

## **Federal Environment Agency by-laws for the management of a list of metallic materials which are hygienically suitable for contact with drinking water**

Only the German version of this document is legally binding.

### **General considerations**

The inclusion of a metallic material in the Federal Environment Agency (FEA) list of metallic materials which are hygienically suitable for contact with drinking water occurs either after an application is filed with the Federal Environment Agency (case A) or after the competent office of another EU member state has conducted an assessment in accordance with the specifications of the 4MS scheme for the evaluation of metallic materials and the competent office is submitting its evaluation including the associated application documents to Federal Environment Agency (case B). A decision from the Federal Environment Agency about the inclusion of the metallic material is required in both cases.

### **Case A: application for assessment by the Federal Environment Agency**

#### **A.1 Application**

For the inclusion of a material in the list, an application must be submitted to the  
Federal Environment Agency  
Department II 3 Hygiene of drinking and bathing pool water  
Heinrich-Heine-Straße 12  
08645 Bad Elster  
Germany

Applications may be submitted by the manufacturer of the material, those planning to use the material for the manufacture of products coming into contact with drinking water, unions and associations of industrial enterprises as well as issuers of technical rules relating to the supply of drinking water.

##### **A.1.1 Application for inclusion of a new reference material**

It is recommended to contact the Federal Environment Agency before starting to evaluate a new reference material, in order to clarify the composition of the reference material, the test scope and the definition of the material category.

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

1. Name of the reference material,
2. Composition of the reference material (maximum and minimum limits) and the maximum and minimum limits of impurities,
3. Associated material category including justification. If a new material category is planned, this must be justified and category limits proposed.

4. Product group for which the reference material was tested (factor B according to DIN 50930-6),
5. Three test reports according to DIN EN 15664-1 from accredited laboratories for the tests with the three different types of test water according to DIN EN 15664-2,
6. Test certificates for the material composition of the test specimens,
7. Additional optional information which may be relevant beyond the mentioned tests for the assessment of the hygienic suitability of the material.

#### **A.1.2 Application for inclusion of a commercially available material**

The application must be accompanied by the following information or documents in electronic (pdf) format:

1. Name of the material (standard name for standardized materials),
2. Composition of the material (maximum and minimum limits) and the maximum limits of impurities,
3. Associated material category including justification,
4. Product group for which the material is intended (factor B according to DIN 50930-6),
5. A test report of a reference test according to DIN EN 15664-1 from an accredited laboratory or three test reports according to DIN EN 15664-1 from accredited laboratories for the tests with the three different types of test water according to DIN EN 15664-2,
6. Test certificates for the material composition of the test specimens (new material and reference material),
7. Additional optional information which may be relevant beyond the mentioned tests for the assessment of the hygienic suitability of the material.

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

##### ***A.1.3.1 Exceptions for the inclusion of a material without testing according to DIN EN 15664-1***

- a) In some cases, testing of a material according to DIN EN 15664-1 may not be suitable to assess the hygienic suitability of a metallic material. This concerns stainless steel and ferrous products used under continuous water flow. In these cases, the hygienic suitability must be demonstrated with an expert opinion.
- b) For copper alloys, certain test specimens may be used in representation of different materials to conduct the tests according to DIN EN 15664-1. This is only possible, if
  1. The materials feature a comparable or better corrosion behaviour with respect to the release of metal into the drinking water due to their composition and structure,
  2. The materials belong to the same category,

3. The materials do not differ by additional possible alloy components,
4. The composition of the used test specimens meets the requirements of the entire range of materials, and
5. The used test specimens feature the least favourable metal release behaviour of the entire range of materials.

Corresponding proof (particularly of numbers 1. and 5.) by means of an expert opinion is required.

#### ***A.1.3.2 Requirements for the expert opinion***

The expert opinion must be written in English and comprehensively address the corrosion chemical behaviour of the materials and its interaction with the release of metal into the drinking water. In so doing, the test results according to DIN EN 15664-1 must be considered for case b).

The expert opinion must be compiled by an independent and reliable expert with a proven track record in the fields of metallurgy, corrosion chemistry and damage assessment. Reliability is not given, if the reviewer has been legally convicted to serve a prison sentence or to pay a fine. Reliability is not given either for individuals who are no longer able to hold public office according to section 45 of the Criminal Code. The reviewer must have a degree in engineering or natural sciences in a discipline that is relevant to the field. In addition, the reviewer must have a reputation as a neutral expert based on at least five years of experience in the European standardisation, research, assessment and consulting field. Proof that the requirements outlined above are met must be provided to the Federal Environment Agency upon request.

#### ***A.1.3.3 Application***

The application must be accompanied by the following information or documents in electronic (pdf) format:

1. Name of the material (standard name for standardised materials),
2. Composition of the material (maximum and minimum limits) and the maximum limits of impurities,
3. Associated material category including justification,
4. Product group for which the material is intended (factor B according to DIN 50930-6),
5. For case b): name of the material tested according to DIN EN 15664-1,
6. Justification for the application without separate testing according to DIN EN 15664-1,
7. Expert opinion,
8. Additional optional information which may be relevant beyond the mentioned tests for the assessment of the hygienic suitability of the material.

## **A.2 Processing of the application**

### **A.2.1 Review for completeness of the documents**

The Federal Environment Agency reviews the completeness of the documents within two months after receipt of the application. In the event that the documents are incomplete, the applicant will be notified and asked to submit the missing documents.

### **A.2.2 Assessment basis for the inclusion**

The inclusion is assessed on the basis of the document entitled “4MS Common Approach: Acceptance of metallic materials used for products in contact with drinking water – Part A“ ([http://www.umweltbundesamt.de/wasser-e/themen/downloads/trinkwasser/4ms\\_scheme\\_for\\_metallic\\_materials\\_part\\_a.pdf](http://www.umweltbundesamt.de/wasser-e/themen/downloads/trinkwasser/4ms_scheme_for_metallic_materials_part_a.pdf)) adopted by Germany, France, the Netherlands and the United Kingdom. This document is being implemented in the national rules and regulations within the scope of the revision of DIN 50930-6.

### **A.2.3 Involvement of technical circles**

When making the decision about the inclusion of the material, the Federal Environment Agency takes into consideration the technical opinion of the FEA expert panel “Metallic materials in contact with drinking water“. By submitting the application, the applicant gives permission that the application documents are made available to the members of this expert panel. The members of the expert panel are committed to handling the documents confidentially.

Upon receipt of the complete application documents, the application will be discussed during the next meeting of the expert panel, for which the application documents can be mailed in a timely manner. The Federal Environment Agency will inform the applicant about the planned debate.

The applicant and/or a representative (e.g. an employee of the test laboratory in charge) will be invited to the corresponding meeting. The applicant or his representative presents the application to the expert panel.

The expert panel can issue a vote about the application in accordance with the by-laws of the expert panel.

### **A.2.4 Decision process for the inclusion**

The Federal Environment Agency compiles an assessment of the material no later than within two months after the expert panel has issued a vote concerning the application and notifies the applicant thereof in writing. In the event of a positive vote, the Federal Environment Agency forwards its assessment and the application documents to the competent offices of the other EU member states, which are co-operating within the scope of the 4MS coopreation. By submitting the application, the applicant gives permission that the application documents are forwarded to the other member states. If no objections are raised by the other member states within six months, the Federal Environment Agency will make a decision about the inclusion and update the list published on the internet according to the assessment.

### **Case B: Assessment of a material by another EU member state**

If a competent office of another EU member state has conducted a material assessment in accordance with the specifications of the 4MS scheme for the evaluation of metallic materials, and the panel submits its evaluation including the associated application documents to the Federal Environment Agency, the FEA will make a decision about the inclusion in the list. It may likewise obtain an expert opinion from the FEA expert panel for this.

In the event that the Federal Environment Agency does not agree with the assessment of the competent office of another EU member state, it will notify the competent office of the other member state thereof.