of the total height (H_{total}) for the utensil using a gauge (e.g. Vernier calipers) with a precision of 1 mm. The height shall be established by measuring by in straight line along the centreline of the utensil, as illustrated below.

Remark:

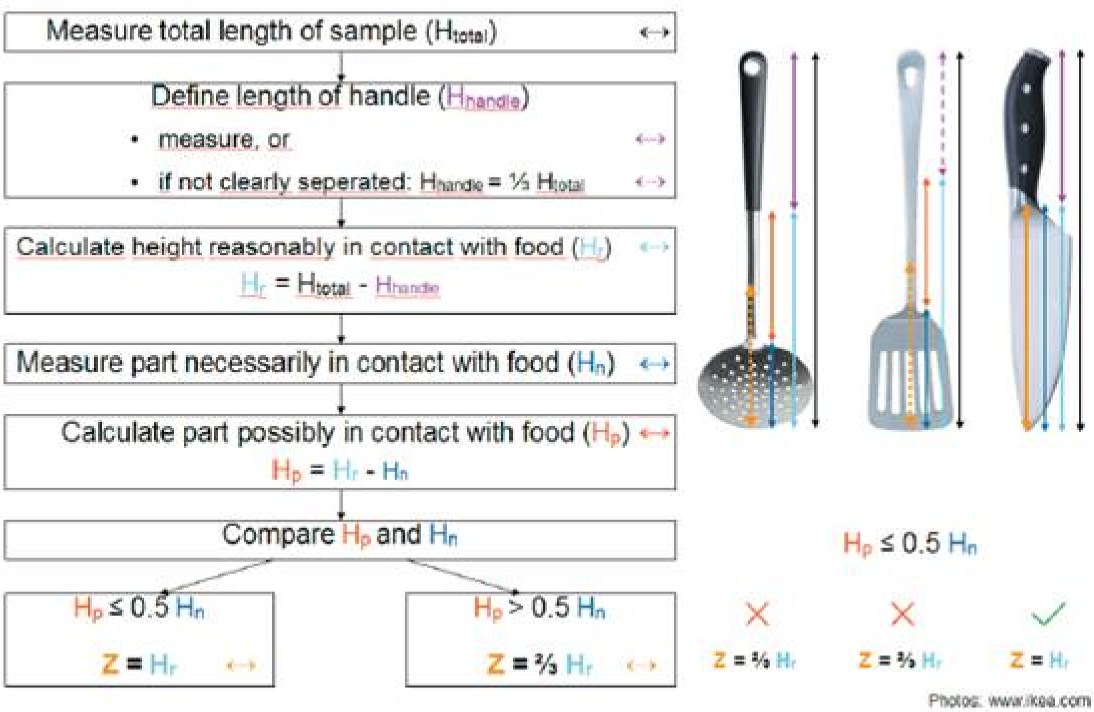
If it is not clear what points should be used to determine the height measurement, the utensil can be suspended (i.e. allowed to hang freely from the highest point of the handle and then lowered until it touches a horizontal surface e.g. a desktop). The height is then be measured from the highest point of the utensil perpendicular to the horizontal surface.

Then determine what portion to the total height (H_{total}) *for the utensil is assigned, respectively, to the handle (*H_{handle}*) and to the part necessarily in contact with food (*H_n*).*

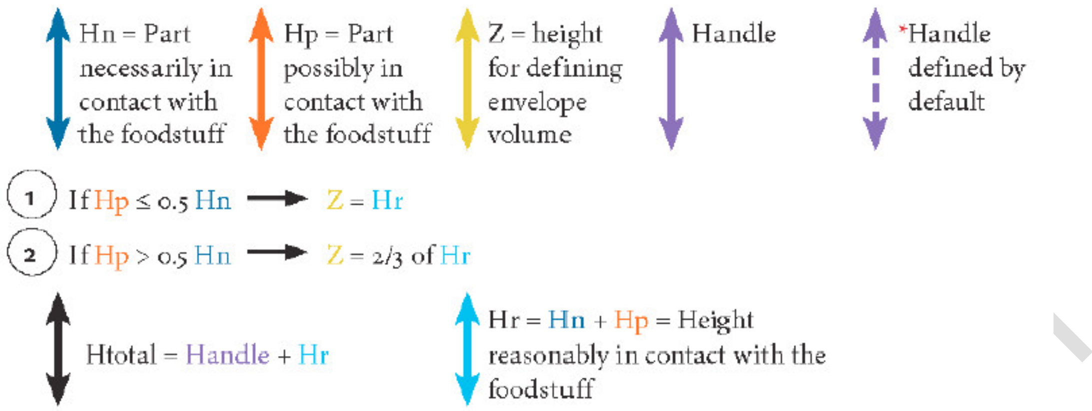
Measure the length of the handle (H_{handle}*) using the gauge. If the handle is made of metal and it is not clearly separate from the rest of the article, it is assigned a default length of 1/3 of total height. Then measure the part necessarily in contact with food (*H_n*).*

Afterwards measure the depth (along the X axis) and the width (along the Y axis) parallel to the horizontal surface using the same orientation of the utensil as described above.

Calculate the height (Z) of the utensil as shown in the following flow diagram defining the height (Z) of utensils:

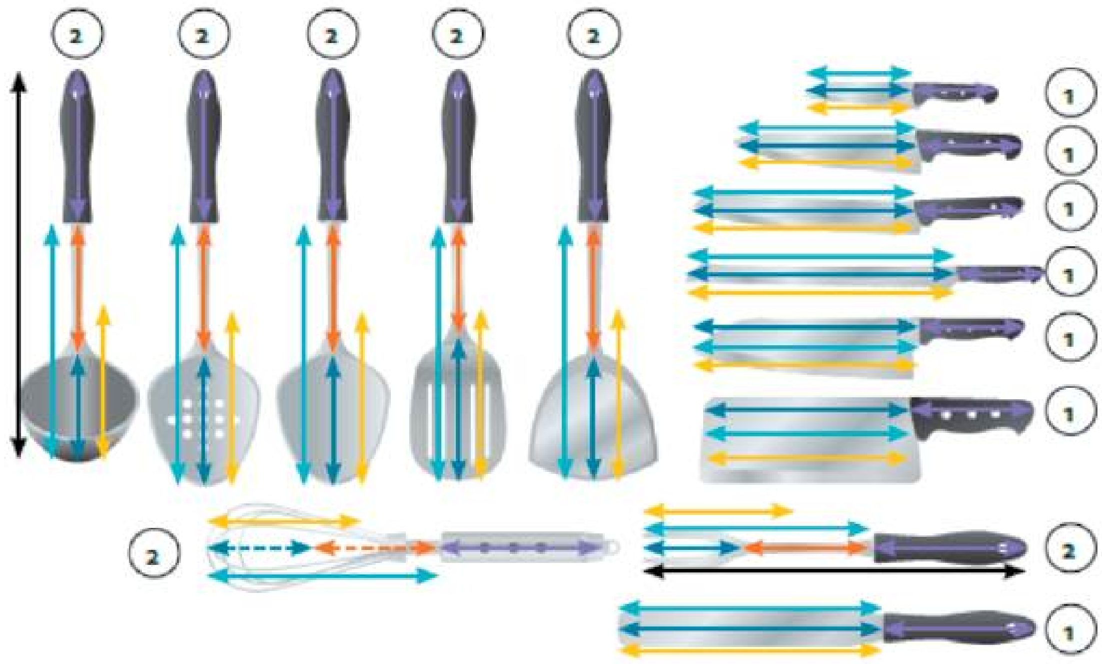


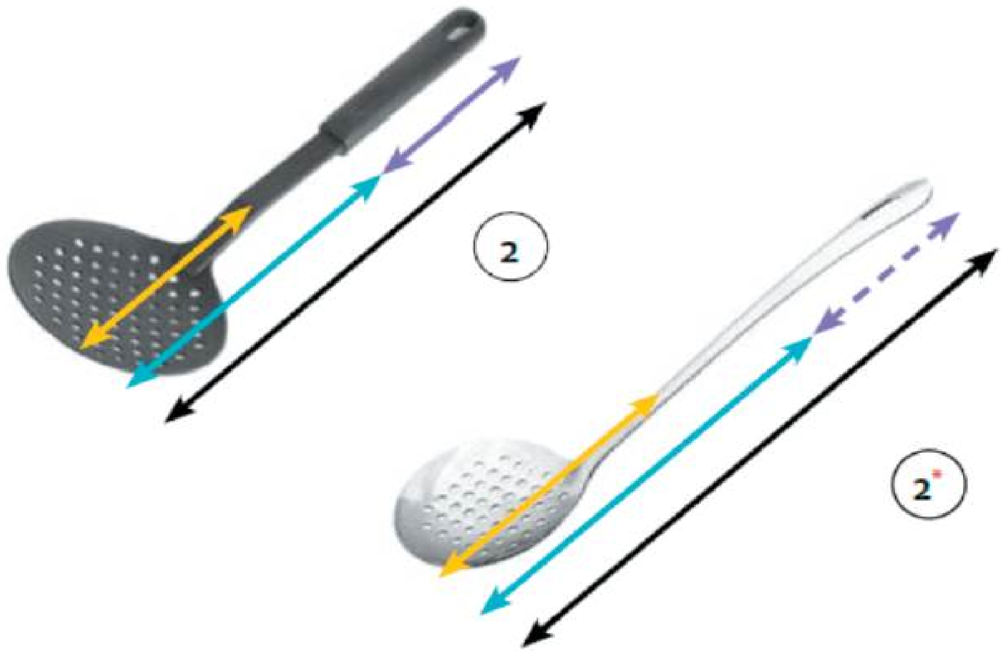
Legend for scheme of defining height of utensils next pages:



* 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





Deviation from the aforementioned process

Articles that cannot be filled may have a shape or may be used in a way, which makes them unsuitable to apply the aforementioned calculation process

Examples are depicted here

In such cases an appropriate adaption of the calculation is necessary. This has to be mentioned in the report along with a justification of the deviation.

Calculation of the envelope volume

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

Envelope volume = X × Y × Z (cm^3)

If any of the used values is below 5 cm it shall be rounded to 5 cm.

Determination of the reference mass (RW)

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

Examples:

– potato masher: 16.0 × 9.5 × 8.7 = 1322 → reference mass = 1.322 kg

– skimmer: 5 × 14.2 × 18.0 = 1278 → reference mass = 1.278 kg

– small ice cream scoop: 5 × 5 × 12.8 = 320 → reference mass = 0.320 kg

Determination of the released mass of a specific element

Immerse the article up to the height of Z in a known volume of food 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. Nevertheless, whenever possible, large volume deviations should be avoided. If in the experimental set-up the simulant does not cover the article’s surface up to the level of the calculated Z, appropriate considerations should allow to add to the release the relative contribution from the handle (if made of the same material).

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

Released mass (M) = V × C

where, V is the volume of simulant used, expressed in L

C is the concentration of the element in the food simulant after contact with the metal/alloy, expressed in [mg Me/L].

Determination of the specific release

As a general rule: SR = M/RW

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

Annex II: Correction factor applied when comparing release test results for cutlery made from silver or silver-plated cutlery with release limits for silver

Recent data from official control laboratories have shown that the release of silver ions from cutlery made from silver or silver-plated cutlery tested with citric acid under conditions for hot use (FSI/CAH1 of the JRC Guideline[7]) may exceed the release limit set for silver. Furthermore, testing under these conditions does not adequately represent real use conditions and consumer exposure.

After considering the following arguments:

a) The analysis of silver in real food is challenging and often error-prone, possibly leading to results that underestimate the release. This may account for the absence, up to the present time, of any reliable comparison between silver release into food simulants and into real food. Therefore, it seems more appropriate to test with citric acid as a simulant. However, as tests using citric acid simulant at high temperatures tend to overestimate (based on available data) the release of silver ions from silver compared to worst foreseeable real use, the test result may have to be corrected.

b) Hot served acidic food represents only a small fraction of the daily food consumption. Even though there are no reliable data available on the consumption of hot acidic food with cutlery, it is safe to assume, that the amount of that particular type of food is less than the overall food consumption.

c) Cutlery made of silver is rare and precious and, therefore, predominantly reserved for use on special occasions - a period ranging from a few special or red-letter days (celebrations, holidays) per year to once or twice a week (e. g. on the weekend). A factor derived from this timeframe could vary from 3.5 (a weekend, twice a week), or 7 (once a week) to as high as 365 (use only once a year). Taking into consideration only the highest possible frequencies of use (e.g. once or twice a week) an average factor of 5 would result.

d) The WHO considered 0.39 mg/person/day as the NOAEL, which was also taken into consideration by EFSA. The SRL for silver was derived based on intake data using criterion 3 (i) of the criteria for establishing SRLs, leading to an SRL of 0.08 mg/kg (which would contribute to 1/5th of the NOAEL). Considering new analytical data for cutlery which indicate that it is not in every case feasible to comply with the limit set and therefore, it may be appropriate to take technically feasible levels (ALARA) into account. At the present time, only few data exist and, until more reliable data exist, an SRL based on ALARA cannot be derived.

It was concluded that a correction factor to be applied to the test results for cutlery made from silver or silver-plated cutlery is justified.

[7] Beldi G., Senaldi C., Robouch P. and Hoekstra E. (2021) Testing conditions for kitchenware articles in contact with foodstuffs: Plastics, Metals, Silicone and Rubber. European Commission, Ispra, JRC125894.

Therefore:

For cutlery made from silver or silver-plated cutlery the specific release can be corrected by a factor. The correction factor is set to 5.

The correction factor shall be applied in accordance with the following rules.

A correction is only applicable for the release of silver ions from cutlery made from silver or silver-plated cutlery tested as in food serving implements for cold/ambient or hot use (FSI/CAH1) of the JRC guideline with citric acid as simulant.

For silver-plated cutlery the correction can only be applied to items that comply with the requirements of international standard ISO 8442-2[8].

The factor is only applicable to silver or silver-plated cutlery labelled in accordance with article 15 (1b) of Regulation (EC) No 1935/2004, as not suitable for food preparation or cooking, and not for a daily use. As an example the label could be: “This cutlery is intended for food serving and eating purposes, not for cooking or food preparation. Due to specific characteristics of silver, it is recommended not to use silver articles on a daily basis.”

The release test results shall be divided by the correction factor prior to comparison with the release limits.

[8] ISO 8442-2:1997-12, Materials and articles in contact with foodstuffs - Cutlery and table hollowware - Part 2: Requirements for stainless steel and silver-plated cutlery.