Metals and alloys used in food contact materials and articles, 2nd edition

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The European Directorate for the Quality of Medicines & HealthCare (EDQM) has published the second edition of the Technical Guide for Metal and Alloys for Food Contact Use[1]. This update supplements Council of Europe Resolution CM/Res (2020) 9 [2] and is intended to ensure the safety and suitable quality of food contact materials (FCM) and articles made from metals and alloys.

As this is a guidance document, no transitional period is applicable and the released information can be used immediately as guiding information for the safety assessment of metallic food contact materials. Please refer to below for a summary of noteable changes.

UPDATE IN SPECIFIC RELEASE LIMITS

The release limit of several elements has been updated based on further scientific opinions and inputs from EFSA as well as national risk assessment bodies.

ELEMENT	LIMIT 1ST EDITION	LIMIT 2ND EDITION	REMARK
Chromium (III)	0.25 mg/kg	**1 mg/kg**	SRL of Chromium (IV) was removed
Manganese	1.8 mg/kg	**0.55 mg/kg**	Tightened from previous edition
Thallium	0.0001 mg/kg	**0.001 mg/kg**	Correction of the limit
Zirconium	-	**2 mg/kg**	Newly added in this edition

TESTING CONDITION ALIGNMENT TO JRC GUIDELINE

To check whether the SRL requirements can be fulfilled, testing conditions and simulant choices play an important role. The 2nd edition of the technical guideline removed the indicative examples from the previous edition and refers to the JRC (Joint Research Centre) guideline “Testing conditions for kitchenware articles in contact with foodstuffs: plastics, metals, silicone & rubber, paper & board”[3], where simulants and testing conditions are suggested for a wide variety of food contact articles.

1 https://freepub.edqm.eu/publications/PUBSD-128/detail
2 https://search.coe.int/cm?i=09000016809fe04a
3 https://publications.jrc.ec.europa.eu/repository/handle/JRC134290

UPDATED CALCULATION RULE FOR ENVELOPE VOLUME

In the first edition, the envelope volume concept was introduced specifically for articles for which it is impractical to estimate the actual food volume (e.g. kitchen utensils). The calculation for estimation of the envelope volume is based on measuring the length, width and depth of the food contact article. The measuring rule has been updated in the second edition and instead of the previous 5 cm increments this is now narrowed down to 1 mm increments for dimensions exceeding 5 cm.

BRIEF IMPACT ASSESSMENT

- The update of the SRLs should not raise too many concerns in the elements Chromium and Thallium, as the adjusted SRLs are higher. However, the limit of Manganese has become stricter, so customers are recommended to check the values of their latest test results. Also, Zirconium is newly added, and it is recommended to start asking laboratories to include release testing of this element Zirconium can be used as passivation agents in metal food contact materials.
- Update in testing conditions recommendation should have in general lower impact because the JRC guideline in its latest release (in 2023) was already including metallic FCMs in the scope.
- The new calculation rule for envelop volume will require more attention. Because of the smaller increments used, the estimated food volume of the applicable articles might be smaller, and consequently this could yield higher test results. Customers are highly recommended to check and take contact with TÜV Rheinland experts in case of further questions.

Further information on current legal changes can also be found on our homepage at www.tuv.com or https://www.tuv.com/regulations-and-standards/en/.

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Infobox: You can also find more information about services for food contact material at:

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