

As at: 2 July 2018

Rules of procedure of the German Environment Agency for the management of the positive list of metallic materials suitable for use in contact with drinking water

Only the German version of this document is legally binding.

General Points

A metallic material can be included in the positive list of metallic materials suitable for use in contact with drinking water of the German Environment Agency (UBA) either by an application to the German Environment Agency (Case A) or by the fact that the competent authority of another EU Member State has performed an assessment according to the specifications of the 4 Member States (4MS) scheme about the assessment of metallic materials (see A 2.2) and the competent authority has forwarded its assessment including the relevant application documents to the German Environment Agency (Case B). In both cases, a decision by the German Environment Agency about inclusion of the metallic material in the positive list is required.

Case A: Application for assessment by the German Environment Agency

A.1 Application

To include a material in the positive list, an application must be submitted to the

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Department II 3
Drinking Water and Swimming Pool Water Hygiene
Heinrich-Heine-Straße 12
08645 Bad Elster
Germany

Applications may be submitted by the manufacturer of the material, those who want to use the material for the manufacture of products in contact with drinking water, associations and federations of industrial companies and technical regulatory bodies in the field of drinking water supply.

Applications for assessment by the German Environment Agency must be submitted on the form "Application for a material for inclusion in the positive list of metallic materials suitable for use in contact with drinking water pursuant to § 17 Drinking Water Ordinance (TrinkwV) (Antrag zur Aufnahme eines Werkstoffs in die Positivliste der Bewertungsgrundlage

German Environment Agency
Section II 3.4
Heinrich-Heine-Str. 12
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für metallene Werkstoffe im Kontakt mit Trinkwasser gemäß §17 Trinkwasserverordnung, TrinkwV) (Annex 1).

A.1.1 Application for the inclusion of a new reference material

It is recommended that contact is made with the German Environment Agency before starting to test a new reference material to clarify the composition of the reference material, the extent of testing and the definition of the material category.

The application for the inclusion of a new reference material must be accompanied with the following information or documents in electronic form (PDF format):

1. Designation of the reference material,
2. Composition of the reference material (minimum and maximum limits) and minimum and maximum limits of impurities,
3. Relevant material category with explanation. If a new material category is suggested, this must be explained and category limits proposed.
4. Product group for which the reference material has been tested (Factor B according to DIN 50930-6)
5. Three test reports according to DIN EN 15664-1 by accredited laboratories for tests with three different test waters in accordance with DIN EN 15664-2,
6. Test certificates evidencing the material composition of the specimens,
7. Additional information, where appropriate, relevant to the hygienic suitability of the material beyond the mentioned tests.

A.1.2 Application for the inclusion of a commercially available material

The application must be accompanied with the following information or documents in electronic form (PDF format):

1. Designation of the material (standard name if the material is standardised),
2. Composition of the material (minimum and maximum limits) and minimum and maximum limits of impurities,
3. Relevant material category with explanation.
4. Product group for which the material has been envisaged (Factor B according to DIN 50930-6)
5. A test report of a comparative test according to DIN EN 15664-1 by an accredited laboratory or three test reports according to DIN EN 15664-1 by accredited laboratories for tests with three different test waters in accordance with DIN EN 15664-2

6. certificates evidencing the material composition of the specimens (new material and reference material),
7. Additional information, where appropriate, relevant to the hygienic suitability of the material beyond the mentioned tests.

A.1.3 Application for the inclusion of a material commercially available material without testing according to DIN EN 15664-1

A.1.3.1 Exemptions for inclusion of a material without testing according to DIN EN 15664-1

- a) In certain cases, the testing of a material according to DIN EN 15664-1 is not suitable to assess the hygienic suitability of a metallic material. This applies to stainless steels and to ferrous materials that are used under continuous water flow. In these cases, the hygienic suitability must be proven as part of a scientific dossier.
- b) In the case of copper alloys, the test according to EN 15664-1 can be performed on certain test specimens, representative for different materials under special circumstances. This is only possible if
 1. the materials, due to their composition and structure, exhibit a comparable or better corrosion resistance in particular in terms of metal release into the drinking water,
 2. the materials belong to the same category,
 3. the materials do not differ through possible additional constituents,
 4. the composition of the test specimens used meets the requirements for the entire range of materials and
 5. the specimens used exhibit the least favourable metal release behaviour for the entire range of materials.

A.1.3.2. Requirements for the expert report

The expert report must be written in English and it must provide a detailed analysis of the corrosion-chemical behaviour of the materials and its interaction with the metal release into the drinking water. In Case B, test results according to DIN EN 15664-1 must be considered.

The expert report must be issued by an independent and reliable expert who is renowned in metallurgy, corrosion chemistry and damage assessment. Reliability is not acknowledged if the expert has been legally bindingly convicted leading to imprisonment or a fine. Reliability is not accepted for individuals who no longer possess the ability to hold public offices pursuant to § 45 of the Penal Code. The expert must have successfully completed an engineering or science degree majoring in a field relevant to the activity employed. The expert must also have acquired a reputation as a neutral expert based on at least five years of experience

in issues of European standardisation, research, expert opinions and advisory services. Evidence showing fulfilment of the above requirements must be presented to the German Environment Agency on request.

A.1.3.3 Application procedure

The application must be accompanied with the following information or documents in electronic form (PDF format):

1. Designation of the material (standard name if the material is standardised),
2. Composition of the material (maximum and minimum limits) and maximum and minimum limits of impurities,
3. Relevant material category with explanation.
4. Product group for which the material has been envisaged (Factor B according to DIN 50930-6)
5. In the case b): identification of the material that has been tested according to DIN EN 15664-1,
6. Justification for application without special test according to DIN EN 15664-1,
7. Expert report,
8. Additional information, where appropriate, relevant to the hygienic suitability of the material beyond the mentioned tests.

A.2 Application processing

A.2.1 Review of the documentation for completeness

The German Environment Agency checks the completeness of the documents within two months from the date of its receipt. If the documents are not complete, the applicant will be informed and asked to submit the missing documents.

A.2.2 Assessment basis for inclusion

The German Environment Agency assesses metallic materials according to the evaluation criteria document for metallic materials in contact with drinking water

(<https://www.umweltbundesamt.de/en/document/evaluation-criteria-for-metallic-materials-in-0>)

The evaluation criteria document for metallic material is the national implementation of the “4MS Common Approach: Acceptance of metallic materials used for products in contact with drinking water – Part A“ coordinated between Germany, France, the Netherlands and the United Kingdom of Great Britain

(http://www.umweltbundesamt.de/wasser-e/themen/downloads/trinkwasser/4ms_scheme_for_metallic_materials_part_a.pdf).

A.2.3 Involvement of professional bodies

When deciding about the inclusion of the material, the German Environment Agency considers the professional opinion of the national experts committee "Metallic materials in contact with drinking water". By making an application, the applicant agrees that the application documents will be made available to the members of this expert panel. The members of the committee are committed to confidential handling of the documents.

Application documents should be sent to the experts committee within the specified timeframe. After receipt of the complete application documents, these will be considered at the next meeting of the expert panel. The German Environment Agency will keep applicants informed regarding the pending consideration by the expert panel.

The applicant and/or his representative (e.g. a staff member of the laboratory contracted) will be invited to the meeting. The applicant or his representative will present the application to the expert panel.

The experts committee may provide a vote in accordance with the committee's rules of procedure about the application.

A.2.4 Decision process about inclusion

The German Environment Agency prepares a written assessment about the material within two months following the experts committee vote on the application and notifies the applicant therefore in writing. In the case of a positive assessment the German Environment Agency will forward its assessment and the application documents to the competent authorities of the other EU Member States, which work together in the scope of the 4MS cooperation. By making an application, the applicant agrees that the application documents will be forwarded to the competent authorities of the other Member States. If no objections have been expressed by the other Member States within six months, the German Environment Agency makes a decision about the inclusion. The material will be included in the positive list with the next update of the evaluation criteria document.

A.3 Fees

The German Drinking Water Fee Ordinance (Trinkwasser-Gebührenverordnung, TrinkwGebV) came into force on 17 December 2013. Since that date the German Environment Agency levies fees for services individually attributable according to the German Drinking Water Ordinance (TrinkwV).

According to the Annex to § 1 of this Ordinance, the inclusion of starting substances or raw and other materials in a positive list is a chargeable event pursuant to § 17(3)(2)(2) or (3) of the German Drinking Water Ordinance (TrinkwV) on application pursuant to § 17(4)(2) of the German Drinking Water Ordinance (TrinkwV)

The mandatory evaluation criteria for metallic materials together with a positive list of metallic materials suitable for use in contact with drinking

water was published on 10 April 2015. Applications for assessment of a material submitted after issuing this evaluation criteria document are therefore subject to fees according to the German Drinking Water Fee Ordinance (TrinkwGebV).

Case B: Assessment of a material by another EU Member State

If a competent authority of another EU Member State has carried out a material assessment according to the 4MS Common Approach to assess metallic materials and they send their assessment, including the associated application documents, to the German Environment Agency, German Environment Agency will decide about inclusion in the positive list. It may also seek the professional opinion of the national expert committee.

If the German Environment Agency does not agree with the assessment of another EU Member State's competent authority, it will notify the other EU Member State's competent authority to this effect.