

THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)



Technical guide on metals and alloys used in FCM

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History

- 2002 - policy statement concerning metals and alloys
Technical Document “guidelines on metals and alloys used as food contact materials”
- 14 metals + alloys
 - compilation on relevant information and safety aspects
 - no recommendation of release limits
- 2009 - new work on metals and alloy started
- recommendation of release limits
 - release testing
- 2013 - Resolution CM/Res(2013)9 on metals and alloys used in food contact materials and articles and the accompanying Technical Guide
- 23 metals (incl. release limits) + alloys
 - release testing, envelope volume
- 2014 - Ljubljana: international symposium on the safety of metals and alloys used in food contact materials
- co-organised by the EDQM and the Slovenian health authorities

History

2014 - revision of the Technical guide started

- ad hoc group on Implementation of the Resolution
- new developments in the safety assessments of different elements
- review of release testing

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

- guiding principles for FCM not yet harmonized

2022 - stakeholder consultation

- over 200 comments

2023 - editorial work

2024 - Technical Guide

“metals and alloys used in food contact materials and articles”, 2nd edition

2nd edition – differences to 1st edition

- Editorial review
 - correction/check of references
 - introduction of new references
- Harmonisation with Resolution CM/Res(2020)9
 - declaration of compliance deleted
- Review of safety data (all metals and alloys), changes to:
 - Cr
 - Mn
 - Ti
 - Zr
- Release Testing
 - see further slides
- Annexes
 - former annex I (AI by ICP-AES) deleted
 - annex I (formerly II) on the envelope volume revised
 - (new) annex II – correction factor for cutlery made of silver

Review of safety data

- all metals were reviewed to identify new safety data
- relevant changes were identified for the following metals:

Aluminium - 5 mg/kg

- no change of SRL (ALARA)
- contact with acidic food leads to unacceptable release levels
- labelling to prevent contact with acidic and salty food

Chromium - 1 mg/kg [Cr(III)] (1st ed. 0.25, transitional 1)

- EFSA derived 2014 a TDI of 0.3 mg/kg bw/day (equals 3.6 mg/kg food – 60 kg person, 20 % allowance)
- former SRL was 0.25 mg/kg, transitionally raised to 1.0 mg/kg
- as this value could be achieved at this time, no need to use up the TDI
- Cr(VI) – should not exceed 6 µg/l, no concern, since chromium in food should be Cr(III)

Manganese - 0.55 mg/kg (1st ed. 1.8)

- ANSES derived 2018 a TRV of 55 µg/kg bw/day (endpoint effects in development)
- therefore SRL derived for toddlers
- SRL 0.07 mg/kg for materials and articles especially for milk or infant food

Review of safety data

Nickel – 0.14 mg/kg

- EFSA derived 2015 a lower TDI, but raised it in 2020
- therefore no change of SRL

Silver – 0.08 mg/kg

- no change of SRL
- reduction factor of 5 introduced for cutlery (no cooking, no daily use)

Zirconium - 2 mg/kg (1st ed. -)

- newly introduced
- based on an assessment of the Netherlands

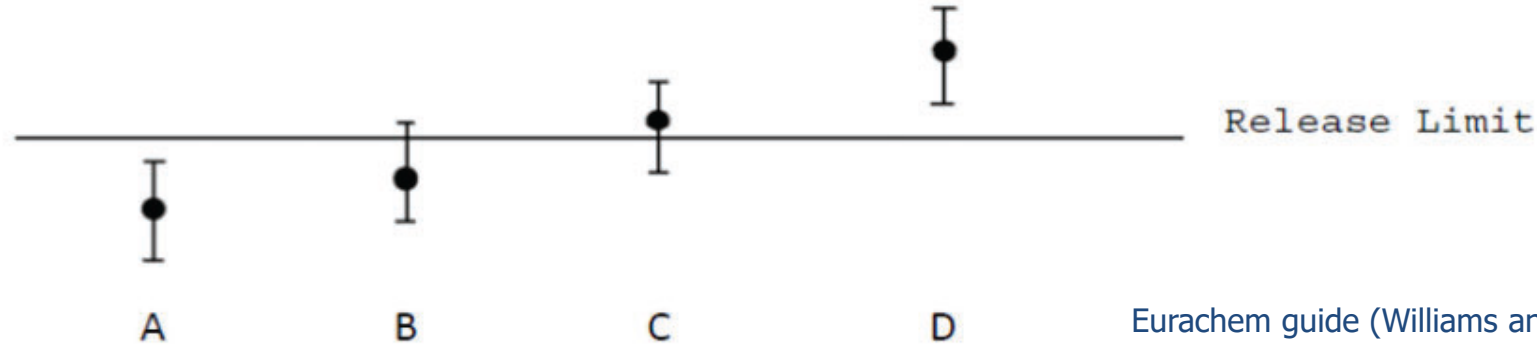
Thallium – 0.001 mg/kg (1st ed. 0.0001)

- calculation in 1st edition was not correct, corrected

Review of release testing

- Review of whole chapter, numerous editorial changes
- Relevant changes:
 - food prevails
 - Release into simulants is at least as high as in food
 - Simulants better specified
 - e.g. CA 5 g/l → CA 0.5 % (m/v) (5 g of citric acid monohydrate)
 - JRC Guidelines on testing conditions for kitchenware articles in contact with foodstuffs referenced for testing conditions
 - Better specification of test conditions for articles that cannot be filled other than cutlery and cooking utensils (e.g. foils, cutting boards)
 - Calculation of uncertainty better specified
 - “How to check compliance” included

How to check compliance



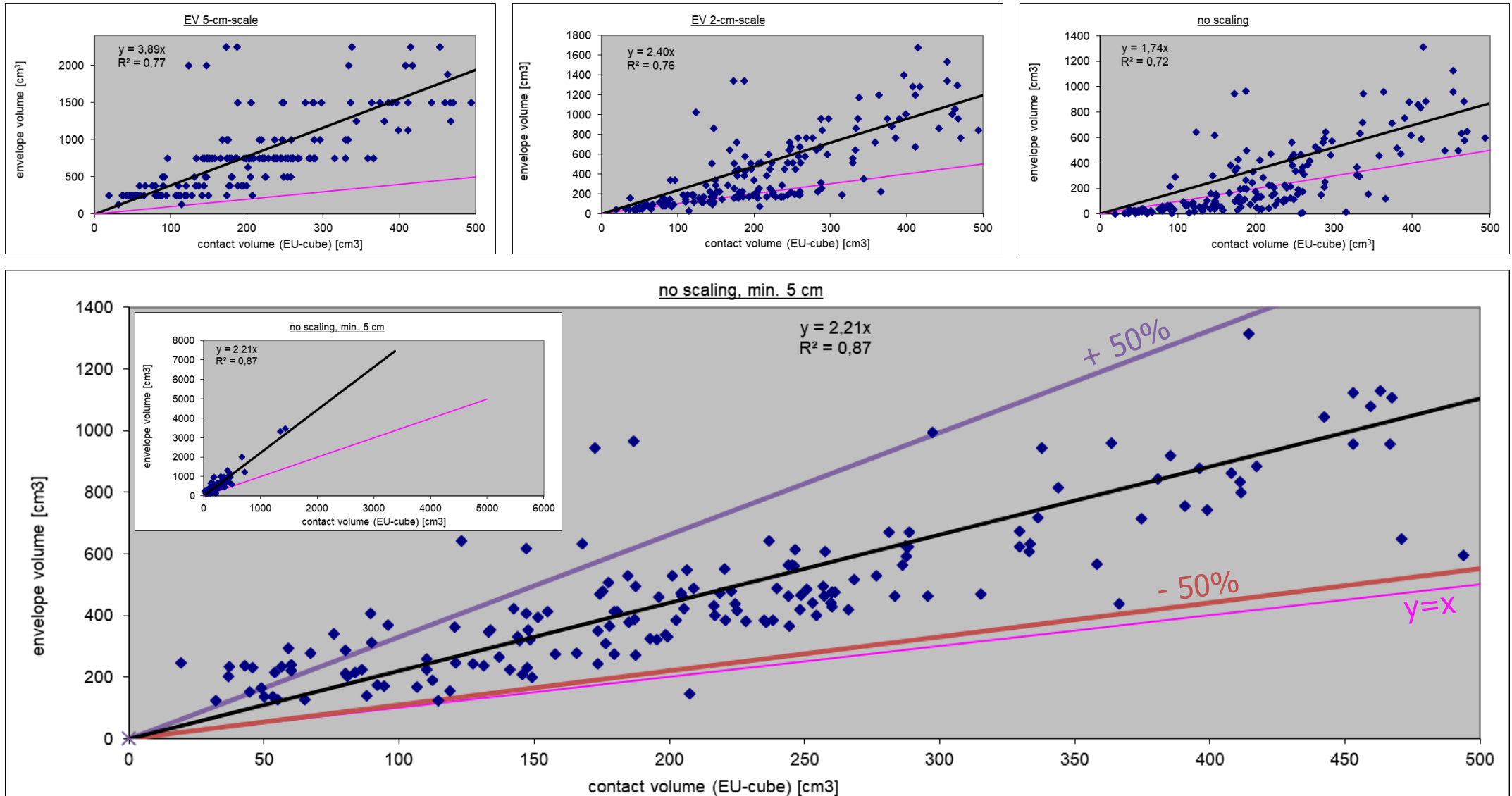
Eurachem guide (Williams and Magnusson, 2021)

- A – undoubtedly compliant
- D – undoubtedly non-compliant
- B, C depend, whether to prove compliance or non-compliance
 - proving compliance: B, C are to be considered as non-compliant
 - proving non-compliance: B, C are to be considered as compliant

Annex I - envelope volume

- compliance of non fillable articles (the amount of food in contact with the article cannot be clearly determined) checked according to conventions:
 - historically EU-cube (Reg (EU) 10/2011, metals: foils etc.): 6 dm²/kg food
 - uniform quality of the material, no relation to real consumer exposure, differs to fillable articles
 - poor reproducibility for surface estimation of complex utensils (EURL-LVU 2013, 77 participants, 5 kitchen utensils, results between 50 und 160 % of 3D-scan-reference)
- 2013, CoE: estimation of exposure according 3D-dimensions of the article
 - measure x-, y-, z-dimensions of utensil, round each value to next 5-cm
 - calculate envelope volume = $X \times Y \times Z$
 - rounding can be prone to large errors in case dimension is near 5 cm in multiple
 - $5 \times 5 \times 5 = 125$, $10 \times 10 \times 10 = 1000$ (800 %)
 - rounding leads to artificial clustering
 - high "overestimates" of contact volume compared to the EU-cube - lower acceptance?
- Revision of envelope volume

Annex I - envelope volume - different possibilities



Annex I - envelope volume

- Calculate Z (height) depending on different characteristics of the utensil
 - total length, length of handle, length of part necessarily in contact with food
- Measure X and Y with a precision of 1 mm
 - inline with measurement of articles that cannot be filled other than cutlery and cooking utensils
- 5 cm minimum value for X, Y, Z
- Calculate envelope volume $X \times Y \times Z$
- Deviations from defined calculation if needed



Annex II - correction factor for silver cutlery

- release from silver or silver-plated cutlery tested with citric acid under conditions for hot use may exceed the SRL for silver
- testing under these conditions does not adequately represent real use conditions and consumer exposure
- Whereas:
 - a) testing with citric acid might overestimate the real release
 - b) hot served acidic food represents only a fraction of the overall consumption
 - c) silver cutlery is normally not used every day
 - d) instead of the TRV used, ALARA could be used, but data are insufficient justify a correction factor
- Therefore a correction factor of 5 is established
 - silver or silver-plated cutlery tested as in food serving implements for cold/ambient or hot use (FSI/CAH1), citric acid
 - cutlery has to comply with ISO 8442-2
 - labelling necessary

Thank you for your attention



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