METALS AND ALLOYS

used in food contact materials and articles

A technical guide for manufacturers and regulators

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

EDQM
2nd Edition
2024

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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Contents

Foreword 7
Acknowledgements 9
Council of Europe Resolution CM/Res(2020)9 on the safety and quality of materials and articles for contact with food 11
Abbreviations used in this Technical Guide 27

Chapter 1 – General provisions and specific release limits for metals 31

Introduction 31
Objectives 31
Involvement of national experts and stakeholders 32
Legal status of the Technical Guide and link with the European Union 32
Definitions, scope and specific release limits 33
Updating of this Technical Guide and further provisions or guidance 39
References 39

Chapter 2 – Safety review and recommendations 41

Metals and alloy components 41
Aluminium (Al) 43
Antimony (Sb) 53

Chromium (Cr) 57
Cobalt (Co) 65
Copper (Cu) 69
Iron (Fe) 75
Magnesium (Mg) 81
Manganese (Mn) 85
Molybdenum (Mo) 93
Nickel (Ni) 99
Silver (Ag) 109
Tin (Sn) 115
Titanium (Ti) 123
Vanadium (V) 127
Zinc (Zn) 131
Zirconium (Zr) 137
Metal contaminants and impurities 143
Arsenic (As) 145
Barium (Ba) 151
Beryllium (Be) 155
Cadmium (Cd) 159
Lead (Pb) 165
Lithium (Li) 173
Mercury (Hg) 177
Thallium (Ti) 183
Stainless steels and other alloys 187
Alloys 187
Stainless steels 190

Chapter 3 – Release testing of food contact materials and articles made from metals and alloys 201

Criteria for the choice of test procedure 201

Testing release from materials and articles into foodstuffs 201

Testing release from materials and articles into food simulants 202

Sampling of materials and articles 204

Pre-treatment of materials and articles 205

Release testing into foodstuffs 206

Release testing into food simulants 209

Methods of analysis 213

Measurements and reporting 216

Calculation of specific release 217

References 219

Annex I – Methods for measurement of articles for which it is impractical to estimate the ratio of surface area to the amount of foodstuff in contact with it 221

Annex II – Correction factor applied when comparing release test results for cutlery made from silver or silver-plated cutlery with release limit for silver 227

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 (FCM) 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 the safety and quality of materials and articles for contact with food, defining guiding principles applicable to FCM not yet harmonised by European material-specific measures, such as coatings, paper and board and metals
- **Chapter 1**: Definitions, scope and specific release limits (SRLs) 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) performed a comprehensive review of the first edition (2013) of this Technical Guide to prepare the present edition.

This revision follows the adoption of Resolution CM/Res(2020)9 and takes into account scientific opinions of 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 *Testing conditions for kitchenware articles in contact with foodstuffs: Plastics, Metals, Silicone & Rubber or its revisions* (Beldi *et al.*, 2021).

The chapter on the declaration of compliance in the first edition was omitted from the current edition in view of the corresponding guiding principles stated in the Appendix to Resolution CM/Res(2020)9, section 8.2.

Acknowledgements

The second edition of this Technical Guide was prepared with the support of the designated national representatives at the CD-P-MCA and other contributors from the public and private sector, with expertise in relevant fields such as analytical methodology and toxicology. They critically reviewed the first edition as published in 2013 and also the relevant background information, recent scientific publications and legislation so that substantial amendments could be made. Their contribution is gratefully recognised and appreciated.

Substantial research was carried out by the Belgian experts (Federal Public Service [FPS] Health, Food Chain Safety and Environment and Sciensano Belgian Institute for Health) in their respective roles as rapporteur on metals and alloys to the CD-P-MCA from 2018 and chair of the *ad hoc* working group that was set up to address technical aspects of metal release into food and food simulants. Tapping into the expertise of this *ad hoc* group – composed of representatives not only from different manufacturer federations, control laboratories and competent authorities but also producers and consultants – relevant amendments were prepared for chapter 3 of the present guide.

Special thanks go to the German Federal Institute for Risk Assessment (BfR) for the experimental work that laid the foundation for the revised recommendations for release testing of food contact materials and articles made from metals and alloys.

The revised Technical Guide was subject to a stakeholder consultation in Spring 2022. The numerous comments received confirmed the wide interest in the subject and guaranteed the high quality of the final text. Special thanks are also due to the General Chemical State Laboratory of Greece who co-ordinated the follow-up to the public consultation and consolidation of the revised document in 2022.

And finally, this second edition would not have been possible without the EDQM Secretariat, whose role in co-ordinating the revision, organising expert meetings, translating relevant contributions and copy-editing the Technical Guide is gratefully acknowledged.

Council of Europe
Resolution CM/Res(2020)9
on the safety and quality of materials and articles for contact with food

Adopted by the Committee of Ministers on 7 October 2020
at the 1385th meeting of the Ministers' Deputies

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

Considering that the aim of the Council of Europe is to achieve greater unity between its member States and that this aim may be pursued, *inter alia*, by the adoption of common action in the health field;

Recalling that protection of health is a social human right and an essential condition for social cohesion and economic stability;

Acknowledging the need to set quality and safety standards to minimise the health risk posed to humans by certain material constituents when released from materials or articles intended for contact with foodstuffs;

Considering that food contact materials and articles are also used in pharmaceutical applications when the said materials are deemed suitable and safe for that purpose;

Having regard to the opportunity to enhance synergies between the food contact materials and articles and pharmaceutical sectors;

Following an approach similar to that published by the European Medicines Agency (EMA) in the "Guideline on Plastic Immediate Packaging Materials", effective since 1 December 2005, which specifies that the provisions of Community legislation on plastic materials and articles for food contact should be taken into account, in cases indicated in the guideline;

Having regard to Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and specific EU measures for particular groups of food contact materials and articles adopted in accordance with that Regulation, Commission Regulation (EC) No. 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food, Regulation (EU) 2017/625

1 States concerned [in 2020]: 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, Republic of Moldova, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and United Kingdom.

of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, Regulation (EC) No. 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin and Regulation (EU) No. 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products or relevant national legislation which, although not binding for all of the States Parties to the Convention, should nevertheless be taken into consideration;

Taking into account that the Technical Guides on food contact materials and articles and resolutions are widely recognised and used as a reference for the safety, quality and use of coatings, colorants, cork, glass, metals, paper and board, plastics, printing inks for food contact materials, resins for adsorption and ion exchange and elastomers such as rubber and silicones;

Taking into account that Resolution CM/Res(2013)9 and the applicable Technical Guide on metals and alloys used in food contact materials and articles are widely recognised and used as a reference for the safety and quality of such materials and articles;

Being convinced that each member State would benefit from harmonised state-of-the-art quality requirements and test procedures, described in the Technical Guides and published under the aegis of the EDQM,

Recommends to the governments of States Parties to the Convention that, in the absence of the specific measures referred to in Article 5 of Regulation (EC) No. 1935/2004, they adopt suitable legislative and other measures aimed at reducing the health risks arising from human exposure to constituents released from materials or articles for contact with food according to the appended "Guiding Principles for food contact materials and articles" and the Technical Guides published under the aegis of the EDQM to supplement this resolution. Likewise, in cases considered appropriate by the national competent authorities, the Committee of Ministers recommends that they apply these principles to materials and containers for pharmaceutical use in the absence of dedicated standards. This resolution shall not prevent governments from maintaining or adopting national measures that implement stricter or different rules and regulations.

Agrees that the CD-P-MCA, taking into account scientific or regulatory developments or needs, will update, as necessary, the appendix "Guiding Principles for food contact materials and articles" and the Technical Guides, published under the aegis of the EDQM to supplement this Resolution.

Appendix: Guiding principles for food contact materials and articles

1. Purpose and Scope

Resolution CM/Res (2020)9, its Guiding Principles and the supplementary Technical Guides contribute to the protection of human health by ensuring, as defined in relevant European legislation, i.e. Regulation (EC) No. 1935/2004, the safety and quality of food contact materials and articles that are not covered by specific European legal provisions or other measures, e.g. at the European Union (EU) level. The resolution therefore complements European legislation taking into account Council of Europe member States' legislations or recommendations. This appendix provides general guidance, e.g. on the use of substances in the manufacture of food contact materials and articles, labelling of these materials and articles and the need for a declaration of compliance and supporting documentation. It applies to all food contact materials and articles under the scope of the resolution. The Technical Guides specify the requirements (or derogations from the principles stated hereafter) for particular types of materials, such as paper and board or metals, and testing.

2. Definitions

The definitions of Regulation (EC) No. 1935/2004 and, where appropriate, of Regulation (EU) No. 10/2011, apply in the context of the resolution, the Guiding Principles and the applicable Technical Guides.

In addition, the following definitions apply:

- *Food contact*: direct (physical) contact or indirect (through the gas phase or through different packaging components or layers in a multi-layer material) contact of a food contact material or article with a food.
- *Officially evaluated substances*: substances for which risk assessment has been carried out according to the principles stated under section 4, by a competent authority of a Council of Europe member State or a relevant European authority.

- *Overall release limit (ORL)* or *overall migration limit (OML)*:[2] the maximum permitted amount of non-volatile substances released from a material or article into food simulants.
- *QM*: the maximum permitted quantity of a substance in the final material or article expressed as mass per mass concentration.
- *QMA*: the maximum permitted quantity of a substance in the final material or article expressed as mass per surface area in contact with food.
- *(Quantitative) structure-activity relationship models ((Q)SAR models)*: theoretical models that can be used to quantitatively or qualitatively predict the physicochemical, biological (e.g. an (eco) toxicological endpoint) and environmental fate properties of compounds from the knowledge of their chemical structure.[3]
- *Specific release limit (SRL)*[4] or *specific migration limit (SML)*: the maximum permitted amount of a given substance released from a material or article into food or food simulants.

3. General Requirements

Food contact materials and articles shall comply with Regulation (EC) No. 1935/2004 and Regulation (EC) No. 2023/2006, or with relevant national legislation. Under normal or foreseeable conditions of use, they shall not transfer their constituents to food in quantities which could:

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2 The term 'OML' is especially used in connection with polymeric materials (e.g. plastics), whereas the term "release" is understood to designate any mechanism of substance transfer from a food contact material and article to food. In the context of these Guiding Principles the general term 'release' is used for substance transfer from food contact materials and articles to food, including polymeric materials.

3 Practical Guide – How to use and report (Q)SARs, ISBN: 978-92-9247-809-4, European Chemicals Agency, 2016. Available online at https://echa.europa.eu/documents/10162/13655/pg_report_qsars_en.pdf.

4 The term 'SRL' was introduced in the context of metals and alloys used in food contact materials. Whereas the more general term 'release' may be applied to various materials, the term 'migration' is especially used in connection with polymeric materials (e.g. plastics), where release is commonly dominated by physical processes such as diffusion.

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

In addition, food business operators shall ensure that they use food contact materials and articles during food production or preparation, storage and distribution in a way that does not compromise compliance with applicable Council of Europe Technical Guides, EU and member States' legislation or recommendations for food contact materials and articles.

3.1. *Substances used in the manufacture of food contact materials and articles*

In the manufacture of food contact materials and articles, substances may only be used after risk assessment has been performed according to the principles stated hereafter under section 4; assessment includes consideration of impurities, reaction and/or degradation products.

Substances can be used in the manufacture of food contact materials and articles, in compliance with any restrictions applicable to them, if they meet any of the following criteria:

a. they are approved by competent authorities of the Council of Europe member States concerned, in accordance with the procedures for the elaboration of lists of officially evaluated substances; or
b. their use is in compliance with material-specific provisions in EU or national legislation or official recommendations, as specified in the applicable Technical Guide; or
c. absence of their release into food and absence of release into food of their impurities, and known or foreseeable reaction or degradation products can be demonstrated by a method of analysis in accordance with Article 34 of Regulation (EU) No. 2017/625 or relevant national legislation with a limit of detection not higher than 0.01 mg/kg. This limit shall apply to groups of compounds if they are structurally and toxicologically related, in particular isomers or compounds with the same relevant functional group.

In the case of substances, their impurities and known or foreseeable reaction or degradation products that belong to any of the following categories and meet criterion 3.1 c, demonstrating absence of release is not sufficient and therefore a specific risk assessment must be performed:

- substances in nano-form;[5]
- substances classified as "mutagenic", "carcinogenic" or "toxic to reproduction" in accordance with the criteria set out in sections 3.5, 3.6 and 3.7 of Annex I to Regulation (EC) No. 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures;
- substances which are assessed to be genotoxic or predicted to be genotoxic using (Q)SAR models if valid data (e.g. complying with the European Food Safety Authority's (EFSA) criteria) confirming absence of genotoxicity are not available.

Criterion 3.1 c applies without prejudice to applicable European and national provisions or the provisions set out in the applicable Technical Guide.

d. When none of the criteria a, b and c are met and without prejudice to applicable European and national provisions, or the provisions set out in the applicable Technical Guide, substances may be used in the manufacture of food contact materials and articles, if they are risk-assessed in accordance with section 4 by or on behalf of the responsible business operator and incompliance with Article 3 of Regulation (EC) No. 1935/2004 or relevant national legislation.

3.2. *European Committee for Food Contact Materials and Articles (CD-P-MCA)*[6]

The CD-P-MCA, in accordance with its terms of reference and resources permitting, prepares technical guidance that supplements the Guiding Principles of the resolution. Further to section 3.1 a, the Committee agrees on the procedures for creating, publishing and updating lists of officially evaluated substances.

5 Nanomaterials as defined in Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterials (OJ L 275, 20.10.2011, p. 38).

6 CD-P-MCA stands for Steering Committee – Partial Agreement – European Committee for Food Contact Materials and Articles (*Comité directeur – Accord partiel – Comité européen sur les matériaux et objets pour contact alimentaire*).

When new substances are subject to assessment and/or authorisation for use in the manufacture of food contact materials and articles, member States are advised to share relevant information with the CD-P-MCA with a view to updating any lists of evaluated substances as indicated in 3.1 a.

3.3. *SML, SRL, OML, ORL, QM and QMA*

1. Food contact materials and articles should not transfer their constituents to foodstuffs or food simulants in quantities exceeding the limits set out in the applicable Technical Guides (i.e. specific or overall release or migration limits or restrictions for the material composition to limit the amount of certain components referred to as “QM” and “QMA”).
2. Unless otherwise specified, a generic SML or SRL of 60 mg/kg applies to those substances listed in the applicable Technical Guide for which no specific release or migration limit or other restrictions are provided.

4. Risk Assessment

The safety of substances used in food contact materials and articles shall be evaluated in accordance with internationally recognised scientific principles on risk assessment, and with, where appropriate, EFSA guidance.[7] The safety evaluations shall also take into account impurities and known or foreseeable reaction and degradation products.

The risk assessment should be reviewed whenever relevant composition or process changes are implemented or new scientific or other data become available.

5. Labelling

Food contact materials and articles not yet in contact with food when placed on the market shall be labelled in accordance with Article 15 of Regulation (EC) No. 1935/2004 or relevant national legislation to ensure

7 Note for guidance for the preparation of an application for the safety assessment of a substance to be used in plastic food contact materials:
https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2008.21r;
https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2011.2379;
https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.5113.

safe and appropriate use. The label shall be sufficiently clear to avoid any misuse or misinterpretation. It shall not mislead consumers and not rule out reasonably foreseeable uses of repeated use articles.

6. Traceability

Traceability of food contact materials and articles shall be ensured at all stages in accordance with Articles 15 and 17 of Regulation (EC) No. 1935/2004 or relevant national legislation.

7. Good Manufacturing Practice

Food contact materials and articles shall be manufactured in accordance with Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food, or with relevant national legislation. If appropriate, guidelines on good manufacturing practice developed by trade and producer associations can also be taken into account without prejudice to any applicable member State legislation.

8. Compliance Documents

8.1. *Documents supporting compliance and safety (supporting documentation)*

Appropriate documentation, demonstrating that food contact materials and articles under the scope of the resolution comply with the requirements applicable to them, must be available from each business operator along the supply chain. It should be compiled as "supporting documentation" and provided to the competent authorities on request, without undue delay.

The supporting documentation is a record, especially of:

- the substance(s) used and corresponding risk assessment (including reference to relevant legislation or recommendation), the process(es) applied, and the reaction(s) and treatment(s) performed;
- the safety of released substances, including impurities and reaction and degradation products, and evidence for compliance with the applicable

requirements supported with data or other adequate reasoning, taking into account the level of release or migration under the most severe conditions of use;

- if applicable, the conditions and results of migration/release testing, i.e. the description of the applied methods and other relevant information, calculations (including modelling), toxicological test descriptions and data as well as the reasoning used for the conclusion.

The supporting documentation may be confidential; however, protection of information in the documentation must not compromise the safety of food contact materials and articles and must not prevent a business operator from disclosing safety information related to released substances and conditions of use in the declaration of compliance.

8.2. *Declaration of compliance*

Food contact materials and articles under the scope of the resolution are to be accompanied by a declaration of compliance.

The declaration of compliance means that the manufacturer of the food contact material or article assumes responsibility for the suitability for food contact, including the safety of all released substances or, whenever applicable, explicitly informs the next business operator in the supply chain of the compliance work that needs to be completed. The declaration also specifies the limitations to the applications of the food contact material or article, any further processing and treatments as well as conditions of food contact and is based on the documentation referred to under 8.1.

The declaration of compliance provides all relevant information to enable subsequent business operators along the supply chain to carry out any additional compliance work in order to deliver safe and compliant food contact materials and articles.

A declaration of compliance is issued at all stages of the supply chain. It is available at all marketing stages, other than the retail stage, and includes, at least (if applicable):

a. the identity and address of the business operator issuing the declaration of compliance;
b. the date the declaration was issued;

c. the identity and address of the manufacturer or importer of the food contact material/article;
d. the identity of the food contact material/article (final or intermediate) or substance intended for the manufacture of the said material/articles (chemical name or description and trade name);
e. confirmation that the food contact material or article (final or intermediate) or substance intended for the manufacture of any material or article complies with the applicable legal or other relevant provisions and requirements laid down in the Guiding Principles and in the applicable Technical Guide;
f. specifications and conditions ensuring safe use of the food contact material/article (e.g. types of foods for which it can be used, maximum temperature, duration of contact, repeated or single contact, the highest food contact surface area to volume ratio for which compliance has been verified);
g. whenever applicable, a statement that the substances used are specified:

   i. in the corresponding Council of Europe list of officially evaluated substances; or
   ii. in European or national legislation or official recommendations as referenced in the applicable Technical Guide, providing the exact reference;

h. whenever applicable, a statement that:

   i. risk assessment has been performed by or on behalf of the business operator for substances that are detailed in the supporting documentation;
   ii. the use of these substances does not infringe relevant EU or national legislation or official recommendations;
   iii. the use of these substances is not in conflict with the provisions set out in the applicable Technical Guide;

i. adequate information on the substances used, impurities and reaction and degradation products for which restrictions and/or specifications apply;
j. adequate information on the substances which are subject to a restriction regarding their use in food (dual use additives);

k. information on substances used, impurities and reaction and degradation products, including those known or foreseen to be generated at later production stages, for which the business operator has identified that further compliance work needs to be conducted at the next stages in the supply chain.

If necessary, additional requirements or derogations for particular types of food contact materials/articles may be specified in the applicable Technical Guides.

The declaration is renewed whenever substantial changes are made to the composition or to the production process that may affect the compliance of materials/articles, or in response to relevant scientific or regulatory developments.

9. Compliance Testing

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.

Tests on release from the material or article into foodstuffs are carried out under the reasonable worst-case conditions during manufacture, storage, distribution and normal or foreseeable use, with respect to time, temperature and composition of the foodstuff.

When it is not feasible or not practical to test release into foodstuffs, food simulants are used to imitate the respective foodstuffs. The food simulants and conditions of contact are selected in such a way that release is at least as high as into food. Specifications for the choice of simulants and test conditions may be laid down in the relevant Guidelines of the Joint Research Centre (JRC) of the European Commission and the applicable Technical Guides.

For verification of compliance with the SML or SRL, solely release from food contact materials and articles (not contamination from any other sources) is taken into account.

10. Technical Guides

The Technical Guides supplementing the resolution[8] cover specific and detailed material requirements and principles as regards the safety and quality of food contact materials and articles.

Technical Guides may cover the following areas:

- general provisions (especially purpose/scope, additional definitions);
- specific requirements (or derogations from general principles) related to the particular material, including particular labelling requirements, if applicable;
- if applicable, officially evaluated substances used for the manufacture of the particular type of food contact material or article including relevant restrictions and specifications applicable to them;
- if applicable, material-specific provisions in European or national legislation or official recommendations;
- testing conditions and methods of analysis;
- additional information relating to supporting documentation and declaration of compliance, if applicable.

Technical Guides are published under the aegis of the EDQM and will be regularly updated, as necessary, by the CD-P-MCA.

8 Technical Guides are available on the EDQM Website.

Abbreviations used in this Technical Guide

ADI	Acceptable Daily Intake
AI	Adequate Intake
ANSES	(formerly AFSSA) Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (French Agency for Food, Environmental and Occupational Health & Safety)
ALARA	As Low As Reasonably Achievable
ATSDR	Agency for Toxic Substances and Disease Registry
BfR	Bundesinstitut für Risikobewertung (German Federal Institute for Risk Assessment)
BMD	Benchmark dose
BMDL	Benchmark dose lower confidence limit
BW	Body Weight
CD-P-MCA	European Committee for Food Contact Materials and Articles
CEN	Comité européen de normalisation (European Committee for Standardization)
CONTAM	Panel on Contaminants in the Food Chain (EFSA)
COT	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (UK)
EC	European Commission
EFSA	European Food Safety Authority

EPA	Environmental Protection Agency (USA)
EVM	Expert Group on Vitamins and Minerals (UK)
FAO	United Nations Food and Agriculture Organisation
FCM	Food Contact Material(s)
FSA	Food Standards Agency (UK)
FSS	Food Standards Scotland (UK)
GMP	Good Manufacturing Practice
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IPCS	International Programme on Chemical Safety
ISO	International Organization for Standardization
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JRC	Joint Research Centre (EC)
LB	Lower Bound
LOAEL	Lowest Observed Adverse Effect Level
LOD	Limit of Detection
LOQ	Limit of Quantification
MOE	Margin of Exposure
NDA	Scientific Panel on Dietetic Products, Nutrition and Allergies (EFSA)
NOAEL	No Observed Adverse Effect Level
PDE	Permitted Daily Exposure (as used in the ICH Guideline on elemental impurities, ICH Q3D(R1))
P(M)TDI	Provisional (Maximum) Tolerable Daily Intake
PTMI	Provisional Tolerable Monthly Intake
PTWI	Provisional Tolerable Weekly Intake
RASFF	Rapid Alert System for Food and Feed

REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RfD	Reference Dose (established by EPA – maximum acceptable oral dose of a toxic substance derived from the NOAEL)
RIVM	Rijksinstituut voor Volksgezondheid en Milieu (Dutch National Institute for Public Health and the Environment)
SCF	EU Scientific Committee on Food
SR	Specific Release
SRL	Specific Release Limit
SML	Specific Migration Limit
TDI	Tolerable Daily Intake
TRV	Toxicological Reference Value
TWI	Tolerable Weekly Intake
UB	Upper Bound
WHO	World Health Organization

Chapter 1 – General provisions and specific release limits for metals

Introduction

Metals and alloys are used in FCM 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 with a coating to reduce ion release into foods.

Metal ions can be released from materials into food and may endanger the health of the consumer if the intake exceeds the TRV, 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

This 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 FCM made from metals and alloys, with a view to harmonising regulations and enforcement activities at the European level.

Safety reviews of individual metals and the restrictions defined for metals and alloys used in FCM 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 Resolution CM/Res(2020)9 and the updating of the Technical Guide. Their representatives in the European Committee for Food Contact Materials and Articles (CD-P-MCA) are experts in the area of FCM or are 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, this Technical Guide has not been submitted for approval in view of its technical nature and the need for timely updates.

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

Experts from national authorities, the JRC, industry, private testing laboratories and other stakeholders continue to share their knowledge and expertise and to contribute to the updating of this Technical Guide.

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

Council of Europe technical guides are not legally binding for member states, but serve as a reference for the implementation of Article 3 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. It is important for business operators to refer to the national law in the market onto which they intend to place the item.

1 Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Republic of Moldova, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Türkiye, Ukraine and United Kingdom.

Definitions, scope and specific release limits

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 FCM 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, made completely or partially of metals and alloys, coated* or uncoated, 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.

> *Note: For metals and alloys used in FCM and articles that are covered with an organic surface coating that has been demonstrated to restrict release of metal ions to less than the applicable SRL, routine testing for compliance with this Technical Guide may be omitted.

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. materials and articles which are supplied as antiques;
b. ceramics, enamels, crystal glass, printing inks, polymerisation aids and other types of FCM that are either covered by specific legislation in the EU or at national level or by Council of Europe resolutions;
c. FCM that were designed to release certain substances into the food (so-called ‘active FCM’); such materials have been addressed in EU legislation on active FCM [Regulation (EC) No 1935/2004 and Regulation (EC) No 450/2009];
d. fixed public or private water supply equipment.

Contribution to the total intake of metal ions due to sources of exposure other than metals and alloys used in FCM and articles has been taken into consideration by applying allocation factors, where appropriate, when deriving SRLs.

3. Labelling

In addition to the requirements in Article 5 of Resolution CM/Res(2020)9, manufacturers of metallic FCM 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 of unintentional release.

Cleaning methods, temperature and storage time are known to influence the release of metal ions from metals and alloys used in FCM 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 selecting cleaning and disinfection regimes to ensure that the integrity of the FCM and/or the organoleptic properties of the food are not compromised, and 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 latest version of the guidelines on Testing conditions for kitchenware articles in contact with foodstuffs: *Plastics, Metals, Silicone & Rubber* (Beldi *et al.*, 2021).

The labelling could, for example, state:

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

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

Remarks: *It should be recognised that industrial use and household use of FCM 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 FCM (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

FCM and articles within the scope of this Technical Guide comply with the SRLs set out below in Tables 1 and 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*
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), see Chromium (Cr) in Chapter 2.

† See See Chapter 3, Annex II for information on applying a reduction factor when assessing the compliance of cutlery made from silver and silver-plated cutlery.

‡ Except in the field of application under Commission Regulation (EU) 2023/915.

§ The generic SRL 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

Establishing an SRL

Toxicological information, the ALARA principle, where appropriate, and relevant legislation are considered. Each metal ion requires a specific approach for setting an SRL, avoiding either over-conservative SRLs or meaningless and unachievable limits.

The following criteria are also considered when defining an SRL:

- appropriate TRVs (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 FCM as one possible source for the human exposure (next to food and dietary supplements): expressed as percentage of the TRV;
- actual release data: rather than setting an SRL on the basis of TRVs, 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 are taken into consideration to avoid conflicts between standards.

Based on the above criteria, the following model approach was used to set SRLs for metals used in FCM:

Criterion 1: appropriate TRVs 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 TRV and a variable, justified allowance in the case of a gap between worst-case oral intake (95th percentile) and the TRV.

Examples in this Technical Guide: *Cu, Mo* and *Zn*.

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

Example in this Technical Guide: *Al*.

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

Calculation of the SRL: based on the TRV and a fixed allowance of 20%, which is in agreement with the WHO Guidelines for Drinking-water Quality (WHO, 2022).

Examples in this Technical Guide: *Co* and *Ni*.

Criterion 3: appropriate TRVs 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 Technical Guide: *Ag* and *V*.

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

Example in this Technical Guide: *Fe*.

Criterion 4: Metals without an SRL.

Setting an SRL 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 TRV, which is applied independently of oral intake data with the exception of Cd (25% allowance) and Pb (26% allowance).

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

Criterion 6: appropriate TRVs exist, but actual release data show much lower release when using GMP.

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

Example in this Technical Guide: *Cr*.

Updating of this 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) are also taken into account, as well as national legislation on the composition of metals and alloys.

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Chapter 2 – Safety review and recommendations

Metals and alloy components

The following metals are relevant metals and alloy components used in FCM 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. It 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. Aluminium is often used in alloys with copper, magnesium, manganese, and zinc (Yokel and Sjögren, 2022).

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 and juices to around 5 mg/kg in tea (AGES, 2017; EFSA, 2008; Kolbaum *et al.*, 2019; Tietz *et al.*, 2019). Exceptionally high aluminium content has been found in spices, mussels, nuts, legumes and oilseeds (around 30-244 mg/kg, with the highest content in spices, Tietz *et al.*, 2019). Due to processing or the use of aluminium-containing food additives, the 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 restricted by Regulation (EC) No 1333/2008, as amended, to a limited number of foodstuffs.

Mean dietary exposure from water and food in non-occupational exposed adults showed large variations between 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 bw/week. In children, estimated exposure at the 97.5th percentile ranged from 0.7 to 1.7 mg/kg bw/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 bw/week (mean – 95th percentile), and for children (3-14 years) of 0.44-0.83 mg/kg bw/week. In 2016, ANSES estimated a weekly intake for infants (0-3 years) from food of 0.21-0.62 mg/kg bw/week (mean – 90th percentile). The 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 as 0.18-0.44 mg/kg bw/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 (ANSES, 2011; Kolbaum *et al.*, 2019; Tietz *et al.*, 2019). However, the main food groups accounted for only around 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). The Istituto Superiore di Sanità (ISS) estimated the aluminium exposure of Italian consumers from the use of aluminium FCM to be in the range of 0.06-0.68 mg/kg bw/week for children and adolescents and in the range of 0.07-0.39 mg/kg bw/day for adults (Feliciani *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 routes (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 in earlier studies (SCCS, 2020).

Metallic food contact materials

Aluminium is widely used in food preparation and storage such as in cookware, coffee pots, beverage cans (Yokel and Sjögren, 2022) and in packaging such as food trays. Aluminium FCM are often coated with a resin-based coating. Aluminium alloys for FCM 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

Aluminium can be found in glass containers and plastic FCM (Yokel and Sjögren, 2022).

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. 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 FCM if the coating does not act as a functional barrier. Release of aluminium from FCM 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; Mei *et al.*, 1993; Müller *et al.*, 1993; Nagy *et al.*, 1994) but values up to 5 mg/L were 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 (Gramiccioni *et al.*, 1996; Hughes, 1992).

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.*, 1987). Typical values for release of aluminium from foil was < 0.05 mg/dm² at 5°C and 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.*, 1987). 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 the cook and chill process. In a similar study, using a wide range of commercially prepared foods that are typically served (stored and heated) in aluminium trays, Nehring (2018) showed that the release of Al can be kept below 5 mg/kg in most foods, with the exception of aggressive ones (sausage salad with a vinegar-based brine, tomato sauce and tomato soup). For the same food, the study showed large deviations between different aluminium trays that could be attributed either to the quality of aluminium or to the applied contact surface to volume ratio.

Safety aspects

- In 1988, JECFA established a PTWI of 7 mg/kg bw/week for total aluminium intake, including food additive uses of aluminium salts, which was subsequently lowered to 1 mg/kg bw/week in 2006 (JECFA, 1989, 2006). In light of new data, JECFA reassessed aluminium in 2011 and introduced a new PTWI of 2 mg/kg bw/week based on a NOAEL of 30 mg/kg bw/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 bw based on the same NOAEL of 30 mg/kg bw per day.
- WHO (2022) 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'.
- Directive (EU) 2020/2184 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%) excreted via urine (Priest, 1995). Unexcreted aluminium is distributed into all tissues, and accumulation takes place especially in the bones, muscles, kidneys 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. WHO (IPCS, 1997) concluded that a causal relationship between aluminium intake and Alzheimer's disease could not be inferred from these studies.

- In 2008, EFSA confirmed the PTWI of 1 mg/kg bw/week previously established by JECFA in 2006. In 2018, EFSA reviewed new toxicological evidence but not with the aim of revising the health-based guidance value for aluminium set by EFSA in 2008.

Conclusions and recommendations

the SRL for aluminium of 5 mg/kg food or food simulant 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 bw/week (Tietz *et al.*, 2019) and the TDI of 0.3 mg/kg bw/day accepted by SCHEER (2017). Certain FCM and articles contribute to the dietary intake of aluminium. Therefore, it is recommended that the SRL for aluminium be set at ALARA level. Such an approach ensures that the manufacturer will apply measures to prevent and reduce the release of aluminium from FCM 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 SRL should be subject to regular review to take account of the advance of scientific and technical knowledge and improvements in GMP.

Based on the current state of the art and available release data from uncoated aluminium FCM (Feliciani *et al.*, 2019), such food contact articles can be safely used in various applications. It is nevertheless 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, Article 15 1(b)).

It should be noted that FCM 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 of the FCM 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 icon shown below (or equivalent)[1]

and the following statement: **DO NOT USE WITH**: ACIDIC FOOD (e.g. peeled fruit, tomatoes, pickles, salad dressing) – SALTY FOOD (e.g. pretzels, white herring, cured meats).

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1 The icon shown was developed by the European Aluminium Foil Industry and can be downloaded from the website www.label.alufoil.org.

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Antimony (Sb)

Antimony is naturally present in the Earth's crust and 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 the element and its compounds (ATSDR, 1992).

Sources and levels of intake

Antimony is detected in most foods. The highest concentrations were measured in meat products (9.9 µg/kg), sugar (8.8 µg/kg), chocolate (4.2 µg/kg), cakes (3.8 µg/kg) and fish (2.6 µg/kg) (ANSES, 2011).

In the 2014 UK 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 'Milk' 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 (e.g. Britannia metal).

European Standard EN 610:1995 applies to tin and tin alloy 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 an SML 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 Fiche MCDA n°1 (V02 – 01/04/2017).

Other food contact materials

Antimony is used in fire-proofing agents in textiles and plastic materials where antimony trioxide acts as a synergist with organochlorine and bromated compounds. It is further used as an opacifying agent in glass, ceramics and enamels, as a pigment in colourants and as a chemical catalyst (IARC, 1989).

Release

During storage of mineral water in PET bottles, the catalyst antimony trioxide (Sb_2O_3, 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 therefore do not raise concern.

Safety aspects

- WHO (2022) set a guideline value of 0.02 mg/L derived from a TDI of 0.006 mg/kg bw/day (0.36 mg/day). This value was based on a NOAEL of 6 mg/kg bw/day from a subchronic, drinking-water study in rats, presenting decreased bw gain and reduced food and water intake. An uncertainty factor of 1 000 (100 for intraspecies and interspecies variation and

10 for the use of a subchronic study) was applied to the NOAEL, resulting in the TDI of 0.006 mg/kg bw/day (WHO, 2003).

- EFSA (2004) set an SML of 0.04 mg/kg for antimony based on the TDI derived by WHO. This value was also adopted by Regulation (EU) No 10/2011.

Conclusions and recommendations

the SRL for antimony is set at 0.04 mg/kg food or food simulant

The SRL was derived from the TDI of 0.006 mg/kg bw/day (0.36 mg/day) assessed by WHO (2003, 2022). Depending on the metallic material, antimony can be considered either as an alloying constituent or an impurity. In order not to weaken consumer protection, it was concluded that an allowance of 10% of the TRV was reasonable. Therefore, assuming that a person of 60 kg bw consumes 1 kg of foodstuffs per day that is packaged and/or prepared with FCM 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 countries such 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 *et al.*, 1980). In most soils and bedrocks, chromium is immobilised in the trivalent state (Florence *et al.*, 1980). Cr(III) is an essential element to humans. 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, 2003; Oskarsson and Sandström, 1995). Chromium is present in the diet mainly as Cr(III) (EVM, 2003). According to the EVM (2003), most of the chromium in food originates from food processing using stainless steel food processors and containers. The EFSA 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 and 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 LB of 0.6 to a maximum UB of 5.9 µg/kg bw/day. The 95th percentile dietary exposure values ranged from 1.1 (minimum LB) to 9.0 (maximum UB) µg/kg bw/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 [sum of Cr(III) and Cr(VI)] 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. Ferrochromium, an alloy of chromium and iron, is produced by direct reduction of the chromite ore and used primarily in manufacturing stainless steel and heat-resistant steel (Sun and Costa, 2022). All stainless steels contain chromium (minimum 10.5% – see section on Main types of alloys) and they are important FCM 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 slaughterhouses, 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, 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 is contained in pigments used for coloured glazes and for metal finishing (Sun and Costa, 2022).

Release

Limited information on the release of chromium from metals and alloys used in FCM and articles was available before the publication of this Technical Guide. 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 *et al.*, 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 and 0.315 mg/kg (Kuligowski and Halperin, 1992). Further, in a market survey of stainless steel cutlery conducted by the German surveillance authorities, elevated levels of chromium of 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).

Release of chromium from a range of seven stainless steel grades used as FCM was examined (using food simulant 5 g/L citric acid, pH 2.4 and 1 cm^2 in 2 mL test medium) after exposure for 2 hours at 70°C followed by 24 and 238 hours at 40°C. Chromium release for all stainless steel grades and test conditions investigated were below the applicable SRL (0.25 mg/kg) and did not exceed 0.2 µg/cm^2. Chromium was released in its trivalent form (Hedberg *et al.*, 2014). The study was extended using as-received and pre-passivated 6 cm^2 specimens and three different simulants; artificial tap water, 5 g/L citric acid and 5 g/L citric acid + 0.5 M NaCl (conditions: 2 hours at 70°C followed by 10 days at 40°C). Chromium release was close to the detection limits for all grades in artificial tap water. Higher release was observed in citric acid, but did not exceed the SRL and release was noted to reduce with time (Mazinanian *et al.*, 2016).

Another study assessed the release of chromium into tomato sauce and lemon marmalade from 18/10 stainless steel pots from different manufacturers. Cooking conditions were 1 hour with or without added EDTA; aqueous solutions at pH 2.3, 7.7 and 9 were also boiled for 1 hour in the same pots. The release of chromium increased with cooking/boiling time, was higher with unused pots, at low pH or with EDTA, and was noted to vary between manufacturers but was in all cases found below 0.3 mg/kg (Guarneri *et al.*, 2017).

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

Safety aspects

- JECFA has not evaluated chromium.
- WHO (2022) established a guideline value of 0.05 mg/L for total chromium.
- 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; Oskarsson and Sandström, 1995). Cr(III) has low toxicity due to low absorption (about 0.5%) (Oskarsson and Sandström, 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 (Oskarsson and Sandström, 1995).
- The 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/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 bw/day was not expected to result in adverse effects. This is based on a dose of 15 mg Cr/kg bw/day, administered as chromium chloride to rats that did not

show adverse effects. An uncertainty factor of 100 was used (10 for inter-species and 10 for intraspecies 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'. They noted that both the limit of 1 mg chromium/day proposed by the SCF and of 250 µg chromium/day for supplementation proposed by WHO were 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, they concluded that 'until more is known about chromium, the value set by 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(R1), the oral chromium PDE is 10 700 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 or Cr(III) rather than the more toxic Cr(VI)); therefore, for drug products, this safety assessment is based on the known toxicity of Cr(III) and Cr(VI) is excluded from the assessment. In 2014, the EFSA CONTAM Panel derived a TDI of 0.3 mg/kg bw/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 $BMDL_{10}$ of 1 mg/kg bw/day from a carcinogenicity study in mice as an appropriate 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 food or food simulant

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 in water is negligible. Therefore, release of Cr(VI) from stainless steel FCMs into 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). In summary, 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 bw/day for Cr(III) that was derived by EFSA (2014), a 20% allocation factor and the conventional assumption that a person of 60 kg bw consumes 1 kg of foodstuffs per day that is packaged and/or prepared using FCM made from metals and alloys, the SRL for Cr(III) could be set at up to 3.6 mg/kg food. However, based on the current state of the art in the production of FCM, the limit of 1 mg/kg is fully achievable. In line with GMP, the SRL for total Cr 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 ($BMDL_{10}$ of 1 mg/kg bw/day, a MOE of 10 000, a person of 60 kg bw consuming 1 litre 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, often occurring in association with nickel, silver, lead, copper and iron ores (Lison, 2022). Cobalt is present in the vitamin cobalamin or vitamin B12.

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 0.1-0.7 mg/kg on a moisture-free basis (Beliles, 1994).

ANSES (2011) estimated mean daily intake at 0.18 µg/kg bw/day in adults and 0.31 µg/kg bw/day in children.

Metallic food contact materials

A major use of cobalt is in the production of steel and alloys of a high melting point and resistant to oxidation (Lison, 2022). 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 as a constituent of vitamin B12. The human body (adult, 70 kg) contains on the average 1.1 mg cobalt, 85% of which is in the form of vitamin B12 (Lison, 2022). Oral bioavailability of inorganic cobalt compounds is reported to vary from 5-45% (Lison, 2022). A marginal part of refined cobalt is used in fertilisers, since a low cobalt concentration in soil may cause cobalt deficiency in sheep and cattle (Lison, 2022). Even though cobalt is essential to humans and animals, a few cases of poisoning have been recorded. Heart failure, polycythemia and thyroid lesions are common findings and, in the worst cases, death were seen after intakes of cobalt via large amounts of contaminated beer (cobalt is used to prevent fermentation) (Lison, 2022).
- 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 salt, the classification of cobalt in SCF-List 3 with a restriction of 0.05 mg/kg. This value has been adopted in 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 EVM. While there was insufficient data to establish a safe upper level, they suggested an intake of 0.023 mg/kg bw/day would not be expected to produce adverse effects. This was based on animal data showing minor testicular effects at 23 mg Co/kg bw/day

with a total uncertainty factor of 1 000 (10 for extrapolation from a LOAEL to a NOAEL and 10 for interspecies and 10 for intraspecies variation).

- RIVM (2001) derived a TDI of 0.0014 mg/kg bw/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 food or food simulant

The TDI established by RIVM in 2001 was derived from human data. Since European intake data are scarce, the default allowance of 20% for exposure through FCM and articles made from metals and alloys was applied to the TDI of 0.0014 mg/kg bw/day. Assuming that a person of 60 kg bw consumes 1 kg of foodstuffs per day that is packaged and/or prepared with FCM 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). It exists in two oxidation states: Cu(I) (cuprous) and Cu(II) (cupric), although it can also occur in a trivalent state due to certain chemical reactions. Copper is amongst the most effective of metal biochemical oxidising agents. It is an essential yet toxic trace element (Birk Møller and Aaseth, 2022). 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, fruits, nuts and green vegetables (Birk Møller and Aaseth, 2022). However, levels of up to 39 mg/kg have been reported for liver and cocoa.

In the European Union Risk Assessment Report, copper exposure from food and beverages, estimated from a wide range of duplicate diet studies and market basket analysis consistently shows copper intakes of < 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.

EFSA (2015) derived AIs based on observed intake in several EU countries. Mean copper intakes in eight EU countries ranged from 1.27 to 1.67 mg/day in men aged 18 years and older and from 1.15 to 1.44 mg/day in non-pregnant women aged 18 years and older. They noted that there was insufficient evidence at the time to set different dietary reference values according to age in adults, but decided to set different AI values for women (1.3 mg/day or 1.5 mg/day for pregnant and lactating women, respectively) and men (1.6 mg/day), as intakes are lower for women. Similarly, based on the observed intakes they concluded the following AIs for infants (0.4 mg/day), for boys and girls aged 1 to < 3 years (0.7 mg/day), for boys and girls aged 3 to < 10 years (1.0 mg/day), for boys aged 10 to < 18 years (1.3 mg/day) and for girls aged 10 to < 18 years (1.1 mg/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, chocolate, dry vegetable, jam and sweet 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

Powders, flakes and fibres of brass, bronze, copper, stainless steel, tin, iron and alloys of copper, tin and iron (FCM number 80), copper iodide (FCM number 412), copper bromide (FCM number 523), or copper hydroxide phosphate (FCM number 972) are authorised for use as additives in plastic FCM under Regulation (EU) No 10/2011, with a limit of migration set at 5 mg/kg food.

Release

Copper is slowly attacked by dilute hydrochloric acid or dilute sulfuric 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 FCM, 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 bw/day from all sources and set a dietary requirement of 0.05 mg/kg bw/day.
- WHO (2022) 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 (IPCS/WHO, 1996).
- The SCF (2003) derived a tolerable upper limit for adults of 5 mg/person/day from a dietary supplementation study, which EFSA adopted as upper limit in 2006. 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. For children aged 1-3 years, an upper limit of 1 mg/day was derived, taking into consideration their lower bw. In the context of the peer review process of plant protection products, EFSA (2008) established an ADI of 0.15 mg Cu/kg bw per day (corresponding to 10 mg/day for a 70-kg adult). This ADI value was confirmed by EFSA in 2018.
- The EVM (2003) assessed copper and derived a safe upper level of 0.16 mg/kg bw/day based on a NOAEL of 16 mg/kg bw/day in a subchronic rat toxicity study and using an uncertainty factor of 100.
- According to ICH Q3D(R1), the oral PDE for copper is 3 400 µg/day. Copper compounds (e.g. copper chromite) are used as catalysts in hydrogenolysis and decarboxylation reactions.

- In 2008, the copper industry submitted a voluntary risk assessment report to the EC, 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 bw/day was derived from a 90 day subchronic 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 bw/day was set as (derived) NOAEL, corresponding to 11.4 mg/day for a person of 70 kg bw (EU-RAR, 2008).

Conclusions and recommendations

the SRL for copper is set at 4 mg/kg food or food simulant

This SRL was derived from the ADI of 0.15 mg/kg bw/day (10 mg/day) assessed by EFSA (2008, 2018). 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 FCM made from metals and alloys.

Consequently, assuming that a person of 60 kg bw consumes 1 kg of foodstuffs per day that is packaged and/or prepared with FCM 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 the SCF (2003) and EFSA (2006) because of the negligible exposure of children to FCM and articles made out of copper (Foster *et al.*, 2010).

Release due to traditional use, as outlined earlier, falls outside the scope of this SRL.

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Iron (Fe)

Fe

Iron is the fourth most abundant element (5%) in the Earth's crust (Tenenbein and Huang, 2022). 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, the iron content of foodstuffs varies greatly from iron-rich foods such as red meat to extraordinarily iron-poor foods such as milk (Tenenbein and Huang, 2022). Within the EU, the fortification of foods with iron is foreseen by Regulation (EC) No 1925/2006. Some countries have specific legislation for the fortification of specific foods such as wheat flour in order to provide the necessary amount of iron in the diet (Oskarsson and Sandström, 1995; and UK Statutory Instrument No 141, 1998).

Mean dietary intakes in various European countries range from 10 to 22 mg/day and the 97.5th percentile from 16 to 72 mg/day (SCF, 1993; 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. It 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. Steel is the most recycled material on the planet (Tenenbein and Huang, 2022).

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 FCM (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 of 0.22-2.85 mg/kg (Kuligowski and Halperin, 1992). Similarly, a survey of teapots showed iron release of 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 minutes (Bolle *et al.*, 2011). Rare cases of release of very high quantities of iron from FCM such as iron kitchen utensils have been observed. For example, the release of 2 500 mg/kg iron from a wok and a cast iron skillet were observed under the conditions mentioned above (Kuligowski and Halperin, 1992).

Safety aspects

- JECFA (1983) established a PMTDI of 0.8 mg/kg bw/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 (2022) proposed that no health-based guideline value be set for iron in drinking water.
- The recommended intake is 10-15 mg/day (Oskarsson and Sandström, 1995).
- Iron is an essential trace metal (JECFA, 1983). Iron problems are usually related to deficiency rather than toxicity. Iron deficiency is generally acknowledged to be the single most common nutritional deficiency in both developing and developed countries (Oskarsson and Sandström, 1995). Certain iron salts, mainly ferrous sulfate and ferrous succinate, are frequently used for the treatment and prevention of iron deficiency in humans (Beliles, 1994). Under normal conditions, only about 10% of the iron is actually absorbed (Tenenbein and Huang, 2022). 10-20 mg/kg elemental iron may produce gastrointestinal symptoms that manifest as nausea vomiting, diarrhea and abdominal pain.
- Iron supplementation of more than 30 mg/day could be associated with iron accumulation indicators in older adults (Fleming *et al.*, 2002).
- The Belgian Royal Decree of 30 May 2021 relating to the placing on the market of nutrients and foodstuffs to which nutrients have been added sets the maximum authorised intake via food supplements at 45 mg/day.
- In 2006, the EFSA NDA was 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 to 72 mg/person/day (EFSA, 2006).
- The EVM (2003) 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 bw/day (17 mg/day) would not be expected to produce adverse effects in the majority of people. This is based on data showing that doses between 50 and 220 mg/day cause effects in humans,

Fe

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 interspecies 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(R1): Iron is one of the elemental impurities for which PDEs have not been established due to their low inherent toxicity.

Fe

Conclusions and recommendations

the SRL for iron of 40 mg/kg food or food simulant is reasonably achievable

Since no toxicologically derived upper limit could be set, it was decided that an SRL for iron should be set at ALARA level. Such an approach ensures that the manufacturer applies measures to prevent and reduce the release of iron from FCM and articles as far as possible.

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

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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 *et al.*, 2000).

Excess consumption is naturally eliminated, although intake of large quantities of magnesium can cause 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, as a laxative (milk of magnesia) and also 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 (197-242 mg/100 g), cocoa (150-400 mg/100 g) and whole grains (100-150 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. The highest concentrations in the French Total Diet Study were measured in tofu (1 340 mg/kg), chocolate (1 143 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 sulfur. 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

- The 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 and 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. The SCF (2001) and AFSSA (2001) recommended that daily intake should not exceed 700 mg/day. The Belgian Royal Decree of 30 May 2021 relating to the placing on the market of nutrients and food products with added nutrients set the maximum authorised intake via food supplements at 450 mg/day.
- The EVM (2003) assessed magnesium and considered there to be insufficient data to derive a safe upper level. 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 bw/day for a 60 kg adult.

Mg

Conclusions and recommendations

deriving an SRL for magnesium was unnecessary

With regard to the safety aspects mentioned above, it can be assumed that release of magnesium from FCM 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 (carbohydrate and lipid metabolism, bone formation, healing processes, antioxidant protection, etc.). It is widely distributed in the environment, comprising approximately 0.1% of the Earth's crust (Lucchini *et al.*, 2022). About 90% of total manganese production is used in steel manufacture as a deoxidising and desulfurising additive and as an alloying constituent (Lucchini *et al.*, 2022). Manganese exists in two common oxidation states, as manganese (II) and manganese (IV) (Florence *et al.*, 1980).

Mn

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 (Hoekman and Broch, 2016). This may result in increasing concentrations of manganese in the environment and in foodstuffs.

The average intake is 2-3 mg/day (SCF, 1993). The UK Total Diet Study reported that the highest total mean and 97.5th percentile exposures were in the 1.5 to 3 year 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 'non-alcoholic beverages', 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 NDA (EFSA, 2013) proposed an AI of 3 mg/day for adults, including pregnant and lactating women (equal to the mean intake in the 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 Total Diet Study (iTDS) (ANSES, 2016) focusing on the 0 to 3-year-old population, the highest manganese concentrations were measured in sweet and salty biscuits (6.26 mg/kg), bread and bakery products (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, the main contributors were follow-on formulae (21%) and infant cereals (15%). Between 7 and 12 months, the main contributors were jarred meat/vegetables and fish/vegetables (16%), infant cereals (13%) and fruits (11%). Between 13 and 36 months, the 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 age group. Considering the 90th percentile, the manganese mean exposures varied from 0.348 to 1.26 mg/day according to age group.

Metallic food contact materials

Manganese is used in steel and other alloys (Lucchini *et al.*, 2022).

Other food contact materials

Manganese is used in the manufacture of glass, for metal cleaning, tanning and bleaching (Lucchini *et al.*, 2022). It is also used in pigments, glazes and other products.

Release

Release of manganese from six different grades of stainless steel containing 0.21-2.0 weight % 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).

Release of manganese from a range of seven stainless steel grades used as FCM was examined (food simulant 5 g/L citric acid, pH 2.4 and 1 cm^2 in 2 mL test medium) after exposure for 2 hours at 70°C followed by 24 and 238 hours at 40°C. Manganese release for all stainless steel grades and test conditions investigated were below the applicable SRL (1.8 mg/kg) and did not exceed 0.4 $\mu g/cm^2$ (Hedberg *et al.*, 2014). The study was extended using as-received and pre-passivated 6 cm^2 specimens and three different simulants; artificial tap water, 5 g/L citric acid and 5 g/L citric acid + 0.5 M NaCl (conditions: 2 hours at 70°C followed by 10 days at 40°C). Manganese release was close to the detection limits for all grades in artificial tap water. Higher release was observed in citric acid, but did not exceed the SRL and release was noted to reduce with time (Mazinanian *et al.*, 2016).

Mn

Safety aspects

- JECFA has not evaluated manganese.
- The SCF (1993) recommends 1-10 mg/day as the acceptable intake range.
- The SCF (1996) recommends a maximum limit of 0.5 mg/L for manganese in natural mineral waters.
- In its 2001 recommendation, AFSSA (France) set a safety limit of 10 mg/day. In the iTDS, a security upper limit of 2 mg/day (fixed by the

institute of medicine) was retained by ANSES (2016) for 1 to 3-year-old infants.

- The Belgian Royal Decree of 30 May 2021 sets the maximum authorised intake via food supplements at 1 mg/day.
- WHO (2003) derived a limit of 0.06 mg/kg bw/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 bioavailability of manganese in water) and resulted in a guideline value of 0.4 mg/L. In 2022, a provisional guideline value was set at 0.08 mg/L (WHO, 2022).
- Both the 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 LOAELs following oral administration observed are 0.28 mg/kg bw/day in growing male rats and 0.36 mg/kg bw/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, 2012). Although manganese is an essential nutrient, exposure to high levels via inhalation or ingestion may cause some adverse health effects (ATSDR, 2012). Excess manganese affects the central nervous system and neurological effects have been observed in cases of occupational exposure. No problems have been reported in connection with dietary intake of manganese, since it 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 (2003) could not derive an upper intake limit. 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 bw/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 bw/day (12 mg/day) using the higher concentration.

- ICH Q3D(R1): manganese is one of the elemental impurities for which PDEs have not been established due to their low inherent toxicity.
- In the ANSES opinion (2018) related to the maximal safety value of manganese in drinking water, the TRV of 55 µg/kg bw/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 bw/day based on neurological effects observed in rats during development after postnatal exposure (Kern *et al.*, 2010 and 2011, Beaudin *et al.*, 2013 and 2015).

Mn

Conclusions and recommendations

the SRL for manganese is set at 0.55 mg/kg food or food simulant

The SRL is based on the TRV of 55 µg/kg bw/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 FCM is applied. Since the endpoint for the calculation of this reference value was based on neurological effects observed during development after postnatal exposure, the recommended SRL is calculated considering toddlers as the 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 bw/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 bw/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. In its elemental state, it is a hard silvery-grey metal with a density of 10.2 g/cm^3 (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, sulfite 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 (Rumble, 2022).

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.

EFSA (2009) estimated oral intake for adults from food at up to 500 µg/day, and for children aged 1-3 years old, up to 89 µg/day. The 2006 UK 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 bw 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 corrosion, such as pitting and cracking. 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 also used (Euro Inox, 2006). Hastelloy C-276 (a highly corrosion-resistant Ni-Cr-Mo-Fe alloy) has been used for coffee flash dryers. Inconel and Hastelloy B & C have been used for the following food applications: fruit juice and syrups, pectin, gelatine, salad dressings, vinegar, monosodium glutamate, 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 FCM.

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 5 g/L citric acid for 2 hours at 70°C followed by 10 days at 40°C released 0.02 µg/cm2 of molybdenum (i.e. 0.012 mg/6 dm^2) (Hedberg *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 and 0.06 µg/cm2 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 2.4).

Safety aspects

- The 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 bw/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). It is categorised in Class 3 of the ICH Q3D(R1) Guideline, metals of relatively low toxicity, with an oral PDE of 3 400 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 bw of 50 kg and a safety factor of 250 (Murray *et al.*, 2013).

Mo

Conclusions and recommendations

the SRL for molybdenum is set at 0.12 mg/kg food or food simulant

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

Intake data from multiple European countries was provided by EFSA (2009). However, the data used in 2009 had been taken from earlier SCF opinions and contained data originating from the 1980s.

Since newer intake data were only available from two European countries, the default allowance of 20% for exposure to FCM 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 bw consumes 1 kg of foodstuffs per day that is packaged and/or prepared with FCM 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 FCM and articles containing molybdenum (Foster *et al.*, 2010).

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Mo

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Nickel (Ni)

Nickel, combined with other elements, occurs naturally in the Earth's crust and is found in all soils. It is the 24th most abundant element and, in the environment, nickel is found primarily as oxides or sulfides (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 in the nickel hypersensitive population. 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).

Ni

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' (~ 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 UK 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 bw/day) and 0.18 mg/day (3.01-3.08 µg/kg bw/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 older 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 bw/day in adults and 3.83 µg/kg bw/day in children. In the Infant Total Diet Study (iTDS), these mean exposures were used (ANSES, 2016). Exposure at the 95th percentile was 3.76 and 7.44 µg/kg bw/day 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 LB, 'Elderly') to 13.1 µg/kg bw/day (maximum UB, 'Toddlers'). The 95th percentile dietary exposure ranged from 3.6 (minimum LB, 'Elderly') to 20.1 µg/kg bw/day (maximum UB, 'Toddlers'). In the update of its risk assessment, EFSA (2020) established that: the exposure ranged from 1.57 (minimum mean LB, 'Elderly') to 14.6 µg/kg bw/day (maximum mean UB, 'Toddlers'); the 95th percentile dietary exposure ranged from 3.55 (minimum LB, 'Elderly') to 24.8 µg/kg bw/day (maximum UB, 'Toddlers'). The highest exposure was found for toddlers and other children.

Metallic food contact materials

In total, 79% of the worldwide production of nickel is used for the manufacturing of alloys, 6% for plating and 11% for other uses (e.g. batteries) (Nickel Institute, 2022). 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 FCM are stainless steels.

Nickel-containing stainless steels (see Chapter 2, Stainless steels) are important FCM 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, for sinks, bowls, knives, spoons and forks.

Other nickel-containing FCM 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 (electroplated) are less durable and less corrosion-resistant than stainless steel and are therefore not commonly used for articles in contact with food and drink. Electroless nickel coatings (nickel/phosphorus alloy) containing 2-14% phosphorus are durable and have found many applications in the food industry, in particular as a protective coating for many different components which do not come into direct contact with food. The preferred electroless nickel coating for most applications in the food industry is the high phosphorus type containing 10-12% phosphorus. (Parkinson, 2001). For chromium-plated objects, the materials are consecutively given a copper, nickel and then a chromium layer. Kitchen utensils such as strainers and heating coils in electric kettles may be nickel-plated. 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 and Packirisamy, 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 and Halperin, 1992). A survey of teapots showed nickel release of 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 minutes. (Bolle *et al.*, 2011). Release of nickel from a range of seven stainless steel grades used as FCM was examined (food simulant 5 g/L citric acid, pH 2.4 and 1 cm^2 in 2 mL test medium) after exposure for 2 hours at 70°C followed by 24 and 238 hours at 40°C. Nickel release for all stainless steel grades and test conditions investigated was below the applicable SRL (1.4 mg/kg) and did not exceed 0.06 $\mu g/cm^2$ (Hedberg *et al.*, 2014). The study was extended using as-received and pre-passivated 6 cm^2 specimens and three different simulants; artificial tap water, 5 g/L citric acid and 5 g/L citric acid + 0.5 M NaCl (conditions: 2 hours at 70°C followed by 10 days at 40°C). Nickel release was close to the detection limits for all grades in artificial tap water. Higher release was observed in citric acid, but did not exceed the SRL and release was noted to reduce with time (Mazinanian *et al.*, 2016).

For the years 2020 to 2023, RASFF shows 18 notifications for nickel release, especially from bakeware (up to 19.76 ± 1.97 mg/L).

Ni

Safety aspects

- JECFA has not evaluated nickel.
- In 2008, AFSSA set a TDI of 22 µg/kg bw/day, based on a 2-generation 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 2020) identified reproductive and developmental toxicity as the critical effect for the risk characterisation of chronic oral exposure to Ni. They derived a TDI of 2.8 µg Ni/kg bw/day from a $BMDL_{10}$ of 0.28 mg Ni/kg bw/day as calculated from the dose-response

analysis of the incidence of post-implantation foetal 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, taking into account new occurrence data, the updated 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 foetuses (as used in the previous Opinions). A TDI of 13 µg Ni/kg bw/day was derived from a $BMDL_{10}$ of 1.3 mg Ni/kg bw/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 bioavailability 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). It is believed that 5-15% of ingested nickel is absorbed from the gastrointestinal tract (Klein and Costa, 2022). 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 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 (2022) derived a guideline value for nickel in drinking water of 0.07 mg/L and identified leaching from metals in contact with drinking-water as its primary source.
- The EVM also assessed nickel and while they could not derive a safe upper level, they determined that intakes of 0.0043 mg/kg bw/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 bw/day and using uncertainty factors of 10 for interspecies variation, 10 for intraspecies variation and 3 for extrapolation of a LOAEL to a NOAEL.
- The COT (2008) considered that UK dietary exposures above the EVM guidance level were unlikely to be of toxicological concern, though they noted that nickel may exacerbate contact dermatitis/eczema in presensitised individuals. 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 subgroup. In 2018, the COT concluded, based on acute and chronic effects, that it is not possible to determine whether there is a risk of sensitisation to nickel in infants and young children exposed to nickel through the diet. The effect from indigestion of an acute exposure of nickel in sensitised individuals could be a dermal reaction, which although unpleasant is not life-threatening.
- According to ICH Q3D(R1), the oral nickel PDE is 220 µg/day.

Conclusions and recommendations

the SRL for nickel is set at 0.14 mg/kg food or food simulant

This SRL is derived from the EFSA TDI of 0.013 mg/kg bw/day. This conservative TDI is based on human data from nickel-sensitised individuals.

The default allowance of 20% for exposure through FCM and articles made from metals and alloys was applied to the TDI. Assuming that a person of 60 kg bw consumes 1 kg of foodstuffs per day that is packaged and/or prepared with FCM made from metals and alloys, the SRL is set at 0.14 mg/kg.

Care has to be taken to ensure that nickel-plated and electroless 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 alloys containing a minimum of 92.5% by weight of silver and 7.5% by weight of other metals, usually copper, are known as sterling silver (Beliles, 1994).

Sources and levels of intake

In surface water and groundwater, silver concentrations are usually below 5 µg/L; however, detections >100 µg/L, although rare, have been reported (WHO, 2022).

Silver may be ingested via consumption of marine organisms containing low concentrations, and in small amounts released from dental fillings (Hedberg and Nordberg, 2022). The use of silver and silver nanoparticles as antimicrobials and disinfectants is increasing (Hedberg and Nordberg, 2022). Silver is also used as a colouring agent for decorations in confectionery and in alcoholic beverages.

ANSES (2011) estimated mean daily intake between 1.29 and 2.65 µg/kg bw/day (according to LB or UB assumptions) for adults and between 1.60 and 3.47 µg/kg bw/day for children.

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

It has to be noted that although the cited studies are total diet studies, in the 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 (Hedberg and Nordberg, 2022).

Attention should be paid to the European standards EN ISO 8442-2 (ISO, 1997) and EN ISO 8442-3 (ISO, 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 holloware and attachments thereto, respectively.

Other food contact materials

The Provisional list of additives used in Plastics of Regulation (EC) No 10/2011 for plastic FCM includes silver-containing substances. These are surface biocides, used to protect the surface of finished articles from microbial contamination during storage and subsequent use.

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 sulfur or H_2S. Nitric or sulfuric 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 (Hedberg and Nordberg, 2022). The biological half-life of silver ranges from a few days for animals up to about 50 days in the human liver (Hedberg and Nordberg, 2022). 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 (Hedberg and Nordberg, 2022).
- 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 a rise in blood pressure, haemorrhagic gastroenteritis and shock; 10 g of silver nitrate taken orally is considered to be a lethal dose to man, (WHO, 1977). Some silver compounds such as silver oxide and silver nitrate are irritants, and exposure is associated with nose-bleeds and abdominal cramps (Beliles, 1994). High intake of silver, whether in metal or ionic form can lead to renal and pulmonary lesions and argyria or argyrosis. 0.6 mg/kg bw per day of colloidal silver was considered as LOAEL based on a case report of argyria in a woman who ingested this dose of silver for 16 months (WHO, 2022).
- EFSA (2016) summarised the acute toxicity in animals as follows: According to WHO (1977), the LD50 (mice) is 50 mg/kg bw as silver nitrate (corresponding to 32 mg ionic silver/kg bw). According to Tamimi *et al.* (1998), the LD50 in rats and rabbits is 428 and 1261 mg silver nitrate/kg bw, respectively, corresponding to 280 and 794 mg ionic silver/kg bw, respectively).
- There are few studies on subchronic or chronic exposure to silver. In these, effects on the liver, bw, immune system and developmental toxicity were observed – although data were not always consistent (especially for immune toxicity). The lowest NOAEL (0.26 mg ionic silver/kg bw/day) was identified for reproductive 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 bw gain of the pups and reduced numbers of implants and post-implantation loss. However, it should be noted that the selection of the NOAEL is questionable, because the reduced bw was only observed in one dose group (middle dose: 2.6 mg/kg bw/day), was not dose dependent, and could be explained by a slightly increased number of pups. Reduced numbers of implants and post-implantation loss were only observed in the high dose group (26 mg/kg bw/day). Hence it would be possible to identify this dose as LOAEL, resulting in a NOAEL of 2.6 mg ionic silver/kg bw/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).
- The EPA has established a chronic oral RfD for silver ingestion of 5 µg/kg bw/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.
- WHO (2022) set a provisional reference value of 0.1 mg/L for silver. Available data are inadequate to permit the derivation of health-based guideline value.
- EFSA (2005) established a group restriction for substances containing silver at 0.05 mg/kg food and concluded that this restriction would limit the silver intake to less than 13% of the human NOAEL.
- Remark: FCM 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 food or food simulant

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 bw/day (0.08 mg/day) and assuming that a person of 60 kg bw consumes 1 kg of foodstuffs per day that is packaged and/or prepared with FCM 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 FCM was applied.

Silver or silver-plated 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 SRL, 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. The recovered tin is recycled within product-line industries and, hence, is used again in alloys (Ostrakhovitch, 2022).

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 UK 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 bw/day and 300 μg/kg bw/day, respectively. The highest contributing food group to total mean exposure was 'canned vegetables' with a mean exposure of 61 μg/kg bw/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. The highest concentrations were measured in stewed fruits (8.55 mg/kg) and cheese (1.94 mg/kg).

Metallic food contact materials

Tin is used in tinplated food cans and containers (Ostrakhovitch, 2022) and the major source of tin in the diet is from FCM, 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), and 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 and 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

Direct applications include the use of mixed tin oxide-metal oxide systems as pigments. The other commercial applications of inorganic tin compounds are in the ceramics and glass industries (Ostrakhovitch, 2022).

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 of 14 mg/kg bw/week including tin from food additives. JECFA also states that 'tin levels should be as low as practicable because of possibility of gastric irritation'. In 2005, JECFA maintained the PTWI of 14 mg/kg/week.
- WHO (2022) has concluded that, because of its low toxicity, the establishment of a guideline value for inorganic tin was not deemed 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 are poorly absorbed from the gastrointestinal tract (less than 5%) (Ostrakhovitch, 2022). Tin compounds act as an irritant for the gastrointestinal tract mucosa, causing nausea, vomiting, diarrhoea, fatigue and headache (WHO, 2005). Only a limited number of cases indicating possible gastrointestinal irritation 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 $SnCl_2$. EFSA assessed tin in 2005, but considered the available data insufficient to derive a tolerable upper intake level. They noted that current daily intakes in the EU, ranging up to 6 mg/day in the UK, appear to be well below levels associated with adverse effects.
- In their assessment, the EVM (2003) could not establish a safe upper level, but considered that 0.22 mg/kg bw/day (13.2 mg/day) would not be expected to produce adverse effects in humans. This was based on a NOAEL for liver cell changes and anaemia of 22-33 mg/kg bw/day from a subchronic study in rats with uncertainty factors of 10 for interspecies and 10 for intraspecies 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. Therefore, the EVM's assessment was used as a guidance level. While dietary exposure for high-level intake by pre-school children exceeded the EVM guidance level by approximately 55%, all other estimated subgroup dietary exposures (mean- and high-level intakes) were within the EVM guidance level. Hence, the COT concluded that the slight exceedance of this guidance level is within an area of uncertainty, but that current dietary exposures were unlikely to be of toxicological concern.
- 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 were detected, even at the highest dose (1 000 mg/kg bw/day). However, the study was considered inadequate because tin was administered in powder form, which is not representative of human dietary exposure.
- According to Commission Regulation (EU) 2023/915 setting maximum levels for certain contaminants in foodstuffs, the maximum levels of tin (inorganic) are:
  - 50 mg/kg for certain canned foods for babies and young children
  - 50 mg/kg canned dietary foods for special medical purposes for infants

Sn

– 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 or food simulant

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 to Commission Regulation (EU) 2023/915, at 100 mg/kg. This limit does not apply to food contact applications that are covered by Commission Regulation (EU) 2023/915.

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 humans (Jin *et al.*, 2022).

Sources and levels of intake

In the EU, titanium dioxide was used as a food additive (E 171) until 2022 and is still used in toothpastes, sunscreens and pharmaceuticals.

As of August 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 Commission Regulation (EU) No 2022/63. Until 7 August 2022, foods produced in accordance with the rules applicable before 7 February 2022 could 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 (EU) No 2022/63).

The EC '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 (EU) No 2022/63.

In the UK, the use of titanium dioxide as a food colour is still permitted, and there is no indication that the UK will follow the EU at this time. The FSA and FSS have launched their own independent risk assessment of the safety of titanium dioxide when used as a food and feed additive and any risk management action will be informed by this risk assessment (COT, 2022).

Metallic food contact materials

Titanium is often used in the form of alloys that are stronger and more resistant to corrosion than the metal itself (Jin *et al.*, 2022). 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; Jin *et al.*, 2022). Titanium compounds are also used as catalysts in the manufacture of plastics.

Release

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

Safety aspects

- Titanium dioxide was assessed by 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 (Jin *et al.*, 2022). Studies on titanium alloys used in implants and titanium compounds used in cosmetics and pharmaceuticals do not indicate any significant local tissue effects (Jin *et al.*, 2022). A distinct toxicological dichotomy exists between TiO_2, the insoluble, unreactive non-metabolised form that is devoid of toxicity, and the soluble, inorganic salts that metabolise normally with absorption, distribution, and excretion (Beliles, 1994).
- EFSA (2021) provided an updated safety assessment of the food additive titanium dioxide (E 171) taking into account all new relevant data available to them. Along with all the uncertainties, in particular the fact that genotoxicity concern could not be ruled out, EFSA 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 specified in the 2019 opinion and as described in Commission Regulation (EU) 2022/63 (amending Commission Regulation (EU) No 1333/2008).

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. Measures related to the use of E 171 as an additive in FCM and articles (e.g. plastics or coatings) may follow EFSA's 2019 Opinion.

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Ti

Vanadium (V)

Vanadium is a white, shiny, soft, ductile metal. It is highly resistant to corrosion by alkali compounds as well as hydrochloric and sulfuric 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*., 2012).

ANSES (2011) estimated mean daily intake at 52 µg/day (0.86 µg/kg bw/day) in adults and 1.06 µg/kg bw/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 such as knives and parts for rotating machinery. Adding vanadium to steel in proportions of approximately 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 acceptance criteria for vanadium amounts in steel.

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 of 1.8 mg/day for vanadium. This value was derived from a LOAEL of 7.7 mg/kg bw/day (460 mg/day) from a rat study, an average bw 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 upper limit is based on adverse effects in laboratory animals and this data could be used to set an upper limit 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(R1), the oral vanadium PDE is 120 µg/day.

Conclusions and recommendations

the SRL for vanadium is set at 0.01 mg/kg food or food simulant

It was decided to follow the opinion issued by 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 bw consumes 1 kg of foodstuffs per day that is packaged and/or prepared with FCM 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 (Wolf *et al.*, 2022). It 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 offal, 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 UK 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 'miscellaneous cereals' and 'dairy products' 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.*, 2012). 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 the 95th percentile at 13.3 mg/day.

Metallic food contact materials

A major use of zinc is the production of alloys, including brass, bronze and galvanised steel (Wolf *et al.*, 2022). Metallic zinc is commonly used to coat iron or other metals so that they do not rust or corrode (ATSDR, 2005). Zinc compounds are further used in household applications (Wolf *et al.*, 2022). The use of FCM 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

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 FCM and articles are scarce. One study, a survey of teapots, showed zinc release of 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 minutes (Bolle *et al.*, 2011).

Safety aspects

- JECFA (1982) established a PMTDI of 0.3-1 mg/kg bw/day.
- The required daily intake for adults is about 15 mg/day. However, the requirement varies with age (JECFA, 1982).

- WHO (2022) 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 *et al.*, 1980). The absorption rate is inversely related to the zinc intake and ranges from 16% to 50% but can be increased in zinc deficiency up to 92% in a low-phytate diet (Wolf *et al.*, 2022). 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 *et al.*, 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 (2003) derived a safe upper level of 0.42 mg/kg bw/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 bw/day would not be expected to result in any adverse effect.
- The SCF (2003) and EFSA (2006) interpreted, for the same endpoint (inhibition of eSOD), the value of 50 mg/day as the NOAEL. Using an uncertainty factor of 2 to account for the small number of subjects surveyed, the upper limit was set to 25 mg/day. Furthermore, for children aged 1-3 years, an upper limit of 7 mg/day was extrapolated from the adult upper limit.
- In the 2008 European Risk Assessment Report, the overall oral NOAEL of 50 mg/day was confirmed using the same studies as the SCF (2003). However, no additional uncertainty factor was used. (JRC, 2008).
- ICH Q3D(R1): zinc is one of the elemental impurities for which PDEs have not been established due to their low inherent toxicity.

Conclusions and recommendations

the SRL for zinc is set at 5 mg/kg food or food simulant

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 FCM made from metals and alloys.

Consequently, assuming that a person of 60 kg bw consumes 1 kg of foodstuffs per day that is packaged and/or prepared with FCM 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 (NLM HSDB; ILO, 2011).

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 (NLM 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 (NLM HSDB).

Exposure 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 (NLM 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 FCM 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 FCM, 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, 2016).

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 (NLM LCSS; 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 (Health Council of the Netherlands, 2002). 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 (NLM 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 (NLM HSDB). Overall, based on the available literature, no definitive conclusion can be drawn on the potential for zirconium to produce toxic effects. The Health Council of the Netherlands concluded in 2002 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.

An SML of 2 mg/kg has been established for zirconium used for passivation of metals and alloys in the Netherlands (Dutch WVG Regulation). Based on the example material tested in the application dossier, the limit of 2 mg/kg is fully achievable. Available toxicity studies showed absence of genotoxic potential, and the overall NOAEL of 41 mg/kg bw/day derived from a combined repeated dose toxicity study (OECD TG 422) in rats led to a MOE for the potential exposure from use of zirconium in food contact of over 1 000, which was considered sufficient.

According to the Dutch WVG Regulation, the following provision is also applicable: 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[1].

Conclusions and recommendations

the SRL for zirconium is set at 2 mg/kg food or food simulant

Given the lack of sufficient data available to derive a TDI, the SRL of zirconium is set at 2 mg/kg, as 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 can be used in direct contact with food where the properties of that foodstuff are non-acidic or acidic, if the acidic character is derived from an acid other than acetic acid.

1 The zirconium released forms ZrO_2 that is insoluble in 3% acetic acid. Its precipitation results in misleading determination of the release of zirconium (only soluble part in the supernatant) while formation of nanoparticles cannot be excluded. Analogous precipitation does not take place in citric acid. Summary Data Sheet on Zirconium. Dutch G4-commission. 2014 and amended in 2021 (unpublished).

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Metal contaminants and impurities

The following metals are relevant contaminants and impurities that may occur in FCM 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 the 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) (Arnich *et al.*, 2012; Guéguen *et al.*, 2011; Schoof *et al.*, 1999). 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 LB and UB concentrations, has been estimated to range from 0.13 to 0.56 µg/kg bw/day for average consumers, and from 0.37 to 1.22 µg/kg bw/day for 95th percentile consumers. Dietary exposure to inorganic arsenic for children under 3 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 UB 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 sulfide mineral found naturally or produced artificially. It is also known as yellow 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 (2022) 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 of 15 µg/kg bw/week (2.1 µg/kg bw/day) for arsenic was set in 1988 (JECFA, 1989). In 2010, at the 72nd JECFA meeting, arsenic was reassessed and a BMD approach was used to assess the epidemiological data available. The inorganic arsenic lower limit of the BMD for a 0.5% increased incidence of lung cancer ($BMDL_{05}$) was determined from epidemiological studies to be 3.0 µg/kg bw/day (2-7 µg/kg bw/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 (JECFA, 1989) 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.

- EFSA (2009) used a 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 ($BMDL_{01}$) causing this response was considered. Lung cancer had the lowest $BMDL_{01}$, with an overall range of 0.3-8.0 µg/kg bw/day. There is little or no MOE between estimated dietary exposure and this range and therefore the possibility of a risk to consumers cannot be excluded.

- In a 2016 assessment of exposure to arsenic in infants (0-1 years) and young children (1-5 years), the COT concluded that total exposure to inorganic arsenic, from dietary and non-dietary sources generally leads to MOEs of significantly less than 10 and could therefore pose a risk to health. When comparing the estimated exposures from different sources, it becomes apparent that in these age groups, dietary sources generally contribute more significantly to exposure than non-dietary sources such as soil and dust. It is therefore reiterated that efforts to reduce the levels of inorganic arsenic in food and water should continue.

- The COT also concluded (2018) that dietary exposure to organic arsenic is unlikely to constitute a risk to health.

Conclusions and recommendations

the SRL for arsenic is set at 0.002 mg/kg food or food simulant

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 EFSA, JECFA and COT assessments (COT, 2016; EFSA, 2009; JECFA, 2010), using the JECFA (1989) PTWI as a basis for deriving an SRL was not considered appropriate. Instead, the lower end of the $BMDL_{01}$ from the EFSA (2009) assessment was used, resulting in a limit of 0.0003 mg/kg bw/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 TRV was reasonable. Therefore, assuming a person of 60 kg bw consumes 1 kg of foodstuffs per day that is packaged and/or prepared with FCM made from metals and alloys, the SRL for arsenic is set at 0.002 mg/kg.

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Barium (Ba)

The mineral barite (or *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). Estimates of barite global production are available on the internet and place 2022 figures in the region of 7.9 million metric tons (Garside, 2023). 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).

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

Health Canada (2020) recommends a maximum acceptable concentration (MAC) for total barium in drinking water of 2.0 mg/L (2 000 µg/L). They estimate the average intake of barium from drinking water at 2 µg/kg bw/day (rounded) for an adult of 74 kg and a consumption of 1.53L/d water.

In the UK 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).

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-metallic compounds and alloys with lead, potassium, platinum, magnesium, silicon, zinc, aluminium and mercury (Hansen, 1958). Metallic barium reduces oxides, halides, sulfides and most of the less reactive metals to 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. The chromate ($BaCrO_4$) is an anti-corrosion pigment for metals.

Other food contact materials

Besides the use of barium and barium compounds in ceramics, the chloride, $BaCl_2$, is used in the pigment, lacquer and glass industries. In the dyeing industry, it is used as a mordant 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

- The EPA (1985) derived an RfD of 0.2 mg/kg/day. In 2005 the EPA reassessed barium and confirmed the RfD for barium of 0.2 mg/kg bw/day. However, new studies were taken into consideration and a BMDL approach was chosen. Consequently, the RfD was derived from a $BMDL_5$ of 63 mg/kg bw/day for a 5% increased risk of nephropathy in mice with an uncertainty factor of 300 (100 for intra- and interspecies variability and 3 for database deficiencies).

- WHO (2001) specified a TDI of 0.02 mg/kg bw/day (1.2 mg/day) from an epidemiological study. In that study, populations from two cities with 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, a TDI of 0.21 mg/kg bw/day was derived and divided by an uncertainty factor of 10 to account for database deficiencies and possible differences between adults and children.
- WHO (2022) established a guideline value for barium in drinking water of 1.3 mg/L.
- In their 2008 statement, the 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 over-precautionary. 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 food or food simulant

It was decided to use the EPA RfD of 0.2 mg/kg bw/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 TRV was reasonable. Therefore, assuming that a person of 60 kg bw consumes 1 kg of foodstuffs per day that is packaged and/or prepared with FCM 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, WHO (2022) 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.*, 2012).

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 an RfD of 0.002 mg/kg bw/day (i.e. 0.12 mg/day for a person weighing 60 kg) for beryllium. In 1987, the EPA estimated beryllium intake in the USA at 0.423 µg/day via water and food, which is negligible compared to the RfD.
- WHO (1990; 2001) shows that there is little data available on oral toxicity of beryllium. The bulk of the information available pertains to inhalation toxicity and, in particular, the effects of inhalation in

occupationally-exposed workers. WHO (2001) derived an oral tolerable intake of 0.002 mg/kg bw/day. This value was estimated using the BMD10 of 0.46 mg/kg bw/day at the lower 95% confidence limit for a 10% incidence of small intestinal lesions in dogs chronically exposed to beryllium sulfate tetrahydrate and considered equal to the NOAEL. In addition, an uncertainty factor of 300 (10 for interspecies, 10 for intraspecies 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 food or food simulant

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 bw/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 TRV was reasonable. Therefore, assuming that a person of 60 kg bw consumes 1 kg of foodstuffs per day that is packaged and/or prepared with FCM 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. It is widely distributed, occurring in all soils and rocks, including coal, in very low concentrations (<0.1 mg/kg) (ATSDR, 2012; Lind, 1997). Cadmium occurs with zinc and lead in sulfide ores (Nordberg *et al.*, 2022). Cadmium is released to the air, land and water by human activities (WHO, 1992). Increases in soil cadmium content result in an increase in the uptake of cadmium by plants. The application of phosphate fertilisers and atmospheric deposition are significant sources of cadmium input to arable soils in some parts of the world; sewage sludge can also be an important source at the local level (WHO, 1992). Cadmium metal was previously used as an anti-corrosive when electroplated onto steel (Nordberg *et al.*, 2022). 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 (Nordberg *et al.*, 2022). Certain foodstuffs, e.g. kidneys and oysters, may contain much higher concentrations (Nordberg *et al.*, 2022). The lowest levels of cadmium are found in dairy products and beverages (EC, 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 bw/week and the high exposure was calculated to be 3.0 μg/kg bw/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 bw/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 bw/week, respectively (EFSA, 2009). ANSES (2011) estimated mean daily intake at 1.12 µg/kg bw/week in adults and 1.68 µg/kg bw/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 equipment and machinery in food production is forbidden according to Regulation (EC) No 1907/2006 (REACH). Cadmium can occur as an impurity in zinc galvanised pipes and in solders in fittings, water heaters, water coolers, and taps (Nordberg *et al.*, 2022).

Other food contact materials

Historically, cadmium sulfide and cadmium selenide have been used as red, yellow and orange colour pigments in plastics and various types of paint (Nordberg *et al.*, 2022). Cadmium stearate was previously used as a stabiliser in plastics (Nordberg *et al.*, 2022). Cadmium can still be used as a pigment in certain enamels in FCM. Leachable cadmium in enamel pottery and glazes may be a source of food contamination.

Release

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

Safety aspects

- JECFA (1993) established a PTWI of 0.007 mg/kg bw/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 JECFA in 2003. During their 73rd meeting in 2010, JECFA withdrew the PTWI of 0.007 mg/kg bw/week and replaced it by a PTMI of 0.025 mg/kg bw/month, due to the exceptionally long half-life of cadmium (JECFA, 2010).
- WHO (2022) 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 (EU) 2020/2184).
- Cadmium is unique among the metals because of its combination of toxicity in low dosages, long biological 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 (Nordberg *et al.*, 2022). About 5% of ingested cadmium is absorbed (Nordberg *et al.*, 2022). 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 bw/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 BMDL for a 5% increase in the prevalence of elevated B2M ($BMDL_5$) resulted in a limit of 1 µg Cd/g creatinine. Subsequently, the dietary cadmium intake that corresponds to a concentration below 1 µg Cd/g creatinine in the urine was estimated from exposure data, resulting in the above TWI.

Conclusions and recommendations

the SRL for cadmium is set at 0.005 mg/kg food or food simulant

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 bw/week as a starting point resulted in a TDI of 0.00036 mg/kg bw/day (0.02 mg/person/day). Using an allowance of 10% of the TRV and assuming that a person of 60 kg bw consumes 1 kg of foodstuffs per day that is packaged and/or prepared with FCM made from metals and alloys, the calculated limit for cadmium would be 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 (EU) 2020/2184. This equals an allowance of 25% of the TRV.

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Lead (Pb)

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, manufacturing or 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 were used as gasoline additives to increase octane rating, have been replaced by other additives (ATSDR, 2020). 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 comparatively large 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 bw/day in average adult consumers and up to 2.43 μg/kg bw/day in high consumers. Exposure of infants ranges from 0.21 to 0.94 μg/kg bw/day and of children from 0.80 to 3.10 μg/kg bw/day (average consumers) and up to 5.51 μg/kg bw/day (high consumers) (EFSA, 2010). ANSES (2011) estimated mean daily intake at 0.20 μg/kg bw/day in adults and 0.27 μg/kg bw/day in children.

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

Metallic food contact materials

Canned foodstuffs used to contribute to the general intake of lead, but lead-soldering of tin cans is less common today (Bergdahl and Skerfving, 2022). 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 lead, that may be released when in 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 lead 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 currently 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). Lead may still be used as an alloying element in copper and in steel (for machining purposes, according to Directive 2011/65/EU). In addition, crystal glass may contain more than 24% lead, in which case it is specifically named lead crystal glass (Directive 69/493/EEC).

Release

The information on release of lead from metallic FCM 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 hours' contact time (Dessuy *et al.*, 2011). 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 of 0.025 mg/kg bw/week or 0.214 mg/day/person (average bw ~60 kg). This limit was confirmed by JECFA in 2000. During their 73rd meeting in 2010, JECFA withdrew the PTWI, concluding that it could no longer be considered protective of health. In children, the level of 1.9 µg/kg bw/day was associated with a decrease of 3 intelligence quotient (IQ) points, which is deemed by the Committee to be of concern.
- WHO (2022) 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 health-based guideline value, concentrations should be maintained as low as reasonably practical.

- In the EU, the limit for lead in drinking water has been set at 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 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 IQ, efforts should continue to reduce lead exposure from all sources. The COT also looked at this for their infant diet work, concluding that 'calculated MOEs for dietary exposures in infants were generally >1, indicating that at most, any risk from this source of exposure is likely to be small. When allowance is made for the uncertainties, it appears that total exposure to lead is unlikely to pose a material risk to health in the large majority of UK infants' (COT, 2013). However, there remains a concern that adverse effects could occur where concentrations

of lead in water or soil are unusually high. In 2022, the COT started to discuss lead in maternal diet.

- In 2010, EFSA published an opinion on lead using a 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, 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, EFSA concluded that the JECFA PTWI is no longer appropriate and that further efforts to derive a PTWI would not be appropriate. EFSA derived the following 3 BMDLs:
  - developmental neurotoxicity $BMDL_{01}$: 0.50 µg/kg bw/day
  - effects on systolic blood pressure $BMDL_{01}$: 1.50 µg/kg bw/day (90 µg/day)
  - effects on prevalence of chronic kidney disease BMDL: 0.63 µg/kg bw/day (38 µg/day).

Conclusions and recommendations

the SRL for lead is set at 0.01 mg/kg food or food simulant

Since dietary intake of lead in certain populations exceeds levels where adverse health effects are caused, its release from FCM 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 $BMDL_{10}$ of 0.63 µg/kg bw/day (38 µg/day) for chronic kidney disease. As lead is considered an impurity in the metallic material and intake can be higher than the $BMDL_{10}$, the allowance for lead release from FCM and articles should not exceed 10% of the TRV. Therefore, assuming that a person of 60 kg bw consumes 1 kg of foodstuffs per day that is packaged and/or prepared with FCM made from metals and alloys, the calculated limit for lead would be 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 TRV.

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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. Grains and vegetables were identified as the main contributors (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 FCM 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 bw/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 food or food simulant

Based on the limited information available, the SRL was derived from the TDI of 0.008 mg/kg bw/day (0.48 mg/day) established by RIVM (1991). As lithium is considered an impurity in the metallic material, it was concluded that an allowance of 10% of the TRV was reasonable. Therefore, assuming that a person of 60 kg bw consumes 1 kg of foodstuffs per day that is packaged and/or prepared with FCM 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 greatest 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 *et al.*, 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; Fowler and Zalups, 2022). In Commission Regulation (EU) 2023/915, maximum levels for mercury in relevant foods such as fish, fishery products, crustaceans, salt and in food supplements have been specified.

The EC (2004) estimated a mean dietary intake of mercury among 13 European states equal to 0.006 mg/day (0.1 µg/kg bw/day). In the UK Total Diet

Study (2014), total mercury was measured (sum of inorganic mercury and methyl mercury) 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 bw/day in adults and between 0.014 and 0.26 µg/kg bw/day in children (according to LB or UB concentrations). Mean daily intake of organic mercury via fish and seafood products was estimated at 0.017 µg/kg bw/day in adults and 0.022 µg/kg bw/day in children.

Other sources of mercury may include 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 is subject to Regulation (EU) 2017/852.

Metallic food contact materials

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

Release

No information available.

Safety aspects

- JECFA (1978; 1988) established a PTWI of 0.005 mg/kg bw/week for mercury, but with a maximum of 0.0033 mg/kg bw/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 bw/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 bw/week was based on the BMDL ($BMDL_{10}$ of 0.06 mg/kg bw/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 EFSA CONTAM Panel established a TWI for inorganic mercury of 4 μg/kg bw, expressed as mercury (EFSA, 2012).
- WHO (2022) 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) (Fowler and Zalups, 2022). At high exposure levels, mercurial tremor is seen, accompanied by severe behavioural and personality changes, increased excitability, loss of memory and insomnia (Fowler and Zalups, 2022). 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 bw/day for inorganic Hg based on the NOAEL of 0.23 mg/kg

bw/day for kidney effects from a 26-week study in rats (NTP, 1993) and applying an uncertainty factor of 100 (for interspecies and intraspecies 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 bw/day from a 2-year study in rats (NTP, 1993).

Conclusions and recommendations

the SRL for mercury is set at 0.003 mg/kg food or food simulant

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 bw/week as a starting point resulted in a TDI of 0.0006 mg/kg bw/day (0.03 mg/day). As mercury is considered an impurity in the metallic material, it was concluded that an allowance of 10% of the TRV was reasonable. Therefore, assuming that a person of 60 kg bw consumes 1 kg per of foodstuffs day that is packaged and/or prepared with FCM 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).

Tl

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 UK 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 August 1987 lays down a maximal quantity of thallium in aluminium of 0.05%. 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.

Release

No information available.

Safety aspects

Tl

- In humans, gastroenteritis, polyneuropathy and alopecia are the classical symptoms of poisoning. Most assessments are based on a subchronic 90-day-study in rats (MRI, 1988) identifying alopecia as the most critical endpoint. The authors of this study derived a NOAEL of 0.2 mg/kg bw from the highest concentration applied.
- The 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 (UK) statement, the current UK dietary exposures were considered unlikely to be of toxicological concern despite the lack of health-based guidance values for thallium. COT made this assessment based on the considerations of WHO (1996).
- 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 bw/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 bw).

- The Netherlands' 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 bw) (RIVM, 1998).

Conclusions and recommendations

the SRL for thallium is set at 0.001 mg/kg food or food simulant

The acceptable oral exposure of 10 µg/person/day derived by WHO (1996), the UBA's limit (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 TRV is applicable. Assuming that a person consumes 1 kg of foodstuffs per day that is packaged and/or prepared with FCM made from metals and alloys, the SRL for thallium is set at 0.001 mg/kg.

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Stainless steels 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 (Euro Inox, 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 FCM 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% copper, 3.5-4.5% tin, 3-5% lead, 3-9% zinc, 1.5% iron, 19-21.5% nickel, 1% manganese, and 0.15% silicon.
- 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 FCM 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. In addition, 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 SRL (see 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, and 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 nanometres 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 steels 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. The 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 chef's 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, holloware, 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, holloware 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 (Euro Inox 2006).

The so-called 200 series stainless steels, where manganese (up to 8%) is substituted for nickel, are also used for food contact applications (cookware, baking tins, serving implements, etc.). 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 8442-2 austenitic stainless steels for cutlery are divided into two groups:

- CrNi –17% Cr (min), 8% Ni (min) (300 series)

- CrNiMn –17% Cr (min), 4% Ni (min), 7.5% Mn (max) (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) and also for steam-heating systems, boilers, briners, etc.

- Austenitic-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% 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 FCM. 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 included in the Bibliography.

In addition, there are European and International standards for certain types of application of stainless steels. The composition limits for stainless steels 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 the Outokumpu Stainless Corrosion Handbook (2017).

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. equipment for processing fruit and vegetables, dry foods such as cereals, flour, sugar, and fish, as well as 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) as well as bowls, knives, spoons and forks.

A wide range of stainless steels is highly resistant to corrosion in acetic acid (concentration range 1-20%) at temperatures up to boiling point (Outokumpu, 2017). Similar corrosion resistance is seen for beer, citric acid (up to 5%), coffee, fruit juices, wines, lactic acid, milk and various detergents. It is well known that molybdenum improves the corrosion resistance of stainless steels in contact with foods or fluids that contain chloride ions. In Italy, stainless steels must meet certain release criteria in a variety of media before they can be approved for food contact applications. The list of approved stainless steels includes the standard austenitic grades 304 (18% Cr, 10% Ni) and 316 (17% Cr, 12% Ni+Mo). In addition, some European standards (e.g. EN ISO 8442-2) specify the finished 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 this Technical 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 steels is generally assumed to be a time-dependent measure of metal transition. Tests have shown that metal release from stainless steels 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 and Strompen, 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 for both.

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 and Halperin, 1992). A study of the levels of nickel and chromium found in 11 foodstuffs commonly cooked in glass and stainless steel saucepans showed values within or 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 where particular corrosion resistance characteristics are required (e.g. those involving contact with relatively high levels of chloride ions).

Compliance with SRLs, as presented in this Technical Guide, 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 – 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 FCM 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 SR 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 (canned food, beer kegs, etc.) and as far as possible at the 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 (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 (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, an alternative representative food can be used. The natural metal content of the foodstuff should be considered and reported with the analytical result (see *Natural metal content of the foodstuff*, Release testing into foodstuffs).

Testing release from materials and articles into food simulants

Following 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 based on:

- the findings from the third test. This takes account of the passivation process that some alloys or metals undergo.
- the sum of the results of the first and second tests that should not exceed an exposure equivalent to daily use for one week (i.e. seven times the SRL) according to the formula:

$$\mathbf{RESULT1st\ test + RESULT2nd\ test \leq 7 \times SRL}$$

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 labelled 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 (like corrosion) 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 FCM.

A sampling strategy should be defined which allows an appropriate and representative sample of the production batch to be obtained. 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. When 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 a 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 an 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
≤ 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

In official controls (e.g. as part of a market surveillance 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 FCM or article should be avoided, especially for metal-plated products.

Release testing into foodstuffs

Pre-treatment and handling of materials and articles, where appropriate, are described under Pre-treatment of materials and articles.

If appropriate, test conditions may be selected using the times and temperatures set out under Testing release from materials and articles 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 with 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 sulfur 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 *et al.* (2016) have created 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

* 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.

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.

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 interference 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

The release of a particular metal from a metallic FCM 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):

$$\mathbf{SR = C_1 - C_0 \text{ expressed in [mg Me/kg food] or in [mg Me/dm}^2\text{]}.}$$

Release testing into food simulants

Food simulants

As it is not always possible to test release from FCM 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 Guide 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 (ATW) EN 16889*
Acidic foods (pH ≤ 4.5)	Citric acid 0.5% (m/v)†

* EN 16889:2016 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, sulfate 13 mg/L and pH adjusted to 7.5 using 0.1M NaOH or 0.1M HNO_3. ATW (pH 7.5) should be prepared fresh every day. When used for a release test at 100°C, it should be heated slowly to a gentle boil, to avoid changes in the pH. After the release test, a few drops of HNO_3 acid should be added to avoid metal ion precipitation.

† 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.

If an article is intended for contact with only a specific dry food it should be tested with that food.

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 (e.g. for metal cans the experimental set-up should imitate the absence of oxygen).

Articles that can be filled

Kitchenware articles and other articles that can be filled should be filled with the food simulant to approximately ⅔ total capacity and then suitably covered to reduce evaporation. Metal cans should be filled to their nominal volume. 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 (Beldi *et al.*, 2021). 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), 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 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 Beldi *et al.*, 2021).

B. *Materials and articles at the end-use level that cannot be filled other than A*

This applies to materials and articles such as 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 dm^2, determined with a measurement precision of 1 mm for each side. Only the food contact surface is taken into account when determining the SR value. For symmetrical samples only, including both surfaces in the calculation is sometimes valid. This is when it can be shown that the SR value obtained in the total immersion test including both surfaces in the calculation is, allowing for analytical tolerance, the same as that obtained by single surface testing. The areas of cut edges are taken into account only if their thickness exceeds 2 mm.

The ratio of the food contact area to simulant volume during the test is maintained equal to the one during actual use. If the actual area to volume ratio is not known, it is set to 6 dm^2/kg simulant and this is reported. Testing conditions are selected as described above for articles that can be filled.

As an alternative to testing by immersion, an appropriate set-up (e.g. applying a glass jar to a metal lid) or a test cell for samples of flat (non-fillable) articles can be used. The sample is mounted to the test cell with the food contact surface facing towards the foodstuff or food simulant.

Test cells can be used if the applicable test conditions as described in the JRC guideline are met (Beldi *et al.*, 2021).

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 the potential release of metals from the test cell itself. In the blank configuration, an inert sheet that does not release any metals should be used in 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 1 200 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 (Beldi *et al.*, 2021) specify the testing time and temperature for a wide variety of kitchenware articles.

C. *Food processing appliances*

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

Test conditions

The appliances (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. If during its intended use the material or article is subjected only to precisely controlled time and temperature conditions in food processing equipment, either as part of food packaging or as part of the processing equipment itself, testing may be done using the worst foreseeable contact conditions that can occur during the processing of the food in that equipment.

For hot beverage appliances, testing should be performed in accordance with EN 16889 (CEN, 2016).

Methods of analysis

Methods of analysis used for release testing of FCM and articles must comply with the provisions of Annex III (*Characterisation of methods of analysis*) of Regulation (EU) 2017/625. Laboratories performing analyses must use validated methods for the determination of metals and other elements according to the guidelines and criteria specifically set out in the EUR 24105 Guideline (Bratinova *et al*., 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 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 deionised (Ph. Eur., 2022), or water of similar quality must be used.

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 hours 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 is achieved as far as possible.

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 LOD 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 LOQ 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. LOD < 1/10 SRL
2. 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 relative standard deviation (RSD), under conditions of reproducibility, depending on concentration (Bratinova et al., 2009)*

Analyte %	Analyte ratio	Unit	RSD (%) predicted
0.01	10^{-4}	100 mg/kg	8.0
0.001	10^{-5}	10 mg/kg	11.3
0.0001	10^{-6}	1 mg/kg	16.0
0.00001	10^{-7}	100 µg/kg	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 FCM (Bratinova *et al.*, 2009) 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 is tested (see Sampling of materials and articles). The sample is considered compliant only if all the test specimens of the sample are compliant.

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

In the case of repeated-use materials or articles, the results after the third release test are used for the compliance statement. Additionally, the sum of the results of the first and second release tests should not exceed seven times the SRL (see Testing release from materials and articles into food simulants, *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 it, the SR is calculated according to the rules set out in Annex I. The corresponding envelope volume must be reported.

For articles that consist of separate parts (including accessories) and for which the surface area to volume ratio is not known for the assembled article, the total mass of any given released element must be calculated by adding all the release values from the individual parts that come into contact with food. This total mass of each released element must be converted into mg/kg food by taking into account the real 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 SR of silver when justified (see Annex II).

Calculation of specific release

When the foodstuff or food simulant used for the release test contains the element under investigation (see Release testing into foodstuffs, *Natural metal content of the foodstuff*), 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/dm²].

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

Example:

Assuming

$$C_0 = 2.0 \text{ mg Me/kg}, u(C_0) = 0.4 \text{ mg Me/kg}$$

$$C_1 = 8.0 \text{ mg Me/kg}, u(C_1) = 1.6 \text{ mg Me/kg}$$

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

$$SR = C_1 - C_0 = 8 - 2 = 6 \text{ mg Me/kg}$$

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

where U(SR) is the expanded uncertainty, calculated using a coverage factor (k) of 2, and applying the law of uncertainty propagation according to BIPM (2008).

The final result should be reported as

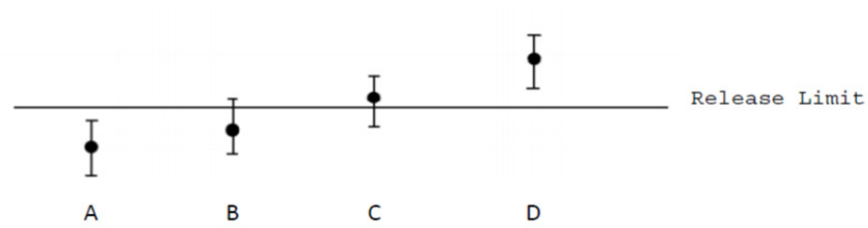
SR = 6.0 ± 3.3 [(k=2) or (95%)] mg Me/kg.

This approach is also applicable when C_0 and C_1 are expressed in mg Me/dm².* The final result should then be multiplied by 6 to obtain a result expressed in mg Me/kg.

* Applicable for articles described in section *Materials and articles at the end-use level that cannot be filled other than A.*

How to check compliance

The Eurachem guide (Williams and Magnusson, 2021) defines the four cases presented in this figure:



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

The assessment of whether the results for cases B and C comply with the release limit depends on whether it is necessary to demonstrate compliance or non-compliance of materials and articles. For the former, the conservative approach (intended to protect the consumer) would consider cases B and C as non-compliant. For the latter, to provide evidence of non-compliance beyond reasonable doubt, only case D would be considered non-compliant, so cases B and C would be compliant.

Calculating the SR for articles as defined in Annex I

The calculation is described in Annex I.

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Annex I – Methods for measurement of articles for which it is impractical to estimate the ratio of surface area to the amount of foodstuff in contact with it

This annex describes a method for calculating the foreseeable mass of foodstuff in contact with articles from the section Articles 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 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 SR in mg/kg. It defines a rectangular cuboid with three dimensions (X = depth, Y = width, Z = height) that encloses a space called the 'envelope volume'. The envelope volume is equivalent to the amount of food in contact with the material and therefore relates to the consumer's exposure.

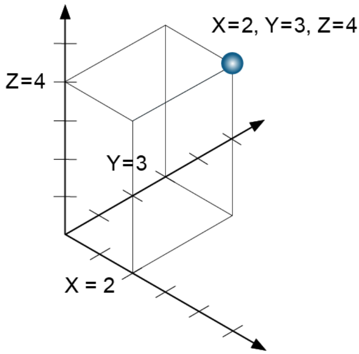
This method deviates from the method currently described in European Regulation (EU) No 10/2011 on plastic materials and it is proposed as more appropriate for a number of utensils whose surface area is not correlated with the amount of food in contact with it, and therefore consumer exposure.

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 X, Y and Z axes



The figure above illustrates the three-dimensional envelope 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 ($\mathbf{H}_{\mathbf{total}}$) for the utensil using a gauge (e.g. Vernier calipers) with a precision of 1 mm. The height shall be established by measuring in a straight line along the centreline of the utensil.

Remark

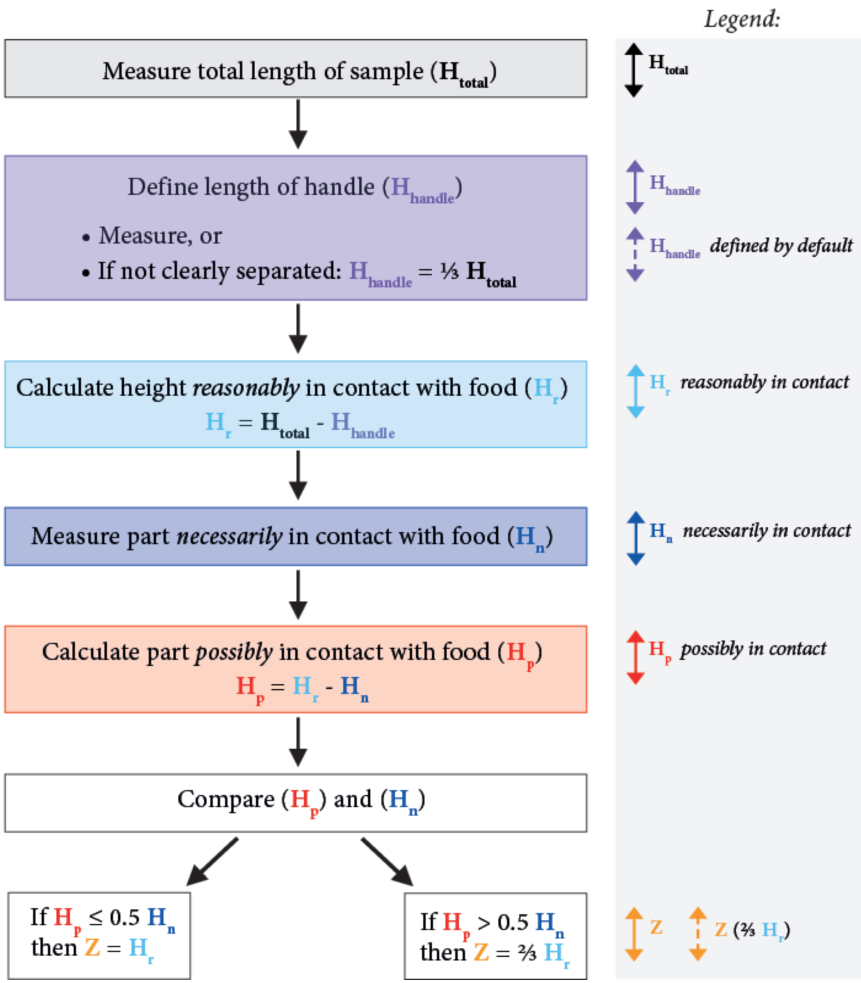
If it is not clear what points should be used to determine the height measurement, the utensil can be suspended (i.e. allowed to hang freely from the highest point of the handle and then lowered until it touches a horizontal surface e.g. a desktop). The height is then measured from the highest point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

Then determine what portion of the total height ($\mathbf{H}_{\mathbf{total}}$) *of the utensil is assigned, respectively, to the handle* ($\mathbf{H}_{\mathbf{handle}}$) *and to the part necessarily in contact with food* ($\mathbf{H}_{\mathbf{n}}$).

Measure the length of the handle ($\mathbf{H}_{\mathbf{handle}}$) *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 measurement of 1/3 of total height.*

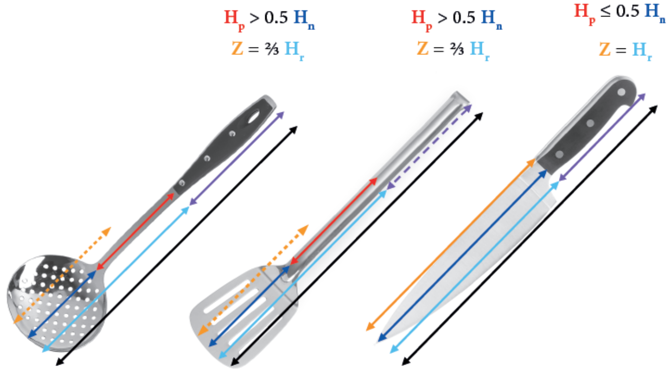
Afterwards measure the depth (along the X axis) and the width (along the Y axis) parallel to the horizontal surface using the same orientation of the utensil as described above.

Calculate the height (Z) for defining envelope volume of the utensil as shown in the following diagram and examples defining the height (Z) of utensils:



Source: German Federal Institute for Risk Assessment (BfR)

Examples:



If there is a metallic decorative element between the functional part and the handle or if the metallic decorative element is part of the handle and is in contact with the functional part, this decorative element shall not be taken into account when measuring the handle.

Deviation from the aforementioned process

Articles that cannot be filled may have a shape or may be used in a way that makes them unsuitable for the aforementioned calculation process.

Examples:

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 cuboid has been constructed, calculate the envelope volume as follows:

$$\textbf{Envelope volume} = X \times Y \times Z\ (cm^3)$$

If any of the 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:

$$\textbf{RW (kg)} = \textbf{Envelope volume}\ (cm^3)/1000$$

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 LOD) 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 the relative contribution from the handle to be added to the release (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.

$$\textbf{Released mass (M)} = V \times C$$

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].

For consideration of the original metal content in the foodstuff or food simulant, the rules laid down in 'calculation of specific release (SR)' apply.

Determination of the specific release

As a general rule:

$$\textbf{SR} = \textbf{M/RW}$$

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 limit 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 (Beldi *et al.*, 2021) 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, to date, 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. at 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. 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, it may be appropriate to take technically feasible levels (ALARA) into account. However, at the present time, there are insufficient data to establish an SRL based on ALARA.

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.

Therefore:

For cutlery made from silver or silver-plated cutlery the SR 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.

The factor is only applicable to silver or silver-plated cutlery labelled in accordance with Article 15 1(b) 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 limit.

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ISO. Materials and articles in contact with foodstuffs – cutlery and table holloware – Part 2. Requirements for stainless steel and silver-plated cutlery. Ref: ISO 8442-2:1997.

Following the adoption of Council of Europe Resolution CM/Res(2020)9, this revised technical guide aims to ensure the safety and suitable quality of food contact materials and articles made from metals and alloys and is the result of a comprehensive review by the European Committee for Food contact materials and articles (CD-P-MCA).

The second edition reflects scientific opinions, relevant research from national risk assessment bodies and a concerted consultation of stakeholders; it features modified safety data concerning specific release limits (SRLs) for chromium, manganese, thallium and a new section on zirconium and general recommendations for release testing. The updated methods for the measurement of certain articles facilitate the calculation of specific release for control laboratories.

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