

ACCEPTANCE OF METALLIC MATERIALS USED FOR PRODUCTS IN CONTACT WITH DRINKING WATER

4MSI Common Approach

Part A – Methodologies for testing and accepting compositions to be included in the Positive list of compositions for metallic materials

Part B – Positive list of compositions for metallic materials

Part C – Procedure and methods for testing and accepting final materials as used in a product made from compositions on the Positive List

Adopted by the 4MSI Joint Management Committee

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France, Germany, the Netherlands, the United Kingdom and Denmark work together in the framework of the 4MSI Common Approach as laid down in the Declaration of Intent (January 2011). This common approach aims for convergence of the respective national approval schemes for materials and products in contact with drinking water.

The 4MSI have adopted Part A of this document as a common basis for implementing the concept of accepting metallic compositions. The document is subject to revisions agreed by the 4MSI.

Part B of this document includes a Positive List of metallic compositions accepted in all of the Member States of the 4MSI following the procedure described in Part A.

Part C includes the procedure and methods for accepting metallic products or components.

The structure of this document (Part A, B, C) follows the different implementing acts as described in the new article 11 paragraph 2 (a), (b), (c) of the European Drinking Water Directive.

Further information may be obtained from any of the competent authorities of the 4MSI.

Bundesministerium für Gesundheit (Deutschland)

Ministère du Travail, de l'Emploi et de la Santé (France)

Ministerie van Infrastructuur en Milieu (Nederland)

Department for Environment, Food and Rural Affairs (United Kingdom)

The Danish Transport, Construction and Housing Authority and Ministry of Environment
(Denmark)

Denmark joined the 4MSI after the development of this common approach, and has therefore not assessed the content of the approach.

Principles

Acceptance of metallic compositions

Council Directive 98/83/EC on the Quality of Water Intended for Human Consumption (DWD) establishes a high level of protection for the consumer and requires Member States to ensure that substances and materials used in preparation and distribution of drinking water do not reduce that level of protection. The Directive's point of compliance is at consumers' taps. This implies a need for control of all products in contact with drinking water (PDW), including pipes and fittings within consumers' premises.

Most of the metals used in metallic PDW are controlled as parameters by the DWD. Monitoring carried out by Member States provides evidence that metallic pipes and fittings can increase concentrations of metals in drinking water.

Metal release into drinking water is caused by corrosion. This is a long-term process and leads to the build-up of corrosion product layers which influence further metal release. Two different periods of metal release from a PDW can be distinguished. The initial period about three months (short term behaviour) is mainly influenced by the surface characteristics of the product (e.g. lead film on the surface), whereas the long-term behaviour is characterized by the corrosion of the bulk metallic composition. As it is the bulk metallic composition that defines the long-term behaviour of products, it is possible to accept metallic compositions for use with drinking water. For the acceptance of metallic compositions other factors affecting the interaction between metals and water have to be taken into account, such as:

- chemical and physical characteristics of water
- design and construction of the distribution system (e.g. density of use of fittings, design of products)
- flow regime, as determined by the water consumption habits of consumers
- contact time of the metallic composition with water

The procedure described in this document for accepting metallic materials (compositions) takes reasonable worst-case situations of the above mentioned factors into account. The procedure refers to EN 15664-1 as the testing method for metallic materials. The testing conditions specified in this standard simulate the use of metallic materials in plumbing systems within buildings.

The interpretation of test results can be very complex in some cases and it is recommended to get advice from a "Committee of Experts" during the decision making process.

The acceptance will lead to a listing of the accepted compositions on a Positive List (Composition List).

The acceptance of compositions and their listing in the Positive List requires a clear definition of the material's composition and test methods to identify the complete composition.

The Positive List in Part B of this document lists the metallic compositions (materials) accepted by the 4MSI.

Acceptance of products

The acceptance procedure for metal containing products (see Common Approach on Metallic Materials - Part C) is based on requirements for:

- the short-term behaviour (product specific surface properties) and
- the long-term behaviour (composition specific properties)

The long-term behaviour of products is not tested; however, the product's metallic composition must be listed on the Positive List.

Test procedures for the surface properties are in development.

The scientific aspects considered in producing this acceptance procedure are given in Annex A.

Restrictions on use of metallic PDW in certain Water compositions

The use of a product in contact with drinking water must be safe over its expected lifetime and under all reasonable conditions of use. However, it may be necessary to restrict the use of certain metallic PDW in certain water compositions in the European Union. Based on their long-term experience of use of certain compositions, Member States may need to impose restrictions depending on the local drinking water composition. Annex B gives guidance on how to identify "at risk" water compositions.

Part A – Methodologies for testing and accepting compositions to be included in the Positive List of compositions for metallic materials

1 Procedure for the addition of materials to the Positive List

1.1 Committee of Experts

The interpretation of test results and the application of acceptance criteria described below is complex. For this reason, a Committee of Experts should advise in the decision-making process.

The Committee of Experts should have the following expertise:

- Competent knowledge of corrosion and metal release
- Competence on toxicology and evaluation of drinking water quality related to human health aspects
- Understanding of the ways in which metallic materials and products are used in drinking water treatment and supply

1.2 4MSI Procedure

The primary responsibility for assessment of compositions will remain at the national level making use of established processes and the expert resources available there. Thus, a manufacturer may approach a national regulatory body (or its appointed agencies) for evaluation of a new composition. There are obvious practical advantages for a manufacturer in the 4MSI countries to work with his “home” assessment body, but he would not be required to do so. Applicants from outside the 4MSI area would be free to use any of the national arrangements.

The national arrangements will continue to operate largely as at present, but instead of producing findings and recommendations for local decision, will create assessment information and proposals in a common form (Opinions). These draft opinions will be reviewed by the appropriate bodies within each of the other MS, who will offer their comments. The aim will be to achieve agreement on where and how a composition is listed and, on any restrictions, or other information that should be included in the listing.

2 Structure of the Positive List

The assessment of metallic composition is intended to accept the composition and to include the composition in the Positive List.

The Positive List contains different categories of metallic materials.

A **Category** is defined as:

a group of compositions (materials) with the same characteristics in respect of their field of application, behaviour in contact with drinking water and restrictions with regard to water composition and/or surface area.

The Positive List contains the categories’ range of compositions.

Each category has one reference material.

A **Reference Material** is defined as:

a composition falling within a category for which the characteristics of metal release into drinking water are known and reproducible, the composition is strictly controlled and the elements of interest will be at or near the upper limit of acceptability. Possible effects of some constituents to inhibit the metal release have to be taken into account.

Under each category commercially available metallic compositions accepted for use in products will be listed. The compositions may only be used for certain products due to the restrictions with respect to the surface area (Table 1).

Table 1: Product Groups for metallic compositions

Product Group	Examples of products or parts of products	Assumed contact surface “a”
A	Pipes in building installations Uncoated pipelines in water supply systems	100%
B	Fittings, ancillaries in buildings installations (e.g. pump bodies, valve bodies, water meter bodies used in buildings installations)	10%
C	Components of products of product group B (e.g. the spindle of a pump or the moving parts in water meter in building installations). The sum of the surfaces in contact with drinking water of all these components has to be less than 10% of the total wetted surface of the product. 2. Fittings, ancillaries in water mains and water treatment works with permanent flow (e.g. pumps bodies, valves bodies used in water supply systems)	1%
D	Components of fittings and ancillaries in water mains and in water treatment works (C2).	

- **Product Group A: up to 100% contact surface**

For pipes in a buildings installation the same composition can be used for all diameters. A single composition can contribute to nearly 100% of the surface in contact with water e.g. copper, galvanised steel or stainless steel. The evaluation of

the conditions for safe use must assume the maximum possible percentage. The acceptance of a composition for the use as pipes includes the acceptance for all uses (e.g. fittings or components).

This group also includes uncoated metallic pipelines in water supply systems and water treatment processes.

▪ **Product Group B: up to 10% contact surface**

Fittings or ancillaries can be produced from one composition or from slightly different compositions throughout the building's installation. The most common are made from copper alloys. Due to their potential to release metals (e.g. lead) to water there is a need to restrict the total surface contact of products made from these alloys. For assessments of compositions for these products a contribution of 10% water contact surface area is assumed.

This group also includes the main metallic parts of pumps and valves used in buildings installations.

▪ **Product Group C: less than 1% contact surface**

- 1) For technical reasons, there might be a need to produce small parts from compositions not accepted for Product Group B. Other compositions with higher release rates may be accepted in these parts as long as their use will not significantly increase the total contamination of drinking water. The use of such compositions should be restricted to parts (as sum) that do not exceed 1% of the total surface in contact with drinking water; for example, the body of a water meter would need to be produced from an accepted composition for Product Group B but a moving part may be produced from a composition listed for Product Group C. The sum of the water contact surfaces of all parts in one product made from Product Group C compositions shall be less than 10% of the water contact surface of the product.
- 2) This group also includes the main metallic parts of fittings and ancillaries used with water mains and in water treatment works. For these products a permanent flow of the drinking water has to be ensured.

▪ **Product Group D: trivial contact surface**

Components of fittings and ancillaries in water mains and in water treatment works (C2). The sum of the water contact surfaces of all parts in one product made from Product Group D compositions shall be less than 10% of the water contact surface of the product. For these products a permanent flow of drinking water has to be ensured.

3. Data required for assessment

3.1 Data required for the assessment of metallic compositions for Product Groups A, B and C by testing in accordance with EN 15664-1

Acceptance of metallic compositions is based on results of long-term tests on a rig test according to EN 15664-1. The minimum test period is six months and which can be extended. Additional requirements for the testing according to EN 15664-1 are described in 4 and 5.

Acceptance of a reference material for a category requires acceptance of results from the EN 15664-1 test carried out with different waters (see EN 15664-2) representing the normal range of compositions of drinking waters in the EU.

Acceptance of a commercial composition in an existing category can be based on one of two test procedures:

1. A comparative test (see chapter 8) against the reference material according to EN 15664-1. For comparative testing it is sufficient to use a local drinking water, provided that the water is suitably corrosive (see EN 15664-2).
2. An absolute test (see chapter 7) with the most critical test water(s) according to EN 15664-1 and EN 15664-2. The most critical test waters are identified when the reference compositions are tested and are listed in the European Positive List for each Category. For one Category more than one critical test water can be required.

The following information shall be provided:

- Test reports according to EN 15664-1
- Test reports for the composition of the test specimens
- For each composition, information on the boundaries for major alloying constituent elements and maximum values for impurities. Such boundaries will be tighter for Reference Materials than for commercial alloys
- Existing applicable European standard(s) for the composition
- The composition characteristics
- Products to be manufactured from the composition and their uses (a-factor)
- The production process
- Other information considered appropriate in support of the assessment

3.2 Data required for the assessment of metallic compositions of Product Groups A, B and C without testing according to EN 15664-1

In some cases, testing of a composition according to EN 15664-1 is not necessary for the acceptance of the composition. This applies for the following cases:

- a) For stainless steel or other passive compositions, the test according to EN 15664-1 is not suitable to assess the hygienic fitness. This can be demonstrated based on the passive behaviour of the composition.
- b) For ferrous compositions used under permanent water flow the hygienic fitness can be demonstrated by a scientific dossier. The use of ferrous compositions has to be limited on certain water compositions (e.g. high oxygen concentration and redox potential) and flow conditions (no stagnating water, turbulent flow). This has to be addressed in the scientific dossier.
- c) For copper alloys, a certain composition of test specimens may be representative for different compositions. In this case it is sufficient to test the test specimens according to EN 15664-1 to accept different compositions. This is only possible if:
 1. Due to the composition and metallic structure the compositions exhibit a comparable corrosion behaviour with respect to the release of metals into the drinking water than the composition of the test specimens,
 2. The compositions belong to the same category,
 3. The compositions do not differ by alloying elements (constituents),
 4. The composition of the used test specimens meets the requirements of the entire range of compositions, and

5. The constituents in the alloy composition have a Reference Concentration (RC) of greater than or equal to 100 µg/l (i.e; Cu, Al, Fe, Zn, Sn)

Corresponding proof by means of a scientific dossier is required.

Requirements for the scientific dossier:

The scientific dossier must comprehensively address the corrosion chemical behaviour of the compositions and its interaction to EN 15664-1 must be considered for case c). The dossier will be used for the approval making process. It is recommended that the dossier is reviewed by the expert committee.

3.3 Data required for the assessment of metallic compositions of Product Group D

Commercial Alloys used exclusively for Product Group D will not be assessed and listed in the European Positive List. Restrictions for the composition type are given in the European Positive List.

3.4 Data required for the assessment of metallic compositions of Product groups A, B and C by testing in accordance with EN 16056

For metallic compositions, which show a passive behaviour a test in accordance with EN 15664-1 is not appropriate to assess the hygienic fitness in contact with drinking water.

To confirm passivity, a test according to EN 16056 shall be performed instead of a test according to EN 15664-1.

The following information shall be provided:

- Test report according to EN 16056
- Test reports for the composition of the test specimens
- For each composition, information on the boundaries for major alloying constituent elements and maximum values for impurities.
- Existing applicable European standard(s) for the composition
- The composition characteristics
- Products to be manufactured from the composition and their uses (a-factor)
- The production process
- Other information considered appropriate in support of the assessment

For product group D further passive alloys can be used. They don't have to be listed on the European Positive List.

4. Specification of the test specimens

For the testing of a composition according to EN 15664-1 the test specimens have to be of a certain composition.

All elements exceeding 0.02% could be of relevance and have to be declared for the composition of the composition to be listed. For impurities below 0.02% it is the responsibility of the producer of the alloys/compositions to guarantee that no release occurs with the potential to cause negative health impacts.

The composition of the **test specimens** shall be as follows:

4.1 Reference material

The test specimens submitted for testing a new reference material and the test specimens used as reference materials for the comparative testing have to meet the following requirements:

- Constituents and impurities have to be in the range as declared.

Note: The composition of the reference material should be accepted before testing is started. The range of composition should be very narrow and the reference material should represent a worst case composition in respect of the metal release of concern for the category.

4.2 Commercial compositions

For the candidate compositions the range of composition and its allowed impurities have to be defined. It is recommended that the compositions are standardized and that the composition is defined in the standard. The defined range of composition of the candidate composition has to comply with the definition of an existing category of compositions.

The composition of the test specimens used for testing has to be more restricted than the defined range of composition of the composition. Based on the knowledge about copper alloys the composition of the test specimens has to meet the following requirements:

Constituents:

- Cu, Zn, Sn as constituents have to be in the range as declared
- As a constituent shall be greater than 66% of the declared range. (e.g. if the declared range is $\leq 0.15\%$ then 66% of the range (0.15%) is 0.10%; therefore, element content should be 0.10 – 0.15%.)
- Al, Si and P shall be less than 50% of the declared range
- For all other constituents the content shall be greater than 80% of the declared range (e.g. if the declared range is 1.6% to 2.2% then 80% of the range (0.6%) is 0.48%; therefore, element content should be greater than 2.08%).

Impurities:

- Impurities to be analysed in the contact water (see chapter 5) shall be greater than 60% of the declared maximum content

For other non-copper alloys these requirements may be different. This has to be assessed within the 4MSI.

5. Water analysis

If a new reference material is tested the **contact water** according to EN 15664-1 has to be analyzed for all elements exceeding 0.02% in the composition of the declared composition with the exception of:

- S, Sn, Si and P if present as constituents
- Fe, Sn, Mn, Al, Si, P and Zn if present as impurities in the alloy

For comparative testing the analysis of contact water may be limited to certain elements specified for each category in the European Positive List.

6. Acceptance criteria

Table 2 gives the acceptable contributions from metallic PDW to the overall concentrations of metals at consumers' taps. It is based on the acceptance values for chemical and indicator parametric values in the DWD. The acceptable contributions were derived using the following principles:

- 90% for elements for which metallic PDW constitute the only major source of contamination;
- 50% for elements for which other sources of contamination are possible

In the case of other parameters not listed in the DWD, the following criteria have been used:

- Zinc: this element is not toxic at the concentrations encountered in water supply systems where galvanised steel pipes have been used. However, zinc can give rise to complaints about the taste and appearance of water. The proposed reference value has been set to ensure that zinc does not reduce the aesthetic acceptability of water (WHO, 2004).
- Tin, bismuth, molybdenum, titanium: these reference values are based on provisional values recommended by a toxicology expert (Fawell, 2003).
- Other metals: advice will be sought from toxicology experts on an appropriate reference value as necessary

In order to allow time for the development of natural protective layers, the test procedure simulates a conditioning period of three months, in which a non-compliance with the reference concentration is tolerated.

Table 2 Acceptable contributions and reference concentrations for acceptance of metallic constituents of metallic PDW

Parameter	Acceptable contribution from metallic PDW	DWD parametric value or reference value in DW (µg/l)	Reference concentration "RC" for Acceptance Scheme (µg/l)
<i>Part B: Chemical parameters</i>			
Antimony	50%	5	2.5
Arsenic	50%	10	5
Chromium	50%	50	25
Cadmium	50%	5	2.5
Copper	90%	2000	1800
Lead	50%	10	5
Nickel	50%	20	10
Selenium	50%	10	5
<i>Part C: Indicator parameters</i>			
Aluminium	50%	200	100
Iron	50%	200	100
Manganese	50%	50	25
<i>Others: not listed in DWD</i>			
Bismuth	90%	10	9
Molybdenum	50%	20	10

Tin	50%	6000	3000
Titanium	50%	15	7.5
Zinc	90%	3000	2700

7. Acceptance by absolute testing

7.1 Creating a Category by Testing a Reference Material

Alloys that do not fall within one of the existing categories of the European Positive List may be tested, accepted and added to the European Positive List by creating a new category. In this case a restricted composition of the alloy will have to be tested as Reference Material and the following information shall be provided:

- The information listed in 3.1
- The full test results from pipe rig testing according to EN 15664-1 using at least three different test waters defined in EN 15664-2

See Figure A for a schematic of the procedure.

7.2 Adding a commercial alloy to an existing Category

A commercial alloy can be accepted by absolute testing with the worst case test water(s). The worst case test water is the test water exhibiting the highest metal releases when the Reference Material for the Category is tested. The worst case test water will be mentioned for the Category in the European Positive List. If the worst case test water is not obvious (e.g. for the lead release the worst case test water is test water 1 and for the nickel release it is test water 2) several (up to the three test waters according to EN 15664-2) can be defined as worst case. In this case the test according to EN 15664-1 has to be completed with all worst case test waters.

For the acceptance of a commercial alloy by absolute testing the following information shall be provided:

- The information listed in 3.1
- Full test results from pipe rig testing according to EN 15664-1 using the worst case test water(s)

7.3 Applying the acceptance criteria

For the assessment of the test rig results (according to EN 15664-1) the arithmetic mean of the equivalent pipe concentrations $MEP_n(T)$ shall be considered.

For all periods of operation (T) an average of the $MEP_n(T)$ of the three test lines in one rig is calculated: $MEP_a(T)$.

For the assessment of the test rig results (according to EN 15664-1) the arithmetic mean ($c^*EP(T,4h)$) of the 4h stagnation values ($c^*EP_{,n}(T,4h)$) shall be considered.

The composition can be accepted for a product group with the assumed contact surface a (see Table 1), if the following criteria are met for all required test waters:

- A. The reference concentrations (see Table 2) have to be met for all analyzed elements beginning from week 16
- B. Metal concentrations (parameters) should not increase so that there is a risk of exceeding the reference concentration beyond the duration of the test

Criterion A is considered fulfilled, if

(I) $MEPa(T) * a \leq RC$ for $T = 16, 21$ and 26 weeks

Criterion B is considered fulfilled, if

(II) $MEPa(T_b) \geq MEPa(T)$ for $\{T_b, T\} = \{12, 16\}, \{16, 21\}$ and $\{21, 26\}$ weeks or

(III) a negative slope of a linear fit of the $c*EP(T,4h)$ for $T > 12$ weeks is obtained or

(IV) $c*EP(T,4h) * a \leq 0.5*RC$ for $T = \{16 - 26$ weeks}

The test may be extended up to 1 year, if criterion B is not met after 26 weeks.

In this case Criterion A is considered fulfilled, if

(V) $MEPa(T) * a \leq RC$ for $T = 16, 21, 39$ and 52 weeks

Criterion B is considered fulfilled, if

(VI) $MEPa(T_b) \geq MEPa(T)$ for $\{T_b, T\} = \{26, 39\}$ and $\{39, 52\}$ weeks or

(VII) a negative slope of a linear fit of the $c*EP(T,4h)$ for $T > 26$ weeks is obtained or

(VIII) $c*EP(T,4h) * a \leq 0,5*RC$ for $T = \{26 - 52\}$ weeks

The application of the acceptance criteria has to be based on expert judgement (see 1.1 for the use of a Committee of Experts). Deviations of results to the criteria in formula (I) to (VIII) might be justified.

In some cases, compliance to the formula (I) – (VIII) can be difficult to establish clearly because of deviations (outliers) due to uncertainty of the determination and/ or minor variations in the test water composition. In such cases, the complete set of available data has to be considered. For the test rig according to EN 15664-1 these are:

- Results of individual test lines,
- 4h stagnation results,
- parameters of water composition,
- temperature of the test rig
- stagnation samples that were in addition to the requirements in EN 15664-1

An expert judgement is also required to decide, whether the data available is of sufficient quality (e.g. no major difference of the three test lines, interpretation of outliers) for an assessment to be carried out.

8. Acceptance by comparative testing

8.1 Adding a commercial alloy for an existing Category

Where the constituents of a candidate composition for approval are shown to fall within a Category, the composition can be added to the European Positive List provided that a comparative test run against the respective Reference Material in a standardised rig test, EN 15664-1, using one water defined in EN 15664 2 shows satisfactory results.

For each composition, the following information shall be provided:

- The information listed in 3.1

- Results from comparative testing using the pipe rig test EN 15664-1 relative to the Category's Reference Material

Note: The assessment of the results by comparative testing proved to be difficult due to the uncertainties of measurements. Instead of the assessment by comparative testing further compositions can be accepted in an existing Category when the composition is tested with the most critical test water according to EN 15664-1 and EN 15664-2 and the test results comply with the requirements for absolute testing (7.2).

See Figure B for a schematic of the procedure.

8.2 Applying the acceptance criteria

For the assessment of the test rig results (according to EN 15664-1) the arithmetic mean of the equivalent pipe concentrations $MEP_n(T)$ shall be considered.

For all periods of operation (T) an average of the $MEP_n(T)$ of the three test lines in the rig is calculated: $MEP_a(T)$.

For the Reference Material $MEP_{a,RM}(T)$ of the three reference lines shall be considered.

The composition can be accepted for a product group with the assumed contact surface a of the Reference Material (see Table 1), if the following criteria are met for all required test waters:

- A. The candidate composition shows a better or equal performance than the reference material for all analyzed elements
- B. Metal concentrations (parameters) should not increase so that there is a risk of exceeding the reference concentration beyond the duration of the test

Criterion A is considered fulfilled, if

$$(I) \quad MEP_a(T) \leq MEP_{a,RM}(T) \quad \text{for } T = 16, 21 \text{ and } 26 \text{ weeks}$$

Criterion B is considered fulfilled, if

- (II) $MEP_a(T_b) \geq MEP_a(T)$ for $\{T_b, T\} = \{12, 16\}, \{16, 21\}$ and $\{21, 26\}$ weeks or
- (III) a negative slope of a linear fit of the $c^*_{EP}(T,4h)$ for $T > 12$ weeks is obtained or
- (IV) $c^*_{EP}(T,4h) * a \leq 0.5 * RC$ for $T = \{16 - 26 \text{ weeks}\}$

The test may be extended up to 1 year, if criterion B is not met after 26 weeks.

In this case Criterion A is considered fulfilled, if

$$(V) \quad MEP_a(T) * a \leq MEP_{a,RM}(T) \quad \text{for } T = 16, 21, 26, 39 \text{ and } 52 \text{ weeks}$$

Criterion B is considered fulfilled, if

- (VI) $MEP_a(T_b) \geq MEP_a(T)$ for $\{T_b, T\} = \{26, 39\}$ and $\{39, 52\}$ weeks or
- (VII) a negative slope of a linear fit of the $c^*_{EP}(T,4h)$ for $T > 26$ weeks is obtained or
- (VIII) $c^*_{EP}(T,4h) * a \leq 0.5 * RC$ for $T = \{26 - 52\}$ weeks

The application of the acceptance criteria has to be based on expert judgement (see 1.1 for the use of a Committee of Experts). Deviations of results to the criteria in formula (I) to (VIII) might be justified.

In some cases, compliance to the formula (I) – (VIII) can be difficult to establish clearly because of deviations (outliers) due to uncertainty of the determination and/ or minor variations in the test water composition. In such cases, the complete set of available data has to be considered. For the test rig according to EN 15664-1 these are:

- Results of individual test lines,
- 4h stagnation results,
- parameters of water composition,
- temperature of the test rig
- stagnation samples that were in addition to the requirements in EN 15664-1

An expert judgement is also required to decide, whether the data available is of sufficient quality (e.g. no major difference of the three test lines, interpretation of outliers) for an assessment to be carried out.

9. Acceptance by testing according to EN 16056

9.1 Adding a commercial alloy to the category “passive compositions”

The passivity can be proved by means of a test in accordance to EN 16056.

9.2 Applying the acceptance criteria

To prove the passivity the alloy has to fulfil the following criteria:

Epit > free corrosion potential + 500 mV

with:

Epit: pitting potential according to EN 16056

Free corrosion potential: potential at the beginning of the test (open circuit potential), which corresponds the potential of oxygen in the neutral test water

Figure A: Procedure for accepting reference materials for a Category and approval testing of compositions not falling under a listed Category

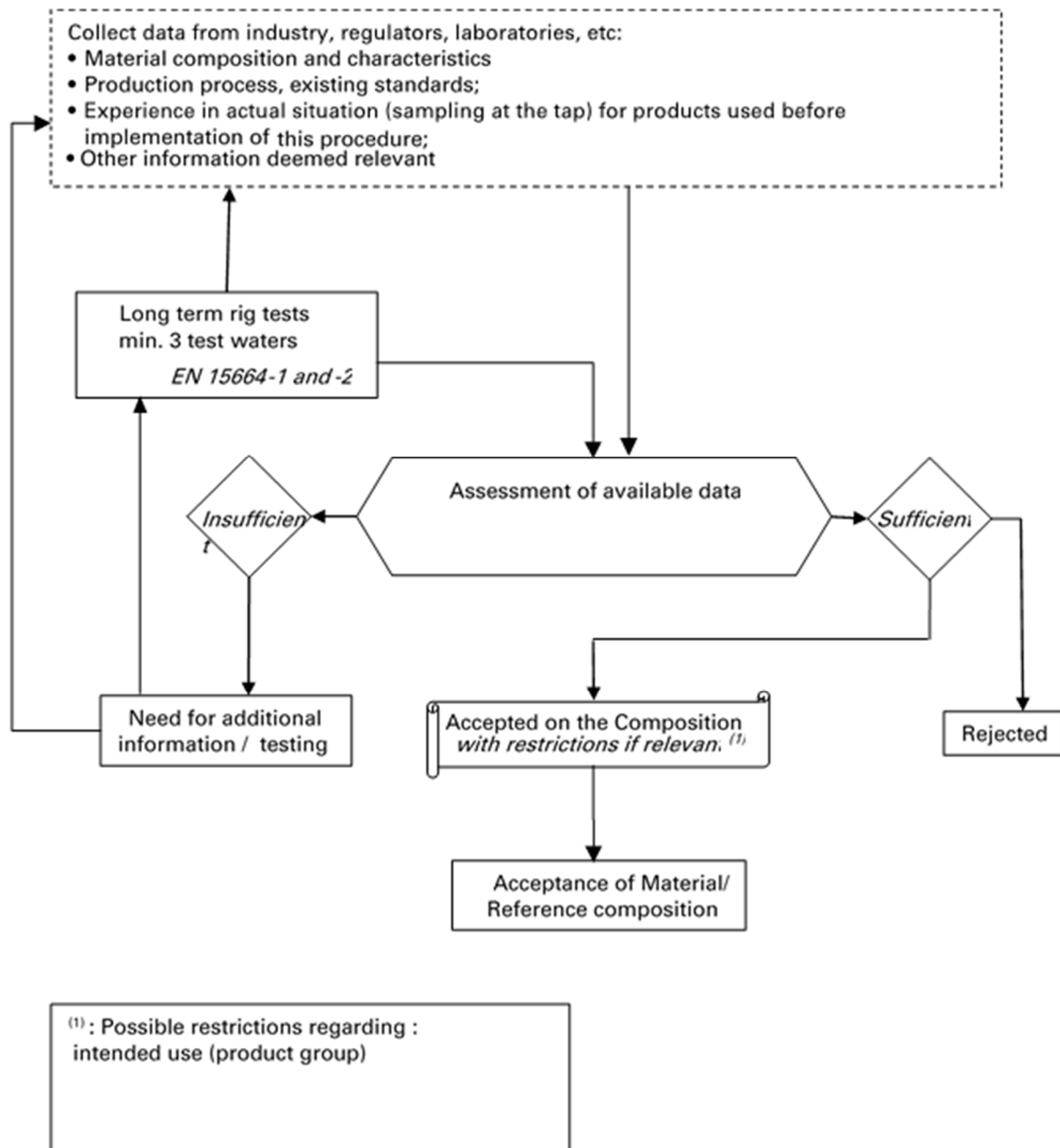
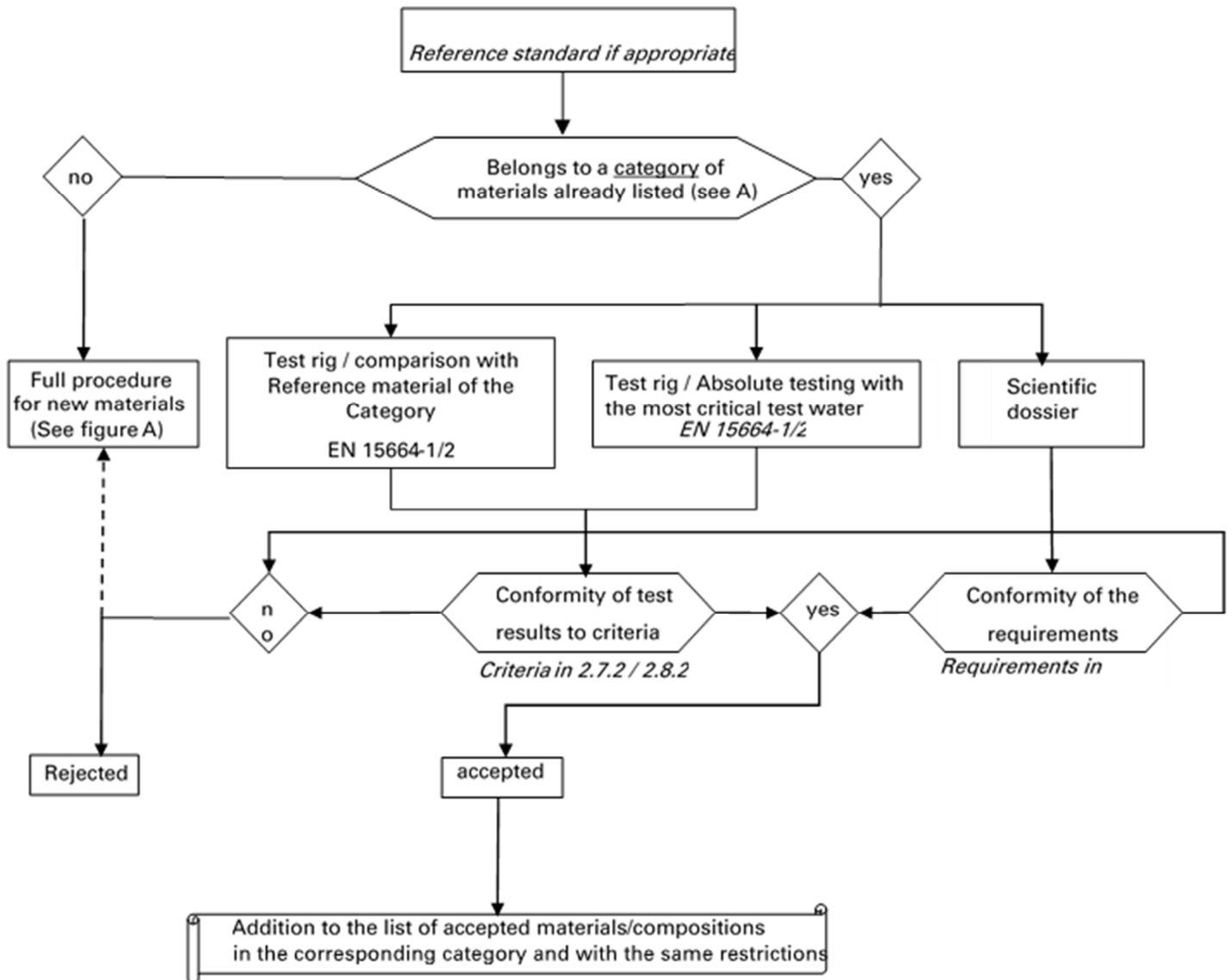


Figure B: Procedure for the addition of a commercial composition to the list of accepted composition



Annex A: Scientific aspects considered in the development of the acceptance procedure

A.1 Metals in drinking water

The use of a construction product in contact with drinking water must be safe over its expected lifetime and under all reasonable conditions of use. However, it may be necessary to restrict the use of certain metallic PDW in certain water compositions.

The DWD sets parametric values for a number of metals that may be released from metallic PDW. These include antimony, arsenic, boron, cadmium, chromium, copper, lead, nickel, selenium (DWD Annex I Part B), aluminium, iron and manganese (DWD Annex I Part C). Of these, the values for lead, copper and nickel relate to a weekly average. The values must be complied with at consumers' taps.

Many factors affect the interaction between metals and water. These include the following five factors, which are not in priority order:

- the composition and surface properties of the material in contact with water
- the design of the distribution system, including:
 - the density of use of fittings and appliances relative to length of pipe work
 - the surface to volume ratio of fittings and appliances
 - the relative position of fittings and appliances within the network
- the flow regime, as determined by the water consumption habits of consumers
- the time the product has been in use
- the chemical and physical characteristics of water

Additional complexities arise because of the potential for subtle changes in water composition to affect significantly the extent and/or rate of interaction.

These factors dictate that an acceptance system for metallic PDW must be based on experience gained under both practical and experimental conditions.

A.2 Sampling procedure for acceptance of metallic PDW

The sampling procedures used in the testing and acceptance of metallic PDW must characterise the performance of the PDW over its expected lifetime and under all reasonable conditions of use. In both short-term static tests and long-term rig tests that use flowing water, samples are taken after a period of stagnation to represent a reasonable worst-case situation.

This is in contrast to the sampling procedures Member States will use to monitor compliance with the limits for metals in the DWD. In this case, the normal practice for routine sampling will be to take random day time samples or samples after a fixed stagnation period.

A.3 Effect of residence time

The time elapsing between the entry of water into a part of the distribution system (e.g. a domestic installation) and its exit (e.g. from the tap) is the residence time in that part of the system. The concentration of metal ions for a given water in general depends on the residence time, it includes times of stagnation and times of flow. In test procedures the residence time is simulated by stagnation times alone, i.e. when there is no flow. The test method defined by TC164/WG3, EN 15664-1, specifies stagnation times for sampling purposes.

The residence time for water in a domestic distribution system depends on:

- the capacity of the system;
- the consumer's water consumption habits, including activities such as toilet flushing and use of washing machines.

There are variations in residence time even when consumption is averaged over a certain period (e.g. a week). For most consumers the average residence time prior to consumption will show a distribution of between 15 minutes, in the most favourable situations, and several hours, in realistic worst-case situations.

It is proposed that an assumption of a residence time prior to consumption of four hours will be used as a basis for sampling in acceptance testing. The assumption of an average residence time of four hours includes the possibility of a few situations with residence times prior to consumption of 12 hours. This approach will provide an adequate level of protection, given that an authoritative study has demonstrated that the concentration of metals after a half-hour stagnation provides a reasonable estimate for a weekly average (EUR 19087, 1999).

A.4 Selection of test water

Experience with current test methods indicates that the choice of test waters is a critical aspect of the test methodology that is fundamental to the interpretation of test results. The options considered included a range of waters covering all situations with respect to European water compositions and materials used, and a selection of waters for each composition or category of compositions. The simple idea of having a "worst case test water" is not practicable for the following reasons:

- The use of the "worst case water" would allow only those compositions that can be used in any water composition to be accepted.
- The results obtained in "worst case water" cannot be extrapolated to performance of the product in water of another chemical composition; for example, there is no correlation between the test results in the NSF61 static test for copper pipes and the behaviour of accepted copper pipes in real life situations.
- The "worst case composition" depends on the nature of the composition, although using a number of test waters could in principle solve this problem.
- There are considerable experimental difficulties in producing large volumes of stable test water with a defined composition.
- It is extremely difficult to simulate the effect of TOC in the test water. TOC describes the concentration of organic substances from natural sources: it is not feasible to simulate the effects of natural TOC by means of synthetic additions to the test water.

EN 15664-2 defines three types of natural drinking waters characterising the range of possible drinking waters in Europe. The test according to EN 15664-1 with these three waters allows an acceptance of a metallic composition to be used with all drinking waters in Europe.

A.5 Effects of relative surface area of products

The extent to which a metallic product contributes to the concentration of a metal in drinking water depends on its surface area in contact with the drinking water relative to the total surface area of other products in the system. Products may contain individual components that have a very small contact with drinking water. For such components, requirements that are less stringent than those applied to large contact components may be appropriate.

A.6 Contribution of metallic PDW to overall metals concentrations

Metals in drinking water are derived from a variety of sources. It is therefore necessary to take account of the contribution that other sources, apart from metallic PDW, make to the overall concentrations of metals at consumers' taps by setting a percentage contribution level for each metal.

A.7 Restrictions on use of metallic PDW in certain water compositions

The metallic pipe compositions copper and galvanized steel are not suitable for use with all drinking waters in Europe. Based on their long-term experience of use of these compositions, Member States may need to impose restrictions depending on the local drinking water composition. Annex B of this report contains guidance on how to identify "at risk" water compositions.

Annex B: Identification of water compositions where restrictions on uses of metallic PDW may be necessary

Introduction

There is widespread practical experience of the performance of metallic PDW in different water compositions. However, because of differences in the sampling protocols it is difficult to draw general conclusions about the relationship between water composition and corrosion rates. The effects of trace constituents pose a special challenge as presence or absence of a particular constituent can have a marked effect on corrosion potential.

Formulae relating to the chemical characteristics of water to corrosion potential have been developed (Van den Hoven et al., 1998; Priggemeyer et al., 2001; DTU 60.1 NF P 40-201 (1993); DIN 50930-6, 2001). It has to be considered that formulae provide guidance on compatibility of metallic PDW with a specific water composition. However, it may be necessary to generate analytical data for some distribution systems to justify a restriction or prohibition for a particular composition.

Where there is anecdotal evidence of an existing problem it is possible to confirm this with the results of systematic stagnation sampling programmes in consumers premises. A protocol for stagnation sampling is included in Annex B 1 and B 2.

Alternatively, potential for high corrosion rates can be demonstrated by results of studies in test rigs (EN 15664-1). A test rig permits greater flexibility in terms of stagnation periods and flow regimes than can be achieved via sampling from consumers premises. Testing also allow studies to be made on the impact of anticipated change in water quality. However, test rigs do not simulate the actual exposure conditions in a water supply area and they provide only an estimate of actual corrosion rates in consumer premises. Protocols for operation of test rigs are given in Annex B 3.

B.1 Protocol for taking samples in consumers' premises to identify whether restrictions on the use of copper PDW are needed

Principle

Monitoring using a fixed stagnation time is carried out after flushing the consumer's drinking water installation until the water standing in the system has been displaced by mains water. The tap is then closed for a fixed period of time. For the purposes of investigating the need for restrictions on use of metals, a four hour stagnation period is used. Guidance only is given on the methods to be employed and Member States should ensure that accredited techniques are used for all sampling and analysis operations.

Selection of consumers' premises

The premises chosen for the investigation should have between 5 and 10 metres of copper pipe upstream of the tap. This should be established by surveying the premises before sampling. In order to obtain a representative data set at least 15 premises should be selected in the water supply area that is under investigation. 3 samples should be taken from each the premises on separate occasions.

The age of the water supply installation and copper pipes should be recorded. Samples should not be taken from premises where copper pipes have been installed or renewed within the last 3 months.

Method

Before stagnation, the installation should be flushed thoroughly. It is possible to monitor displacement of standing water by checking its temperature; when mains water has displaced standing water, its temperature vs. volume flushed will become constant. Alternatively the approximate volume need to displace standing water can be calculated after surveying the premises.

After the 4 hour stagnation period, the first 250 ml of the stagnation water should be run to waste (Alternatively it can be used to assess copper, nickel or lead concentrations arising from the tap). The next 1000 ml of water should be collected in a plastic container and stabilised using acid and reserved for copper analysis. It is recommended that as well as copper analysis, other parameters are measured (after flushing) that characterise the water composition and its corrosive tendency (e.g. pH and temperature on site, TOC, alkalinity, hardness, conductivity, copper in running water). For the second and third samples from each premise, it is acceptable to measure only the copper concentration in the 1000 ml sample and a limited selection of parameters to confirm that the composition of the water is unchanged.

Interpretation of results

The exposure level in each of the premises should be calculated from the average of the results of copper in the three 1000 ml samples. Where premises show results of less than 100 µg/l copper in the stagnation samples, it should be assumed that copper plumbing is not present. This data should be excluded from the data evaluation process for the water supply area.

Where 3 or more premises in 15 show average copper concentrations over 3 sampling occasions of greater than 2000 µg/l after 4 hours stagnation, then the water supply area can be considered as an area where the use of copper needs to be restricted.

B.2 Protocol for taking samples in consumers' premises to identify whether restrictions on the use of galvanized steel PDW are needed

Selection of consumers' premises

The age of the water supply installation and galvanised pipes should be recorded. Samples should not be taken from premises where galvanised pipes have been installed or renewed within the last three months, neither should samples be taken from premises where galvanised steel pipes were installed or renewed more than 10 years ago.

The protocol in Annex B 1 will not be applicable unless the consumer's premises are plumbed entirely in galvanised steel up to the drinking water tap. If this is not the case, it may be possible to carry out stagnation sampling by taking samples from a tap adjacent to the water meter, assuming galvanised steel is used to carry water from the mains to the premises.

Where sampling at the meter is not possible but it is possible to determine the volume of water between the tap and the galvanised pipe, then controlled flushing of the pipe prior to taking a 1000 ml sample for zinc analysis may allow a representative estimate of zinc concentrations. It will be useful to carry out analysis for both zinc and iron, since iron may be released if the zinc layer has been partially removed.

If representative sampling for zinc is not possible, it will be necessary to investigate the need for restrictions by means of the test rig described in Annex B 3.

Interpretation of results

The exposure level in each of the premises should be calculated from the average of the results of zinc in the three 1000 ml samples. Where galvanised pipe has been installed and all of the sample results show low zinc and elevated iron concentrations, it may be assumed that the zinc layer has been removed by corrosion. In this case, the water supply area can be considered as an area where the use of galvanised steel needs to be restricted.

Where more than 3 premises in 15 show average zinc concentrations over 3 sampling occasions of greater than 3000 µg/l after 4 hours stagnation, then the water supply area can be considered as an area where the use of galvanised steel needs to be restricted.

B.3 Protocols for operation of a test rig to assess corrosion potential of drinking water

General

To assess the corrosion potential of drinking water a rig test should be carried out as in EN 15664-1.

The test method given in this standard is designed to provide information on the release over time of metals from metallic compositions into water intended for human consumption. The test consists of a programme of alternating periods of once-through flow and stagnation in a rig, simulating the conditions in a domestic distribution system.

Water samples are taken at specified intervals after specified stagnation times throughout the period of operation and analysed for concentrations of relevant metals.

Samples

The rig shall contain three commercially available pipes with an inner diameter of (13±1) mm shall be used. Where this diameter is not commercially available then the next largest commercially available size shall be used. The length of the pipes is at least 3 m.

Test water

Test water is the water as supplied from the water works that supplies the area under investigation.

Method

Through each line 145 l/day flows according to a complex running/static flow regime. The flow rate of the water is about 0.5 m/s.

The test rig shall be constructed in accordance with the instruction as given in the standard.

Duration and sampling

The duration of the test shall be a minimum of 26 weeks and a maximum of 104 weeks.

Stagnation curves shall be determined every month up to 6 months for the relevant metal. When applicable, further sampling shall be carried out 39, 52, 65, 78, 91 or 104 weeks after the start of the operation of the test rig and the determination of stagnation curves shall be continued.

Presentation of test results

The results shall be presented as graphs of the average concentrations of the released metals $MEP(T)$ against the period of operation (T).

References

Australian/New Zealand Standard AS/NZS 4020 (1999) *Products for use in contact with drinking water*

American National Standards Institute ANSI/NSF 61 – 1999a *Drinking water system components – Health effects*

BS 7766 (1994) *Assessment of the potential for metallic materials to affect adversely the quality of water intended for human consumption*

DIN 50931-1 (1999) *Korrosion der Metalle - Korrosionsversuche mit Trinkwässern – Teil 1: Prüfung der Veränderung der Trinkwasserbeschaffenheit*

CEN WI 00164182 *Influence of metallic materials on water intended for human consumption - Dynamic rig test for assessment of metal leaching*

Council Directive 98/83/EC on the quality of water intended for human consumption. Official Journal of the European Communities, L330/31-54, Brussels 1998

DIN 50930-6 (2001) *Korrosion der Metalle; Korrosion metallischer Werkstoffe im Innern von Rohrleitungen, Behältern und Apparaten bei Korrosionsbelastung durch Wässer; Teil 6: Beeinflussung der Trinkwasserbeschaffenheit*

DTU 60.1 NF P 40-201 (1993) *Plomberie sanitaire pour bâtiments à usage d'habitation* (France)

EUR 19602 (2000) *Co-normative Research on test methods for materials in contact with drinking water: metallic materials* by P. Leroy, S. Rigal, J. Baron, Th.J.J. van den Hoven, P.G.G. Slaats, M. Morlot, C. Autugelle, I. Wagner, W. Werner, R. Oliphant, P. Conroy, R. Miller and Ph. Quevauviller. Published by the European Commission DG XII- Science, Research and Development, Brussels

EUR 19087 (1999). *Developing a new protocol for the monitoring of lead in drinking water* by Th.J.J. van den Hoven, P.J. Buijs, P.J. Jackson, S. Miller, M. Gardner, P.Leroy, J. Baron, A. Boireau, J. Cordonnier, I. Wagner, H. Marecos do Monte, M.J. Benoliel, I. Papadopolous and Ph. Quevauviller. Published by the European Commission DG XII- Science, Research and Development, Brussels

Fawell J. (2003) *Metals in drinking water and possible guidance values for leaching from metallic fittings* (RG-CPDW 177)

Hoven Th.J.J, van den and M.W.M. van Eekeren (1988) *Optimal composition of drinking water* Kiwa-report 100, Nieuwegein

Lytle D.A. and M. R. Schock (1996) *Stagnation time, composition pH and orthophosphate effects on metal leaching from brass* EPA report 600/R-96/103, U.S. EPA Cincinnati, Ohio

Nielsen K. and A. Andersen (2001) *Metal release from domestic water installations* CeoCor 2001, Biarritz

NKB Product Rules 12 for metal compression fittings for copper tubes for water supply installation (Sweden)

Nuttall, John (2006). *Proposals for commercially available metals to be added to the Composition List for copper and copper alloys and supporting information* European Copper Institute, Version 20 February 2006

Acceptance of Metallic Materials Used for Products in Contact with Drinking Water

4th revision, Version 2, 16 July 2021

Oliphant R. (2000) *A review of the national standards currently used to determine the potential of metallic materials to contaminate potable waters* RG-CPDW 0....

EN 12502-3 (2003) *Protection of metallic materials against corrosion – Guidance on the assessment of corrosion likelihood in water distribution and storage systems – Part 3: Influencing factors for hot dip galvanised ferrous materials*

Priggemeyer St., S. Piggemeyer, E. Meyer, W. Sauter, M. Breu G. Schüz, P. Arens and A. Boukloh, (2001) Copper release of copper tubes in contact with hard drinking waters, Proceedings CEOCOR 2001, Biarritz

Slaats P.G.G. and H. Brink (2002) *Testing of metal release from copper and copper alloys to drinking water* Kiwa report KOA2001.130 Nieuwegein, The Netherlands.

WHO (2004) *Guidelines for Drinking-water Quality, Third edition, Volume 1, Recommendations* World Health Organization, Geneva

WRc-NSF (2002) *Reliability of test methods for metallic products* - final report to the Drinking Water Inspectorate, London, UK