Regulation issued by the State Secretary for Infrastructure and the Environment dated June 29, 2011, Nr. BJZ2011048144 laying down further rules for the use of materials and chemicals in the supply of drinking water and warm tap water (Materials and chemicals in the supply of drinking water and warm tap water Regulation)

The State Secretary for Infrastructure and the Environment,

Acting upon consultation with the Minister of the Interior and Kingdom Relations;

In view of Directive 98/83/EC of the European Community Council of 3 November 1998 on the quality of water intended for human consumption (EC Official Journal L 330), Decision 2002/359/EC of the Commission of the European Communities of 13 May 2002 on the procedure for attesting the conformity of construction products in contact with water intended for human consumption, and pursuant to Article 20(2) of Directive 89/106/EEC of the European Union Council, Article 20(1)(b) of the Drinking Water Decree, and Article 3.107 of the 2003 Building Decree;

Hereby resolves as follows:

CHAPTER 1. DEFINITIONS

Article 1

The following definitions shall apply in the context of the present Regulation:

Committee: the committee of experts as described in Article 20(2), of the Decree;
Composition List:: pursuant to Article 11, the list included in Annex B of constituent components and the maximum allowed contaminations for metallic products;
Conversion factor: conversion factor for testing the results of the migration test as described in Annex D(2);
Decree: Drinking Water Decree;
Drinking water and warm tap water supply: extracting, preparing, treating, storing, transporting or distributing drinking water or warm tap water;
Migration: moving substances from materials to water for treatment or drinking water or warm tap water;
Migration test: test method to identify the migration speed, as established in Annex C;
Minister: the Minister for Infrastructure and the Environment;
MTC (maximum tolerable concentration): maximum tolerableconcentration of a substance in drinking water or warm tap water;
Positive lists: pursuant to Article 11, the lists included in Annex B of substances of which the presence in products or the use in a manufacturing process is permissible under the set conditions;
Product: object made by humans in its finished state or a component thereof composed of materials or chemicals that may come into contact with water for treatment or drinking water or warm tap water;
QM: maximum permissible level of the remainder of a substance in the material or product;
Recognised certifying body: body recognised by the Certification Council authorised to issue a quality certificate;
Recognised quality certificate: quality certificate recognised by the Minister pursuant to Article 12, as described in Article 20(1) of the Decree, or Article 1.6 of the 2003 Building Decree, consisting of written evidence issued by a recognised certifying body showing that materials or chemicals comply with the requirements set on the basis of the present Regulation;
Statement of no objection: statement that may be issued by the Minister that a product intended for killing the Legionella bacteria in drinking water and warm tap water systems, other than a biocide covered by the Plant Protection Products and Biocides Act, may be used under the set conditions and restrictions to identify the efficacy of the product in a real environment;
Sub-committee: a group of experts as described in Article 4(3), providing support to the Committee;
Substances: chemical elements and their compounds as they appear in nature or materialise through the intervention of humans;
TDI (Tolerable Daily Intake): permissible daily dose of a substance;

Threshold dose: quantity of a substance administered or ingested per unit of body mass expressed, for example, as mg/kg of body weight, that just does not have harmful effects for the health;
TOC (Total Organic Carbon): the total amount of organic carbon in drinking water or warm tap water originating from a product that comes into contact with drinking water or warm tap water, calculated and derived by using the measuring method and migration tests included in Annex C, to which the maximum permissible concentration of 2 mg carbon per litre of drinking water or warm tap water applies, as described in Annex B.

CHAPTER 2. THE COMMITTEE

Article 2

1. The Committee has at least seven and no more than eleven members, including the President.

2. The Minister appoints the members of the Committee to a four-year term. This term may be extended no more than two times, each time by another four years. The names of the members of the Committee will be published in the Government Gazette.

3. The Minister may, in special circumstances, suspend or dismiss the members of the Committee.

Article 3

1. The Committee has a secretary. The secretary shall support the Committee and is responsible for the administration of the data files created by the Committee in the performance of its duties.

2. The Minister appoints the secretary to a four-year term. This term may be extended each time by another four years. The appointment and the extension of the term will be announced in the Government Gazette.

3. The Minister may, in special circumstances, suspend or dismiss the secretary.

Article 4

1. The Committee shall advise the Minister on the following:

a. In view of the protection of health, the requirements for materials and chemicals used in the supply of drinking water or warm tap water;
b. The tests and assessments of such materials and chemicals pursuant to Articles 6-11;
c. Authorising the issue of recognised quality certificates;
d. Recognising quality certificates;
e. The cases described in Articles 10 and 20(3); and
f. Pursuant to the guidelines set forth in Article 5(2), assessing if and when any quality certificate may be considered the equivalent of a recognised quality certificate on the basis of Article 16.

2. In addition, the Committee has the following tasks:

a. Pursuant to the guidelines set forth in Article 5(2), the investigation into and the assessment of potential adverse effects for public health of materials or chemicals if no test methods and assessment methods are included for them in the Annexes to the present Regulation; and
b. The maintenance of the Annexes to the present Regulation.

3. In the performance of the tasks specified in the first and second paragraphs, one or more sub-committees may support the Committee. The members of any sub-committee shall be appointed and dismissed in accordance with the rules specified in Article 5(1).

Article 5

1. The Committee shall draw up the rules for its mode of operation and the mode of operation of any sub-committee specified in Article 4(3). The Committee shall thereby include the rules for compensating any costs incurred. The Payment of Advisory Boards and Committees Decree shall apply.

2. Included in the rules described in the first paragraph, shall be the mode of operation and guidelines to be used by the Committee in the tests and assessments described in Article 4(1)(f) and Article 4(2)(a) and (b).

3. Drawing up and amending the rules will require the Minister's approval. Once the rules are drawn up or amended, they will be announced in the Government Gazette.

CHAPTER 3. TESTS AND REQUIREMENTS FOR MATERIALS AND CHEMICALS

Article 6

1. Materials, other than metallic materials, and chemicals must meet the requirements set forth in Articles 7-9. To this end, materials, other than metallic materials, and chemicals, as well as their constituent substances or the substances used in their manufacturing processes, will be assessed as indicated in these Articles to identify potential adverse effects on public health.

2. If the assessment specified in the first paragraph identifies an MTC for a substance or a QM in the product and the substance may come into contact with water for treatment, drinking water or warm tap water in the drinking water or warm tap water supply, the migration of the substance or its residual content in the product will be decided by using the methods specified in Annex C, or, pursuant to Article 8(2) and (3), by using the standard calculations listed in Annex D for identifying the concentration of the substance in the drinking water or warm tap water.

3. Metallic products must meet the criteria for their composition and purity specified in Annex B(3) thereby considering the category the product might be assigned to. There is no need to test the release of substances pursuant to Annex A(2.8), if a metal product meets the criteria of the Composition List specified in Annex A(3).

4. If a metallic product belonging to product group A or B specified in Annex A
(2.8) fails to meet the criteria of the Composition List included in Annex B(3), the product will be tested and assessed as set forth in Annex A(2.3).

5. In addition to the first paragraph, cementitious products must also comply with the requirements set forth in Annex A(2.9).

6. If the assessment of cementitious products specified in the fifth paragraph identifies an MTC for a substance or QM in the product, and the substance may enter the water for treatment or the drinking water or warm tap water in the drinking or warm tap water supply, the migration of the substance or its residual content in the product will be decided by using the methods specified in Annex C, or, pursuant to Article 8(2) and(3), by using the standard calculations listed in Annex D for identifying the concentration of the substance in the drinking water or warm tap water.
7. The assessment of a substance as specified in the first paragraph, second sentence, is not required if the substance is included in the positive list in Annex B(1).

8. To assess the substances specified in the second sentence of the first paragraph, and the products described in the fifth paragraph that are not included in the positive list of Annex B(1), the information specified in Annex E must be submitted.

9. Products made of materials other than metallic materials must meet the requirements for the organoleptic aspects specified in Annex C, if relevant for the product at issue in accordance with Annex A.

Article 7

1. To the constituent substances of materials, other than metallic materials, and chemicals or the substances used in their manufacturing processes applies the rule that these substances basically contribute up to 10 % of the parameter values, which are listed in Table II of Annex A attached to the Decree, to the concentration of these substances in drinking water or warm tap water or the water to be treated, with the exception of acrylamide, vinyl chloride and epichlorohydrin.

2. For substances specified in the first paragraph with a threshold dose that are not listed in Table II of Annex A attached to the Decree, an MTC in drinking water or warm tap water will be derived by using the toxicity data listed in Annex D, and in accordance with Annex D(1) and (2).

3. The requirement that, under reasonably to be expected practical conditions, the migration from the product is lower than 0.1 µg/L, applies to substances without a threshold dose.

4. The requirements listed in the Table of Annex A(2.8.3.7) apply to the constituent components of metal products and contaminations in these products.

5. The second and third paragraphs will apply accordingly to the constituent components of metallic products and contaminations in these products that are not included in the Table of Annex A(2.8.3.7).

Article 8

1. Pursuant to Article 4(2)(a) and Annex C, all materials may be subjected to laboratory tests to verify if the requirements were met.

2. The following is required for materials other than metallic materials:
a. The expected concentration of the substances in drinking water or warm tap water tested pursuant to Article 7, which is measured in a migration test, must be lower than the migration limit after conversion as specified in Annex D(3);
b. The TOC measured in the migration test must not exceed 2 mg/L after conversion as specified in Annex D(3);
c. If applicable, QM of a substance must be lower than the indicated limit; and
d. The migration must not increase during the migration test.

3. If a suitable measuring method is not available for a substance, the admissibility of the substance may be assessed by using the criteria and standard calculations listed in Annex C(3) and Annex D(4) respectively.

4. Departing from the first paragraph, at the Committee's discretion, the standard calculations specified in the third paragraph may also be used to identify the necessity of the migration test specified in the second paragraph for substances for which a measuring method is available.

5. To prevent products from being wrongfully rejected or approved, the Committee may decide that a migration test be completed if it is expected that the MTC value measured as described in the third and fourth paragraphs will be exceeded. The expected concentration measured by using the migration test and the conversion specified in Annex D(3) shall be binding for the admissibility of the related product.

6. The requirements for tests and assessments listed in Annex A(2.8) shall apply to metallic products that fail to meet the criteria listed in Annex B(3).

Article 9

1. Pursuant to Article 4(2)(a) and Annex A(3), all chemicals may be subjected to laboratory tests to verify that the requirements were met.

2. The maximum tolerable concentrations of contaminations for chemicals at maximum dosage must be lower than the limits set forth in Article 7.

Article 10

1. Tests and assessments specified in the Articles 6-9 will be conducted in accordance with the state of the art.

2. The Minister may issue further instructions for the performance of the tests and assessments specified in the first paragraph.

Article 11

1. Substances for which MTC is identified in the assessment specified in Articles 6 and 7 will be added to the positive lists of Annex B(1) and (2). If said assessment takes place for the application to issue a

recognised quality certificate, the applicant's consent will be required to add the substance to the positive lists.

2. When a metallic product is tested and assessed as specified in Article 6(4), and identified as meeting the requirements set forth in Articles 6-9, it will be added to the List of Components for Metals described in Annex B(3). If these tests and assessments take place for the application to issue a recognised quality certificate, the applicant's consent will be required to add the composition of the related metallic product to the List of Components for Metals.

CHAPTER 4. RECOGNISED QUALITY CERTIFICATE

Article 12

The Minister may recognise a quality certificate to be issued by a recognised certifying body upon the request of such body, if the quality certificate and the related application and other procedures meet the criteria specified in Articles 13 and 14.

Article 13

1. The minimum required data to be submitted by the applicant with the application for a recognised quality certificate are those listed in Annex E. The applicant shall submit these data in the format required by the recognised certifying body.

2. The certifying body, as referred to in the first paragraph, will send a copy of the application and the data specified in the first paragraph to the Committee immediately upon receipt of the application.

3. The product information submitted with the application for a recognised quality certificate will be handled as confidential information.

4. The Minister will grant the approval to issue a recognised quality certificate upon the Committee's recommendation pursuant to Article 4(1)(c), within six months of the date of submission of the data specified in the first paragraph.

Article 14

1. Without prejudice to the requirements set forth in Articles 6-9, the manufacturer or supplier must have a quality system in place in order to obtain a recognised quality certificate. Such system shall at least consist of the following:

a. An internal schedule for quality monitoring with a description of the inspections that are part of the quality system; and
b. The procedures that may be relevant for the issue of a recognised quality certificate. These include in any case the steps to be followed when shortcomings are observed and the process to deal with complaints about the products supplied.

2. The following items must in all cases be included in the quality monitoring schedule referred to in the first paragraph, under a:

a. Raw materials purchased or acquired or the constituent materials;
b. Manufacturing process;
c. Finished products;
d. Status of measuring and test devices;
e. Inspection of how rejected products are further processed;
f. Inspection of products with variances; and
g. Internal transport, storage and identification of markings of semi-finished and finished products.

3. The applicant for a recognised quality certificate shall have the following written documentation in relation to items a-g of the second paragraph:

a. The aspects of the manufacturing process to be checked, including at least the purity of raw materials and auxiliary materials that will be used, the temperature, the mixing process and applications during manufacturing, thickness of walls and diameters of the pipes, calibration of the measuring devices, and how pipes will be sealed during the transportation;
b. The test methods used; and

c. Test frequencies and how test results will be recorded and archived.

4. The quality monitoring schedule and any relevant procedures will be recorded in an annex to the recognised quality certificate.

5. If assurance of consistent quality in the production of materials or chemicals is required to identify the manufacturing process requirements, these requirements shall be recorded in an annex to the recognised quality certificate.

6. If it is important for correctly processing materials and chemicals to set criteria for processing or for the related guidelines set by the applicant for a recognised quality certificate, especially focusing on their feasibility, the criteria to this end shall be recorded in an annex to the recognised quality certificate.

7. In addition, it must be recorded in an annex to the recognised quality certificate how a certifying body will perform periodic inspections of the manufacturer's manufacturing process and quality system in accordance with the applied certifying rules. The manufacturer or supplier shall cooperate in this inspection.

8. If the manufacturing process referred to in the second paragraph is not a continuous process or is a non-recurring process, the Committee will identify further rules for the issue of the recognised quality certificate in addition to the provisions set forth in Article 13 and paragraphs 1-7.

Article 15

1. The certifying body shall notify the Committee of the issue of a recognised quality certificate.

2. Certifying bodies shall keep the Committee informed of their activities related to this subject matter by submitting once a year, by 1 April, the following documents to the Committee's secretary:

a. The results of the inspection and admissibility tests performed in the past calendar year; and
b. Any informativel and complementary comments by the certifying body in relation to one or more inspections.

3. If the data specified in the second paragraph are deemed to be not complete the Committee may demand additional information.

Article 16

A quality certificate issued by an independent certifying body in another Member State of the European Union than the Netherlands or in another signatory state to the Agreement on the European Economic Area shall be considered the equivalent of a recognised quality statement, provided the Minister deems the quality certificate of the other state in compliance with similar or better criteria than those set forth in the present Regulation.

Article 17

The Minister shall notify the issue of a recognised quality certificate or the equivalent thereof as specified in Article 16 by means of an announcement in the Government Gazette, thereby listing the materials or chemicals the certificate was issued for.

CHAPTER 5. BIOCIDES

Article 18

1. For products that are biocides covered by the Plant Protection Products and Biocides Act, and biocides brought into contact with drinking water or warm tap water in the process of their supply, or added to them with the intention of changing water quality, a recognised quality certificate is required in addition to the authorisation issued by the Board for the Authorisation of Plant Protection Products and Biocides (College voor de toelating van gewasbeschermingsmiddelen en biociden, Ctgb).

2. Articles 12-17 shall apply accordingly to the issue of a recognised quality certificate for the biocides referred to in the first paragraph.

CHAPTER 6. STATEMENT OF NO OBJECTION

Article 19

1. Products other than biocides covered by the Dutch Plant Protection Products and Biocides Act intended to affect the microbiology quality of the drinking water or warm tap water shall be used only if the Minister has issued the related statement of no objection.

2. The statement of no objection will stay in effect for the period defined by the Minister on a per product basis. The product's efficacy and side effects must be investigated during this period by using the criteria identified by the Committee.

3. If the efficacy of a product specified in the first paragraph has been proven, and it has been determined that its side-effects are not harmful to public health, then the Minister may recognise, following the period described in the second paragraph, a quality certificate issued by a recognised certifying body upon that body's request, if the quality certificate and the related procedures are based on the requirements specified in the Articles 13 and 14 for the product.

CHAPTER 7. TRANSITIONAL PROVISIONS AND FINAL CLAUSES

Article 20

1. The present Regulation does not apply to products used prior to the Regulation's effective date in existing domestic installations, existing collective mains systems, existing collective water supplies, existing distribution systems, and existing water supply works.

2. If a recognised quality certificate has been issued for any product in accordance with the present Regulation and the Minister later confirms the amendment of the authorisation criteria, the authorisation criteria in effect on the date of issue of the recognised quality certificate shall stay in effect in the new situation for two years following the date when the amendments were notified in writing to the interested party.

3. In the case and during the period referred to in the second paragraph, the Minister may put restrictions in place for the products specified in that paragraph for the supply of drinking water and warm tap water, if the Minister is of the opinion that the use may have adverse effects on public health.

4. If a recognised quality certificate for materials and chemicals was issued prior to the effective date of the present Regulation on the grounds of the Water Supply Act, the latter certificate will be considered as a recognised quality certificate in the application of the present Regulation.

Article 21

The present Regulation shall come into effect on the effective date of the Drinking Water Act. If the Government Gazette, in which this Regulation is included, will be published on or after the date meant in the first sentence this Regulation shall come into effect the day after the publication date of the Government Gazette in which this Regulalation is included.

Article 22

The present Regulation will be quoted as: Materials and chemicals in the supply of drinking water and warm tap water Regulation.

This Regulation will be published in the Government Gazette together with its explanatory memorandum.

The Hague, 29th June 2011,
The State Secretary for Infrastructure and the Environment,
J.J. Atsma

ANNEX A - PRODUCT DESCRIPTION AND ASSESSMENT

1. Distinction between materials and chemicals

The Regulation uses the traditional distinction between materials and chemicals.
In general, one may say that materials are specifically used for construction purposes, such as storage and piping systems, and interior systems, while chemicals include products contacting or added to drinking water or warm tap water to change the water's quality.
Part 2 of this Annex deals with materials as described above, while descriptions of chemicals are included in Part 3.

2. Materials

2.1 Introduction

The Regulation applies to all end products made from organic or inorganic materials, or a combination thereof, that may come into contact with drinking water or warm tap water. The end products must meet all toxicological, organoleptic and microbiological requirements described in the present Regulation.
To verify if a product meets the toxicological requirements, complete specifications of the raw materials and auxiliary materials and potential contaminations must be submitted for each product, in consistence with Annex E. As shown with the descriptions of the specific materials or products in this Annex, the following specification levels apply[1]:

Material/product	Specified level (m/m) in the formulation
PVC	0.1 %
PE	0.1 %
Rubber O-rings	0.5 %
Adhesives for fittings in piping systems	1 %

The listed specification levels apply to both the individual substances and all substances together in the related formulation.

The specifications of raw and auxiliary materials must be compared with the related positive list of Annex B. If a substance is not included in the positive list, the required toxicity data described in Annexes D and E must be submitted. The Committee will define the MTC for this substance, and will then determine which tests must be performed for the product to be granted an authorisation.

To verify the organoleptic criteria for a product, the testing and assessment methods of Annex C must be considered. The table at the end of Annex C shows again for which of the products below organoleptic data are required for the authorisation to be granted.
The assessment criteria to verify the Biomass Production Potential (BPP) of products are still to be defined by the Minister.
It is not necessary or possible in all cases to perform all the tests when conducting the study for authorisation. The selection and performance of certain tests primarily depend on the end product's composition. The product will be tested only for the release of substances that may actually be released. The decision whether or not to perform a migration test also depends on the concentration of the relevant substance(s) in the end product, the expected migration of this (these) substance(s), and the end product's actual contact surface with drinking water or warm tap water.
The Regulation provides for the option to use calculations to estimate the migration of a substance thereby indicating an expected concentration of the substance in drinking water or warm tap water. If the calculation clearly evidences that the MTC will not be exceeded, no laboratory tests are to be

[1] Specification level in this context means that toxicity data listed in Annex D do not have to be submitted for substances in quantities under the level set in the formulation, because the expected concentration of such substances in drinking water and warm tap water will not be higher than 0.1 µg/L, *i.e* the *Threshold of Toxicological Concern* (TTC) value for substances with a so-called *structural alert* for genotoxicity (see also Annex D).

performed. Even if an analysis method is unavailable, a conclusion about the permissibility can be reached by using the calculation.
The guideline for the required testing and assessment methods for the authorisation of a certain product is described below. The Committee is authorised to depart from this guideline if the composition or the intended use of the product to be assessed warrants such departure. Any product is authorised if it meets the criteria applicable to that product on the basis of the Regulation.
One important instrument in the product authorisation process is the use of the positive lists of Annex B for plastics, rubber products, and dyes and pigments, and the composition lists for metallic materials. Also of relevance is the list of the raw and auxiliary materials for cementitious products as included in paragraph 2.9 of this Annex. These lists, including paragraph 2.9, are not exhaustive lists and do not exclude the use of other substances. Such other substances may be used if they have been assessed and authorised in accordance with Articles 6-8 of the Regulation.

2.2 Plastics and rubber products

2.2.1 General

Plastics are organic macromolecular compounds undergoing polymerisation, polycondensation, polyaddition or any other similar process to be manufactured from molecules with a lower molecular weight, or made by a chemical modification of natural macromolecules (monomers and other starting substances).

Plastics are distinguished in thermoplastics (melt when heated up), thermosets (degenerate when heated up) and elastomers.

The term ‘rubber’ is used both for elastomers which obtain their characteristics by vulcanization and mixtures of these elastomers with one or more auxiliary materials or additives. Vulcanization creates a network at molecular scale, usually at elevated temperature whether or not under pressure. There are also unvulcanised elastomers, the so-called thermoplastic elastomers (TPE).

Elastomers are macromolecular (natural and synthetic) compounds distinguished from thermoplastics and thermosets, because they rapidly and powerfully regain their shapes at temperatures between 18 °C and 29 °C if their activity was ended after strong deformation because of a deforming power.

2.2.2 Thermoplastics

Thermoplastics are used frequently in the drinking water or warm tap water supply for the piping systems (pipes and fittings). These thermoplastics include: polyvinyl chloride (PVC, PVC-C, PVC-U, PVC-P), polypropylene (PP, PP-R), polyethylene (PE 80, PE 100, PE Xa, PE Xb, PE Xc, PE RT), polybutene (PB), acrylonitrile butadiene stryrene (ABS), and polyacetale (POM). Polysulfone (PPSU – polyphenylsulfone) is used in membrane filtration modules. Teflon (polytetrafluoroethylene – PTFE) is also used in some products.

2.2.3 Thermosets

Thermosets are less frequently used in the drinking water or warm tap water supply than thermoplastics. Examples of thermosets are epoxy, melamine formaldehyde and urea formaldehyde (MF and UF), alkyd resins and polyester resins. From these plastics, especially glass-reinforced polyester resins are used in the manufacture of (parts of) piping and storage systems. Coatings (protection layers) for metallic products and cementitious products may be based on epoxies.

2.2.4 Elastomers

Elastomers (rubber products) are specifically used in the drinking water or warm tap water supply for sealing (rubber rings), flexible connections, and in compensators (coupling units in piping systems as buffers for movements). Frequently used elastomers include: styrene butadiene rubber (SBR), nitrile rubber (NBR) and EPDM (ethylene propylene diene monomer). Other examples of elastomers include natural rubber, isoprene rubber, neoprene and polyurethane (PUR) and silicone rubber.

The molecules of elastomers consist of at least 500 structural units. They may be chlorinated and/or bromated.

Elastomers may be vulcanised to a state in which they become virtually insoluble in boiling benzene, methyl ethyl ketone or in an azeotropic mixture of ethanol and toluene. However, swelling of the elastomer is possible under the influence of these liquids.

Elastomers in vulcanised condition without other substances than those needed for the vulcanisation process do not break if stretched at a temperature between 18 °C and 29 °C to three times the initial dimensions. After being stretched to twice the original length for one minute, within one minute they shrink to less than 1.5 times the original length.

2.2.5 Positive list for plastics, including elastomers and rubber products

For the manufacture and processing of plastics, elastomers, and natural and synthetic rubber products coming into contact with drinking water or warm tap water, Annex B(1), contains a list of authorised monomers and other starting substances, polymer production aids (PPA), aids to polymerisation (AP) and additives, *i.e.* the so-called positive list.[2]

The positive list is not an exhaustive list and does not exclude the use of other substances. Substances not included in the list may be used if they have been assessed and are authorised in accordance with Chapter 3 of the Regulation.

PPA means any substance used to provide a suitable medium for polymers and plastic manufacturing. They may be present but are neither intended to be present in the finished materials or products nor have a physical or chemical effect in the finished materials or products.

AP means substances which initiate the polymerisation reaction and control the macromelocular structure of te polymer.

Additives are substances intentionally added to plastics and rubber products to achieve a physical or chemical effect during processing of the plastic or in the finished product. It is intended to be present in the finished materials or products.

Monomers and other starting substances, PPA, AP and additives must be of good technical quality, and should not be used in larger quantities than strictly necessary for manufacturing the end product.

2.2.6 By-products

The following substances may be present in end products:

- Contaminations in the used monomers and other starting substances, PPA, AP, additives, dyes and pigments;
- Intermediates and oligomers created during the polymerisation, polycondensation, polyaddition or other similar processes;
- Decomposition products of the substances used.

The Committee will decide whether or not contaminations, intermediates, oligomers and decomposition products will obtain an authorisation.

In certain cases, the Committee may decide that a study of unknown substances by using the proper analysis methods must be conducted.

2.2.7 Testing and assessing[3]

The authorisation study for plastics and rubber products must in general, in accordance with Chapter 3 of the Regulation and Annex C, include the following tests:

- Assessment of the formulation, verification with the positive lists of Appendix B, determination of MTCs. For PVC and PE pipes, a specification level of 0.1 % (m/m) applies to the formulation, this level for rubber rings is 0.5 % (m/m);
- Migration test;

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[2] Within the 4MS Common Approach, joint positive lists are being prepared on the basis of the EFSA guidelines, Commission Regulation (EU) 10/2011 and the national positive lists. Annex B will be updated as soon as these lists are complete. Please refer to paragraphs 2.3 and 3.3.of the Explanatory Memorandum to the Regulation.

[3] As explained in paragraphs 2.2.2-2.2.4, plastics and rubber products are primarily used in piping systems and their parts (pipes and coupling units), sealing systems (O-rings) and flexible connectors (compensators). However, they are also used to manufacture foils, for example to get waterproof separations in water exploration areas and as the interior lining in storage systems. They may also be a part of a unit, such as membranes in filtration modules. Foils and membranes are described separately on the basis of their specific uses (Parts 2.3 and 2.4 respectively).

- Verification of the organoleptic aspects;
- Checking the Biomass Production Potential.

In general, a limited set of laboratory tests is sufficient for products with a relatively small contact surface for which, in accordance with Annex D(3), a conversion factor of < 0.01 d/dm can be determined. The authorisation studies required for these products are listed in the related product descriptions. The following aspects may apply to products that are not listed, if decided by the Committee:

- Assessment of the formulation, verification with the positive list of Annex B, measuring MTCs;
- Calculation of the expected concentration in drinking water or warm tap water for substances to which an MTC applies in accordance with Part 3 of Annex C and/or Part 4 of Annex D;
- The organoleptic aspects, if it is impossible to properly remove the product (adhesives, for example);
- Biomass Production Potential.

2.3 Foils

2.3.1 Description

Foils in the context of the Regulation are relatively thin layers of a plastic which may directly come into contact with drinking water, such as in emergency drinking water supplies, or which may be used for the protection of the environment, especially to protect the soil and ground water from potential harmful substances. Foils for the protection of the environment are also called “Geomembranes”.
In the manufacture of synthetic foils, in general three different types of PE are used (HDPE, LDPE and LLDPE (Linear Low Density Polyethylene) and a softened polyvinyl chloride (PVC-P). These plastics may be reinforced with a fine or course mesh tissue.

2.3.2 Testing and assessing

The authorisation study for plastic foils must in accordance with Chapter 3 of the Regulation and Annex C, include the following tests:

- Assessment of the formulation, verification with the positive lists of Annex B, measuring MTCs;
- Migration test;
- Verification of the organoleptic aspects;
- Biomass Production Potential.

2.4 Membranes

2.4.1 Description

Depending on the filtration type, such as microfiltration, ultrafiltration, nanofiltration, reverse osmosis and electro-dialysis, membrane filtration modules and the membranes may come in various physical appearances. The modules consist of various types of materials. The quality certificate will be the issued for the entire module.

2.4.2 Testing and assessing

Only these parts of a membrane filtration module directly coming into contact with water intended for human consumption must be tested and assessed.

Membranes are not tested for organoleptic aspects, because the water passing the membrane is not yet drinking water or warm tap water and may be further processed.

The necessity of the use of the Biomass Production Potential test is still under discussion.

A membrane filtration module is a assembled product and should preferably be tested as a whole, as used in real-case scenarios, in accordance with NEN-EN 12873-4:2006 (EN) (see Part 2.10.3 of this Annex and Part 1.3 of Annex C). Complementing NEN-EN 12873-4:2006 (EN), Part 3 of Annex D applies to the measurement of the estimated concentration of relevant substances in drinking water and the verification of the estimated concentration with the MTC applicable to the substance.

In exceptional cases, which must be reviewed by the Committee, the various parts of a membrane filtration module may be tested individually in accordance with NEN-EN 12873-1:2003 (EN) thereby following the manufacturer's or supplier's instructions with regard to the pre-treatment of the membrane filtration module. To estimate the concentration of a substance in drinking water, the results of the third migration period must be used. The estimated concentration in drinking water must be calculated in accordance with Part 3 of Annex D, and must be followed by verification with the applicable MTC for the substance.

If the related MTC is still exceeded after the three migration periods set forth in NEN-EN 12873-1:2003 (EN), and if it can be evidenced or expected that the migration rate will decrease over time, the migration test may be extended up to a maximum migration period of 30 days.
Complementing Annex C of NEN-EN 12873-1:2003 (EN), the migration periods for testing at 23 °C are: 72 hours, 72 hours, 72 hours, 96 hours, 72 hours, 96 hours, 72 hours, 96 hours and 72 hours. The migration of the relevant parameter(s) must be studied in all migration waters obtained with a 72 hours migration period. The estimated concentration in the drinking water must then be calculated in accordance with Part 3 of Annex D, and must be followed by verification with the applicable MTC for the substance.

The assessment of a membrane-filtration module will be done on the total effect (the sum) of the various parts.

If the model calculation described in Part 3.1 of Annex C is used for identifying the migration, the following assumptions and data will apply:

TTC value:	0.1µ/L (see Annex D)
Temperature/migration time:	T = 23 °C and t = 10 days (1 x 24 hours + 3 x 72 hours)
Structure of the module:	List of parts, used materials[4] and contact surface with water of the individual parts
Conversion factor (F_{go}):	to be calculated for each individual part
MTC (not leading to exceeding the TTC value):	to be calculated on the basis of the conversion factor, polymer type and migrant size

2.5 Lubricants

2.5.1 Description

Lubricants in this context are used to lubricate parts of drinking water or warm tap water systems, for example, pumps and sanitary valves. The lubricants need to be persisting throughout the (economic) life of the product in which or for which they are used.

2.5.2 Testing and assessing

[4] Some materials will be used at the supply side of the membrane module. Migrant substances coming in the water at this point must pass the membrane before they can be present in the drinking water. The removal of the related substance(s) must not be accounted for in the calculation.

In general, it does not make sense to subject lubricants to a migration test. In most cases, the formulation and calculations can be used to show that the agent meets the requirements, including the supplier's instructions for application and use. The following aspects may be included in the calculation of the estimated concentration of a relevant substance in drinking water or warm tap water in accordance with and supplementing Part 4 of Annex D:

- The average quantity used per application;
- Potential disappearance of solvent(s) due to evaporation;
- The (poor) solubility of a lubricant (for which, for example, the substance's molar mass is of relevance);
- The (relatively small) contact surface of the lubricant in relation to the total surface of a drinking water or warm tap water system;
- The volume of water flowing by.

2.6 Adhesives

2.6.1 Description

In this context, adhesives are products used to make adhesive connections in thermoplastic and thermoset piping systems, whereby the material fills the gap between the exterior of a pipe and the interior of a fitting, and is used for the adhesion between both parts.

2.6.2 Testing and assessing

In general, it does not make sense to subject adhesives to a migration test. In most cases, the formulation with a specification level of 1 % (m/m) and calculations can be used to show that the agent meets the requirements, including the supplier's instructions for application and use, such as the time for drying or curing. The following aspects may be included in the calculation of the estimated concentration of a relevant substance in drinking water or warm tap water, in accordance with and supplementing Part 4 of Annex D:

- The average quantity used per connection;
- Potential disappearance of solvent(s) due to evaporation;
- Possible interaction between the starting substances (for thermoset materials);
- The piping system's applicable conversion factor;
- The total number of adhesive connections per meter of piping;
- The relatively small contact surface of the adhesive in relation to the total surface of a piping system contacting drinking water or warm tap water.

2.7 Slipping agents

2.7.1 Description

Slipping agents in this context are used in the assembly of rubber seals in the mains or water distribution systems of various types, such as concrete, cast iron, steel or the various thermoplastics and thermosets. The rubber seals may have various physical appearances (sealing rings, cuffs, etc.).

2.7.2 Testing and assessing

In general, it does not make sense to subject slipping agents to a migration test. In most cases, the formulation and calculations can be used to show that the agent meets the requirements, including the supplier's instructions for application and use. The following aspects may be included in the calculation of the estimated concentration of a relevant substance in drinking water or warm tap water, in accordance with and supplementing Part 4 of Annex D:

- The average quantity of the slipping agents used per connection;
- How the slipping agent is applied, and the assembly of a connection;
- Potential disappearance of solvent(s) due to evaporation;
- Potential disappearance of the slipping agent when the piping system is pre-flushed as a result of the behaviour of all substances in the slipping agent in an aqueous environment (solubility);

- The piping system's applicable conversion factor;
- The total number of connections per meter of piping;
- The relatively small contact surface of the slipping agent in relation to the total surface of a piping system contacting drinking water or warm tap water.

2.8 Metallic materials

2.8.1 Description

2.8.1.1 Permissible products and materials

The definition of "Metallic materials" in this context covers the following products that may contact drinking water or warm tap water:

- Pipes and fittings (being parts of a piping system) made of copper, whether or not tinned, and/or copper alloys (copper/zinc and copper/tin alloys);
- Appendages (such as sanitary valves and water meters) made of copper (alloys) and stainless steel;
- Stainless steel pipes and fittings (being parts of a piping system);
- Solders and brazes for copper piping systems;
- Welding materials for use in stainless steel piping systems.

2.8.1.2 Exclusions

The use of lead as a material in pipes is banned.
The Committee must assess authorisations for soldering and welding supplies (at this point, soldering and welding supplies are not listed in Annex B(3)).
Composition lists for stainless steel and aluminium alloys are not listed in the third part of Annex B, because the lists are still being discussed. The Committee will assess authorisations for stainless steel or aluminium products.

2.8.1.3 Cast iron, steel and carbon steel

It is allowed only to use pipes and fittings made of (nodular and lamellar) cast iron and steel as parts of piping systems if the interior surface of the related products is equipped with a permissible protective layer, such as an epoxy or cement-mortar *lining*. Cast iron without a protective layer may be used in specific applications, such as pumps and valves, and in other products with a relatively small surface area (conversion factor < 0.01 d/dm, see Part 3 in Annex D).
It is allowed only to use carbon steel pipes and reservoirs if the interior surface of the related products is equipped with a permissible protective layer (carbon steel without a protective layer is allowed only if used in products for which a conversion factor of < 0.01 d/dm can be measured, such as pumps and valves).

2.8.1.4 Galvanised steel

Part three of Annex B, under the title "Galvanised steel", lists the requirements for zinc layers (Note: zinc layers may also be galvanised in a thermal process), including a calculation method for identifying water compositions for which the rate of corrosion for galvanised steel may be unacceptable.
It is noted in the Dutch Vewin Water Worksheet 2.2 H that galvanised steel products should not be used in systems where the water is intended (whether or not exclusively) for human consumption and personal care. With regard to the use of metals, the Regulation does not distinguish between drinking water or warm tap water systems and water distribution systems. The Vewin Drinking Water Supply Not In Buildings Guideline applies to water distribution systems. This guideline is based on NEN-EN 805:2000. Water treatment and water exploration systems, storage units, and pumping stations are not covered by the VEWIN Guideline and NEN-EN 805:2000.

2.8.1.5 Supplies

Supplies for soldering and welding connections, such as flow-control agents, are not included in the definition of "Metallic masterials" and their authorisations must be assessed separately.

Supplies used in the manufacture of pipes, fittings and appendages, such as lubricating and cutting oils, are not assessed for the requirement related to residual carbon in copper (alloys) and stainless steel staining/passivating.

2.8.1.6 Non-metal parts

Synthetic or rubber parts in the connections of metal piping systems (for example, rubber rings in clamp fittings and gasket rings in flange connections), sealing agents and (Teflon) tape are assessed as described in Part 2.2 of this Annex.

2.8.2 Classification in product groups, structure of the Composition List

The Composition List of Annex B(3) includes various Categories of metallic materials.

A Category is defined as a group of materials with the same characteristics in respect of their field of application, behaviour in contact with drinking water, andrestrictions with regard to water composition and/or surface area..

A Reference Material is defined as a material 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 acceptibility. Possible effects of some constituents to inhibit the metal release have to be taken into account.

Under each category commercially available metallic materials accepted for use in products contacting drinking water will be listed

Based on their area of application (see also Annex B(3)), metallic materials can be subdivided into three product groups:

Product group A: > 10 % of contact surface[5]

1. For pipes in a domestic installation the same material can be used for all diameters. A single material 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, components, etc.).
   This group also includes uncoated metallic pipelines in water supply distribution systems and water treatment processes.

2. Product group B: 1-10 % of contact surface
   Fittings or ancillaries can be produced from one material or from slightly different materials throughout the domestic installation. The most common are made from copper alloys that contain lead. Due to their potential to release lead to water there is a need to restrict the total surface contact of products made from these alloys. For assessments of materials for these products a contribution of 10% water contact surface area is assumed.
   This group also includes metallic parts of pumps and valves used in domestic installation.

3. Product group C: < 1 % of contact surface
   For technical reasons, there might be a need to produce small parts from compositions not accepted for the Product Group B, fittings and ancillaries. Other compositions with higher release rates may be accepted in these devices 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 that do not exceed 1% of the total surface in contact with drinking water; for example, the body of a water

[5] "Contact surface" is defined as the percentage of the interior area of the drinking water or warm tap water system.

meter would need to be produced from an accepted composition for Product Group B but a moving part may be produced from a material listed for Product Group C.

This group also includes metallic parts of pumps and valves used in water supply distribution and water treatment processes.

2.8.3 Testing and assessing

2.8.3.1 Additional data to be submitted for the assessment of a material

For the assessment of a material, additional data must be submitted for:

- The threshold values of the alloy's main ingredients, and the maximum values of contaminations;
- The existing applicable European standard(s);
- The material characteristics;
- The products made with the material;
- The manufacturing process;
- Other information that may be relevant for the assessment.

2.8.3.2 Organoleptic Aspects

Appendix C sets forth that metals must not be tested for potential organoleptic aspects, because MTCs defined for metals or metal ions are (much) lower than the concentrations in which organoleptic aspects have any relevance.

2.8.3.3 Microbiology Aspects

With the exception of the presence of potential organic remainder on the surface of metals caused by the use of adjuvants, such as lubricating and cutting oils in the manufacturing process, potentially in combination with selected surface characteristics (ruggedness), the release by these products of microbiologically degradable organic compounds in drinking water or warm tap water may be excluded. For this reason, metals are not tested for microbiological aspects.

2.8.3.4 Residual carbon

The requirement of maximum 0.2 mg/dm^2 residual carbon in the interior surface applies in accordance with NEN-EN 1057:2006
This requirement also applies to fittings made of copper and copper alloys. One of the typical steps of manufacturing processes for such pipes and fittings is the removal of residual carbon to under the level of this requirement.

2.8.3.5 Toxicological aspects

The composition of metallic materials must primarily meet the criteria listed in Annex B(3) (Composition List for metallic materials.
If a metallic product meets the criteria listed in Annex B(3), no rig test or only a limited rig test (see below) must be performed in an authorisation or inspection process. The Committee makes the related decisions.

A rig test will be required if a product group A or B metallic product fails to meet the criteria of the composition list of Annex B(3), and an application is submitted to add (the ingredients of) the product to the composition list.

Product group C metallic products are not tested.

2.8.3.6 Rig test

For the assessment of the metal release standard NEN-EN 15664-1:2008 (EN), "Influence of metallic materials on water intended for human consumption - Dynamic rig test for assessment of metal release - Part 1: Design and use" applies.

The minimum test period is 6 months. The Committee will decide if this period needs to be extended.

Before a reference material will be accepted for a Category, the results of the NEN-EN 15664-1 test performed on the following test waters (in accordance with NEN-EN 15664-2:2008 Draft) must be accepted:

	Description of test water	**pH**	**[HCO_3^-]**	**Total of [Cl^-] and [SO_4^{2-}]**	**Oxygen**	**TOC[6]**
			mmol/L	mmol/L		mg/L
Test water 1	Very hard, neutral	7,1 – 7,5	> 5,0	> 3	> 70 % saturation	> 1,5
Test water 2	Soft, slightly acidic	6,7 -7,1	0,5 – 1,3	-	> 70 % saturation	-
Test water 3	Soft, alkaline	8,0 – 84	0,7 – 1,3	-	> 70 % saturation	-

Before any material is added to a Category, using NEN-EN 15664-1 needs a comparative test with the reference material. Only one water must be used in the comparative test.

The parameters to be measured depend on the composition of the product at issue; the parameters are listed in Annex B(3).

2.8.3.7 Authorisation criteria

The table below shows to what level any metal product may contribute to the MTC for the related parameter. The following principles apply to the permissible contribution (reference concentration):

- The contribution may be 90 % for contaminations (parameters) for which metallic products are the main source;
- The contribution may be 50 % if there are other potential contamination sources, and the metallic material is essential to manufacture the related product.

Substance/parameter	**Permissible contribution of a metal (%)**	**MTC (µg/L)**	**Reference concentration in drinking water or warm tap water (µg /L)**
Chemical parameters in accordance with Table !! [sic] *of Annex A of the Water Supply Decree*			
Antimony	50	5	2,5
Arsenic	50	10	5
Cadmium	50	5	2.5
Chromium	50	50[1]	25
Copper	90	2 000[1]	1 800
Lead	50	10[1]	5
Nickel	50	20[1]	10
Selenium	50	10	5
Indicator parameters in accordance with Table IIIb of Annex A of the Water Supply Decree			
Aluminium	50	30[2]	15
Iron	50	200	100
Manganese	50	50	25

[6] The TOC value of >1,5 mg/L should not be increased by adding organic substances to the test water.

Substance/parameter	Permissible contribution of a metal (%)	MTC (µg/L)	Reference concentration in drinking water or warm tap water (µg /L)
Zinc	90	3 000	2 700
Other parameters (not listed in Annex A of the Water Supply Decree)			
Bismuth	90	10[3]	9
Molybdenum	50	20[3]	10
Tin	50	6 000[4]	3 000

[1)] The values for chromium, copper, lead and nickel apply to a sample obtained at the tap, and are deemed to be representative for the *average value of a consumer's weekly intake.*
[2)] Pursuant to Annex B(1.1.14).
[3)] The values for bismuth and molybdenum have been defined by the Committee on the basis of the proposal by the 4MS Group of 14 November 2008 (*Procedure for the acceptance of metallic materials for PDW*, CvD MC [Expert Commission for Metals and Chemicals] 23 08-071).
[4)] Derived from a TDI of 2 mg/kg of body weight (WHO *Guidelines for drinking-water quality*), not on the basis of organoleptic aspects.

2.8.3.8 The addition of reference materials or materials not included in a listed Category

The addition to or modification of an alloy's composition may result in the alloy not meeting the criteria of the related Category. The addition or modification may significantly alter the alloy's migration characteristics. If that is the case, the following information must be submitted for alloys that are representative for a Category (reference material):

- The information listed under 2.8.3.1;
- If the suggested new composition is not comparable with a listed Category, the data pursuant to NEN-EN 15664-1 with the three test waters listed under 2.8.3.6 must be submitted.

Figure A shows a diagram of the steps to be followed.

2.8.3.9 The acceptance of reference materials

The arithmetic mean of equivalent concentrations $MEP_n(t)$ applies to the assessment of the rig test results in accordance with NEN-EN 15664-1.
For each operational period (t), the mean of $MEP_n(t)$ must be calculated for the three test lines in a rig test : $MEP_a(t)$.

The material may be accepted for a product group with a contact surface "a" (see 2.8.2) if:

(I) $MEP_a(t)$ a ≤ RC with t = 16, 21 and 26 weeks
(II) $MEP_a(t_b) \geq MEP_a(t)$ with $\{t_b, t\}$ = {12, 16}, {16, 21} and {21, 26} weeks

applies to the test waters listed under 2.8.3.6.

If the criterion under II cannot be met, the length of the test may be extended to up to 1 year. The material will then be accepted if

(III) $MEP_a(t_b) \geq MEP_a(t)$ with $\{t_b, t\}$ = {26, 39} and {39, 52} weeks

applies to the test waters listed under 2.8.3.6.

If samples from the stagnation period are analysed to supplement the requirements set forth in NEN-EN 15664-1, these data as well must be considered in the assessment.

The Committee will decide if the quality of the available data is adequate. For the test pursuant to NEN- EN 15664-1 they are: the results of the individual test lines, the results of the 4-hour stagnation period, and the data related to the ingredients of the water.

The Committee will decide if the quality of the data is adequate for an authorisation assessment. Once authorised by the Committee, the related material, with the class and the reference material, may be added to the composition lists of Annex B(3).

2.8.3.10 The addition of materials to the composition list within a Category

If the composition of a material is within the criteria for a Category, the material may be added to the composition list, if the results of the comparative test with the related reference material in the standard rig test set forth in NEN-EN 15664-1, with one of the test waters listed in 2.8.3.6, meet the requirements.

The following information must be submitted for each material:

- The information listed under 2.8.3.1;
- The results of the aforementioned comparative test.

Figure B shows a diagram of the steps to be followed.

2.8.3.11 The acceptance of a material for a comparative test

The arithmetic mean of equivalent concentrations $MEP_n(t)$ applies to the assessment of the migration test results in accordance with NEN-EN 15664-1.
For each operational period (t), the mean of $MEP_n(t)$ must be calculated for the three test lines in a *test rig*: $MEP_a(t)$.
$MEP_{a,RM}(t)$ applies to the reference material.

The material may be accepted for a product group with a contact surface a of the reference material (see 2.8.2) if:

(I) $MEP_a(t) \leq MEP_{a,RM}(t)$ with t = 16, 21 and 26 weeks
(II) $MEP_a(t_b) \geq MEP_a(t)$ with $\{t_b, t\}$ = {12, 16}, {16, 21} and {21, 26} weeks

applies to the used test water.

If the criterion under II cannot be met, the length of the test may be extended to up to 1 year. The material will then be accepted if

(III) $MEP_a(t_b) \geq MEP_a(t)$ with $\{t_b, t\}$ = {26, 39} and {39, 52} weeks

applies.

If samples from the stagnation period are analysed to supplement the requirements set forth in NEN-EN 15664-1, these data as well must be considered in the assessment.

The Committee will decide if the quality of the available data is adequate. For the test pursuant to NEN- EN 15664-1 they are: the results of the individual test lines, the results of the 4-hour stagnation period, and the data related to the ingredients of the water.

The Committee will decide if the quality of the data is adequate for an authorisation assessment. Once authorised by the Committee, the related material may be added to the composition list of the reference material's Category of Annex B(3).

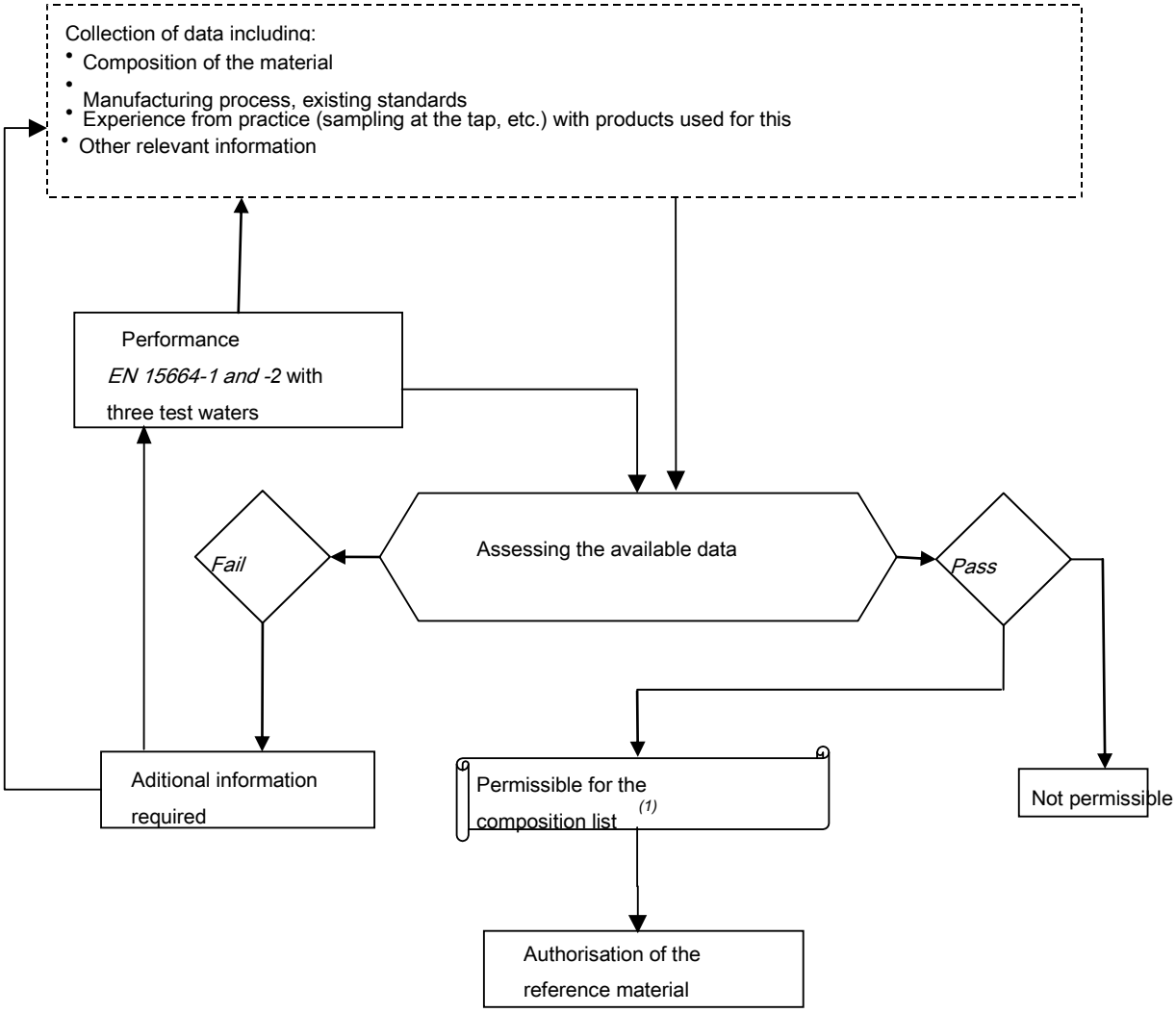
2.8.3.12 Product authorisations

Any product is permissible if the composing metallic materials meet the criteria of the composition list.

For sanitary valves, a separate assessment policy will be included because of the differences in the manufacturing process. This policy is being developed.

Figure C shows a diagram of the steps to be followed for product authorisations.

Figure A – Steps for the authorisation of reference materials for a Category and authorisation test for materials not belonging to a Category of the composition list



(1): Potential restrictions on the use

Figure B – Steps to add materials to the list of authorised compounds

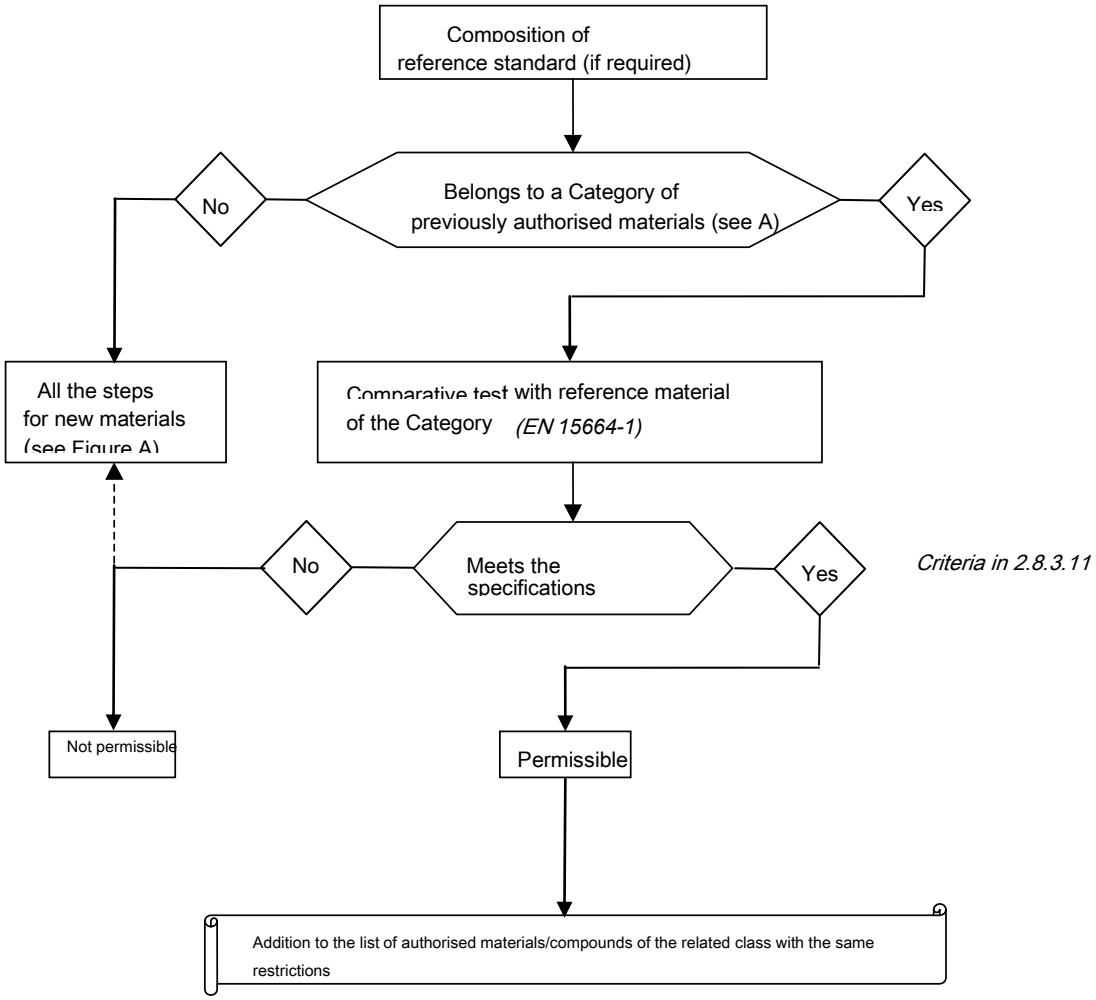
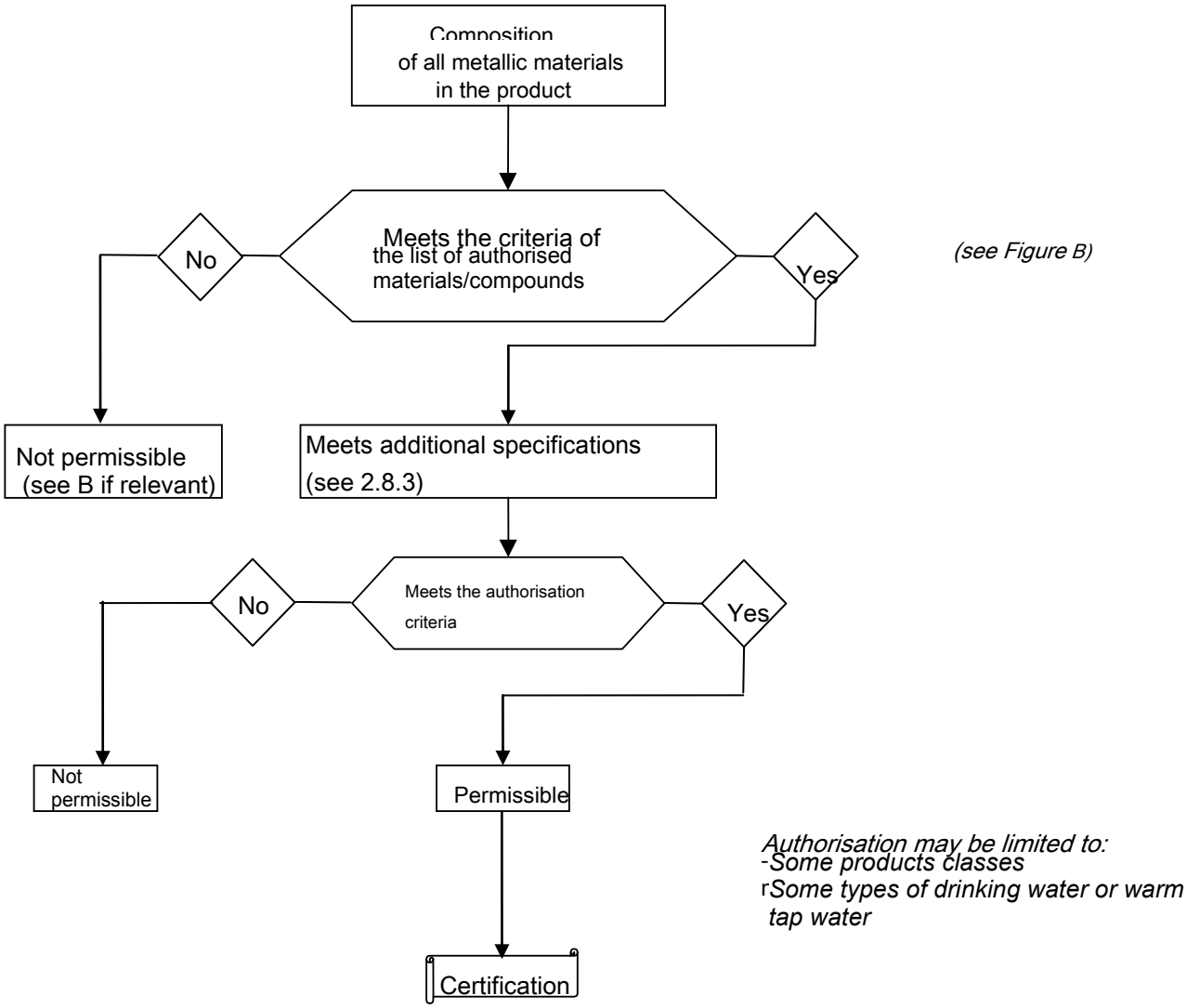


Figure C - Procedure for product authorisations

NB: Any product may consist of various metals or one or more metals combined with organic materials or products



2.9 Cementitious products

2.9.1 Description

In Europe, only types of cement with the CE mark are allowed for processing. These types of cement are listed in NEN-EN 197-1:2000/A1:2004 (EN).[7]

Pursuant to NEN-EN 197-1:2000/A1:2004 (EN), only products and materials on the basis of Portland and blast furnace cement, CEM I and CEM III respectively, are allowed for use in the drinking water or warm tap water supply.[8]

Due to structural reasons, blast furnace cement ("CEM III" is only allowed for use in storage systems.

The following is a description of ementitious products and materials that contact drinking water or warm tap water may include:

- Cement mortar lining for (lamellar and nodular) cast iron supply systems;
- Cement mortar lining for (galvanized) steel supply systems;
- Concrete supply systems;
- Concrete storage systems;
- Repair supplies for use in concrete water supply or storage systems;
- Joint fillers for use in concrete water storage systems.

Only drinking water or warm tap water is allowed for use as the mixing water for cement products and materials.

Additives for concrete (sand and gravel) must comply with NEN-EN 12620:2002 (EN).

Sand for use in internal cement-mortar linings must comply with NEN-EN 13139:2002 (EN).

Parts may be used in or around cement products, such as rubber cuffs, rubber sealing rings in connections and joint fillers for dilatation joints. These parts must be assessed individually, as set forth in paragraph 2.2 of this Annex.[9]

Of the technological auxiliary agents, the mould release agents and *curing compounds* are described separately, in 2.9.4 and 2.9.5 respectively.

2.9.2 Testing and assessing

To verify if a product meets the toxicological requirements, complete specifications of the raw materials and auxiliary materials and potential contaminations must be submitted for each product, in consistence with Annex E. These specifications must be compared with the positive list of Annex B, Part 1. If a substance is not included in the related positive list, the required toxicity data described in Annex D must be submitted. The Committee will define the MTC for this substance, and will then determine which tests must be performed for the product to be granted an authorisation.
To identify the migration of substances from factory-made cementitious products or materials in view of assessing the toxicological aspects, NEN-EN 14944-3:2005 Draft (EN) applies (see Annex C, paragraph 1.6).[10]

Cementitious products or materials for which the authorisation for use in the drinking water or warm tap water supply is applied for, may have been assessed and tested previously, for example, on the basis of the Building Materials Decree. The test results of such an assessment may be used if they were obtained pursuant to the criteria described in Annex C.

On the basis of the rate of migration measured pursuant to NEN-EN 14944-3:2005 Draft (EN) and the applicable conversion factor (see Part 3 of Annex D), the expected concentration in drinking water or warm tap water must be calculated for each substance/parameter.

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[9] In the future, an individual assessment will most likely also be required for so-called seal coats (multi-layer system of a cement liner and epoxy coating). The application is not yet used in the Netherlands.

[10] NEN-EN 14944-4 describes the migration test for materials made on site (*site-applied materials*). This standard is still being developed.

Cementitious products will be tested for organoleptic aspects in drinking water or warm tap water pursuant to NEN-EN 14944-1:2006 (EN) and the methods for identification described in paragraph 2.1 of Annex C.

2.9.3 Additional criteria and requirements

The following two requirements with regard to the pH apply to the performance of the migration test and the obtained results:

- After pre-rinsing for 7 days, the pH of the rinsing water must be lower than or equal to 9.0. If the pH is higher than 9.0, the test will be discontinued and the product/material will not be permissible.
- At the end of the migration test, the pH of the migration water must be lower than or equal to 9.0.

In addition to the specifications for antimony, arsenic, cadmium, chromium, mercury, nickel, lead and selenium on the basis of the 10% rule (Appendix D, second part), the following requirements apply to cement products:

- Aluminium 30 µg /L
- Vanadium 2.5 µg /L

A cementitious product will be authorised if the expected concentration in drinking water or warm tap water of the relevant substance(s) is lower than the applicable MTC.

2.9.4 Mould release agents

2.9.4.1 Description

Mouls release agents are used in concrete products (concrete pipes and cisterns) to avoid adhesion between the concrete and the shuttering material, thereby preventing damage to the hardened material when the mould is removed.

2.9.4.2 Testing and assessing

In general, it does not make sense to subject mouls release agents to a migration test. In most cases, the formulation and calculations can be used to show that the agent meets the requirements, including the supplier's instructions for application and use. The following aspects may be included in the calculation of the estimated concentration of a relevant substance in drinking water or warm tap water, in accordance with and supplementing Part 4 of Annex D:

- The quantity of any mould release agent used per surface unit;
- Potential disappearance of solvent(s) due to evaporation;
- A realistic percentage of the original amount of a mould release agent remaining on the concrete surface after removal of the mould;
- Potential steps to remove any remaining mould release agent (for example, by hosing off the concrete surface);
- Potential disappearance of the mould release agent when the water supply or storage system is pre-flushed as a result of the behaviour of all substances in the mould release agent in an aqueous environment (solubility);
- The conversion factor listed in Part 3 of Annex D applicable to the water supply or storage system.

2.9.5 Curing compounds

2.9.5.1 Description

Curing compounds are applied to concrete surfaces after removal of the mould to delay the drying process of the concrete mortar.

2.9.5.2 Testing and assessing

In general, it does not make sense to subject *curing compounds* to a migration test. In most cases, the formulation and calculations can be used to show that the agent meets the requirements, including the supplier's instructions for application and use. The following aspects may be included in the calculation of the estimated concentration of a relevant substance in drinking water or warm tap water, in accordance with and supplementing Part 4 of Annex D:

- The quantity of any *curing compound* used per surface unit;
- Potential disappearance of solvent(s) due to evaporation;
- Potential steps to remove the *curing compound* (for example, by hosing off the concrete surface);
- Potential disappearance of the *curing compound* when the water supply or storage system is pre-flushed as a result of the behaviour of all substances in the *curing compound* in an aqueous environment (solubility);
- The conversion factor listed in Part 3 of Annex D applicable to the water supply or storage system.

2.10 Multi-layer and assembled products[11]

2.10.1 Multi-layer products

In real-case scenarios, the following multi-layer products are used in the drinking water or warm tap water supply:

- Plastic piping with an organic or inorganic barrier layer to avoid the permeation of contaminants in the direct environment into the drinking water or warm tap water;
- With fibreglass reinforced polyester products;
- Foils;
- Rubber compensators.

A limited assessment of the various layers may be sufficient for selected multi-layer pipes; see 2.10.2.2.

The assessment for fibreglass-reinforced products includes the collection of information about the composition of the interior layer (*liner)*, the intermediate layer (*effective* layer or *structural layer*) containing glass fibres, glass rovings and polyester tissue, and the exterior layer (*top coat*). In addition, information about the stripping agent is required. In general, it is required that the glass fibres are to be fully embedded.

2.10.2 Multi-layer products with a barrier layer

2.10.2.1 Description

Multi-layer products (pipes) with a barrier layer may be subdivided into the following two types:

a. Completely plastic products typically consisting of three layers:

- The interior layer that will contact drinking water or warm tap water;
- An adhesive layer;
- The oxygen-resisting outer layer consisting of an ethylene vinyl alcohol copolymer.

b. Products with an aluminium barrier layer consisting of five layers:

- The interior layer;
- An adhesive layer;
- An aluminium layer glued in coils or welded over its length;

[11] The distinction between multi-layer and composed products is not always clear in reality. In this context, multi-layer products shall mean "non-decomposable" products. Composed products are "decomposable, *i.e.* it is possible to test the various parts individually.

- An adhesive layer;
- The outer layer.

Unlike (laser) welded aluminium, in coils glued aluminium may be permeable for chemicals.

2.10.2.2 Testing and assessing

The toxicological, organoleptic and microbiological aspects of multi-layer products must be tested as set forth in Part 2.2 (Plastics and rubber products) of this Annex.

The entire end product must be tested with only the interior layer contacting the (migration) water, in accordance with the testing methods of Annex C.

In addition, the following will apply to multi-layer products with an aluminium layer:
- The aluminium layer must meet the applicable requirements set forth in Part 2.8 of this Annex;
- If the aluminium layer is glued (not welded), all layers of the product must be assessed; and
- If the aluminium layer is low-welded, specifications of the raw materials and auxiliary materials must be submitted for the outer layer only. Only the interior layer and the first adhesive layer will then be assessed.

2.10.3 Assembled products

Assembled products consist of two or more components made of different materials, such as membrane modules, water meters, taps, showerheads and boilers, with plastic and metallic parts.

The materials used to make each part of an assembled product must be reported.

Only parts coming into contact with drinking water and warm tap water must be tested and assessed to obtain an authorisation, with the methods described in Annex C and Annex D thereby observing the conditions listed in these Annexes for the various materials and products. If needed, the Committee will make decisions with regard to the (chemical) specifications and the specification levels of the related raw materials and auxiliary materials.

If an assembled product must be tested, it is preferred that the entire product is tested, as it is done in practice. In exceptional cases, if so decided by the Committee, the various parts may be tested individually. The assessment will be done on the total effect (the sum) of the various parts.

3. Chemicals

3.1 Introduction

Within the context of the Regulation, chemicals are defined as solid, liquid or gaseous substances in the drinking water or warm tap water supply that contact water to be treated, drinking water or warm tap water, or are added to the water to change its quality.

Not covered by this definition of chemicals are, for example, lubricants and slipping agents.

Also covered are the products made of the chemicals included by the definition, including biocides covered by the 2007 Plant Protection Products and Biocides Act. Only Articles 12-17 of Chapter 2 apply to the biocides.

The basis for the assessment of chemicals are the standards prepared within CEN context (EN 878-EN 15030), and implemented in any NEN-EN.. Depending on the product application, the conditions set forth in Annex D, paragraph 2.5, are applicable to the purity criteria or the maximum permissible concentrations in the leaching test. This means that contaminants in chemicals listed in the Drinking Water Decree may contribute for maximum 10 % of the threshold value set forth in the Drinking Water Decree to the concentration in the drinking water or warm tap water. In addition, exposure through drinking water or warm tap water to contaminations not listed in the Drinking Water Decree is not allowed to contribute for more than 10 % to the tolerable daily intake (TDI) of the relevant contaminant.

In special situations, the Committee may depart on a per-case-basis from any of the aforementioned starting points for the assessment.

For chemicals used in dissolved or gaseous form, the maximum dosage to which the set limit applies is indicated.

Chemicals are further classified into the following four sub-classes:
a. Chemicals used in solid form;
b. Chemicals used as solutions;
c. Gases; and
d. Chemicals used as biocides pursuant to the 2007 Plant Protection Products and Biocides Act.

As of now, the various chemicals are listed and described in the sub-classes under the general title of the objective of their use. Examples include: antiscalants, conditioning agents, corrosion inhibitors, filter materials, ion exchange resins and related polymeric adsorbents and flocculants (flocculating agents).

Chemicals used as a solution or in gaseous form are tested for authorisation and inspection purposes by complete digestion of the product. To be included in any test is at least a test of the presence of the contaminants listed below for the related products. The levels of the listed components in the product form described may not be higher than the values listed for the related components. The Committee may set further requirements.

Chemicals used in solid form must be tested in the leaching test described in NEN-EN 12902:2004 (EN). The levels in the extraction water may not be higher than the values listed for the related components. The Committee may set further requirements for these products as well.

3.2 Chemicals used in solid form

3.2.1 Bentonite

3.2.1.1 Description

Bentonite (named after Fort Benton in Wyoming, US, where it was discovered) is a type of raw clay found in many locations and consisting primarily of minerals of the montmorillonite group. The chemical formula is $Si_4Al_{2-x}M_x^{2+}M_x^{+}O_{10}(OH)_2.n\ H_2O$, with x ranging from 0 to 2.
Bentonite is obtained in opencast mining, is then pulverised in a factory process to the desired particle size (95 % of the product (m/m) must have a particle size of under 500 µm), and dried. By mixing with sodium carbonate during the pulverisation process, the bivalent metal (in general, Ca^{2+}) is partially replaced by Na^{+} thereby enhancing the swelling properties of bentonite. The product is then available as a powder (white to light brown or green) in many grades depending on the purity and the Na^{+} concentration.
The CAS number of bentonite is 1302-78-9.

3.2.2.2 Application

Bentonite in the drinking water or warm tap water supply has three types of uses:
- As a flocculant to treat contaminated water for human consumption, as described in NEN-EN 13754:2003 (EN);
- As sealant for a drill hole around the pipe of a well for water catchment to prevent contamination of ground water intended for the preparation of drinking water or warm tap water, in (drilling) tunnels, and to cover refuse dumps; and
- As cover for the basis, for example, in reservoirs.

3.2.2.3 Testing and assessing

Bentonite used in the drinking water or warm tap water supply, as far as its chemical and physical composition and properties are concerned, must comply with NEN-EN 13754:2003 (EN).

In the authorisation and inspection tests for bentonite, the release of the heavy metals listed in the table below must be measured in a leaching test in accordance with NEN-EN 12902:2004 (EN). The levels of each heavy metal may not be higher than the values (expressed in **µg** /L) listed for the related parameter.

In selected cases at the Committee's discretion, data of a purity study completed to apply for a different authorisation may be used in the assessment of bentonite. The heavy metal levels must meet the soil/sediment criteria for background concentrations expressed as mg/kg of dry substance set forth in the Soil Sanitation Target and Intervention Values Circular, which has been published in 2000 by the former Ministry of Housing, Spatial Planning and the Environment (Ministry of VROM), at present the Ministry of Infrastructure and the Environment, as listed in the table below.

Parameter	Soil/sediment background concentration in mg/kg of dry product	Maximum concentration in extraction water in µg/l
Antimony	3	0.5
Arsenic	29	1
Cadmium	0.8	0.5
Chromium	100	5
Lead	85	1
Mercury	0.3	0.1
Nickel	35	2
Selenium	0.7	1

3.2.2 Agents for drilling

Agents for drilling are used in making wells for ground water catchment to reinforce the borehole wall. When the well is drilled, the agents are added to the so-called working water (mixture of the available ground water and added water) in relatively low quantities. The working water with the agent for drilling is removed once the well is drilled. The well is then equipped for ground water catchment, pumped out, and is then operational.

In reality, traces of the agents for drilling may enter the drinking water or warm tap water, and must therefore be fully specified. Agents are permissible if, in accordance with the methods for assessment described in Annex D, it is not expected that they will adversely affect the health of consumers.

3.2.3 Filter materials

In this context, filter materials include silica sand, silica gravel, active carbon, anthracite, garnet sand, calcium carbonate and dolomite.
Of these products, only silica sand, silica gravel and anthracite may be used as a filtering material.
The use of granular and powdered activated carbon is a method of separation (adsorption) that is, in strict sense, not considered as filtration, but may be classified there for practical reasons. During the purification process, powdered activated carbon dosages are continuously added to the water to be treated. The powdered activated carbon is caught in a later phase through coagulation, sedimentation or filtration.
Calcium carbonate and dolomite are products able to remove particles, but used in practice as a conditioning agent whereby the water to be treated is guided over a bed with the conditioning agent.

3.2.3.1 Silica sand, silica gravel and anthracite

Silica sand and silica gravel are described in NEN-EN 12904:2005 (EN), anthracite is described in NEN-EN 12909:2005 (EN).

Silica sand, silica gravel and anthracite must be tested in the leaching test for granulates in accordance with NEN-EN 12902:2004 (EN). The concentrations in the extraction water for the parameters listed below may not be more than the value listed for the related parameter:

Parameter	Maximum concentration in extraction water in µg/l
Antimony	0.5
Arsenic	1
Cadmium	0.5
Chromium	5
Lead	1
Mercury	0.1
Nickel	2
Selenium	1

3.2.3.2 Granular activated carbon

Granualr activated carbon is described in NEN-EN 12915-1:2008 (EN)[12].

Granular active carbon must be tested in the leaching test for granulates in accordance with NEN-EN 12902:2004 (EN). The concentrations in the extraction water for the parameters listed below may not be more than the value listed for the related parameter:

[12] Granular re-activated carbon is described in Draft Standard NEN-EN 12915-2:2008 Draft (EN). As of today, quality certificates (ATAs) for re-activated active carbon have not been issued in the Netherlands.

Parameter	Maximum concentration in extraction water in µg/l
Aluminium	30
Antimony	0.5
Arsenic	1
Cadmium	0.5
Chromium	5
Lead	1
Mercury	0.1
Nickel	2
PAKs	0.1
Selenium	1

Note 1: PAKs need to be measured only if coal tar pitch is used as binder.

Note 2: PAKs to be measured in accordance with the Drinking Water Decree include: pyrene, benzo(a)pyreen, benz(a)anthracene, benzo(ghi)perylene, phenantrene, indeno(1,2,3-cd)pyrene, anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, chrysene and fluoranthene

3.2.3.3 Powdered activated carbon

Powdered activated carbon is described in NEN-EN 12903:2003 (EN).

Powdered activated carbon must be tested in a leaching test for powders in accordance with NEN-EN 12902:2004 (EN). The concentrations in the extraction water for the parameters listed below may not be more than the value listed for the related parameter:

Parameter	Maximum concentration in extraction water in µg/l
Aluminium	30
Antimony	0.5
Arsenic	1
Cadmium	0.5
Chromium	5
Cyanides	5
Lead	1
Mercury	0.1
Nickel	2
Selenium	1

3.2.3.4 Garnet sand

Garnet sand is described in NEN-EN 12910:2005 (EN).

Garnet sand must be tested in a leaching test for granulates in accordance with NEN-EN 12902:2004 (EN). The concentrations in the extraction water for the parameters listed below may not be more than the value listed for the related parameter:

Parameter	Maximum concentration in extraction water in µg/l
Antimony	0.5
Arsenic	1
Cadmium	0.5
Chromium	5
Lead	1
Mercury	0.1
Nickel	2
Selenium	1

3.2.3.5 Calcium carbonate

Calcium carbonate is described in NEN-EN 1018:2006 (EN).

The purity of calcium carbonate must be 98 % or higher.

For the chemical parameters, the following maximum levels in mg/kg of dry product apply:

Parameter	Maximum concentration in mg/kg of dry product
Antimony	3
Arsenic	3
Cadmium	2
Chromium	10
Lead	10
Mercury	0.5
Nickel	10
Selenium	5

Grinding agents may be used to process calcium carbonate. For such agents, the applicant for a quality certificate must submit all the required information about the formulation, ingredients and quantities used. An MTC will be set for the substances in the grinding agent's formulation, as described in Annex D of the Regulation. It is decided whether or not the concentrations of the related substances in the drinking water or warm tap water meet the MTC criteria by measuring values on the basis of a realistic worst-case scenario.

Calcium carbonate must not be tested for cyanides and PAKs.

3.2.3.6 Dolomite

Dolomite (semi-burnt, chemical formula: $CaCO_3.MgO$) is described in NEN-EN 1017:2008 (EN).

For the chemical parameters, the following maximum levels in mg/kg of dry product apply:

Parameter	Maximum concentration in mg/kg of dry product
Antimony	3
Arsenic	3
Cadmium	2
Chromium	10
Lead	10
Mercury	0.5
Nickel	10
Selenium	5

Grinding agents may be used to process dolomite. For such agents, the applicant for a quality certificate must submit all the required information about the formulation, ingredients and quantities used. An MTC will be set for the substances in the grinding agent's formulation, as described in Annex D of the Regulation. It is decided whether or not the concentrations of the related substances in the drinking water or warm tap water meet the MTC criteria by measuring values on the basis of a realistic *worst-case* scenario.

Dolomite must not be tested for cyanides and PAKs.

3.2.4 Ion exchangers and related polymeric adsorbents

Ion exchange resins (both anionic and cationic) are used to modify the composition of water, for example, for water softening purposes. The related polymeric adsorbents are used to remove unwanted substances from water.

Ion exchange resins and related polymeric adsorbents must be tested as set forth in NEN-EN 12873-3:2006 (EN) (see Annex C(1.4)) thereby observing the supplier's instructions for any pre-treatment processes.

3.3 Chemicals used as solutions

3.3.1 Antiscalants

Antiscalants or scale-inhibitors are used in systems to desalinate (brackish) water and seawater and make it into drinking water or warm tap water. Such systems are vaporisation plants (distilling) and membrane filtration systems. Antiscalants dosages are continuously added to the raw water to prevent or reduce the deposits of salts with poor solubility (scaling) or the formation of a bio-film (fouling).

In vaporisation plants, the antiscalant may enter the distillate that will be enhanced to become drinking water or warm tap water through carry-over. In normal conditions, the carry-over is approximately 0.4 %, and approximately 4 % in the worst-case scenario. In general, monitoring is based on the level of salt in the distillate thereby preventing the carry-over of the raw (salty) water and the antiscalant from becoming too significant.

The expected maximum concentrations in drinking water or warm tap water through carry-over are calculated on the basis of the following data:

- Concentrations of (raw) materials, including potential contaminations, in the product on the basis of the formulation, and, if applicable, residual levels of monomers;

- The maximum dosage; and
- The percentage of carry-over in the worst-case scenario.

Antiscalants in a membrane filtration process are used only in systems equipped with nanofilter (NF) or reversed osmosis membranes (RO). Depending on the type of membrane and the molecular size, at least 3 log units of the substance will be removed. However, small molecules will completely pass through the membranes and enter the product water. The threshold is 200 D for NF membranes and 50 D for RO membranes respectively.
The antiscalant will be able to enter the product water from which the drinking water is made through seepage and leakage. In normal conditions, maximum 0.1 % of the dosage of antiscalant will enter the drinking water. In general, the membranes are monitored for their integrity with fast alerts if the membrane is broken. This prevents insufficiently purified water and too much antiscalant from entering the product water.

The expected maximum concentrations in drinking water or warm tap water are calculated on the basis of the following data:
- Concentrations of (raw) materials, including potential contaminations, in the product on the basis of the formulation, and, if applicable, residual levels of monomers;
- Area of application:
- The maximum dosage;
- The molecular weights of the ingredients in the formulation, including contaminations, and, if applicable, residual levels of monomers;
- Type of membrane (either NF or RO); and
- The percentage of seepage/leakage.

3.3.2 Conditioning agents

Conditioning agents are used to prepare drinking water or warm tap water to obtain the best possible composition of the drinking water. One of the objectives for adding conditioning agents is to minimise corrosion and inconvenient deposits in the water distribution system, and to enhance the comfort of users by supplying “soft water.”

3.3.2.1 Calcium hydroxide ($Ca(OH)_2$) and calcium oxide (CaO)

The descriptions of calcium hydroxide and calcium oxide are included in NEN-EN 12518:2008 (EN).

Calcium hydroxide (slaked lime or hydrated lime) is used to soften hard water, typically by using pellet reactors. The substance is supplied in solid form or as a lime milk suspension.

Calcium oxide (lime or quicklime) is “burned” on site with water thereby creating a suspension of calcium hydroxide (milk of lime). In general, a filtration process catching the carry-over of lime particles follows the process of softening, and partially removing contaminations introduced with the calcium hydroxide.

Grinding agents may be used to manufacture calcium oxide. For such agents, the applicant for a quality certificate must submit all the required information about the formulation, ingredients and quantities used. An MTC will be set for the substances in the grinding agent’s formulation, as described in Annex D. It is decided whether or not the concentrations of the related substances in the drinking water or warm tap water meet the MTC criteria by measuring values on the basis of a realistic *worst-case* scenario.

The maximum dosage for both agents is 135 mg Ca per litre of water to be treated.

For the chemical parameters, the following maximum levels in mg/kg of dry product apply (not accounting for potential removal in a further purification step):

Parameter	Maximum concentration in mg/kg of dry product	
	$Ca(OH)_2$	CaO
Antimony	4	4
Arsenic	5	5
Cadmium	2	2
Chromium	20	20
Lead	20	20
Mercury	0.3	0.3
Nickel	20	20
Selenium	4	4

When using calcium hydroxide and calcium oxide, the concentration of aluminium in the water may increase. In accordance with the Drinking Water Decree, the regulating authority must be notified if the value for aluminium of 30 µg/L is exceeded (or if exceeding is imminent).

3.3.2.2 Sodium carbonate (Na_2CO_3)

Sodium carbonate used to treat water for human consumption is described in NEN-EN 897:2005 (EN). Sodium carbonate (soda ash, washing soda) is used to soften water and to correct the pH.
Sodium carbonate is obtained by saturating a sodium chloride solution with ammonia and carbonic acid forming and depositing sodium bicarbonate. Filtration and then heating form sodium carbonate, water vapour and carbonic acid. The latter two components escape, and the sodium carbonate is cooled and stored in silos.

The maximum dosage is 60 mg of Na_2CO_3 per litre of water to be treated.

For the chemical parameters, the following maximum levels in mg/kg of product apply (not accounting for potential removal in a further purification step):

Parameter	Maximum concentration in mg/kg
Arsenic	17
Cadmium	8.5
Chromium	85
Lead	17
Mercury	2
Nickel	34

3.3.2.3 Sodium hydroxide (NaOH)

Sodium hydroxide used to treat water for human consumption is described in NEN-EN 896:2004 Draft (EN).
Sodium hydroxide is used to soften water by using pellet reactors. In addition, it is used in much lower dosages at various steps of the manufacturing process for pH correction. In general, sodium hydroxide is supplied as a watery solution in a concentration ranging from 20 % to 50 %. It is obtained by electrolysis of sodium chloride by using various procedures, *i.e.* continuous processes with typically minor amounts of contaminations.

The maximum dosage is 130 mg of NaOH per litre of water to be treated.

For the chemical parameters, the following maximum levels in mg/kg of product (as a solution in water) apply (not accounting for potential removal in a further purification step):

Parameter	Maximum concentration in mg/kg		
	NaOH 50%	NaOH 33%	NaOH 20%
Arsenic	4	2,5	1.5
Cadmium	2	1,3	0.8
Chromium	20	13	8
Mercury	0.4	0,3	0.15
Lead	4	2,5	1.5
Nickel	8	5	3

3.3.2.4 Hydrochloric acid (HCl)

Hydrochloric acid to treat water for human consumption is described in NEN-EN 939:1999 (EN).
Hydrochloric acid is used for various purposes in the production of drinking water, such as decarbonisation of mixing water for slaked lime, and pH reduction of the effluent of pellet reactors and the supply water of membrane filtration systems. In general, it is supplied as a solution of 33 % to 36 % in water. It is produced through a reaction of chlorine gas with hydrogen where the hydrochloride gas is absorbed in demineralised water.

The maximum dosage is 100 mg of HCl per litre of water to be treated.

For the chemical parameters, the following maximum levels in mg/kg of product (as a solution in water) apply (not accounting for potential removal in a further purification step):

Parameter	Maximum concentration in mg/kg	
	HCl 33%	HCl 36%

Arsenic	3.4	3.7
Cadmium	1.7	1.9
Chromium	17	19
Lead	3.4	3.7
Mercury	0.4	0.4
Nickel	6.8	7.4

3.3.3 Corrosion inhibitors

Corrosion inhibitors are protective agents used only in drinking water or warm tap water systems or parts thereof, such as heating systems, central heating and combination boilers.

Agents are permissible if, in accordance with the methods for assessment described in Annex D, it is not expected that they will adversely affect the health of consumers.

3.3.4 Flocculants (flocculating agents)

Inorganic iron and aluminium salts are used as flocculants. In the preparation of drinking water, these substances are used in the coagulation/flocculation and sedimentation of surface water to facilitate and enhance the removal of floating particles in water. Ninety-eight per cent of the added flocculant is removed in the sedimentation step; the remainder is removed in the following quick filtration step.

In addition, flocculating agents are used to support the activity of flocculants. These products are based on starch or polyacrylamide, and are always used in combination with flocculants.

Flocculants may be made of waste products in the (chemical) industry with high iron or aluminium content. In general, the levels of heavy metals and cyanides in these products are toxicologically relevant.

3.3.4.1 Flocculants on the basis of aluminium

Aluminium chloride and aluminium hydrochloride are described in NEN-EN 881:2004 (EN), aluminium sulphate is described in NEN-EN 878:2004 (EN).

The chemical formula for the active ingredients is: $Al_2Cl_{(n)}(OH)_{(m)}(SO_4)_{(p)}\cdot(q)(H_2O)$.

Examples of selected applications include:

Formula	*CAS No*	*Molecular weight*
$Al_2Cl(OH)_5\cdot 2\text{-}3\ H_2O$	12042-91-0	210,5-228,5
$Al_2Cl_3(OH)_3$	12445-51-0	211,3
$Al_2Cl_3(OH)_{2,5}(SO_4)_{0,25}$	39290-78-3	226,9
$Al_2(SO_4)_3\cdot 14\ H_2O$	17927-65-0	594,3
$Al_2(SO_4)_{0,55}(OH)_3Cl_{1,6}$	214,5	

Flocculants on the basis of aluminium in solid form are white to light brown powders, or white to light brown nuts or chunks with a content of maximum 470 g/kg of aluminium oxide, corresponding to approximately 250 g/kg Al. In liquid form, they are clear to slightly cloudy, viscous, and colourless to light yellow. Their content of aluminium oxide is maximum 235 g/kg, corresponding with approximately 125 g/kg Al. The density at 20 °C ranges from 1,2 to 1,35 kg/dm^3.

There are two different procedures for preparation starting with aluminium (hydr)oxide being treated with either hydrochloric acid or sulphuric acid.
Products on the basis of polyaluminium chloride are obtained by treating aluminium oxide (sometimes in combination with aluminium sulphate) with hydrochloric acid.
Products on the basis of aluminium sulphate are obtained by treating aluminium hydroxide with sulphuric acid, which may be supplemented by a further reaction with hydrochloric acid in the presence of selected types of chalk.

The maximum dosage must be 15 mg of aluminium per litre of water to be treated.

The levels of the parameters listed below in the described product form may not be higher than the values listed for the related components:

	Concentration (in g/kg) of the active ingredients in the product						
as Al_2O_3	83	100	150	170	180	235	470
as Al	44	54	79	90	95	124	248

Parameter	mg/kg of aluminium based flocculant						
Antimony	1,5	1,8	2,5	3	3,2	4,1	8,3
Arsenic	2,9	3,6	5	6	6,4	8,3	16,5
Cadmium	1,5	1,8	2,5	3	3,2	4,1	8,3
Chromium	15	18	25	30	32	41	83
Cyanides	15	18	25	39	32	41	83
Lead	2,9	3,6	5	6	6,4	8,3	16,5
Mercury	0,3	0,4	0,5	0,6	0,6	0,8	1,7
Nickel	6	7,2	10	12	12,8	16,4	33,2
Selenium	2,9	3,6	5	6	6,4	8,3	16,5

The regulating authority must be notified if the concentration of aluminium in the supplied drinking water or warm tap water exceeds 30 µg/L, because of the potential use of the drinking water or warm tap water for dialysis purposes, as set forth in the Water Supply Decree.

3.3.4.2 Ferric aluminium sulphate

The chemical formula for the active ingredients is:

$Al_2(SO_4)_3 \cdot 14\text{-}16\ H_2O$
$Fe_2(SO_4)_3 \cdot 9\ H_2O$

The relevant CAS numbers are:

61114-26-9
10043-01-3 ($Al_2(SO_4)_3$)
10028-22-5 ($Fe_2(SO_4)_3$)

The molecular weight ranges from 617 to 621.

The granulates are composed as follows:

Aluminium (Al^{3+})	7.2 – 8.4 % (13.7 – 15.9 % Al_2O_3)
Aluminium as	$Al_2(SO_4)_3.4\text{-}16\ H_2O$
Iron (Fe^{3+})	0.7 – 3.0 % (1.0 – 4.3 % Fe_2O_3)
Iron as	$Fe_2(SO_4)_3.\ H_2O$
Active ingredient (Me^{3+})	3,2 mol/kg
In water insoluble ingredients	3 %

The maximum dosage is 100 mg of ferric aluminium sulphate per litre of water to be treated.

The levels of the parameters listed below in the described product form may not be higher than the values listed for the related parameters (in mg/kg ferric aluminium sulphate):

Parameter	Maximum concentration in mg/kg
Antimony	5
Arsenic	10
Cadmium	5
Chromium	50
Lead	10
Mercury	1
Nickel	20
Selenium	10

The regulating authority must be notified if the concentration of aluminium in the supplied drinking water exceeds 30 µg/L, because of the potential use of the drinking water or warm tap water for dialysis purposes, as set forth in the Water Supply Decree.

3.3.4.3 Iron(III) chloride

Iron(III) chloride ($FeCl_3$) is described in NEN-EN 888:2004(EN).

The product is obtained by means of a reaction of iron or iron(III) oxide with chlorine, or a reaction of iron(III) oxide with hydrochloric acid. It may also be produced by treating iron (scrap) with hydrochloric acid whereby iron(II) chloride is created, which oxidises with chlorine to become iron(III) chloride. In general, iron(III) chloride is supplied as a solution of 40 % in water.

When the product is produced from scrap iron, the scrap is typically pre-treated with agents containing organic amines. For such agents, the applicant for a quality certificate must submit all the required information about the formulation, ingredients and quantities used. An MTC will be set for the substances in the related agent's formulation, as described in Annex D. A risk analysis on the basis of a realistic *worst-case* scenario will identify whether or not the related substances' concentrations in drinking water or warm tap water exceed the MTCs.
In addition, when made from scrap iron, the levels of cyanides are toxicologically relevant.

The maximum dosage of ferric chloride is 50 mg of Fe per litre of water to be treated.

For the chemical parameters, the following maximum levels in mg/kg of iron(III) chloride solution (40 %) apply:

Parameter	Maximum concentration in mg/kg
Antimony	1.5
Arsenic	2.6
Cadmium	1.5
Chromium	70
Cyanides	13
Lead	2.6
Mercury	0.3
Nickel	70
Selenium	3

3.3.4.4 Iron(III) chloride sulphate

Iron(III) chloride sulphate ($FeClSO_4$) is described in NEN-EN 891:2004 (EN).

The product is obtained after a reaction of iron(II) sulphate with chlorine gas. In general, it is supplied as a solution of 40 % in water.

The maximum dosage of ferric chloride sulphate is 50 mg of Fe per litre of water to be treated.

For the chemical parameters, the following maximum levels in mg/kg of iron(III) chloride sulphate solution (40 %) apply:

Parameter	Maximum concentration in mg/kg
Antimony	1.5
Arsenic	2.6
Cadmium	1.5
Chromium	70
Mercury	0.3
Nickel	70
Selenium	3

3.3.4.5 Iron(II) sulphate

Iron(II) sulphate is described in NEN-EN 889:2004(EN).

The product is the iron(II) sulphate heptahydrate ($FeSO_4.7H_2O$) supplied in crystals. It is made by staining steel with sulphuric acid, or through a reaction of a ferric titanium ore/iron mixture with sulphuric acid and water.

The maximum dosage of iron(II) sulphate is 50 mg of Fe per litre of water to be treated.

For the chemical parameters, the following maximum levels in mg/kg of iron(III) sulphate crystals (40 %) apply:

Parameter	Maximum concentration in mg/kg
Antimony	2
Arsenic	4
Cadmium	2
Chromium	70
Lead	4
Mercury	0.4
Nickel	70
Selenium	4

3.4 Gases

To prepare drinking water in the Netherlands, carbon dioxide (CO_2) and oxygen (O_2) are used. Carbon dioxide is used to change the pH or to reduce over-saturation of water after it is softened, for example following a membrane filtration application. Oxygen is used to a limited extent to increase the oxygen level, or as a process gas to ozonise drinking water. Dosages of both gases are continuously added to the water.

3.4.1 Carbon dioxide

The product must meet the purity criterion (in % v/v) listed in NEN-EN 936:2006 (EN). This is related to impurities listed in the EIGA (*European Industrial Gases Association*) document IGC DOC 70/99E, *Carbon dioxide source certification; quality standards and verification.* Depending on the manufacturing method used, additional information must be submitted.

3.4.2 Oxygen

The product must meet the purity criterion for “Grade A” listed in NEN-EN 12876:2001 (EN).

3.4.3 Assessment

On the basis of the submitted information about the impurity and the maximum dosage of the product, the expected (maximum) concentrations of the related substances in drinking water or warm tap water should be calculated. Impurity are in many cases measured as vpm (volume parts per million). On the basis of the ideal gas law and the maximum dosage, the levels of the related substances in the gas are converted into the expected (maximum) concentrations in drinking water or warm tap water.

3.5 Cleaning agents

Cleaning agents other than biocides covered by the Plant Protection Products and Biocides Act must be tested and assessed as set forth in Articles 6-9, before a recognised quality certificate may be issued in accordance with Articles 13 and 14.

For the assessment, the expected maximum concentrations in drinking water or warm tap water are calculated on the basis of the following data:

- The concentration of substances, including contaminants, in the product on the basis of the formulation;
- The maximum dosage;
- The expected remaining content in drinking water after the rinsing process.

3.6 Disinfectants and disinfecting cleaning agents

Disinfectants and disinfecting cleaning agents are used to clean and disinfect parts of the drinking water or warm tap water supply, such as water storage and distribution systems and parts thereof. They are also used to regenerate drinking water or warm tap water sources.
When used in water storage and distribution systems and in drinking water or warm tap water systems, the related parts should be disconnected from the drinking water or warm tap water supply. After use, the surfaces treated must be rinsed with drinking water or warm tap water.

For disinfectants and disinfecting cleaning agents for specific use in drinking water or warm tap water applications, an authorisation issued by the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) is required pursuant to the 2007 Plant Protection Products and Biocides Act (see Article 1). In cases of doubt with regard to the disinfecting action of a cleaning agent, the applicant for a quality certificate must obtain clarification from the Ctgb.

Agents assessed and authorised by the Ctgb must then be issued a recognised quality certificate in accordance with Article 18.

ANNEX B - POSITIVE LISTS

Note: Within the 4MS Common Approach referred to in the Explanatory Memorandum,[13] joint positive lists are being prepared on the basis of the EFSA guidelines, the *EU Substances* document and the national positive lists. Annex B will be updated as soon as the list is complete (expected for 2011). Please also refer to paragraphs 2.3 and 3.3 of the Explanatory Memorandum to the present Regulation.

1 Plastics, elastomers and rubber products

1.1 Introduction

1.1.1 For the manufacture and processing of plastics, elastomers, and natural and synthetic rubber products that (may) contact drinking water or warm tap water, this Annex contains a list of authorised monomers and other starting substances, polymer production aids and additives, *i.e.* the so-called positive list.

1.1.2 The list is not an exhaustive list and does not exclude the use of other substances. Substances not included in the list may be used if they have been assessed and are authorised in accordance with Chapter 3 of the Regulation.

1.1.3 See Annex A for descriptions of plastics, elastomers and natural and synthetic rubber products.

1.1.4 Included in the list are:

- Monomers and other starting substances, polymer production aids and additives defined above;
- Natural and synthetic macromolecular compounds used as monomers and other starting substances not included in the list, but required for the synthesis of these compounds;
- Substances used to modify natural and synthetic macromolecular compounds;

1.1.5 The list does not include salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium,and zinc of the authorised acids, phenols or alcohols which are also authorised. However, names containing '…acid(s), slats' appear in the list if the correspondending free acid(s) is (are) not mentioned. In each case the meaning of the term 'salts' is ''salts of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc'..

1.1.6 The following are deemed to be the equivalent of substances included in the list, and must be assessed accordingly The list does not include the following substances although they may be present:

- Mixtures of the authorised substances;
- Oligomers and natural and synthetic macromolecular substances as well as their mixtures, if the monomers or other starting substances required for the synthesis of these substances are included in the list;
- Substances which could be present in the end product as:
    a. impurity in the substance used,
    b. reaction intermediates,
    c. decomposition products.

1.1.7 Substances shall be of good technical quality, and should not be used in larger quantities than strictly necessary for manufacturing the end product.

1.1.8 The specifications for carbon black, paraffin oil (white mineral oil) and waxes (obtained from fractions of petroleum or synthetic hydrocarbon mixtures, refined) must meet the following

requirements. In selected cases, the Committee will decide whether or not the analysis method(s) used is (are) allowed.

Carbon black:

- Substances extracted with toluene: maximum 0.1 %, identified in accordance with the ISO 6 209 method;
- UV absorption of a cyclohexane extract at 386 nm: Extinction < 0.02 for a 1 cm cuvette or < 0.1 for a 5 cm cuvette identified on the basis of a generally recognised method for analysis;
- Benzo[a]pyrene content: Maximum 0.25 mg/kg carbon black;
- Maximum concentration for use of carbon black in the polymer:[14] 2.5 % (m/m).

Paraffin oil:

- Content of mineral hydrocarbons with carbon chain under 25: Maximum 5 % (m/m);
- Viscosity at 100 °C not less than 8.5 cSt (8.5 $x10^{-6}$ m^2/s);
- Average molecular weight not less than 480 Da.

Waxes

- Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w);
- Viscosity at 100 °C not less than 11 cSt (11 $x10^{-6}$ m^2/s);
- Average molecular weight not less than 500 Da.

1.1.9 The list contains the following data:

- Column 1 (CAS No): Chemical Abstracts Service (CAS) registration number;
- Column 2 (Name): The chemical name of the substance or substance group;
- Column 3 (Restrictions): These may include:
  a. the Maximum Tolerable Concentration (MTC) in drinking water or warm tap water;
  b. the maximum permitted quantity of the substance in the end product (QM);
  c. other specifically indicated restrictions or references.

1.1.10 If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.

1.1.11 If the CAS number is inconsistent with the substance's chemical name, the chemical name shall prevail. If the CAS number in the Einecs is inconsistent with the number in the CAS registration system, the CAS number in the CAS registration system shall prevail.

1.1.12 "Not detectable" when used in the Regulation shall mean that the specific migration of a substance must be less than 0.1 μg/L. If an adequate, validated method for analysis is unavailable for this purpose, a method with suitable identification characteristics for the indicated limit of detection may be used in anticipation of the development of a validated method.

[14] The 2.5 % (m/m) value is not applicable to rubber products.

1.1.13 Abbreviations or expressions used in the list shall mean the following:

EP = end product
QM = maximum permitted quantity of the 'residual' substance in the end product

QM in the context of the Regulation also means that the remaining content of the substance in the end product must be measured with a validated method for analysis for the indicated threshold value. If such a method is not available yet, a method with suitable identification characteristics for the indicated threshold value may be used in anticipation of the development of a validated method.

MTC = Maximum Tolerable Concentration in drinking water or warm tap water

In reasonable conditions of use, the specific migration, if multiplied by the applicable conversion factor listed in the present Regulation's Annex D, shall not be higher than the value indicated for the related substance.
MTC in the context of the Regulation also means that the specific migration of the substance must be measured with a validated method for analysis for the indicated threshold value. If such a method is not available yet, a method with suitable identification characteristics for the indicated threshold value may be used in anticipation of the development of a validated method.

MTC(T)= Maximum Tolerable Concentration in drinking water or warm tap water expressed as total of moiety or substance(s) indicated.

MTC(T) in the context of the Regulation also means that the specific migration of the substance must be measured with a validated method for analysis for the indicated threshold value. If such a method is not available yet, a method with suitable identification characteristics for the indicated threshold value may be used in anticipation of the development of a validated method.

1.1.14 For the following groups of compounds, with the exception of substances included individually in the list, MTC(T) = 0.1 µg/L applies:

Secondary and *tertiary* aliphatic amines
Aromatic amines
Phenolic compounds (as phenol)
Nitrosamines
Peroxides
Polycyclic aromatic hydrocarbons

1.1.15 The expected aluminium concentration in drinking water or warm tap water derived from the measured migration and the applicable conversion factor described in the present Regulation's Annex D, or obtained with a theoretical calculation may not be higher than 30 µg/L for aluminium compounds.

1.1.16 In reasonable conditions for use, the TOC (*Total Organic Carbon*) emission of products that may contact drinking water or warm tap water, if multiplied by the applicable conversion factor described in the Regulation's Annex D, must not be higher than 2 mg/L of drinking water or warm tap water.

1.1.17 An MTC will not be listed for a substance if:
1. The MTC is higher than 3 mg/L. This limit is based on the assumption that measuring the specific migration of substances with a *Tolerable Daily Intake* (TDI) over 1 mg/kg of body weight (60 mg/person) is not necessary (see Annex D); or
2. The substance is an organic compound and the MTC is higher than 2 mg/L, *i.e.* the threshold value for the TOC parameter (see 1.1.16).

1.1.18 The lead compounds listed in the positive list may no longer be used from 1 January 2015. Pursuant to Article 20(2) these compounds will be removed from the positive list from 1 January 2013.

Substances allowed for use in the manufacture of plastics, elastomers and rubber products

CAS No	Name	MTC and/or specifications
000075-07-0	acetaldehyde	0,3 mg/L
000064-19-7	acetic acid	-
000108-24-7	acetic acid hydride	-
000067-64-1	acetone	-
003179-56-4	acetyl cyclohexane sulphonyl peroxide	0,1 µg/L
000079-06-1	acrylamide	0,1 µg/L
015214-89-8	2-acrylamido-2-methylpropane sulphonic acid	2,5 µg/L
000079-10-7	acrylic acid	0,3 mg/L
-	acrylic acid, esters with alcohols, monohydric, aliphatic, saturated, C1-C18	0,3 mg/L
000107-13-1	acrylonitrile	0,1 µg/L
000103-23-1	adipic acid, bis(2-ethylhexyl) ester	0,9 mg/L
-	adipic acid, esters with alcohols, monohydric, aliphatic, primary, saturated, C6-C12	-
-	alcohols, monohydric, primary, unbranched, saturated, C4-C22	-
-	alkadiene C3-C8	-
-	1-alkene C2-C8	-
-	alkyl (C8-C18) benzene sulphonates, sodium salts	MTC(T) 1.5 mg/L[(1)]
-	alkyl (C8-C18) naphthalene sulphonates, sosium salts	MTC(T) 1.5 mg/L[(1)]
-	alkyl (C*-C18) sulphates, sodium salts	MTC(T) 1.5 mg/L[(1)]
-	alkyl (C8-C18) sulphonates, sodium salts	MTC(T) 1.5 mg/L[(1)]
068037-49-0	alkyl (C8-C22) sulphonic acid	0,3 mg/L
-	N-alkyl (C14-C18)-N,N',N'-triacetoyl-1,3-diaminopropane	0,1 µg/L
-	alkyl (C8-C22) sulphonic acids, unbranched, primary, with an even number of carbon atoms	-
000096-05-9	allyl methacrylate	2,5 µg/L
021645-51-2	aluminium hydroxide	-
011097-59-9	aluminium magnesium hydroxide carbonate	-
001344-28-1	aluminium oxide	-
001335-30-4	aluminium silicate	-
007446-70-0	aluminium trichloride	-
002855-13-2	1-amino-3-aminomethyl-3,5,5-trimethylcyclohexane	0,3 mg/L
013560-49-1	3-aminocrotonic acid, diester with thio-bis(2-hydroxyethyl) ether	-
006642-31-5	6-amino-1,3-dimethyluracil	0,25 mg/L
001760-24-3	[3-(2-aminoethyl) aminopropyl] trimethoxysilane	0,1 µg/L
-	2-aminoethyl carbaminic acid	0,1 µg/L
-	6-aminohexyl carbaminic acid	0,1 µg/L
002432-99-7	11-aminoundecanoic acid	0,25 mg/L
007664-41-7	ammonia	-
001066-33-7	ammonium carbonate	-
001309-64-4	antimony trioxide	0,5 µg/L(as antimony)
025551-14-8	azobis(cyclohexanecarbonitrile)	-
000078-67-1	2,2'-azobis(isobutyronitrile)	-
007727-43-7	barium sulphate	50 µg/L (as barium)
001477-55-0	1,3-benzenedimethaneamine	2,5 µg/L
004422-95-1	1,3,5-benzenetricarboxylic acid trichloride	2,5 µg/L
000065-85-0	benzoic acid	-
000100-51-6	benzyl alcohol	-
001761-71-3	bis(aminocyclohexyl)methane	2,5 µg/L
015484-34-1	4,4'-bis(aminocyclohexyl)methane carbamate	0,1 µg/L
007128-64-5	2,5-bis(5-tert-butylbenzoxazol-2-yl) thiophene	30 µg/L
015520-11-3	bis(4-tert-butylcyclohexyl) peroxydicarbonate	0,1 µg/L
-	2,2-bis(3-tert-butyl-4-hydroxyphenyl)propane esterified with p-nonylphenylphosphite	0,1 µg/L
026511-61-5	3,3-bis(tert-butylperoxy)butanecarboxylic acid, n-butyl ester	0,1 µg/L
002212-81-9	1,3-bis(tert-butyl peroxyisopropyl)benzene	0,1 µg/L
002781-00-2	1,4-bis(tert-butyl peroxyisopropyl)benzene	0,1 µg/L
063397-60-4	bis(2-carbobutoxyethyl)tin-bis(isooctyl mercaptoacetate)	0,9 mg/L
023128-74-7	N,N'-bis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl]-1,6-diaminohexane	-
032687-78-8	N,N'-bis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl]hydrazide	0,75 mg/L
026741-53-7	bis(2,4-di-tert-butylphenyl)pentaerytritol diphosphite	30 µg/L
135861-56-2	bis(3,4-dimethylbenzylidene)sorbitol	-
171090-93-0	3,5-bis(1,1-dimethylethyl)-4-hydroxybenzene propane acid, ester with C13-C15 branched and linear alcohols	-
016111-62-9	bis(2-ethylhexyl)peroxy dicarbonate	0,1 µg/L

004066-02-8	bis(2-hydroxy-3-cyclohexyl-5-methylphenyl)methane	2,5 µg/L
-	N,N'-bis(2-hydroxyethyl)alkyl(C8-C18)amine	60 µg/L
006200-40-4	bis(2-hydroxyethyl)-2-hydroxy-3-dodecoxypropylmethyl ammonium chloride	90 µg/L
-	bis(2-hydroxy-3-nonyl-5-methylphenyl)methane	0,1 µg/L
-	bis(2-hydroxy-3-tert-octyl-5-methylphenyl)methane	0,1 µg/L
054208-63-8	2,2-bis(2-hydroxyphenyl)methane bis(2,3-epoxypropyl) ether	2,5 µg/L
000080-05-7	2,2-bis(4-hydroxyphenyl)propane (bisphenol A)	30 µg/L
001675-54-3	2,2-bis(4-hydroxyphenyl)propane, bis(2,3-epoxypropyl) ether	0,45 mg/L
-	bis(4-methoxyphenyl) amine	0,1 µg/L
000085-60-9	bis(2-methyl-4-hydroxy-5-tert-butylphenyl) butane	15 µg/L
000096-69-5	bis(2-methyl-4-hydroxy-5-tert-butylphenyl) sulphide	24 µg/L
000991-84-4	2,4-bis(octylthio)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	1,5 mg/L
110553-27-0	2,4-bis(octylthiomethyl)-6-methylphenol	0,25 mg/L
052829-07-9	bis(2,2,6,6-tetramethyl-4-piperidyl) sebacate	0,3 mg/L
010043-35-3	boric acid	50 µg/L (as boron)
007637-07-2	boron trifluoride	50 µg/L (as boron)
000109-63-7	boron trifluoride etherate	50 µg/L (as boron)
000106-99-0	butadiene	0,1 µg/L
000106-97-8	butane	-
002425-79-8	1,4-butanediol-bis(2,3-epoxypropyl) ether	QM = 1 mg/kg
000505-65-7	1,4-butanediol formal	0,1 µg/L
000106-98-9	1-butene	-
000141-32-2	n-butyl acrylate	-
000095-31-8	N-tert-butyl-2-benzothiazolyl sulpheneamide	0,1 µg/L
181314-48-7	5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-3H-benzofuran-2-one	0,25 mg/L
025013-16-5	tert-butyl-4-hydroxyanisol (BHA)	1,5 µg/L
000142-77-8	butyl oleate	-
000107-71-1	tert-butylperoxyacetate	0,1 µg/L
000614-45-9	tert-butylperoxybenzoate	0,1 µg/L
026748-41-4	tert-butylperoxy-2,2-dimethyloctanoate	0,1 µg /L
003006-82-4	tert-butylperoxy-2-ethylhexanoate	0,1 µg/L
000927-07-1	tert-butylperoxypivalate	0,1 µg/L
013122-18-4	tert-butylperoxy-3,5,5-trimethylhexanoate	0,1 µg/L
000088-18-6	2-tert-butyl phenol	0,1 µg/L
000098-54-4	4-tert-butyl phenol	2,5 µg/L
000471-34-1	calcium carbonate	-
010043-52-4	calcium chloride	-
007789-75-5	calcium fluoride	-
001305-62-0	calcium hydroxide	-
006107-56-8	calcium octanoate	-
001305-78-8	calcium oxide	-
001344-95-2	calcium silicate	-
001592-23-0	calcium stearate	-
000105-60-2	caprolactam	0,75 mg/L
000502-44-3	caprolactone	MTC(T) 2,5 µg/L[(2)]
063438-80-2	(2-carbobutoxyethyl)tin-tris (isooctyl mercaptoacetate)	1,5 mg/L
001333-86-4	carbon black	-
009000-11-7	carboxymethyl cellulose	-
000079-38-9	chloortrifluorethylene	0,1 µg/L
007782-50-5	chlorine	-
000126-99-8	2-chloro-1,3-butadiene	2,5 µg/L
010025-73-7	chromium (III) chloride	5 µg/L (as chromium)
011118-57-3	chromium oxide	5 µg/L (as chromium)
000077-92-9	citric acid	-
006147-53-1	cobalt acetate tetrahydrate	5 µg/L (as cobalt)
-	condensation products of ethylene oxide and/or propylene oxide with ethylenediamine, molecular weight > 12 000	-
-	copolymers of maleic acid anhydride and vinyl methyl ether	-
004180-12-5	copper (II) acetate	0,2 mg/lll (as copper)
007787-70-4	copper (I) bromide	0,2 mg/lll (as copper)
001184-64-1	copper (II) carbonate	0,2 mg/lll (as copper)
007681-65-4	copper (I) iodide	0,2 mg/lll (as copper)
003724-65-0	crotonic acid	-
-	cumarone indene resins	0,1 µg/L
000095-33-0	N-cyclohexyl-2-benzothiazolylsulphenamide	0,1 µg/L
001631-25-0	N-cyclohexylmaleic acid imide	0,1 µg/L
000110-29-2	n-decyl-n-octyladipate	0,1 µg/L
-	diacyl(C8-C14) peroxides	0,1 µg/L

-	dialkyl (C4-C16) sulphosuccinates, sodium salts	-
000101-77-9	4,4'-diaminodiphenyl methane (DDM; MDA)	0,1 µg/L
009046-10-0	diaminopolypropylene glycol	2,5 µg/L
068953-84-4	N,N'-diaryl-p-phenylenediamine	0,1 µg/L
-	1,3: 2,4-dibenzaldehyde sorbitol	-
061790-53-2	diatomaceous earth	-
000120-78-5	2,2'-dibenzothiazyl disulphide	MTC(T) 0,15 mg/L [8]
000094-36-0	dibenzoyl peroxide	0,1 µg/L
002568-90-3	dibutoxymethane (butylal)	-
002668-47-5	2,6-di-tert-butyl-p-phenyl phenol	0,1 µg/L
004221-80-1	3,5-di-tert-butyl-4-hydroxybenzoic acid, 2,4-di-tert-butylphenyl ester	-
065140-91-2	3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	0,3 mg/L
000087-97-8	2,6-di-tert-butyl-4-methoxymethylphenol	0,1 µg/L
000128-37-0	2,6-di-tert-butyl-4-methylphenol (BHT)	0,15 mg/L
000110-05-4	di-tert-butyl peroxide	0,1 µg/L
-	1,1-di-tert-butylperoxy-3,3,5-trimethylcyclohexane	0,1 µg/L
000084-74-2	dibutyl phtalate	3 µg/L
000109-43-3	dibutyl sebacate	-
004253-22-9	dibutyltin sulphide	2 µg/L (as tin)
-	α,ω-dicarboxylic acids (C6-C12), aliphatic, unbranched	-
026322-14-5	dicetylperoxydicarbonate	0,1 µg/L
000133-14-2	2,4-dichlorodibenzoylperoxide	0,1 µg/L
000080-07-9	4,4-dichlorodiphenylsulphone	2,5 µg/L
000080-43-3	dicumyl peroxide	0,1 µg/L
000461-58-5	dicyanodiamide	-
001561-49-5	dicyclohexyl peroxydicarbonate	0,1 µg/L
000077-73-6	dicyclopentadiene	2,5 µg/L
000105-97-5	di-n-decyl adipate	0,1 µg/L
000123-28-4	didodecylthiodipropionate	MTC(T) 0,25 mg/L [3]
000111-46-6	diethylene glycol	MTC(T) 1,5 mg/L [4]
000111-40-0	diethylene triamine	0,25 mg/L
000140-01-2	diethylenetriamine pentaacetate, pentasodium salt	-
000117-81-7	di(2-ethylhexyl) phtalate	15 µg/L
003710-84-7	diethyl hydroxylamine	2,5 µg/L
000105-55-5	N,N'-diethyl thiourea	0,1 µg/L
001047-16-1	5,12-dihydroquino(2,3-b)acridine-7,14-dione	-
000123-31-9	1,4-dihydroxybenzene	30 µg/L
000131-56-6	2,4-dihydroxybenzophenone	MTC(T) 0,3 mg/L [5]
000092-88-6	4,4'-dihydroxybiphenyl	0,3 mg/L
000080-09-1	4,4-dihydroxydiphenylsulphone	2,5 µg/L
026761-40-0	di-isodecylphtalate	See phtalic acid diesters with primary, saturated, branched C9-C11C11C11 alcohols
028553-12-0	di-isononylphtalate	See phtalic acid diesters with primary, saturated, branched C8-C10 alcohols
-	di-isooctylphtalate	-
-	di-isooctyl sebacate	0,1 µg/L
000105-64-6	di-isopropylperoxydicarbonate	0,1 µg/L
000109-87-5	dimethoxymethane	-
003271-22-5	2,4-dimethoxy-6-(1-pyrenyl)-1,3,5-triazine	-
000108-01-0	dimethylaminoethanol	0,9 mg/L
002867-47-2	2-(dimethylamino)ethylmethacrylate	0,1 µg/L
000793-24-8	N-1,3-dimethylbutyl-N'-phenyl-p-phenylenediamine	2,5 µg/L
-	dimethyl dialkyl (C16 and/or C18) ammonium acetate	-
000078-63-7	2,5-dimethyl-2,5-di(tert-butylperoxy)hexane	0,1 µg/L
001068-27-5	2,5-dimethyl-2,5-di-(tert-butylperoxy)-3-hexyne	0,1 µg/L
000068-12-2	N,N-dimethylformamide	0,25 mg/L
001459-93-4	dimethylisophtalate	2,5 µg/L
134701-20-5	2,4-dimethyl-6-(1-methylpentadecyl)phenol	0,25 mg/L
000102-78-3	2,6-dimethylmorpholine-2-thiobenzothiazol	0,1 µg/L
000576-26-1	2,6-dimethylphenol	2,5 µg/L
053880-86-7	dimethyldiphenylthiuram disulphide	50 µg/L
000126-30-7	2,2-dimethyl-1,3-propanediol	2,5 µg/L
000067-68-5	dimethyl sulfoxide	-

000120-61-6	dimethylterephtalate	-
026636-01-1	dimethyltin bis(isooctylmercaptoacetate)	90 µg/L (as tin)
053220-22-7	dimyristyl peroxydicarbonate	0,1 µg/L
003135-18-0	di-n-octadecyl-3,5-di-tert-butyl-4-hydroxybenzylphosphonate	-
002500-88-1	dioctadecyl disulphide	0,15 mg/L
003806-34-6	dioctadecyl pentaerytritol diphosphite	-
000693-36-7	dioctadecyl thiodipropionate	MTC(T) 0,25 mg/L [3]
000117-84-0	di-n-octyl phtalate	0,11 mg/L
000122-62-3	di-n-octyl sebacate	0,1 µg/L
015571-58-1	di-n-octyltin-S,S'-bis(2-ethylhexylmercaptoacetate	MTC(T) 2 µg/L [6]
026401-97-8	di-n-octyltin-S,S'-bis(isooctylmercaptoacetate)	MTC(T) 2 µg/L [6]
-	di-n-octyltin bis(maleic acid monoester with primary, unbranched, saturated C1-C18 alcohols)	MTC(T) 2 µg/L [6]
003648-18-8	di-n-octyltin dilaurate	MTC(T) 2 µg/L [6]
-	di-n-octyltin maleate polymer (the polymer must fit the formula [(C8H17)2SnC4H2O4]n, where n = 2-4)	MTC(T) 2 µg/L [6]
000646-06-0	1,3-dioxolane	2,5 µg/L
005518-18-3	N,N'-dipalmitoyl diaminoethane	-
000126-58-9	di-pentaerythritol	-
000971-15-3	di-N-pentamethylenethiuram hexasulphide	MTC(T) 50 µg/L [7]
000120-54-7	di-N-pentamethylenethiuram tetrasulphide	MTC(T) 50 µg/L [7]
000122-39-4	diphenyl amine	-
000102-06-7	1,3-diphenylguanidine	2,5 µg/L
000101-68-8	diphenylmethane-4,4'-diisocyanate	0,1 µg/L or QM = 1 mg/kg
000074-31-7	diphenyl-p-phenylenediamine	0,1 µg/L
000127-63-9	diphenyl sulphone	0,15 mg/L
000110-98-5	dipropyleneglycol	-
013573-18-7	disodiumtriphosphate	-
016545-54-3	ditetradecyl-3,3'-thiodipropionate	2,5 µg/L
015017-02-4	N,N'-di-o-tolyl-phenylenediamine	0,1 µg/L
001321-74-0	divinylbenzene (containing no more than 45% (w/w) ethylvinylbenzene)	MTC(T) 0,1 µg/l [9]
000693-23-2	dodecane diacid	-
027176-87-0	dodecylbenzenesulphonic acid	1,5 mg/L
052047-59-3	2-(p-dodecylphenyl) indole	3 µg/L
028519-02-0	dodecyl(sulphophenoxy)benzenesulphonic acid, sodium disalt	0,45 mg/L
000106-89-8	epichlorohydrin	0,1 µg/L
000112-84-5	erucamide	-
000074-85-1	ethene	-
023676-09-7	p-ethoxyethylbenzoate	0,175 mg/L
000140-88-5	ethyl acrylate	0,3 mg/L
000075-04-7	ethylamine	-
000110-31-6	N,N'-ethylene-bis(oleamide)	-
005518-18-3	N,N'-ethylene-bis(palmitamide)	-
000110-30-5	N,N'-ethylene bis(stearamide)	-
000107-15-3	ethylenediamine	0,6 mg/L
000060-00-4	ethylenediaminetetraacetic acid	-
000107-21-1	ethyleneglycol	MTC(T) 1,5 mg/L [4]
032509-66-3	ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]	0,5 µg/L
000097-90-5	ethylene glycol dimethacrylate	0,1 µg/L
000151-56-4	ethyleneimine	0,1 µg/L
000075-21-8	ethylene oxide	0,1 µg/L
026221-27-2	ethylene vinylalcohol copolymer (EVOH)	-
000149-57-5	2-ethylhexanoic acid	2,5 µg/L
016219-75-3	5-ethylidene-bicyclo[2,2,1]-hept-2-ene	-
028106-30-1	ethylvinylbenzene	MTC(T) 0,1 µg/L [9]
-	fats and oils, from animal or vegetable food sources	-
-	fats and oils, hydrogenated, from animal or vegetable food sources	-
-	fatty acids, unbranched, saturated and unsaturated, with an even number of carbon atoms, C8-C22, with a maximum content of 2% unsaponifiable matter	-
-	fatty acids as described above, as compounds with bis(2-hydroxyethyl)amine	1,5 mg/L
-	fatty acids as described above, as salts with aluminium, ammonium, calcium, potassium, lithium, magnesium, manganese, sodium and zinc	30 µg/L (as lithium)
-	fatty acids as described above, amides of	-
-	fatty acids as described above, esterified with alcohols, monohydric, primary, unbranched, saturated, C4-C18, as well as oleyl alcohol	-

-	fatty acids as described above, esterified with glycerol to produce mono-, di- and triglycerides	-
085116-93-4	fatty acids as described above, esterified with pentaerytrithol	-
061790-37-2	fatty acids, talc	-
061790-38-3	fatty acids, talc, hydrogenated	-
061790-12-3	fatty acids, tall oil	-
-	fatty acids, saturated, C8-C18, ammonium, potassium and sodium salts	-
068410-23-1	fatty acids, C18-unsaturated, dimers, reaction products with polyethylenepolyamines	0,1 µg/L
007705-08-0	feric (III) chloride	-
007758-94-3	ferrous (II) chloride	-
000050-00-0	formaldehyde	0,75 mg/L
009003-36-5	formaldehyde, polymer with (chloromethyl)oxirane and phenol (Novolak glycidyl ether, NOGE)	2,5 µg/L
000064-18-6	formic acid	-
000110-17-8	fumaric acid	-
009000-70-8	gelatin	-
-	glass fibres	-
000056-81-5	glycerol	-
007782-42-5	graphite	-
000111-14-8	heptanoic acid	-
016096-31-4	1,6-hexanediol diglycidyl ether	0,1 µg/L
000592-45-0	1,4-hexadiene	-
000116-15-4	hexafluorpropene	0,1 µg/L
023128-74-7	1,6-hexamethylene-bis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)proprionamide]	-
035074-77-2	1,6-hexamethylene-bis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	0,3 mg/L
000124-09-4	hexamethylenediamine	0,12 mg/L
000100-97-0	hexamethylenetetramine	0,75 mg/L (expressed as formaldehyde)
007647-01-0	hydrochloric acid	-
001333-74-0	hydrogen	-
012304-65-3	hydrotalcite	-
003896-11-5	2-(2-hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorobenzotriazole	MTC(T) 1,5 mg/L [11]
003864-99-1	2-(2-hydroxy-3,5-di-tert-butylphenyl)-5-chlorobenzotriazole	MTC(T) 1,5 mg/L [11]
009004-62-0	hydroxyethyl cellulose	-
065447-77-0	1-(2-hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethylpiperidine-dimethyl succinate copolymer	1,5 mg/L
009032-42-2	hydroxyethylmethyl cellulose	-
001191-25-9	6-hydroxyhexanoic acid	MTC(T) 2,5 µg/L [2]
000131-57-7	2-hydroxy-4-methoxybenzophenone	MTC(T) 0,3 mg/L [5]
037353-59-6	hydroxymethyl cellulose	-
002440-22-4	2-(2-hydroxy-5-methylphenyl)benzotriazole	MTC(T) 1,5 mg/l [11]
001843-05-6	2-hydroxy-4-n-octyloxybenzophenone	MTC(T) 0,3 mg/L [5]
009004-64-2	hydroxypropyl cellulose	-
009004-65-3	hydroxypropylmethyl cellulose	-
000106-14-9	12-hydroxystearic acid	-
006303-21-5	hypophosphoric acid	-
001332-37-2	iron oxide (mixture)	-
000115-11-7	isobutene	-
000121-91-5	isophtalic acid	0,25 mg/L
000097-65-4	itaconic acid	-
092704-41-1	kaolin, calcined	-
000050-21-5	lactic acid	-
000143-07-7	lauric acid	-
000947-04-6	laurolactam	0,25 mg/L
008002-43-5	lecithin	-
000553-54-8	lithium benzoate	30 µg/lll (as lithium)
000554-13-2	lithium carbonate	30 µg/lll (as lithium)
-	lead chloride sulphate complex	1 µg/L (as lead)
001072-35-1	lead (II) distearate (dibasic)	1 µg/L (as lead)
056189-09-4	lead (II) distearate dioxide	1 µg/L (as lead)
012578-12-0	lead (II) distearate trioxide	1 µg/L (as lead)
001344-40-7	lead (II) phosphite, (dibasic) ($Pb(PO_3H)$)	1 µg/L (as lead)
007446-14-2	lead (II) sulphate ($Pb(SO_4)$)	1 µg/L (as lead)
012036-93-0	lead (II) sulphate, dibasic ($Pb_3O2(SO4)$)	1 µg/L (as lead)
012036-76-9	lead (II) sulphate, monobasic ($Pb_2O(SO_4)$)	1 µg/L (as lead)
012202-17-4	lead (II) sulphate, tribasic ($Pb4O_3(SO_4)$)	1 µg/L (as lead)
013717-00-5	magnesium carbonate	-
007786-30-3	magnesium chloride	-

001309-48-4	magnesium oxide	-
001343-88-0	magnesium silicate	-
000110-16-7	maleic acid	MTC(T) 1,5 mg/L [12]
000108-31-6	maleic acid anhydride	MTC(T) 1,5 mg/L [12]
000141-82-2	malonic acid	-
068891-01-0	melamine-formaldehyde condensation products	-
000149-30-4	2-mercaptobenzothiazol	MTC(T) 0,15 mg/L [8]
000060-24-2	2-mercaptoethanol	2,5 µg/L
059118-78-4	2-mercaptoethyl oleate	1,5 mg/L
068440-24-4	mercaptoethyl thallate	1 500 µg/L
000096-45-7	2-mercaptoimidazoline	2,5 µg/L
000096-53-7	2-mercaptothiazoline	0,1 µg/L
000079-41-4	methacrylic acid	MTC(T) 0,3 mg/L [16]
-	methacrylic acid, esters with alcohols, monohydric, aliphatic, saturated, C1-C18	MTC(T) 0,3 mg/L [16]
000106-91-2	methacrylic acid, 2,3-epoxypropyl ester	1 µg/L
000067-56-1	methanol	-
000096-33-3	methyl acrylate	MTC(T) 0,3 mg/L [16]
000078-79-5	2-methyl-1,3-butadiene	0,1 µg/L
009004-67-5	methyl cellulose	-
004088-22-6	N-methyldioctadecylamine	-
000694-91-7	5-methylene-bicyclo[2,2,1]hept-2-ene	2,5 µg/L
000119-47-1	2,2-methylene-bis(4-methyl-6-tert-butylphenol)	75 µg/L
000077-62-3	2,2′-methylene-bis(4-methyl-6-(1-methylcyclohexyl)phenol)	0,3 mg/L
007786-17-6	2,2'-methylene-bis(4-methyl-6-nonylphenol)	0,1 µg/L
000078-93-3	methyl ethyl ketone	0,25 mg/L
000693-98-1	2-methylimidazole	0,1 µg/L
000534-26-9	2-methylimidazoline	0,1 µg/L
002682-20-4	2-methyl-4-isothiazoline-3-one	0,1 µg/L
000080-62-6	methyl methacrylate	MTC(T) 0,3 mg/L [16]
000872-50-4	N-methylpyrrolidone	-
000098-83-9	α-methylstyrene	2,5 µg/L
201687-58-3	methyltin-2-mercaptoethyl thallate	9 µg/L
012001-26-2	mica	-
000108-90-7	monochlorobenzene	10 µg/L
054849-38-6	monomethyltin-S,S',S"-tris(isooctylmercaptoacetate)	10 µg/L (as tin)
027107-89-7	mono-n-octyltin tris(ethylhexyl mercaptoacetate)	60 µg/L (as tin)
026401-86-5	mono-n-octyltin tris(isooctylmercaptoacetate)	60 µg/L (as tin)
-	mono-n-octyltin tris(maleic acid monoester with C1-C18, primary, unbranched, saturated alcohols)	1 µg/L (as tin)
008002-53-7	montan wax	-
-	montanic acid esters with ethyleneglycol and/or 1,3-butanediol and/or glycerol	-
000102-77-2	morpholinothio-2-benzothiazol	MTC(T) 0,15 mg/L [8]
-	myristyl polyethylene oxide(3-8) ether of oxyacetic acid	-
009084-06-4	naphtalene sulphonic acid-formaldehyde condensation product, sodium salt	0,1 µg/L
027253-31-2	neodecanoic acid, cobalt salt	2,5 µg/L (as cobalt)
000506-48-9	octacosanoic acid	-
002082-79-3	n-octadecyl-β-(4-hydroxy-3,5-di-tert-butylphenyl)propionate	0,3 mg/L
000111-66-0	1-octene	0,75 mg/L
000143-28-2	oleyl alcohol	-
000144-62-7	oxalic acid	-
070331-94-1	2,2'-oxamido-bis[ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	-
007782-44-7	oxygen	-
-	paraffin, microcrystalline	-
008012-95-1	paraffin oil (mineral oil)	-
-	paraffin, solid, including synthetic	-
-	paraffin, liquid (refined mineral oil),	-
000109-66-0	pentane	-
000115-77-5	pentaerythritol	-
013845-36-8	pentapotassiumtriphosphate	-
007601-89-0	perchloric acid, sodium salt monohydrate	2,5 µg/L
000108-45-2	1,3-phenylenediamine	0,1 µg/L
000948-65-2	2-phenylindole	0,75 mg/L
-	N-phenyl-N'-isohexyl-p-phenylenediamine	0,1 µg/L
007774-80-3	phenyl-o-tolyl-phenylenediamine	0,1 µg/L
007664-38-2	phosphoric acid	-

010294-56-1	phosphorous acid	-
000088-99-3	o-phtalic acid	-
000085-44-9	phtalic acid anhydride	-
068515-48-0	phtalic acid diesters with primary, saturated, branched C8-C10 alcohols	MTC(T) 45 µg/L (10)
068515-49-1	phtalic acid diesters with primary, saturated, branched C9-C11 alcohols	MTC(T) 45 µg/L (10)
000110-85-0	piperazine	75 µg/L
068132-00-3	polycyclopentadiene resins, hydrogenated	0,25 mg/L
063148-62-9	polydimethyl siloxane Viscosity at 25 °C not less than 100 cSt (100 × 10^{-6} m^2/s)	-
-	polyesters with an average molecular weight > 1 000, obtained by a reaction with adipic acid, azelaic acid, succinic acid, decanedicarboxylic acid, phthalic acid or sebacic acid with 1,3-butanediol, 2,2-dimethyl-1,3-propanediol, ethanediol, glycerol, 1,6-hexanediol or 1,2-propanediol, with the reaction being (or not being) terminated using fatty acids or alcohols, as described in this list	-
-	polyester from 1-(2-hydroxyethyl)-4-hydroxy-2,2,6,6- tetramethylpiperidine and the dimethyl ester of ethane-1,2-dicarboxylic acid, with a molecular weight higher than 1 500 and lower than 5 000	-
025322-68-3	polyethylene glycol	-
-	polyethylene glycol, esters with aliphatic monocarbonic acids (C6-C22) and their ammonium and sodium sulphates	-
009005-00-9	polyetheneglycol, stearyl ether	-
-	polyethylene oxide, molecular weight > 200	-
-	polyethylene oxide (8-14), esterified with lauric acid, oleic acid, ricinoleic and/or stearic acid	-
-	polyethylene oxide desorbitan monolaurate	-
009005-65-6	polyethylene oxide desorbitan monooleate	-
-	polyethylene oxide(4-14) ethers of n-alkyl(C8-C12)phenol	0,25 mg/L
-	polyethylene oxide (4-14) ethers of monohydric, primary, unbranched, saturated C12-C18 alcohols	0,25 mg/L
-	polyethylene, oxidised, molecular weight > 5 000, oxygen content > 1,2%, epoxy groups, not detectable	QM = 0,5 %
009002-88-4	polyethylene wax	-
025101-03-5	poly(propylene adipate)	-
025322-69-4	polypropylene glycol	-
-	polypropylene oxide	-
-	polypropylene oxide, esterified with lauric acid, oleic acid, ricinoleic and/or stearic acid	-
071878-19-8	poly[6-(1,1,3,3-tetramethylbutylamino)-1,3,5-triazine-2,4-diyl]-[4-(2,2,6,6-tetramethyl-piperidyl)imino]hexamethylene-[4-(2,2,6,6-tetramethylpiperidyl)imino]]	0,15 mg/L
192268-64-7	poly[[6-[N-(2,2,6,6-tetramethyl-4-piperidinyl)-n-butylamino]-1,3,5-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidinyl)-imino]-1,6-hexanediyl[(2,2,6,6-tetramethyl-4-piperidinyl)imino]]-α-[N,N,N',N'-tetrabutyl-N"-(2,2,6,6-tetramethyl-4-piperidinyl)-N"-[6-(2,2,6,6-tetramethyl-4-piperidinylamino)hexyl][1,3,5-triazine-2,4,6-triamine]-ω-N,N,N',N'-tetrabutyl-1,3,5-triazine-2,4-diamine]	0,25 mg/L
009002-89-5	polyvinyl alcohol (viscosity of the 4% solution in water at 20 °C at least 20 cP)	-
-	poly-N-vinyl-N-methylformamide, molecular weight > 40 000	-
009003-39-8	polyvinyl pyrrolidone (viscosity of a 5% solution in water at 20 °C at least 34 cP)	-
007758-02-3	potassium bromide	-
000584-08-7	potassium carbonate	-
001310-58-3	potassium hydroxide	-
007681-11-0	potassium iodide	-
012136-45-7	potassium oxide	-
007727-21-1	potassium peroxodisulphate	0,1 µg/L
001312-76-1	potassium silicate	-
000074-98-6	propane	-
000057-55-6	1,2-propanediol	-
000071-23-8	1-propanol	-
000067-63-0	2-propanol	-
000115-07-1	propene	-
000079-09-4	propionic acid	-
019019-51-3	propionic acid, cobalt salt	2,5 µg/L (as cobalt)
000075-56-9	propylene oxide	-
000094-13-3	propyl-4-hydroxybenzoate	-
002466-09-3	pyrophosphoric acid	-
-	rapeseed oil	-

119345-01-6	reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4- di-tert-butylphenol with Friedel-Crafts reaction product of phosphorus trichloride and biphenyl[15]	0,9 mg/L
068442-12-6	reaction product of oleic acid, 2-mercaptoethyl ester with dichlorodimethyltin, sodium sulphide and trichloromethyltin	9 µg/L (as tin)
068442-68-2	reaction product of styrene and diphenylamine	2,5 µg/L
-	reaction products of styrene and/or methylstyrene and/or alkenes (C3-C12) with phenol and/or methylphenol	2,5 µg/L
000141-22-0	ricinoleic acid	-
008001-79-4	ricinus oil	-
008050-09-7	rosin	-
008050-26-8	rosin, ester with pentaerythritol	-
000111-20-6	sebacic acid	-
-	silanols, with at least one hydroxyl group and one or more methyl, vinyl or phenyl groups on every silicon atom	0,1 µg/L
-	silicates of aluminium, calcium, potassium, magnesium and sodium, including diatomaceous earth, glass fibres, infusorial earth, kaolin, mica and talc	-
001343-98-2	silicic acid	-
000409-21-2	silicon carbide	-
007631-86-9	silicon dioxide	-
010026-04-7	silicon tetrachloride	-
007631-90-5	sodium bisulphite	0,5 µg/L
000497-19-8	sodium carbonate	-
007647-14-5	sodium chloride	-
007681-49-4	sodium fluoride	-
001310-73-2	sodium hydroxide	-
001561-92-8	sodium methallyl sulphonate	0,25 mg/L
001313-59-3	sodium oxide	-
007775-27-1	sodium peroxodisulphate	0,1 µg/L
001344-09-8	sodium silicate	-
007757-83-7	sodium sulphite	-
001330-43-4	sodium tetraborate	50 µg/L (as boron)
001303-96-4	sodium tetraborate decahydrate	50 µg/L (as boron)
-	softeners refined from petroleum	0,1 µg/L
000110-44-1	sorbic acid	-
001338-39-2	sorbitan monolaurate	-
026266-57-9	sorbitan monopalmitate	-
000050-70-4	sorbitol	-
-	soybean oil, whether or not modified with sulphur (faktis)	-
008013-07-8	soybean oil, epoxidised, with oxiran content < 8 % and iodium number < 6	0,3 mg/L
000057-11-4	stearic acid	-
058446-52-9	stearoyl benzoyl methane	-
000100-42-5	styrene	-
-	styrene (2 mol) condensed with 1 mol of a mixture of phenol and o-, m- en p-cresols, Brookfield viscosity of the end product at 25 °C between 1 400 and 1 700 cP	0,1 µg/L
007704-34-9	sulphur	-
007664-93-9	sulphuric acid	-
014807-96-6	talc	-
000087-69-4	tartaric acid	-
000100-21-0	terephtalic acid	0,375 mg/L
001634-02-2	tetrabutylthiuram disulphide	MTC(T) 50 µg/L [13]
000097-77-8	tetraethylthiuram disulphide	MTC(T) 50 µg/L [13]
000116-14-3	tetrafluorethene	2,5 µg/L
000109-99-9	tetrahydrofuran	30 µg/L
000126-33-0	tetrahydrothiophene-1,1-dioxide	0,1 µg/L
-	tetrakis(2,4-di-tert-butylphenyl)-2,4'-biphenylene diphosphonite	0,9 mg/L
038613-77-3	tetrakis(2,4-di-tert-butylphenyl)-4.4'-biphenylene diphosphonite	0,9 mg/L
006683-19-8	tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]methane	-
000137-26-8	tetramethylthiuram disulphide	MTC(T) 50 µg/L [13]
000097-74-5	tetramethylthiuram monosulphide	MTC(T) 50 µg/L [13]
041484-35-9	thiodiethanol-bis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	0,12 mg/L
000111-17-1	thiodipropionic acid	-
001912-84-1	tin (II) oleate	2,5 µg/L
011130-18-0	titanium chloride	-
013463-67-7	titanium dioxide	-
051745-87-0	titanium oxide	-
007550-45-0	titanium tetrachloride	-

000108-88-3	toluene	60 µg/L
000093-69-6	o-tolyl biguanide	0,1 µg/L
-	trialkyl (C5-C15) acetic acid, 2,3-epoxypropyl ester	QM = 1 mg/kg
000101-37-1	triallyl cyanurate	0,1 µg/L
001025-15-6	triallyl isocyanurate	0,1 µg/L
000108-78-1	2,4,6-triamino-1,3,5-triazine	0,6 mg/L
000102-82-9	tri-n-butyl amine	0,1 µg/L
000813-94-5	tricalcium dicitrate	-
000090-72-2	2,4,6-tri(dimethylaminomethyl)phenol	0,1 µg/L
000102-71-6	triethanolamine	2,5 µg/L
000121-44-8	triethylamine	0,1 µg/L
000112-27-6	triethylene glycol	-
036443-68-2	triethylene glycol bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionate]	0,45 mg/L
000078-40-0	triethyl phosphate	0,375 mg/L
000122-20-3	triisopropanolamine	0,25 mg/L
000528-44-9	trimellitic acid	0,25 mg/L
003236-53-1 025620-58-0	trimethyl-1,6-hexaandiamine (2,2,4- and 2,4,4-isomers)	0,25 mg/L
003290-92-4	1,1,1-trimethylolpropane trimethacrylate	2,5 µg/L
001709-70-2	1,3,5-trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene	-
000110-88-3	trioxane	2,5 µg/L
010380-08-2	triphosphoric acid	-
027676-62-6	1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6-trione	0,25 mg/L
040601-76-1	1,3,5-tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6-trione	0,3 mg/L
031570-04-4	tris(2,4-di-tert-butylphenyl)phosphite	-
000077-99-6	1,1,1-tris(hydroxymethyl)propane	0,3 mg/L
001843-03-4	1,1,3-tris(2-methyl-4-hydroxy-5-tert-butylphenyl)butane	0,25 mg/L
-	tris(mono- and dinonylphenyl)phosphite	1,5 mg/L
000057-13-6	urea	-
-	urea-formaldehyde condensation products	-
007718-98-1	vanadium chloride	2,5 µg/L (as vanadium)
011099-11-9	vanadium oxide	2,5 µg/L (as vanadium)
008009-03-8	vaseline, pharmaceutical quality	-
000108-05-4	vinyl acetate	0,6 mg/L
000075-01-4	vinyl chloride	0,1 µg/L
-	vinyl esters of monohydric, saturated, aliphatic carboxylic acids, C2-C20	2,5 µg/L (in total)
000075-35-4	vinylidene chloride	0,1 µg/L
000075-38-7	vinylidene fluoride	0,25 mg/L
003048-64-4	vinyl norbornene	2,5 µg/L
000088-12-0	vinyl pyrrolidone	-
002768-02-7	vinyl trimethoxysilane	QM = 5 mg/kg
007732-18-5	water of potable quality	-
013983-17-0	wollastonite	-
011138-66-2	xanthan gum	-
007646-85-7	zinc chloride	-
014726-36-4	zinc dibenzyldithiocarbamate	MTC(T) 50 µg/L [14]
000136-23-2	zinc dibutyldithiocarbamate	MTC(T) 50 µg/L [14]
014324-55-1	zinc diethyldithiocarbamate	MTC(T) 50 µg/L [14]
000137-30-4	zinc dimethyldithiocarbamate	MTC(T) 50 µg/L [14]
000136-53-8	zinc 2-ethylhexanoate	-
014634-93-6	zinc ethylphenyldithiocarbamate	MTC(T) 50 µg/L [14]
000155-04-4	zinc 2-mercaptobenzothiazol	MTC(T) 0,15 mg/L [8]
000557-09-5	zinc octanoate	-
001314-13-2	zinc oxide	-
004991-47-3	zinc palmitate	-
000557-05-1	zinc stearate	-
001314-98-3	zinc sulphide	-
053801-45-9	zirconium oxide	2,5 µg/L (as zirconium)

	Notes
1	In this specific case, the MTC(T) means that the sum of the migration of “alkyl (C8 C18) benzene sulphonates, sodium salts,” “alkyl (C8-C18) naphthalene sulphonates, sodium salts,” “alkyl (C8-C18) sulphates, sodium salts,” and “alkyl (C8-C18) sulphonates, sodium salts,” must not exceed the limit of 1,500 mg/L.
2	In this specific case, the MTC(T) means that the sum of the migration of “caprolactone” and “6-hydroxyhexanoic acid” must not exceed the limit of 2,5 µg/L.
3	In this specific case, the MTC(T) means that the sum of the migration of “didodecyl thiodipropionate,” and “dioctadecyl thiodipropionate” must not exceed the limit of 0,25 mg/L.

4	In this specific case, the MTC(T) means that the sum of the migration of “diethylene glycol” and “ethylene glycol” must not exceed the limit of 1,5 mg/L.
5	In this specific case, the MTC(T) means that the sum of the migration of “2,4 dihydroxybenzophenone,” 2--hydroxy-4-methoxybenzophenone,” and “2- hydroxy-4-n-octyloxybenzophenone” must not exceed the limit of 0,3 mg/L.
6	In this specific case, the MTC(T) means that the sum of the migration of “di-n-octyl tin S,S'-bis(2-ethylhexyl-mercaptoacetate),” “di-n-octyl tin-S,S'- bis(isooctylmercaptoacetate),” “di-n-octyl tin bis(maleic acid monoester with primary, unbranched, saturated C1-C18 alcohols),” “di-n-octyl tin dilaurate,” and “di-n-octyl tin maleate polymer (the polymer must match the formula [(C8H17)2SnC4H2O4]n, where n = 2-4),” must not exceed the limit of 2µg/L.
7	In this specific case, the MTC(T) means that the sum of the migration of “di-N-pentamethylenethiuram hexasulphide” and “di-N-pentamethylenethiuram tetrasulphide” must not exceed the limit of 50 µg/L.
8	In this specific case, the MTC(T) means that the sum of the migration of “dithio-bis(2 benzothiazol),” “2-mercapto-benzothiazol,” “morpholinothio-2- benzothiazol” and “zinc 2-mercaptobenzothiazol” must not exceed the limit of 0,15 mg/L.
9	In this specific case, the MTC(T) means that the sum of the migration of “divinyl benzene” and “ethyl vinyl benzene” must not exceed the limit of 0,1 µg/L.
10	In this specific case, the MTC(T) means that the sum of the migration of “phtalic acid diesters with primary, saturated, branched C8-C10 alcohols” and “phtalic acid diesters with primary, saturated, branched C8-C10 alcohols” must not exceed the limit of 45 µg/l.
11	In this specific case, the MTC(T) means that the sum of the migration of “2-(2 hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorobenzotriazole,” “2-(2-hydroxy-3,5-di-tert-butylphenyl)-5 chlorobenzotriazole” and “2-(2- hydroxy-5-methylphenyl)benzotriazole” must not exceed the limit of 1,5 mg/L.
12	In this specific case, the MTC(T) means that the sum of the migration of “maleic acid” and “maleic acid anhydride” must not exceed the limit of 1,5 mg/L.
13	In this specific case, the MTC(T) means that the sum of the migration of “tetrabutylthiuram disulphide,” “tetraethylthiuram disulphide” “tetramethylthiuram disulphide” and “tetramethylthiuram monosulphide” must not exceed the limit of 50 µg/L.
14	In this specific case, the MTC(T) means that the sum of the migration of “zinc dibenzyldithiocarbamate,” “zinc dibutyldithiocarbamate,” “zinc diethyldithiocarbamate,” “zinc dimethyldithiocarbamate” and “zinc ethylphenyldithiocarbamate” must not exceed the limit of 50 µg/L.
15	Composition — 4,4_-Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 38613-77-3) (36-46 % m/m)10 (*), — 4,3_-Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 118421-00-4) (17-23 % m/m)10 (*)), — 3,3_-Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 118421-01-5) (1-5 % m/m)10 (*)), — 4-Biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 91362-37-7) (11-19 % m/m)10 (*)), — Tris(2,4-di-tert-butylphenyl)phosphite (CAS No 31570-04-4) (9-18 % m/m)10, (*)), — 4,4_-Biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonate-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 112949-97-0) (<5 % m/m) Other specifications — Phosphorus content min. 5,4 %-max. 5,9 % — Acid value max. 10 mg KOH per gram — Melting at 85-110 °C
16	In this specific case, the MTC(T) means that the sum of the migration of “methacrylic acid”, “methacrylic acid, esters with alcohols, monohydric, aliphatic, saturated, C1-C18”, “methyl methacrylate” and “methyl acrylate” must not exceed the limit of 0,3 mg/L.

2 Dyes and pigments

2.1 Requirements set for dyes and pigments

When extracted with 0,1 N hydrochloric acid, the following elements in the dye or pigment must enter the solution with no more than the indicated value, calculated on the dye or pigment:

Parameter	Maximum content
Antimony	0,2%
Arsenic	0,01%
Barium	0,01%
Cadmium	0,1%
Chromium	0,1%
Lead	0,01%
Mercury	0,005%
Selenium	0,01%

When extracted with 2 N ethanolic hydrochloric acid, not more than 0,05 % aromatic amines in the dye or pigment may enter the solution, calculated on the dye or pigment:

2.2 Requirements set for the coloured end product

The migration of the components of dyes and pigments in any end product contacting drinking water or warm tap water measured with the applicable testing and assessment methods described in Annex C and Annex D, must not be higher than the value in µg/L listed below for the related component:

Parameter	Maximum concentration in migration water (µg/L)
Antimony	0,5
Aromatic amines	0,1
Arsenic	1
Barium	50
Cadmium	0,5
Chromium	5
Cobalt	2,5
Lead	1
Manganese	5
Mercury	0,1
Nickel	2
Selenium	1

2.3 Authorised dyes and pigments

C.I. generic name	C.I. number	Chemical or trivial name	CAS number
C.I. Fluorescent Brightener 184:1	-	2,5-bis(5-tert.butyl-2-benzoxazolyl)thiophene	007128-64-5
C.I. Fluorescent Brightener 236	-	7-(2H-naphthol[1,2-d]triazol-2-yl)-3-phenylcoumarin	003333-62-8
C.I. Food Blue 2	42090	triarylmethane	003844-45-9
C.I. Food Yellow 4	19140	tartrazine (E102)	001934-21-0
C.I. Pigment Black 11	77499	iron oxide black (or CAS# 1317-61-9)	012227-89-3
C.I. Pigment Black 28	77428	copper chromite	068186-91-4
C.I. Pigment Black 33	77537	iron manganese trioxide	012062-81-6
C.I. Pigment Black 7	77266	carbon black	001333-86-4
C.I. Pigment Blue 15	74160	phthalocyanine blue (incl. 15:1, 15:2, 15:3, 15:4)	000147-14-8
C.I. Pigment Blue 28	77346	cobalt aluminate	001345-16-0
C.I. Pigment Blue 29	77007	ultramarine blue	057455-37-5
C.I. Pigment Blue 36	77343	cobalt chromite	068187-11-1
C.I. Pigment Blue 74	77366	cobalt zinc silicate	068412-74-8
C.I. Pigment Brown 11	77495	magnesium ferrite	012068-86-9
C.I. Pigment Brown 24	77310	chromium antimony titanate	068186-90-3
C.I. Pigment Brown 29	77500	chromium iron oxide	012737-27-8
C.I. Pigment Green 17	77288	chromium(III)oxide	001308-38-9
C.I. Pigment Green 7	74260	phthalocyanine green	001328-53-6
C.I. Pigment Orange 13	21110	diazo	003520-72-7
C.I. Pigment Red 101	77491	iron(III)oxide	001309-37-1
C.I. Pigment Red 104	77605	lead chromate/molybdate/sulphate	012656-85-8
C.I. Pigment Red 178	-	perylene red	003049-71-6
C.I. Pigment Red 214	-	condensation azo (or CAS# 82643-43-4)	060618-31-3
C.I. Pigment Red 242	20067	disazo condensation	052238-92-3
C.I. Pigment Red 247	15915	monoazo	043035-18-3
C.I. Pigment Red 38	21120	diazo	006358-87-8
C.I. Pigment Red 57:1 (D & C Red 7)	15850:1	monoazo	005281-04-9
C.I. Pigment Violet 15	77007	ultramarine violet	012769-96-9
C.I. Pigment Violet 23	51319	oxazine	006358-30-1
C.I. Pigment White 18	77220	carbonic acid, calcium salt	000471-34-1
C.I. Pigment White 21	77120	barium sulphate	007727-43-7
C.I. Pigment White 26	77718	magnesium silicate (talc)	014807-96-6
C.I. Pigment White 4	77947	zinc oxide	001314-13-2
C.I. Pigment White 5	77115	lithopone (coprecipitate of barium sulphate and zinc sulphide)	001345-05-7
C.I. Pigment White 6	77891	titanium dioxide (rutile form: CAS# 1317-80-2)	013463-67-7
C.I. Pigment White 7	77975	zinc sulphide	001314-98-3
C.I. Pigment Yellow 110	56280	aminoketone	005590-18-1
C.I. Pigment Yellow 119	77496	zinc ferrite	068187-51-9
C.I. Pigment Yellow 191	18795	monoazo	129423-54-7
C.I. Pigment Yellow 53	77788	nickel antimony titanate	008007-18-9
C.I. Pigment Yellow 65	11740	monoazo	006528-34-3
C.I. Solvent Black 7	50415:1	azine	008005-02-5
C.I. Solvent Violet 13	60725	anthraquinone	000081-48-1
D & C Red No 7	15850:1	monoazo	005281-04-9
iron oxide		all iron oxides	001332-37-2

3 Composition list for metallic materials

3.1 Copper alloys

3.1.1 Copper/zinc/lead alloys (brass)

3.1.1.1 Composition limits of the Category

Constituent	Content (%)	Impurity	Maximum (%)
Copper	≥ 57.0	Antimony	0.02
Zinc	Remainder	Arsenic	0.02
Lead	≤ 3,5	Bismuth	0,02
Aluminium	≤ 1,0	Cadmium	0,02
Iron	≤ 0,5	Chromium	0,02
Silicon	≤ 1,0	Nickel	0,2
Tin	≤ 0,5		

3.1.1.2 Composition of Reference Material

Constituent	Content (%)	Impurity	Maximum (%)
Copper	57,0 – 59,0	Antimony	0,02
Zinc	Remainder	Arsenic	0,02
Lead	1,9-2,1	Bismuth	0,02
		Cadmium	0,02
		Chromium	0,02
		Nickel	0,2
		Aluminium	0,2
		Iron	0,3
		Silicon	0,02
		Tin	0,3

Elements for consideration in the migration water:

Lead, nickel, copper, zinc

3.1.1.3 Composition of tested and authorised brass materials

Brass B2[15] (based on CW617N CW612N)

Constituent	Content (%)	Impurity	Maximum (%)
Copper	57,0 – 60,0	Antimony	0,02
Zinc	Remainder	Arsenic	0,02
Lead	1,6 – 2,2	Bismuth	0,02
		Cadmium	0,02
		Chromium	0,02
		Nickel	0,1
		Aluminium	0,05
		Iron	0,3
		Silicon	0,03
		Tin	0,3

Authorised for the following product groups (see also Annex A, paragraph 2.8.2)

Product Group B
Product Group C

[15] B2 is an indication introduced by CEN/TC164/WG3/AHG5 without official status.

Brass B1[16] (based on CW614N, CW603N)

Constituent	Content (%)	Impurity	Maximum (%)
Copper	57,0 – 62,0	Antimony	0,02
Zinc	Remainder	Arsenic	0,02
Lead	2,5 – 3,5	Bismuth	0,02
		Cadmium	0,02
		Chromium	0,02
		Nickel	0,2
		Aluminium	0,05
		Iron	0,3
		Silicon	0,03
		Tin	0,3

Authorised for the following product groups:

Product group C

3.1.2 Copper/zinc/lead/arsenic alloys (dezincification-resistant brass)

3.1.2.1 Composition limits of the Category

Constituent	Content (%)	Impurity	Maximum (%)
Copper	≥ 61,0	Antimony	0,02
Zinc	Remainder	Bismuth	0,02
Arsenic	≤ 0,15	Cadmium	0,02
Lead	≤ 2,2	Chromium	0,02
Aluminium	≤ 1,0	Nickel	0,2
Iron	≤ 0,5		
Silicon	≤ 1,0		
Tin	≤ 0,5		

3.1.2.2 Composition of Reference Material

Constituent	Content (%)	Impurity	Maximum (%)
Copper	61,0-63,0	Antimony	0,02
Zinc	Remainder	Bismuth	0,02
Arsenic	0,09-0,13	Cadmium	0,02
Lead	1,4-1,6	Chromium	0,02
Aluminium	0,5-0,7	Nickel	0,2
		Iron	0,12
		Silicon	0,02
		Tin	0,3

Elements for consideration in the migration water:

Lead, nickel, arsenic, copper, zinc

Authorised for the following product groups (see also Annex A, paragraph 2.8.2) :

Product Group B
Product Group C

[16] B1 is an indication introduced by CEN/TC164/WG3/AHG5 without official status.

3.1.3 Copper/tin/zinc/lead alloys (gunmetal and bronze)

3.1.3.1 Composition limits of the Category

Constituent	**Content (%)**	**Impurity**	**Maximum (%)**
Copper	Remainder	Aluminium	0,01
Zinc	≤ 6,5	Antimony	0,1
Tin	≤ 13,0	Arsenic	0,03
Lead	≤ 3,0	Bismuth	0,02
Nickel	≤ 0,6	Cadmium	0,02
		Chromium	0,02
		Iron	0,3
		Silicon	0,01

3.1.3.2 Composition of Reference Material

Constituent	**Content (%)**	**Impurity**	**Maximum (%)**
Copper	Remainder	Aluminium	0,01
Zinc	5,9-6,2	Antimony	0,1
Tin	3,9-4,1	Arsenic	0,03
Lead	2,8-3,0	Bismuth	0,02
Nickel	0,5-0,6	Cadmium	0,02
		Chromium	0,02
		Iron	0,3
		Silicon	0,01

Elements for consideration in the migration water:
Lead, nickel, antimony, copper, zinc, tin

3.1.3.3 Tested and authorised materials

Gunmetal GM1 (based on CC491K)

Constituent	**Content (%)**	**Impurity**	**Maximum (%)**
Copper	84,0 – 88,0	Aluminium	0,01
Zinc	4,0 – 6,0	Antimony	0,1
Tin	4,0 – 6,0	Arsenic	0,03
Lead	2,5-3,0	Bismuth	0,02
Nickel	0,1-0,6	Cadmium	0,02
		Chromium	0,02
		Iron	0,3
		Silicon	0,01

Authorised for the following product groups (see also Annex A, paragraph 2.8.2) :
Product Group B
Product Group C

3.2 COPPERS

3.2.1 Copper

3.2.1.1 Composition limits for the Category

Constituent	**Content (%)**	**Impurity**	**Maximum (%)**
Copper	≥ 99,9	Others total	≤ 0,1
Phosphorus	≤ 0,04		

3.2.1.2 Composition of Reference Material

Component	EN number
Cu-DHP	CW 024A

Elements for consideration in the migration water:
None: no need for comparative testing

3.2.1.3 Tested and authorised alloys

Copper (Cu-DHP)

Constituent	Content (%)	Impurity	Maximum (%)
Copper	≥ 99,9	Others total	≤ 0,1
Phosphorus	≤ 0,04		

Authorised for the following product groups (see also Annex A, paragraph 2.8.2):
Product Group A
Product Group B
Product Group C

Note:
The contamination of drinking water or warm tap water due to copper pipes depends on various characteristics of the water composition, and may at times lead to unacceptable concentrations of copper.

3.2.2 Tinned Copper tubes and tinned Copper Fittings

For tinned copper tubes and tinned copper fittings a relatively thin layer of tin is deposited by different processes on the copper basic material. By diffusion of copper ions into the tin layer the formation of an increasing intermetallic phase consisiting of tin and copper (η-phase = Cu_6Sn_5) is formed.

3.2.2.1 Composition limits of the Category: tin layer

Constituent	Content (%)	Impurity or	Maximum (%)
Tin and copper	≥ 99,90	Antimony	0,01
		Arsenic	0,01
		Bismuth	0,01
		Cadmium	0,01
		Chromium	0,01
		Lead	0,01
		Nickel	0,01

3.2.2.2 Composition of Reference Material

- Copper pipes pursuant to EN 1057

Component	EN number
Cu-DHP	CW 024A

3.2.2.3 Tested and authorised alloys

CW 024A copper with a 1 µm tin layer thickness with the following composition:

Constituent	Content (%)	Impurity or	Maximum (%)
Tin	> □90	Antimony	0,01
Copper	< 10	Arsenic	0,01
		Bismuth	0,01
		Cadmium	0,01

		Chromium	0,01
		Lead	0,01
		Nickel	0,01

Authorised for the following product groups (see also Annex A, paragraph 2.8.2):

Product group A
Product group B
Product group C

3.3 GALVANISED STEEL

3.3.1 Requirements

The zinc coating resulting from the galvanising process shall comply with the following:

Constituent	Content (%)	Impurity	Maximum (%)
Zinc		Antimony	0,01
		Arsenic	0,02
		Cadmium	0,01
		Chromium	0,02
		Lead	0,05
		Bismuth	0,01

3.3.2 Tested and authorised alloys

The zinc coating resulting from the galvanising process shall comply with the following:

Constituent	Content (%)	Impurity	Maximum (%)
Zinc		Antimony	0,01
		Arsenic	0,02
		Cadmium	0,01
		Chromium	0,02
		Lead	0,05
		Bismuth	0,01

3.3.3 Guidance on restrictions for the use of galvanised steel use with respect to water composition

The following formula may be used to identify water compositions for which the rate of corrosion for galvanised steel may be unacceptable:

pH ≥ 7,5 or free CO_2 ≤ 0,25 mmol/L

AND Alkalinity ≥ 1,5 mmol/L

AND S_1 < 2 (*see below for the definition of S_1*)

AND Calcium ≥ 0,5 mmol/L

AND Conductivity ≤ 600 µS/cm at 25°C

AND S_2 <1 or S_2>3 (*see below for the definition of S_2*)

$$S_1 = \frac{c(\mathrm{Cl^-}) + c(\mathrm{NO_3^-}) + 2\,c(\mathrm{SO_4^{2-}})}{c(\mathrm{HCO_3^-})}$$ concentrations in mmol/L

$$S_2 = \frac{c(Cl^-) + 2\,c(SO_4^{2-})}{c(NO_3^-)}$$ concentrations in mmol/L

Authorised for the following product groups (see also Annex A, paragraph 2.8.2):
Product Group A
Product Group B
Product Group C

3.4 CARBON STEEL

3.4.1 Carbon steel for pipes and tanks

Carbon steel without a permanent protective layer is not suitable for use in contact with drinking water.

3.4.2 Carbon steel for ancillaries

Carbon steel without a permanent protective layer may be used in specific applications, such as pumps and valves, and other products with a relatively small contact surface.

3.4.2.1 Requirements

The constituents and impurities should not exceed the following maximum levels:

Constituent	Content (%)	Impurity	Maximum (%)
Iron		Antimony	0,02
Carbon	≤ 2,11	Arsenic	0,02
Chromium	≤1,0	Cadmium	0,02
Molybdenum	≤1,0	Lead	0,02
Nickel	≤0,5		

3.4.2.2 Tested and authorised alloys

The constituents and impurities should not exceed the following maximum levels:

Constituent	Content (%)	Impurity	Maximum (%)
Iron		Antimony	0,02
Carbon	≤ 2,11	Arsenic	0,02
Chromium	≤1,0	Cadmium	0,02
Molybdenum	≤1,0	Lead	0,02
Nickel	≤0,5		

Authorised for the following product groups (see also Annex A, paragraph 2.8.2):

Product Group C

3.5 CAST IRON

3.5.1 Cast iron for pipes and tanks

Cast iron without a permanent protective layer is not suitable for use in pipes and tanks that will contact drinking water.

3.5.2 Cast iron for ancillaries

Cast iron without a permanent protective layer may be used in specific applications, such as pumps and valves, and other products with a relatively small contact surface.

3.5.2.1 Requirements

The constituents and impurities should not exceed the following maximum levels:

Constituent	**Content (%)**	**Impurity**	**Maximum (%)**
Iron		Antimony	0,02
Carbon		Arsenic	0,02
Chromium	≤1,0	Cadmium	0,02
Molybdenum	≤1,0	Lead	0,02
Nickel	≤6,0		

3.5.2.2 Tested and authorised alloys

The constituents and impurities should not exceed the following maximum levels:

Component	**Content (%)**	**Impurity**	**Maximum (%)**
Iron		Antimony	0,02
Carbon		Arsenic	0,02
Chromium	≤1,0	Cadmium	0,02
Molybdenum	≤1,0	Lead	0,02
Nickel	≤6,0		

Authorised for the following product groups (see also Annex A, paragraph 2.8.2) :

Product Group C

ANNEX C – TEST METHODS

1 Migration tests

1.1 Migration tests for verification with the MTC

1.1.1 Organic, factory-made products

As set forth in Article 19(3), standard NEN-EN 12873-1:2003 (EN) applies.

1.1.2 Site applied organic materials (other than metals or cement products)

As set forth in Article 19(3) standard NEN-EN 12873-2:2005 (EN) applies.

1.1.3 Membranes

As set forth in Article 19(3) standard NEN-EN 12873-4:2006 (EN) applies.

1.1.4 Ion exchange resins and related polymeric adsorbents

As set forth in Article 19(3) standard NEN-EN 12873-3:2006 (EN) applies.

1.1.5 Metallic materials

As set forth in Article 19(3) standard NEN-EN 15664-1:2008 (EN) applies.

1.1.6 Migration test for cementitious products

As set forth in Article 19(3) standard NEN-EN 14944-3:2005 Draft (EN) applies to factory-made products.

At this point, a standard for site applied materials and associated cementitious products is not available. The Committee may decide which method to use.

1.2 Migration tests to assess the organoleptic aspects

As established in Article 19(3) the following standards apply (see also the table at the end of this Annex):

1.2.1 Organic, factory-made products in water distribution systems

To identify the effects of organic, factory-made products applied in water distribution systems on the odour and flavour of water for human consumption, the migration water must be obtained as set forth in NEN-EN 1420-1:1999 (EN).

To identify the effects of organic, factory-made products applied in water distribution systems on the odour and flavour of water for human consumption, the migration water must be obtained as described in NEN-EN 13052-1:2001 (EN).

1.2.2 Organic materials in storage systems

To identify the effects of organic materials in water storage systems (e.g. tanks, reservoirs and potential coatings used), both for factory-made products and site applied materials, on the organoleptic aspects of water for human consumption, the migration water must be obtained as described in NEN-EN 14395-1:2004 (EN).

1.2.3 Membranes

Membranes are not tested for organoleptic aspects, because the water passing the membrane is not yet drinking water or warm tap water.

1.2.4 Ion exchange resins and related polymeric adsorbents

Ion exchange resins and related polymeric adsorbents are not tested for organoleptic aspects, because the water that has contacted these products is not yet drinking water or warm tap water.

1.2.5 Metallic materials

A method to assess the organoleptic aspects of metals is not described. MTCs defined for metals or metal ions released by metallic products or materials are (much) lower than the concentrations in which organoleptic aspects have any relevance. Therefore, if a metallic product/material meets the toxicological criteria/requirements, testing the organoleptic aspects will not be necessary.

1.2.6 Cementitious products

To identify the effects of factory-made cementitious products on the organoleptic aspects of water for human consumption, the migration water must be obtained as set forth in NEN-EN 14944-1:2006 (EN).

As of now, a standard to identify the effects of site applied cementitious materials and their associated products on the organoleptic aspects of drinking water or warm tap water, is not available.

1.2.7 Technological auxiliary agents

To identify the effects of technological auxiliary agents, *i.e.* soldering-water, slipping agents, mould release agents and curing compounds, on the organoleptic aspects of drinking water or warm tap water, if it is impossible to adequately remove these agents, the Minister may issue further guidelines in accordance with Article 10. The same applies to lubricants in assembled products and sealing materials.

2 Measuring methods

2.1 Measuring methods for organoleptic aspects

As set forth in Article 6(9) the following standards apply to organic, factory-manufactured products in water supply systems, organic materials in storage systems, membranes, ion exchangers and cement products (see also the table at the end of this Annex):

2.1.1 Odour and flavour

The quantitative values of the odour and flavour of migration water obtained by using the tests listed under 1.2.1-1.2.6 are measured in accordance with one of the methods described in standard NEN-EN 1622:2006 (EN).

2.1.2 *Colour*

The quantitative value of the colour of the migration water obtained by using the tests listed under 1.2.1-1.2.6 is measured in accordance with the method described in standard NEN-EN-ISO 7887:1994 (EN).

2.1.3 *Degree of turbidity*

The quantitative value of the turbidity of the migration water obtained by using the tests listed under 1.1.1-1.14 and 1.2.6 is measured in accordance with the method described in standard NEN-EN-ISO 7027:2000 (EN).

2.2 Measuring method for the Biomass Production Potential (BPP)

The standard NVN 1225:2004 EN applies once the Minister has set the assessment criteria.

2.3 Measuring methods to identify the TOC and the specific migrations, and to test the purity

2.3.1 TOC

As set forth in Article 19, third paragraph, standard NEN-EN 1484:1997 (EN/NL) applies to measure the TOC.

2.3.2 Specific migrations, testing the purity of chemicals

If available, the specific migration of compounds for which an MTC has been set, and the purity of chemicals, will be measured in accordance with the related EN standard.
If no EN standards are available, the Committee will decide which method to use. Known characteristics of such method include:

- repeatability;
- reproducibility;
- accuracy;
- measurement uncertainty.

The detection limit must be under one-fifth times the MTC.

The methods will be defined by the Committee in accordance with Article 1(4) of the Committee's rules.

3 Migration modelling

To calculate the migration of substances from materials that contact drinking water or warm tap water, one may use as a guideline the formulas and assumptions derived from the Piringer model, as shown under 3.1, thereby observing the criteria described in Annex D(4). The calculations must be made on the basis of the state of the art, as decided by the Committee. Should the value of the expected concentration in the drinking water or warm tap water calculated on the basis of the migration model used be lower than the MTC in effect, a migration test in the laboratory would not be necessary.

3.1 Formulas and assumptions

The following analytical solution may be derived for a substance's rate of migration from material P to liquid F by using the time-dependent diffusion equation according to Fick's 2nd Law of Diffusion:

$$\frac{m_{F,t}}{1\ A} = 0{,}1 c_{p,0} \rho_p d_p \left(\frac{\alpha}{1+\alpha} \right) \left[1 - \sum_{n=1}^{\infty} \frac{2\alpha(1+\alpha)}{1+\alpha+\alpha^2 q_n^2} \exp\left(-D_p t \frac{q_n^2}{d_p^2} \right) \right]$$

With:
$m_{F,t}$ = a migrant's volume migrated from material P into liquid F after a time t (s) in (mg);
A = the contact surface between material P and liquid F (dm^2);
$c_{P,0}$ = the migrant's initial concentration in material P (µg/g = mg/kg = ppm);
ρ_P = material P's density (g/cm^3);
d_P = material P's thickness (cm);
α = parameter without dimensions according to the equation:

$$2\alpha = \frac{1}{K_{p,f}} \frac{V_F}{V_P} = \frac{c_{F,\infty}}{c_{P,\infty}} \frac{\rho_F}{\rho_P} \frac{V_F}{V_P}$$

with:
V_F = volume of liquid F (cm^3);
V_P = volume of material P (cm^3);
$K_{P,F}$ = partition coefficient of the migrant over material P and liquid F (without dimensions) defined by:

$$K_{p,f} = \frac{c_{P,\infty}}{c_{F,\infty}} \frac{\rho_P}{\rho_F}$$

3

with:

$c_{P,\infty}$ = the migrant's balanced content in material P (mg/kg);
ρ_P = material P's density (g/cm^3);
$c_{F,\infty}$ = the migrant's balanced content in liquid F (mg/kg);
ρ_F = liquid F's density (g/cm^3);
q_n = the positive roots of the "transcendent" equation $\tan q_n = -\alpha q_n$;
D_P = the migrant's diffusion coefficient in material P (cm^2/s);
t = the migration time (s).

It is assumed in this calculation that the migrant at the start of the mass transport is distributed homogenously in the polymer material P, and that there is no threshold resistance for the transfer of the substance between P and F. The migrant is also distributed homogenously in F, and the total volume of the migrant in P and F is constant throughout the migration process. The following prerequisites must always be met in drinking water or warm tap water applications (pipe materials):

- All starting substances in a product's formulation are distributed homogenously;
- There is no resistance throughout the transfer of the substance from the wall of any pipe or fitting to the drinking water or warm tap water;
- The migrant will be distributed homogenously in the water due to the flow of the drinking water or warm tap water (practice) or due to diffusion in the water (migration water);
- The migrant has no other "source of origin"; therefore, its total volume will not change in the synthetic material or in the water.

If it is assumed that the thickness of the packaging (for example, the wall of a pipe) is infinite (thus, enough "availability" at the migrant), that the migrant's solubility in the well mixed liquid is high, and that the migration process is far under the balance (less than 60 % of the initial concentration is migrated), then equation 1 will result in:

$$\frac{m_{F,t}}{A} = 2c_{p,0}\rho_p \sqrt{\frac{D_P t}{\pi}}$$

4

The partition coefficient of polymer/food

The partition coefficient represents the distribution between the concentration of a migrant in the plastic material and in the medium the material is contacting. The value of the partition coefficient depends on the degree of interaction between the migrant and the synthetic material on one hand, and between the migrant and the medium on the other hand. This means that each "pair" of plastic/medium/migrant has its own value for the partition coefficient. If specific data are unavailable, the partition coefficient of a migrant between the plastic material and the medium $K_{P,F}$ = 1 may be used if the migrant has a good solubility in the medium. If a migrant is "not" soluble in the medium, $K_{P,F}$ = 1,000 may be used. It is recommended to use partition coefficients identified in experiments if they are available.

The diffusion coefficient

Similar dependence factors apply to the diffusion coefficient as those for the partition coefficient. The diffusion coefficient depends on the properties of the polymer and the migrant. The maximum diffusion coefficient (D_P^* in lieu of D_P) may be calculated on the basis of the migrant's mass and two constant values that are specific for the polymer:

$$D_P^* = 10^4 \exp\left(A_P - 0{,}1351 M_r^{\frac{2}{3}} + 0{,}003 M_r - \frac{10454}{T} \right)$$

5

With:

$$A_P = A'_P - \frac{\tau}{T}$$

6

A'_P = a polymer-specific “diffusion conducting capacity”;
τ = a polymer-specific “activating energy”;
T = the temperature (K);
M_r = the relative molecular weight of a migrant (D);
D^*_P = the polymer-specific maximum diffusion coefficient (cm^2/s).

The use of the maximum diffusion coefficient D_p^* implies that the migration is overestimated. If an exact diffusion coefficient is available for a certain migrant/polymer pair, it may be used instead of the maximum diffusion coefficient.

Table showing (migration) tests and measuring methods to identify the organoleptic aspects of products contacting drinking water or warm tap water. The products are described in Annex A.

Product	**(Migration) tests**			**Measuring methods**		
	odour/ flavour	colour	turbidity degree	odour/ flavour	colour	turbidity degree
Plastic and rubber products for storage and distribution systems:						
pipes, including coatings	NEN-EN 1420-1	NEN-EN 13052-1	NEN-EN 13052-1	NEN-EN 1622	NEN-EN-ISO 7887	NEN-EN-ISO 7027
fittings, including coatings	NEN-EN 1420-1	NEN-EN 13052-1	NEN-EN 13052-1	NEN-EN 1622	NEN-EN-ISO 7887	NEN-EN-ISO 7027
O-rings	NEN-EN 1420-1	NEN-EN 13052-1	NEN-EN 13052-1	NEN-EN 1622	NEN-EN-ISO 7887	NEN-EN-ISO 7027
coupling units (flexible connection lines and compensators)	NEN-EN 1420-1	NEN-EN 13052-1	NEN-EN 13052-1	NEN-EN 1622	NEN-EN-ISO 7887	NEN-EN-ISO 7027
joint fillers	NEN-EN 1420-1	NEN-EN 13052-1	NEN-EN 13052-1	NEN-EN 1622	NEN-EN-ISO 7887	NEN-EN-ISO 7027
foils	NEN-EN 14395-1	NEN-EN 14395-1	NEN-EN 14395-1	NEN-EN 1622	NEN-EN-ISO 7887	NEN-EN-ISO 7027
adhesives		being developed		NEN-EN 1622	NEN-EN-ISO 7887	NEN-EN-ISO 7027
sealants and/or retainers		being developed		NEN-EN 1622	NEN-EN-ISO 7887	NEN-EN-ISO 7027
Membranes (other than end-of-use products)		none	none	N/A	N/A	N/A
Metallic products for storage and supply systems (pipes, fittings, solder and welding material, reservoirs)	none	none	none	N/A	N/A	N/A
Cementitious products for storage and supply systems						
pipes (concrete and liners)	NEN-EN 14944-1	NEN-EN 14944-1	NEN-EN 14944-1	NEN-EN 1622	NEN-EN-ISO 7887	NEN-EN-ISO 7027
fittings (concrete and liners)	NEN-EN 14944-1	NEN-EN 14944-1	NEN-EN 14944-1	NEN-EN 1622	NEN-EN-ISO 7887	NEN-EN-ISO 7027
reservoirs (on site)	NEN-EN 14944-2	NEN-EN 14944-2	NEN-EN 14944-2	NEN-EN 1622	NEN-EN-ISO 7887	NEN-EN-ISO 7027
concrete repair means	NEN-EN 14944-2	NEN-EN 14944-2	NEN-EN 14944-2	NEN-EN 1622	NEN-EN-ISO 7887-4	NEN-EN-ISO 7027
Compound products, including		being developed		NEN-EN 1622	NEN-EN-ISO 7887	NEN-EN-ISO 7027

lubricants						
auxiliary agents (slipping agents, release agents, mould release agents, curing compounds)	none	none	N/A	N/A	N/A	
Chemicals	none	none	none	N/A	N/A	N/A

ANNEX D – ASSESSMENT METHODS

1 Required toxicity data

The toxicological assessment will be performed by using data collected from a number of standardised animal tests and cell culture system assays. The required tests are further described in Annex E.

1.1 Core set

The required toxicity data must be submitted by the applicant, and must consist of the following basic set:

- 3 mutagenicity studies *in vitro*:
    a) a test for induction of gene mutations in bacteria
    b) a test for induction of gene mutations in mammalian cells (preferably the mouse lymphoma assay)
    c) a test for induction of chromosomal aberrations in mammalian cells

- a 90-day oral toxicity study, normally in two species

- studies on absorption, distribution, metabolism and excretion

- studies on reproduction in one species, and developmental toxicity, normally in two species

- studies on long-term toxicity/carcinogenicity, normally in two species

This set of toxicity data is consistent with the guidelines described in the Note for Guidance issued by the European Food Safety Authority (December 2004, last *update* dated 30 July 2008) for the assessment of substances, and is also consistent with the data set that must be submitted within the context of the Environmentally Hazardous Substances Act for chemicals of which more than 1 000 Tons are produced annually.
If the results of the aforementioned studies or a substance's chemical structure so warrant, further toxicological tests may be required. Further tests may also be required if a substance is widely used, and/or in the case of high and not decreasing migration. In certain cases, data about the toxicity of the decomposition products may be necessary.

1.2 Reduced core set

Under certain circumstances, for example if it is expected that the contact surface or the dosage level of a product results in migrant/contaminant concentrations that are so low that the risks for the health of consumers are negligible, a toxicological assessment may be made on the basis of a reduced core set:

- The three mutagenicity studies described above;

- A 90-day oral toxicity study;

- Data showing the absence of potential for accumulation in man.

In exceptional cases, for example if the related substance is used only in end products with F_{go} under 0,01 (see Part 3 of this Annex), the three mutagenicity studies listed above may suffice.

1.3 Disinfectants and cleaning agents

To assess disinfectants and disinfecting cleaning agents for specific use in drinking water or warm tap water applications covered by the 2007 Plant Protection Products and Biocides Act, an authorisation issued by the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) is required.

Once the Ctgb has issued its authorisation, a quality certificate will be issued for these agents in accordance with the Regulation. Cleaning agents not covered by the Plant Protection Products and Biocides Act are assessed by the Committee.

2 Determining the Maximum Tolerable Concentration - MTC

2.1 MTC for Total Organic Carbon (TOC)

The European Commission has determined that an overall migration limit of 60 mg/kg of food or food simulant applies to plastic materials that come in contact with food. If one assumes that the daily intake of an adult is 1 kg of food and two litres of water, and that a 10 % allocation applies (see 2.5), then an overall migration limit of 3 mg/L applies to plastic and rubber products that contact drinking water. This leads to a 2 mg/L TOC value assuming that the quantity of organic carbon in the migration water is approximately 2/3 of the total migration.

In a stochastic mechanism, the likelihood of effects over a dose range will increase if doses are stepped up. In such cases, it is basically impossible to identify a threshold dose, In general, this action mechanism is related to irreversible effects at molecular level, for example irreversible, self-replicating DNA changes (so-called genotoxic effects). Examples of substances without a threshold dose include the genotoxic and carcinogenic compounds acrylamide, vinyl chloride and epichlorohydrin.

2.2 Functional mechanisms of substances

Exposure to some substances can be associated with a variety of bodily dysfunctions which have health implications. The mechanisms of action of the substances causing these dysfunctions can be divided into two different groups: a stochastic (non-threshold) and a non-stochastic (threshold) mechanism of action.

2.2.1 Stochastic mechanism of action

With a stochastic mechanism of action the chance of a given effect occurring increases as the dose of the substance concerned increases (within a certain dose range). It is not generally possible to discern a threshold dose at or beneath which the change of the effect taking place is zero. Mechanisms of this type are generally associated with irreversible molecular-scale effects such as irreversible DNA changes. Examples of substances with a stochastic mechanism of action are acrylamide, vinyl chloride and epichloro hydrin. As established in Article 7(3) the MTC applicable to these and the substances with a stochastic mechanism of action which are not mentioned in the Drinking Water Decree is 0,1 µg/L.
This 0,1 µg/L value means that substances that are not assigned this threshold value must basically be undetectable (precaution standard). However, it has been documented that the health risks for humans on the basis of the current measures are negligible in case of exposure to genotoxic substances in concentrations under 0,1 µg per litre of drinking water. In this latter case, the 0,1 µg/L value is known as the *Threshold of Toxicological Concern* value (TTC value)[17].

2.2.2 Non-stochastic mechanism of action

With a non-stochastic or deterministic mechanism of action an adverse effect only takes place once the dose of the substance concerned exceeds a certain threshold level. Above that level the size of the effect will increase as the dose increases. For substances with a deterministic mechanism of action health-based recommended exposure limits (Tolerable Daily Intake – TDI) are calculated by dividing the No–Observed–Adverse–Effect Level (NOAEL) obtained in animal experiments by an assessment factor[18] (AF, see the REACH-R.8-Guideline[19]) accounting for interspecies uncertainty and

[17] On the basis of the current state of the art, individual TTC values higher than 0,1 µg/L may be used for various groups of compounds. However, using TTC values higher than 0,1 µg/L is inconsistent with the principle of precaution.
[18] EFSA calls uncertainty factor, UF.
[19] "Guidance on information requirements and chemical safety assessment Chapter R.8: Characterization of dose [concentration]-response for human health"

intraspecies uncertainty and variability. Often an overall AF of 100 is used, although additional AFs may be required, e.g. for differences in exposure duration and deficiencies in the toxicological database. This results in the following formula:

$$\text{TDI (mg/kg body weight)} = \frac{\text{NOAEL (mg/kg body weight)}}{\text{Overall AF}}$$

The TDI is the basis for setting up a MTC_{tap} for substances with a deterministic mechanism of action.

If a NOAEL is not available, then the Lowest-Observed-Adverse-Effect Level (LOAEL) may be used. This has to be accounted for in calculating the overall AF (AF for LOAEL-to-NOAEL extrapolation).

2.2 Allocation to drinking water (default values)

If appropriate information on levels of exposure to a substance from food, air and drinking water is not available, an allocation factor may be applied reflecting the likely contribution of drinking water to the TDI for this substance. In conformity with the derivation of limit values in EC Directive 98/83/EC (DWD), the Drinking Water Decree and the WHO Guidelines for Drinking-water Quality it has been agreed that, in the absence of adequate exposure data, the allocation of the TDI to drinking water should have an arbitrary (default) value of 10%. Deviations are possible if based on well-founded arguments.

Because exposure to the substances named in the Drinking Water Decree[20] can take place via drinking water without this water having been in contact with products in which the same substances occur a supplementary provision has been drawn up to the effect that no more than 10% of the maximum value of the parameter with a non-stochastic mechanism of action named in the Drinking Water Decree on health grounds may originate from a product that comes into contact with the drinking water (10% rule) This means that for Drinking Water Decree parameters with a non-stochastic mechanism of action the allocation factor due to migration from products is 1%.

The Commission Regulation (EU) No 10/2011 and the Dutch Packaging and Consumer Items Decree (WVG) are the cornerstones in identifying MTC values. In these documents specific migration limits (SMLs) are laid down for a large number of substances. The SML is the maximum acceptable quantity of a substance (originating from packaging material) per kg food, assuming that an adult with a body weight of 60 kg consumes 1 kg food per day. When SMLs are laid down, exposure routes other than food are not taken into account. This means that the SML in this case corresponds with the TDI per person (mg/kg body weight converted into mg/person in the event of a daily intake of 1 kg food). Taking into account the abovementioned allocation for drinking water of 10% (default value) and a consumption of two litres drinking water per day, the SML is divided by a factor of 20 to arrive at an MTC.

In practice, it can hardly ever be ascertained that exposure to a specific substance will solely take place via drinking water. The approach that drinking water may not contribute more than 10% of the TDI therefore applies, including for substances for which there are as yet no limit values in the EC Directives 98/83/EC and the Commission Regulation (EU) No 10/2011 and for which a TDI and MTC have to be derived.

2.3 Arithmetical derivation of the MTC

(http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1319614960#r8).

[20] In view of the legal context in which the Regulation is operational, only the Drinking Water Decree can be referred to. The Drinking Water Decree, Directive 98/83/EC and the WHO Guidelines for Drinking water quality are very similar as far as the identified threshold values are concerned.

Based on what has been mentioned in 2.1 and 2.2 the following arithmetical derivations can be used.

2.3.1 For substances with a stochastic mechanism of action:

MTC = 0.1 µg/l

2.3.2 For substances with a deterministic mechanism of action:

If for the relevant substance a parametric value in the Drinking Water Decree exists an MTC can be derived according to formula A. If only a WHO Guideline value exists the MTC is derived analogously.

$$\textbf{A} \qquad \textbf{MTC (mg/l)} = \frac{\textbf{Parametric value in Drinking Water Decree (mg/l)}}{\textbf{10}}$$

If for the relevant substance a specific migration limit (SML) is mentioned in the Commission Regulation (EU) No 10/2011 an MTC can be derived according to formula B.

$$\textbf{B} \qquad \textbf{MTC (mg/l)} = \frac{\textbf{SML (mg/kg of food) x 1 (kg)}}{\textbf{2 (L) x 10}}$$

If for the relevant substance a health-based guideline value is *not* mentioned in the Drinking Water Decree and an SML is also *not* available then an MTC can be derived according to formula C after setting up a TDI on the basis of the required toxicological data (see 1.1).

$$\textbf{C} \qquad \textbf{MTC (mg/l)} = \frac{\textbf{TDI (mg/kg body weight) x 60 (kg)}}{\textbf{2 (L) x 10}}$$

3 Conversion Factors (CFs)

The S/V ratio of the test sample and the contact time used in the migration test according to EN 12873 are different to the real use of the end products in practice. Therefore, the concentrations determined in the migration test have to be converted. The application of CFs (dimension day/dm) aims to recognize the level of impact on drinking water quality that will arise from the product in its normal operating situation.

The purpose of a CF is to achieve a comparison between the results of the experimental migration test or modelling with the relevant MTC.

CFs are dependent on the application of a product. Therefore, a CF is made up of a geometrical factor (F_g – Surface-to-Volume ratio – dimension dm^{-1}), which is determined by the end product, and an operational factor (F_o – dimension day) which is calculated from the residence or contact time of the water. Thus:

$$CF = F_g \times F_o \qquad [d\ dm^{-1}] \qquad (1)$$

In accordance with EN 12873-1 the results of the experimental migration test are calculated as follows:

$$M_n = C_n / (S/V \,.\, t) \qquad [mg\ dm^{-2} d^{-1}] \qquad (2)$$

where

n	is the sequence number of the migration period (1, 2, 3,…..10)
M_n	is the migration rate for the n^{th} migration period
C_n	is the concentration of the measured substance in mg/L for the n^{th} migration period
t	is the duration of the migration period in days
S/V	is the surface area-to-volume ratio in dm^{-1}

The estimated concentration at the consumer's tap (C_{tap}) is calculated from:

$$C_{tap} = M_n \times CF = C_n / (S/V \,.\, t) \times CF \qquad [mg\ dm^{-3}] \qquad (3)$$

Equations (2) and (3) imply the assumption that the migration rate is constant in time, independent of the concentration already present in the drinking water.

The results of the 3rd migration period according to EN 12873 (both for testing at 23 ºC and and at 60 °C or 85 °C) are used to estimate the concentration at the tap (C_{tap}). This value is compared with the respective MTC.

If equation (3) shows that the relevant MTC cannot be met after three migration periods, and if it can be expected or shown that the migration rate will decrease in time, the migration testing (both for testing at 23 ºC and elevated temperatures) can be extended to a total migration time of 30 days at the utmost.

At variance with Annex C of EN 12873-1 and EN 12873-2 the migration periods for cold water testing (23°C) are: 72 hours, 72 hours, 72 hours, 96 hours, 72 hours, 96 hours, 72 hours, 96 hours and 72 hours. All migration samples obtained with a migration period of 3 days have to be analyzed for the relevant substances.
For testing at elevated temperature (60°C or 85°C) the migration periods are: 3 x 24 hours, 72 hours, 4 x 24 hours, 72 hours, 4 x24 hours, 72 hours, 4 x 24 hours, 72 hours and 3 x 24 hours . All migration samples obtained on the 1st, 2nd, 3th, 7th, 12th, 17th and 22nd migration period have to be analyzed for the relevant substances (the periods marked grey in the '30 day' column). If the migration is stopped after the 9th migration period than the samples obtained on the 1st, 2nd, 3rd, 6th, 7th and 8th migration period have to be analyzed for the relevant substances.

The following product groups and relevant CFs are applicable:

Table 1: Product groups and CFs

Product group	CF in d/dm
A. Pipes and their linings:	
1 ID < 80 mm (domestic installations, buildings) [1)]	20
2 80 mm ≤ ID < 300 mm (service piping)	10
3 ID ≥ 300 mm (mains piping)	5
B. Fittings, ancillaries [2)]	
1 ID < 80 mm (domestic installations, buildings)	4
2 80 mm ≤ ID < 300 mm (service piping)	2
3 ID ≥ 300 mm (mains piping)	1
C. Components of fittings, ancillaries [3)]	
1 ID < 80 mm (domestic installations, buildings)	0,4
2 80 mm ≤ ID < 300 mm (service piping)	0,2
3 ID ≥ 300 mm (mains piping)	0,1
D. Storage systems	
1 In domestic installations, buildings	4

2	In water supply	1
E.	**Repair products for storage systems**	
1	In domestic installations, buildings:	
1.1	products covering the total surface or a substantial part of that (e.g. coatings)	4
1.2	products covering < 1% of the total surface	0,04
2	In water supply:	
2.1	products covering the total surface or a substantial part of that (e.g. coatings)	1
2.2	products covering < 1% of the total surface	0,01

Footnotes to Table 1:
1) If from a series of different diameter pipes made from the same raw and ancillary materials under the same manufacturing process (a so-called product family) the smallest diameter pipe is assessed and approved, then the whole series of different diameter pipes is allowed to be used for all application areas within the product group without further testing.
2) Complete functional unit made up of one or more components or materials, parts of which are in contact with water, e.g. taps, valves, pipe connectors and flexible hose assemblies.
3) O-rings, components of assembled products. If an assembled product is tested as a unit (not disassembled) then it attracts a CF from Group B.

The CFs for pipes are estimated according to the following assumptions:

Product Group	**Fg = S/V Worst Case Surface/ Volume ratio in dm^{-1}**	**F_O = t Assumed Residence Time in d**	**CF = $F_g \times F_o$**
Mains piping (ID ≥ 300 mm)	1.33	4	**5**
Service Piping (80 mm ≤ ID < 300 mm)	5	2	**10**
Domestic installations, buildings (10 mm ≤ ID < 80 mm)	40	0.5	**20**

The CFs for the fittings and ancillaries of product group B express the extent to which the CFs of the pipes (and their linings) of product group A are reduced due to the fact that the water only comes into contact with the product over part of the length of the pipe (reduction or fraction factor F_f). For fittings and ancillaries this factor is fixed at 0.2:

$$\text{CF group B} = \text{CF group A} \times 0.2 \quad (4)$$

Analogically, an F_f of 0.1 is fixed for the components of fittings and ancillaries of product group C, expressing the extent to which the CFs of product group B are reduced:

$$\text{CF group C} = \text{CF group B} \times 0.1 \quad (5)$$

For some (parts of) products, a CF < 0,01 d/dm may be calculated. In such cases, the Committee may decide if assessment and test methods may be limited.

4 Calculation of the expected concentration of a substance in drinking water or warm tap water

If it is impossible to provide accurate toxicity data as described in Annex (1), and if it is impossible to avoid the use of the substance, in accordance with Article 7, the substance's authorisation may be assessed on the basis of information collected from a theoretical calculation. The following criteria and assumptions apply:

- The concentration of a genotoxic substance in drinking water or warm tap water, or a substance for which the genotoxic potential has not been (adequately) studied, shall not exceed 0,1 µg/L 10 days after the initial use of the product in which the substance was detected.
- If it has been satisfactorily demonstrated that a substance is not genotoxic, its concentration in drinking water or warm tap water shall not exceed 2,5 µg/L 10 days after the initial use of the product in which the substance was detected.
- Calculations on the expected (end) concentration in drinking water or warm tap water shall include:
    - The residual level of the substance in the end product, as indicated by the manufacturer or supplier;
    - The relevant diffusion coefficient;
    - The conversion factors described in paragraph 3;
    - The end product's application;
    - The life of the end product in which the related substance was detected;
    - A linear decrease of the concentration (migration) of the substance in drinking water or warm tap water;
    - The substance's behaviour in an aqueous environment.
- The Toxicity Subcommittee will make the theoretical calculation, as set forth in Article 4(3), and Article 8(2) and (3), thereafter the Committee will make the decision about the substance's authorisation.

ANNEX E – GENERAL AND SPECIFIC DATA TO BE PROVIDED FOR THE TOXICOLOGICAL EVALUATION OF PRODUCTS, OTHER THAN METALLIC PRODUCTS

1 General, relationship with positive lists and recognised quality certificate

This Annex describes the general and specific data required for the toxicological evaluation of (the raw and auxiliary materials of) end products other than metallic products, and the inclusion of each raw or auxiliary material in one of the positive lists of Annex B.

Pursuant to Article 11, any substance assessed for the purpose of issuing a recognised quality certificate will be added to a positive list only upon the applicant's consent.

The evaluation of raw and auxiliary materials is related to individual substances, mixtures of substances or polymers used as additives, as well as the contaminants, intermediates products and decomposition products in the end product (see also the first section of Annex B). The raw and auxiliary materials must be used to manufacture materials and chemicals described in Annex A (end products), with the exception of metallic materials and end products.
For the evaluation of metallic materials and end products, the rules described in Section 2.8 of Annex A must be used.

End products composed of or with materials for which general assessment criteria are not identified yet, such as ceramic materials, enamel and silicones, must be assessed separately in accordance with Articles 6-9 of the Regulation, and by using criteria further to be defined by the Committee, if necessary.

The rules and criteria in effect to obtain a recognised quality certificate are described in Articles 12-19 of the Regulation.

The application for the evaluation of any end product or an individual substance must be submitted to the Committee's secretary. The mailing address is: Kiwa Nederland BV, Postbus 70, 2280 AB RIJSWIJK, the Netherlands.

2 Data to be provided: the technical dossier

The technical dossier, as well as the supplementary information for a re-assessment, should be submitted in writing or digital.

Recorded on the label affixed to a CD-ROM must be the name of the substance, the name of the applicant, the date of submission, and the number of the CD-ROM (if multiple CD-ROMs are submitted per file).

Recorded on the CD-ROM must be a detailed table of content, of which a copy must be submitted with the application.

The technical specifications shall contain at least the following data about the end product (paragraph 2.1) and the composing raw and auxiliary materials (paragraph 2.2, with the details described in Section 3 of this Annex):

2.1 Data to be provided for the end product

2.1.1 The trade name(s)

2.1.2 The area of application

A description of the use of the end product in the drinking water or warm tap water supply (water storage and distribution systems, drinking water or warm tap water systems)

2.1.3 The manufacturing process

A short description of the manufacturing process with a complete quantitative list of all raw and auxiliary materials used in the manufacturing process

2.1.4 Contaminants, intermediates and decomposition products

Data about the contaminants, intermediates and decomposition products in the end product.

2.2 Data to be provided for the raw and auxiliary materials

2.2.1 Identity of substance

The name and all relevant data about the substance, potential contaminations and data about decomposition and reaction products.

2.2.2 Physical and chemical properties of the substance

All relevant physical and chemical data about the substance, including the decomposition and reaction products.

2.2.3 The substance's function in or for the manufacture of the end product

2.2.4 Information about the authorisation of the substance in a different context

Information about records in EU Directives, the use in other EU Member States, or other countries, such as the United States of America and Japan.

2.2.5 Chemical analysis method(s)

2.2.6 Toxicity data

All the substance's relevant toxicity data. In certain circumstances, the applicant may submit a reduced core set of data (see also Annex D).

3 Further description of data to be provided

3.1 Identity of substance

3.1.1 Individual substance

The information described in 1.1.1-1.1.10 must be submitted for individual substances. The information described under 1.2. must be submitted if the application is not related to an individual substance.

3.1.1.1 Chemical name

3.1.1.2 Synonym(s)

The best known synonyms, such as the IUPAC name.

3.1.1.3 Trade name(s)

3.1.1.4 CAS number

3.1.1.5 Molecular and structural formula

3.1.1.6 Molecular weight

3.1.1.7 Purity (%)

The substance's purity as a percentage, and the method used to define the purity.

3.1.1.8 Impurities (%)

Impurities, the levels of impurities (in percentages), and the methods used to define the impurities.

3.1.1.9 Specifications

Suggested specifications of the substance in the positive list.

3.1.1.10 Additional information

Additional information that may be relevant for the evaluation of the substance.

3.1.2 Defined mixture

The data under 3.1.1 must be submitted for defined mixtures, supplemented with information about the composing ingredients/components. The requested data for non-defined mixtures are described under 3.1.3.
This section only covers *process mixtures* obtained in a reproducible process for which it is easy to define the composition, such as a mixture of isomers. This section does not cover synthetic mixtures knowingly composed of individual substances. Their composing components must be assessed individually.

3.1.3 Non-defined mixture

Undefined mixtures may vary from batch to batch, but are composed on the basis of defined specifications. Examples of undefined mixtures are products originating from natural sources. Technical processes as well, such as ethoxylation, epoxydation and hydrogenation, may result in a large number of individual components. The best suitable specifications must be submitted.

For undefined mixtures, the requested data described under 3.1.1 for the individual substances, supplemented with information about the composing ingredients/components, the manufacturing process, the substances created, and the purification of the mixture.

3.1.4 Polymer used as additive

Polymeric additives are polymers and/or prepolymers and/or oligomers added to plastics to obtain a technical effect, but cannot be used as such to manufacture an end material or product. They may include as well polymeric substances added to the medium in which the polymerisation occurs.

For polymers used as additives, aside from the requested information described under 3.1.1, additional data will be requested about the additives, the structure of the polymer, the viscosity (intrinsic and/or relative), the melt flow index, and the density (g/cm^3).

3.2 Physical and chemical properties of substance

3.2.1 Physical properties

3.2.1.1 Melting point (°C)

3.2.1.2 Boiling point (°C)

3.2.1.3 Solubility (g/L)

Requested information is the solubility in water and organic solvents.

3.2.1.4 Octanol/water partition (log $P_{o/w}$)

3.2.1.5 Additional information

Only other, relevant information.

3.2.2 Chemical properties

3.2.2.1 Reactivity

3.2.2.2 Stability

Information about the stability of the relevant compound towards light, heat, moisture, air, ionising radiation, oxidative treatment, etc.

3.2.2.3 Hydrolysis

If applicable, information about hydrolysis in water, including any test results.

3.2.2.4 Intentional decomposition/transformation

Information about the substance's decomposition or transformation during the manufacturing process of the end product that comes in contact with drinking water or warm tap water. In cases of doubt, additional information about the toxicity of the decomposition products may be requested, and further requirements may be defined. Monomers are deemed embedded in the polymer, while additives are converted in accordance with the application.

3.2.2.5 Unintentional decomposition/transformation

Information about the unintentional decomposition and transformation products of the pure substance, formed in the material during the manufacture of an end product or formed during various treatments likely to be applied to the end product (e.g. ionising treatments).

3.2.2.6 Additional information

Other, relevant information, such as pKa and pKb

3.3 Intended application of substance

3.3.1 Material/end product

For which types of materials and end products the substance at issue may be used. This information may be relevant to estimate the risks (small contact surface, etc.).

3.3.2 Technological function

The substance's function in the manufacturing process or in the end product (monomer, co-monomer, antioxidant, etc.).

3.4 Information about the authorisation of the substance in a different context

It must be reported if the substance is authorised, for example for products that come in contact with food, is used in EU Member States or other countries (USA, Japan), or is being assessed in another country.

3.5 Chemical analysis method(s)

The reasons why the chemical analysis method(s) was (were) used, including data about the detection limit, recovery, calibration, blanks, etc., must be reported.
The chemical analysis method must be described in as much detail as possible, so that test results can be adequately evaluated.

3.6 Toxicity data

The complete, dated and signed reports of the toxicity studies must be submitted. The studies must be performed in observance of internationally accepted methods and guidelines, as described in Directive 67/548/EC, and the most recent versions of the OECD guidelines. In addition, studies must be conducted pursuant to the principles of *Good Laboratory Practice* (OECD Principles of Good Laboratory Practice, Organisation for Economic Co-operation and Development, 1998, Paris).
The test substances must be described accurately (see section 1), and must be the commercial substances for which the authorisation is applied. Especially the test substance's purity, as well as the identification of the contaminations, must be consistent with those of the commercial substance (see Annex D for further details).

3.6.1 Genotoxicity

3.6.1.1 Gene mutation test in bacteria

According to EC method B.13/14 and OECD Guideline 471

3.6.1.2 In vitro mammalian cel gene mutation test

According to EC method B.17 and OECD Guideline 476

3.6.1.3 In vitro mammalian chromosome aberration test

According to EC method B.10 and OECD Guideline 473

3.6.1.4 Other information

If any of the above tests yields a positive or equivocal result, further mutagenicity tests, including *in vivo* assays, may be required to elucidate the genotoxic potential of the substance. The Toxicity Subcommittee will decide which additional test(s) must be conducted.

3.6.2 General toxicity

3.6.2.1 Subchronic (90-day) oral toxicity study

According to EC method B.26 and OECD Guideline 408

3.6.2.2 Chronic toxicity/carcinogenicity

According to EC method B.33 and OECD Guideline 453

3.6.2.3 Reproduction/teratogenicity

According to EC methods B.34 and B.35 and OECD Guidelines 421 and 422

3.6.2.4 Other information

Additional, relevant information, such as data about acute and subacute (28-day) toxicity. Dermal and inhalation effects should be provided when available.

3.6.3 Metabolism

3.6.3.1 Absorption, distribution, biotransformation and excretion
All available, relevant information, including data about potential accumulation in man.

3.6.3.2 Additional information

Additional information about a substance's metabolism that may be relevant for the evaluation.

3.6.4 Other studies

If the results of the aforementioned studies or a substance's chemical structure so warrant, information of the effects on the immune system,neurotoxicity, etc., may be required. The Toxicity Subcommittee will determine the type of additional tests.

EXPLANATORY MEMORANDUM

General

0. Introduction

In 2003, the predecessor of the present Regulation, the Materials and Chemicals in the Tap Water Supply Act (hereinafter referred to as the "2003 Regulation") came into effect. This regulation was, in turn, the continuation of the Inspection of the Guideline Quality of Materials and Chemicals for Drinking Water Supplies (Published Document 92-04 by the of Minister of Housing, Spatiall Planning and the Environmental(VROM), hereinafter referred to as the "Inspection Guideline". The 2003 Regulation created a national legal framework for the assessment of the materials and chemicals that (may) come into contact with drinking water and warm tap water and may affect its quality. This was in accordance with Article 10 of Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330; hereinafter referred to as the Drinking Water Directive).

It was provided during this implementation that the rules for materials based on the drinking water laws would apply only to materials that are not part of a building covered by the Housing Act. The Building Decree applies to materials that are part of a building, and therefore the regulation was also based on Article 3.107 of the Building Decree.

The 2003 Regulation was significantly based on the aforementioned Inspection Guideline. However, this guideline was limited, some items were outdated, and not all products and aspects set forth in the legal provisions were covered. It was specified in the explanatory memorandum attached to the 2003 Regulation that items not covered and items to be amended were being prepared. Today, this preparatory work is completed and the results are included in the present Regulation, which replaces the 2003 Regulation.

1. Legal framework and elements of the Regulation

1.1 Legal framework

It is set forth in Article 10 of the Drinking Water Directive that the Member States must take all measures necessary to ensure that products used in the preparation, distribution and storage of drinking water or warm tap water do not adversely affect the quality of the water and do not adversely affect the protection of public health.
In addition, there is a connection with another European Directive, *i.e.* Directive 89/106/EEC of the Council of the European Economic Community of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products (OJ L 40; hereinafter referred to as the "Construction Products Directive".
Article 10 of the Drinking Water Directive provides that its requirements must be respected by basic documents and technical specifications prepared pursuant to Article 3 and Article 4(1) of the Construction Products.

Article 10 of the Drinking Water Directive was implemented in 2000 with the Water Supply Act. The replacement of the Water Supply Act by the Drinking Water Act has implemented this provision now by means of Article 21(3)(c) (in conjunction with Article 25(1), and Article 29(2)) of the Drinking Water Act, Articles 19 and 20 of the Drinking Water Decree and the present Regulation.

It was provided by the implementation of Article 10 of the Drinking Water Directive into the Dutch drinking water regulations that the rules for materials based on this act would apply only to materials that are not part of a building, which are covered by the Housing Act. Therefore, the rules for materials that are part of a building are based on the 2003 Building Decree. For this reason, the Regulation is also based on Article 3.107 of the 2003 Building Decree.

Article 3.107 of the 2003 Building Decree specifies that a ministerial regulation may provide for the rules for materials to be used in a building that may release toxic or harmful substances or may

generate ionising radiation as specified in Article 1(1)(e) of the Nuclear Energy Act. Because Article 3.107 of the 2003 Building Decree is one of the grounds for the present Regulation, it also applies to the materials used in the distribution of drinking water or warm tap water in (newly built) buildings and other constructions covered by the Housing Act.

Finally, it must be noted that the Regulation is consistent with Decision 2002/359/EC of the Commission of the European Communities of 13 May 2002 on the procedure for attesting the conformity of construction products in contact with water intended for human consumption pursuant to Article 20(2) of the Construction Products Directive. This decision provides that the conformity of said products is determined because a recognised certifying body must be involved in testing and monitoring the manufacturing process of the product, aside from the manufacturer's internal quality monitoring system.

1.2 Elements of the Regulation

The Regulation contains the following requirements and rules:

- Requirements for all products (materials and chemicals) used in the drinking water or warm tap water supply in view of protecting the health of consumers
- Requirements and guidelines for testing and assessing all products (materials and chemicals) and the substances they consist of or those used in the manufacturing process
- Requirements to be complied with by the manufacturer to obtain a recognised quality certificate
- Rules for the issue of a recognised quality certificate by a certifying body
- Rules for recognising quality certificates
- Rules for the issue of a statement of no objection (temporary quality certificate)
- Rules related to the Committee

The issue of a recognised quality certificate also means that the owner of a drinking water company, a collective drinking water or warm tap water system or a collective mains system has complied with the duty of care as set forth in the Drinking Water Decree.

2. Conversion of the 2003 Regulation into a regulation on the basis of the Drinking Water Act and other aspects

2.1 The starting point: the 2003 Regulation

As described above, the 2003 Regulation is based significantly on the Inspection Guideline. One essential part of the Inspection Guideline was the creation of so-called material-related positive lists for selected products or product groups. The Inspection Guideline includes lists for rubber products and four types of plastics, *i.e.* polybutylene, polyethylene, polypropylene and polyvinyl chloride. These lists include raw materials and auxiliary materials that were (and are) permitted for use under conditions to be further described in the manufacturing of the related finished products, or were (or are) allowed to be present in the related finished products. General descriptions of the specific products, maximum dosages and the related purity requirements were included and defined for eleven chemicals.

Since 1992, the aforementioned positive lists have been significantly reviewed and extended. In addition, modifications in the (toxicology) evaluation systems for the substances have been put in place. The introduction of the Regulation has made it possible to assess all materials and chemicals that contact drinking or warm tap water in accordance with the objective of the Water Supply Act. This includes that, aside from plastics and rubber products, metallic and cementitious products, for example, should also be assessed thereby including in the procedures for authorisation not only toxicology aspects, but also organoleptic and microbiology aspects.

When the 2003 Regulation was issued, it was noted that it was still incomplete and that various parts required further investigation. On this basis, the transitional rules for the existing practice referred to in the Inspection Directive have been added to the Regulation. The topics deemed important for the implementation of legal provisions when the 2003 Regulation was introduced, are described in the results of the "Development" of the Dutch assessment system for materials and chemicals for use in

drinking water project. This project has been completed by Kiwa Netherlands BV (formerly Kiwa Certification and Inspection) and was commissioned by (and completed in close cooperation with) the Minister of Housing, Spatial Planning and the Environmental (VROM), the National Institute for Public Health and the Environment (RIVM), the Netherlands Water Works Association (Vewin), the Dutch Standards Institute (NEN), KWR Watercycle Research Institute (formerly Kiwa Water Research), and the following organisations: Bureauleiding (formerly the Association of Plastic Pipe Systems Manufacturers, FKS), Copper Benelux, European Copper Institute, Plastics Europe Association, Stichting Beton Losmiddel Fabrikanten (the Association of Dutch Concrete Mold Release Manufacturers), the Association of Suppliers of Concrete Repair and Protection Products (VLB), the Association of Manufacturers of Mortar and Concrete Supplies (VHB), the Association of Concrete Mortar Manufacturing Companies in the Netherlands (VOBN), and the Association of Dutch Contractors (UNETO-VNI).

2.2 General topics for review

Revisions of the 2003 Regulation added to the present Regulation include the following:

- The material-related positive lists for plastics and rubber products described in the Inspection Guideline have been replaced by one list of permissible substances without distinguishing between plastics and rubber products, while the labelling of “Monomers and other starting substances” and “Additives, polymer production aids and aids to polymerisation has been deleted. However, in view of the 4MS Common Approach specified below, joint positive lists are being prepared on the basis of the EFSA (European Food Safety Authority) guidelines, the *EU Substances* document and the national positive lists. As soon as the list is complete, Annex B will be updated with this information (see also paragraphs 2.3 and 3.3).
- A list of components is included for metallic products.
- For cementitious products, a reference to the so-called *Approved Constituent List* has not been included as of now. Because of this topic’s complexity, a separate toxicology evaluation in accordance with the Regulation is required for most additionsadditives and admixtures. Included in the Regulation is only the description of the cementitious products as they are permitted or may be permitted on the Regulation’s effective date.
- In compliance with the *Note for Guidance* by the *European Food Safety Authority* (issued in December of 2004, most recent *update* dating from 30 July 2008), the required toxicity data and the requirements for the physical and chemical properties have been adjusted.
- Aside from the performance of migration tests, the option to calculate the expected concentration of a substance in drinking or warm tap water has been introduced.
- The conversion factors to convert the outcome of the migration test in mg/dm^2 into the expected concentration in drinking or warm tap water in mg/L, have been updated in accordance with the agreements reached in the context of the 4MS Common Approach.
- Because of the addition of the related test and assessment methods, the Regulation now applies to all materials and chemicals that (may) contact drinking or warm tap water.
- Plastics, rubber products and cementitious products for which the authorisation is applied for, will now also be assessed for their organoleptic aspects. The organoleptic aspects include the following parameters: odour, flavour, colour and degree of turbidity.
- Chemicals, metallic products, membranes used in the purification process, and technological auxiliary agents (documented as disappearing, such as lubricants, mold release agents and curing compounds) are in general not tested for organoleptic aspects. However, it is still compulsory that these products do not affect the organoleptic quality of drinking or warm tap water.
- A method has been included to identify any microbiological effects (Biomass Production Potential - BPP). These aspects will be assessed as soon as the Minister has defined the criteria for assessment.
- The related NENs (Dutch standards) apply to chemicals provided 1) the contaminations listed in the Drinking Water Decree contribute for not more than 10 % of the threshold value specified in the Drinking Water Decree to the concentration in the water to be treated, or 2) the exposure to contaminations through drinking or warm tap water not listed in the Drinking Water Decree contributes for not more than 10 % to the tolerable daily intake tal related contamination exposure.
- Pursuant to Articles 12-17 of the Regulation, as of now, quality certificates may be issued for disinfectant agents covered by the Plant Protection Products and Biocides Act

following authorisation of the Plant Protection Products and Biocides Board (Ctgb) A statement of no objection may be issued for products not covered by the Plant Protection Products and Biocides Act used to affect the microbiology quality of the drinking water or warm tap water (specifically for the prevention of contamination with Legionella bacteria). Such a statement will stay in effect for the period as defined by the Committee, and must document that the agent or method is effective and does not have harmful effects on the health of consumers. Once this had been documented, a recognised quality certificate may be issued.

- A two-year transitional period will start on this Regulation's effective date for:
    - Products not covered by the 2003 Regulation, but covered by the present Regulation, with the exception of products that were present in domestic installations and buildings and collective water supplies prior to this Regulation's effective date;
    - Products for which the criteria have become more demanding *with* the Regulation coming into effect;
    - Products that were authorised, but for which more demanding criteria will be specified *after* the Regulation comes into effect.

2.3 Relationship with European developments and other relevant regulations

2.3.1 The European Acceptance Scheme (EAS) and the Common Approach

In 1999, the European Commission initiated steps to harmonise the national assessment systems in the context of the implementation of the Construction Products Directive and the Drinking Water Directive. The objective was to have one harmonised *European Acceptance Scheme (EAS)* for building products that contact drinking or warm tap water. Representatives of the European Member States, Eureau (European Federation of National Associations of Water and Waste Water Services), CEN (the European Committee for Standardisation), and manufacturers of materials and products have contributed to the development of the EAS. In 2005, their activities resulted in a detailed proposal for the EAS. However, the proposal was not adopted by the European Commission because of the legal and practical consequences if the EAS were to be implemented.
In 2001, the European Commission authorised CEN to develop harmonised testing methods. This mandate was changed in 2010, one of the reasons being the failure to implement the EAS. Of further relevance is 2002/359/EC, the Commission Decision on the procedure for attesting the conformity of construction products in contact with drinking water at level 1+. This system is consistent with the criteria for the recognised quality certificate as set forth in the 2003 Regulation and the present Regulation.
Between 2000 and 2005, the assessment system in the Netherlands was further developed in consistency with the development of the EAS proposal. The results of the activities performed in the Netherlands were added to the EAS project and, vice versa, results from the EAS project were used in the suggestions to modify the 2003 Regulation.
Once it was clear that the EAS would not be realised, Germany, France, the Netherlands and the United Kingdom continued to work together on a common approach to shape the assessment of materials and products in contact with drinking water thereby considering the outcome of the EAS project. This approach is known as the 4MS Common Approach. The objective is to harmonise the assessment systems of the four countries as much as possible, and also to work together on the implementation in a structural way. Other countries may join this initiative in the near future. The joint efforts have already resulted in an agreement on the assessment of metals and organic materials, the outcome of which is included in the Regulation. It is expected that, in the course of 2011, the development of one common approach for cementious materials and products will be finalised. The result thereof will then be added to the Regulation as soon as possible.
With the Common Approach, participating countries will put forth efforts for the joint maintenance and updates of the national assessment systems once the harmonisation is a fact. This will open the way for mutual recognition of the quality certificates, as described in Article XX of the Drinking Water Decree. From then onwards, manufacturers of materials and products in contact with drinking water and warm tap water will be able to benefit from a substantial cost reduction for testing and certifying.

2.3.2 Consistency with the regulation for materials that come into contact with food

Various items in the Regulation, such as the positive lists in Annex B, the required toxicity information specified in Annex D, and the technical specifications described in Annex E, are consistent with the

guidelines issued by the European Commission's *European Food Safety Authority* (formerly, the *Scientific Committee on Food*). These guidelines are included in the *Note for Guidance for Food Contact Materials* (*update* of 30 July 2008). The *Note for Guidance* is a study document linked to *Regulation (EC)* 1935/2004 of the European Parliament and of the Council of 27 October 2004 describing the procedure for the authorisation for substances.
Substances for which the required information has been submitted and declared to be admissible are included in the Regulation 10/2011/EC.
For the sake of clarity, it is noted that the substances listed in Regulation 10/2011/EC, the European Directives or the Dutch Packaging and Consumer Items Decree should not be used without considering anything else when manufacturing products that contact drinking or warm tap water. One factor to consider in the authorisation of these products is the fact that consumers have no choice as to which drinking or warm tap water they use.
Finally, it is noted that the Dutch positive list, as included in Annex B, contains various substances not listed in Regulation 10/2011/EC and specifically authorised for products that contact drinking or warm tap water.

2.4 Business effect test

The Regulation defines the criteria for materials and chemicals to be met in view of public health, and the procedures to test and certify products. This will make it possible for manufacturers to show to their customers that their products are suitable for use in contact with drinking water and warm tap water. Manufacturers may expect that recognised quality certificates issued on the basis of the Regulation will have positive effects for the sale of the related products in the Netherlands and other countries.
The system of recognised quality certificates will make it possible for owners of drinking water companies and collective systems to easily show that they comply with their duty of care as established in the Drinking Water Act and the Drinking Water Decree with regard to the quality of the drinking water and warm tap water.

The Regulation will not result in significant changes for products made of organic materials (plastics) and for chemicals in comparison with the 2003 Regulation. In general, the cost to certify these products will not change.
The Regulation now also provides for requirements for metallic products, unlike the 2003 Regulation. Therefore, as of now, manufacturers of these products will also have certifying costs.
The Regulation also applies to cementitious products. The requirements for these products are not specified yet in anticipation of the agreements to be reached in the context of the 4MS Common Approach and possibly with more European countries.

The cost for certifying is very much dependent on the product. Currently, the average cost for a new certificate is €10 000,00 (a minimum of €5 000,00 and a maximum of €40 000,00), and the average annual cost for the post-certification audit is €3 000,00 per certificate. In the period 2003-2010, on average, 20 new certificates were issued each year. The current database contains approximately 300 certificates. The annual costs for manufacturers for the 2003 Regulation were €1 100 000,00.
The annual costs will increase under the present Regulation. The levels are expected to remain the same.

As described above, the Netherlands are working closely together with Germany, France and the United Kingdom to harmonise the national regulations for materials and products, and to eventually have a mutual recognition of recognised quality certificates in place. The present Regulation is one step closer to this objective.
Once this objective is realised, the certifying cost for manufacturers will decrease significantly because it will not be necessary to obtain a separate certificate for each one of these countries. It is also expected that other countries will join the initiative of the four countries, or will recognise the results.

2.5 Environmental effect test

The present Regulation sets forth the maximum quantities of a substance in materials and chemicals that are allowed to enter the drinking water. The primary objective of setting these maximum values is the protection of public health. The result in a real environment will also be that lower amounts of

these substances will enter wastewater than if the Regulation would not be in place. Therefore, the Regulation has indirect, positive effects on the environment.

2.6 Notification

The Committee of the European Communities has been notified of the Draft Regulation on 14th February 2011 (Notification No 2011/0068/NL) in compliance with Article 8(1), of Directive 98/34/EC of the European Parliament and of the Council of the European Union of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on the services of the Information Society (OJ L 204), as amended by Directive 98/48/EC of 20 July 1998 (OJ L 217).

Overview of Articles

3. Amendments and additions

3.1 Articles

The basis of the present Regulation is the 2003 Regulation. Where needed, articles were updated and completed on the basis of current insights.
The most important changes are related to the assessment of disinfectant agents, the addition of calculations of expected concentrations of substances in drinking water or warm tap water to complement or replace the measured migration of the substances out of finished products by using test methods, and the transitional provisions. The table below is a summary of the articles in the 2003 Regulation and the corresponding articles in the present Regulation.

2003 Regulation	Present Regulation (corresponding provision or amendment in comparison with the 2003 Regulation)
Article 1	Article 1 - Definition of chemicals: in the Drinking Water Decree - Definition of materials: in the Drinking Water Decree - Definition of the maximum level of remainder; added - Definition of MTC: replaces NOAEL (No-Observed-Adverse-Effect Level), flavour threshold value and SML (Specific Migration Limit) - TOC (Total Organic Carbon): added - Statement of no objection: added
Article 2	Article 2
Article 3	Article 3
Article 4	Article 4
Article 5	Article 5 - Addition: provision about the suspension of the Committee
Article 6, paragraphs 1 and 2	Article 6, paragraphs 1 and 2
Article 6, paragraph 3	Article 6, paragraph 7
	- Additions: paragraphs 3, 4, 5, 6, 8 and 9
Article 7	- Additions: paragraphs 4 and 5
Article 8, paragraph 1	Article 8, paragraph 2
Article 8, paragraph 2	- Additions: paragraphs 1, 3, 4, 5, and 6
Article 9	Article 9, paragraph 2
	- Addition: paragraph 1
Article 10	Article 10, paragraphs 1 and 2
Article 11, paragraph 1	Article 11, paragraph 1
Article 11, paragraph 2	Article 11
	- Addition: paragraph 2
Article 12	Article 12

Article 13	Article 13 - Addition: paragraph 4
Article 14, paragraph 1	Article 14, paragraph 1
Article 14, paragraph 2	Article 14, paragraph 2 - Additions: parts e and f
Article 14, paragraphs 3-7	Article 14, paragraphs 3-7 - Addition: paragraph 8
Article 15, paragraph 1	-
Article 15, paragraph 2	Article 15, paragraph 1 - Additions: paragraphs 2 and 3
Article 16	Article 16
Article 17	Article 17
	Additions: Articles 18 and 19
Article 18	Article 20 - Addition: paragraph 4
Article 19	-
Article 20	Article 21
Article 21	Article 22

In comparison with the 2003 Regulation, extensive amendments and additions have been added in the annexes. They are described in the paragraphs below.

3.2 Annex A: Product Description and Assessment

Annex A to the Regulation specifies which products are covered by the Regulation, and which assessment systems apply.

Further specifications of the products with an overview of the required tests and assessments for the authorisation were deemed necessary, because not all products can be assessed and tested in the same way. For example, it is noted that it does not make sense to perform an organoleptic test for metallic products and chemicals. In general, a migration test is not required for products with relatively small surface areas, such as adhesives, sealants and lubricants. The assessment for such products may take place by using a calculation of the migration on the basis of further defined prerequisites. The related NEN (Dutch) standard or NEN-EN (Dutch and European) standard apply to chemicals with – if it is not the case yet – supplementary purity requirements in consistence with the Regulation's 10 % rule added, thereby considering the maximum dosage of the product. For the sake of clarity, it must be noted that the threshold values for disinfectant agents are defined by the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb).

3.3 Annex B: Positive lists

Positive list for Plastics and Rubber Products

The material-related positive lists for plastics and rubber products described in the Inspection Guideline have been replaced by one list of permissible substances without distinguishing between plastics and rubber products, while the labelling of "Monomers and other starting substances" and "Aids to polymerisation and additives" has been deleted. The reason is that substances included in the positive list, regardless of their use, have had a toxicology evaluation, and that, in a real-case scenario, the list in which a substance is included is, in general, not considered in the product's assessment.

The positive list for rubber products does no longer distinguish between products with a relatively large surface area (Class A in the Inspection Guideline) and products with a relatively small surface area (sealants, O-rings; Class B in the Inspection Guideline). An MTC of 0.1 µg/L is included in the positive list for substances that were allowed for use only for Class B products.

In view of the aforementioned 4MS Common Approach (see paragraph 2.3), joint positive lists are being prepared on the basis of the EFSA guidelines, Regulation 10/2011/EC and the national positive lists. Annex B will be updated as soon as the list is complete.

Positive list for Dyes and Pigments

Aside from the list of authorised dyes and pigments, general criteria for their assessment have been included, which are derived from the purity requirements specified in the positive list for dyes and pigments of the Packaging and Consumer Product Regulation (Commodities Act**)**.

Composition List for Metallic Materials

Within the Common Approach it has been set that, consistent with the original EAS proposal, the authorisation assessment for metallic produts should be performed by using the so-called composition lists (*Composition List of Accepted Metallic Materials)*. It is thereby assumed that the long-term behaviour of various products made of the same material with a well-defined composition (alloy) is identical, making long-term testing of each separate product redundant. The composition list is included in Annex B and is prepared within the Common Approach.
Products not meeting the criteria of the composition list must be assessed separately by the Committee using the procedure described in Annex A.

Description of cementitious products

It is expected that consultations with regard to the ACL will lead in 2011 to a proposal for harmonisation within the Common Approach. The focus for the Netherlands will be the authorisation for other types of cement than those currently permitted in the Netherlands. For this reason, Annex A, part 2.9, of this Regulation only describes the currently authorised constituents for cement products.

3.4 Annex C: Test Methods

Annex C describes the currently used test and measuring methods. Where possible, the NEN-ENs developed for the related method are used, which makes the assessment system consistent with the developments at European level.

At the present moment, a migration test for site-applied materials and associated cementitious products is not available for testing toxicology aspects and organoleptic aspects.

Ion exchangers and membranes that are not used in the so-called *point-of-use* water treatment equipment in indoor systems must not be tested for organoleptic aspects, because the water passing the ion exchanger or membrane is not yet drinking water or warm tap water and its composition may change in a further purification process.
Metallic products are not tested for organoleptic aspects and microbiology aspects. These products must not be tested for potential organoleptic aspects, because the MTCs identified for metals or metal ions are (much) lower than concentrations in which organoleptic aspects are relevant. It is further determined that, with the exception of the presence of potential organic remainder on the surface of metals caused by the use of adjuvants, such as lubricating and cutting oils in the manufacturing process, potentially in combination with selected surface characteristics (ruggedness), the release by these products of microbiologically degradable organic compounds into drinking water or warm tap water may be excluded.

As set forth in Article 4, the Committee may make suggestions for the performance of test methods not described in Annex C.

3.5 Annex D: Assessment Methods

General

As described above, the present Regulation requires that a product should never affect the quality of drinking water or warm tap water. This means that criteria and acceptance levels apply to all relevant aspects. As mentioned in paragraph 1.3.2 of the Introduction, not everything has to be measured and theoretical considerations may make it plausible that a certain product will not affect the quality of drinking water or warm tap water, as specified in the fourth part of Annex D.
As set forth in Article 4, the Committee may make suggestions for the performance of evaluation methods and calculations not described in Annex D.

Toxicological evaluation

General

With the objective of protecting the health of humans from potentially harmful effects of substances introduced into the environment by the actions of humans, the Dutch authorities have set threshold values for the concentrations of these substances in the soil, water, air, food, etc. These threshold values are based on health-related or toxicological values determined and advised by experts. The rules used to determine these advisory values were prepared by the Health Council (1996, 2001, 2002) and are consistent with the basics and principles used at international level, for example, by the WHO or the *European Food Safety Authority (EFSA)*. They are the basis for the starting points developed for the evaluation of substances in materials that contact drinking water or warm tap water.

The toxicological evaluation of substances is not product-related. Therefore, the procedure described in the Regulation shall apply to the toxicological evaluation of any individual raw material or auxiliary material and (organic and inorganic) material used to manufacture finished products coming into contact with drinking water or warm tap water.
Procedures should not become so rigid that they lead in certain cases to unwarranted delays. In addition, the system should be open for new insights in toxicology, meaning that the *expert judgement* continues to be important. Departures from the toxicological evaluation guidelines, as those included in Annex D, must therefore be explicit and their reasons must be documented.

Required toxicity information

Usually, a toxicological evaluation will be performed by using data collected from a number of more or less standardised animal tests and cell culture assays. Included in Annex D and Annex E is a basic set of data to be used to conduct a proper toxicological evaluation of a substance.
Selected items in the toxicity criteria listed in Annex D and Annex E depart from the criteria listed in the Inspection Guideline. For example, at the present moment, acute toxicity data are not requested, while the studies of the effects on the reproduction system and the unborn child are not optional. Therefore, substances were included in prior positive lists for which the currently applicable complete set of data was not assessed. It is the Committee's opinion that the changes in the requested toxicity data are of the type that the effect on the health of consumers will be immeasurable or negligible. In practice, the fact that information is limited is accounted for by using safety factors in the extrapolation of the data collected from laboratory animals for use in humans when the Maximum Tolerable Concentration (MTC) and maximum permitted quantity of the substance in the finished material or article (QM) are defined. Again, there will be cases for which a (temporary) evaluation will be done if the full set of data is unavailable. Furthermore, there are various situations in which it is not needed to have all data available. It must be noted in this respect that it has been documented that the health risks for humans on the basis of the current measures are negligible in case of exposure to genotoxic substances in concentrations under 0.1 µg per litre of drinking water. In this case, the 0.1 µg/L value is known as the *Threshold of Toxicological Concern* value (TTC value). For various groups of compounds, individual TTC values higher than 0.1 µg/L may be used. However, using TTC values higher than 0.1 µg/L is inconsistent with the principle of precaution.
The TTC idea is included in the present Regulation as an evaluation instrument.

Methods for analysis

The toxicological evaluation is independent from the question if there is a proper method for analysis of any substance available, although it is explicitly requested. If a method for analysis is not available (yet), the Regulation provides for the option to show with calculations that the substance's migration is under the set MTC.

General requirements for groups and compounds

General requirements apply to groups and compounds. For example, the migration of *secondary* and *tertiary* aliphatic amines, aromatic amines, phenolic compounds, nitrosamines, peroxides and polycyclic aromatic hydrocarbons should not be evident (in real-case scenarios, < 0. µg/L), while the

criteria applicable to copper and lead compounds are derived from the parameter values in the Drinking Water Decree.
For a substance that has not been assessed yet and is covered by the general requirement for a group of compounds, submitting a limited set of toxicity data may be sufficient. If the complete set of toxicity data is submitted for the related substance and an MTC different from the general requirement can be identified for this substance on the basis of this set of data, than this MTC will be the one in effect for the substance.

Conversion Factors

Inspection Guideline
Conversion factors were used in the Inspection Guideline for comparing the results of the migration test (speed of migration in $mg.dm^{-2}.day^{-1}$) with the criteria of the positive list (in mg/L). The conversion factor used was composed of a factor depending on the surface/volume ratio and a factor accounting for the reduction of the migration over the lifetime, *i.e.* it will be lower than if measured in the standard migration test with new material. For piping, a conversion factor of 3 was used, and a factor of 0.1 was used for tanks. For small contact surfaces (rings, adhesives), the factor 3 for piping was reduced by a factor expressing to what extent the water contacts the material at issue over a part of the pipe's length.

Revised conversion factors

In consistence with the provisions set at European level, any conversion factor must consist of a factor representing the geometric ratio (surface/volume ratio) of the related product (F_g), an operational factor for the contact or stagnation time (F_o), and a factor representing the product's contact surface in relation to the total surface of a storage or piping system or a drinking water or warm tap water system (F_f).
The list of conversion factors set within the 4 MS Common Approach is included in Annex D.

"Small contact surface products"

Conversion factors < 0.01 d/dm may be calculated for various products. In general, in real-case scenarios, products with such a relatively low conversion factor are not eligible for extensive testing schedules. Therefore, these products are assessed only for their composition (raw materials and auxiliary materials), and only the potential concentrations of relevant substances in the drinking water or warm tap water are measured. If the effective removal of these products can be documented (in real case scenarios, this applies to lubricants, mould release agents, and *curing compounds),* one may consider skipping the evaluation of organoleptic aspects. Depending on the product, microbiological aspects may be significant. The Minister will decide which tests must be conducted to obtain an authorisation.

Organoleptic Aspects

Background Information

Plastic piping materials (pipes and fittings) have long been tested for aspects of odour flavour and colour in accordance with the current Assessment Directive (BRL). It is required that no products/materials in contact with drinking water or warm tap water emit an odour, flavour or colour in concentrations that cause a nuisance to the drinking water users.
The release of colours is tested with the migration test pursuant NEN-EN 13052-1:2001 (EN) followed by the measurement of values in the migration water according to NEN-EN-ISO 7887:1994 (EN).
The parameters for odour (TON - *Threshold Odour Number*) and flavour (TFN - *Threshold Flavour Number*) are tested with the migration test in accordance with NEN-EN 1420-1:1999 (EN). The presence or absence of odour and flavour is then identified in accordance with NEN-EN 1622:2006 (EN).

Testing organoleptic aspects when the Regulation comes into effect

The section "Organoleptic aspects" is a significant addition to the 2003 Regulation.

Table IIIb of Annex A to the Drinking Water Decree lists ten organoleptic/esthetical parameters derived from the Table listing eighteen indicator parameters in Part C of Annex I to the Drinking Water Directive. It was suggested in the OAS (Ontwikkeling ATA Systeem – Development ATA System) project for materials in contact with drinking water or warm tap water to include only odour, flavour, colour and degree of turbidity of all the parameters listed in the Drinking Water Decree. Testing organoleptic aspects of chemicals is irrelevant. The Committee has defined the following threshold values for the four parameters listed above:

Parameter	Threshold Value
Odour and flavour	The dilution factor of the migration water is 16. Up to 5 of the 8 panel members will select the sample in the migration water as the sample with the strongest smell/flavour
Colour	10 mg/L Pt in drinking water or warm tap water
Degree of turbidity	1 FTU (Formazin Turbidity Unit) in drinking water or warm tap water

The study and evaluation methods for the organoleptic aspects are described in Annex C. In Annex C the threshold values mentioned above have been included.

A method to assess the organoleptic aspects of metallic products is not described. MTCs defined for metals or metal ions released by metal products or materials are (much) lower than the concentrations in which organoleptic aspects have any relevance. Therefore, if a metallic product/material meets the toxicological criteria/requirements, testing the organoleptic aspects will not be necessary.
Annex A and the specific table in Annex C show which materials/products are eligible for a study of the organoleptic aspects. The table in Annex C also describes the standards in effect to obtain the testing water and the related measuring methods.

Microbiology Aspects

In addition to the inclusion of organoleptic aspects, it has been agreed that assessment of the promotion by the products of the growth of microorganisms in the water by releasing degradable compounds would be added to the Regulation. It was determined that the extent of growth promotion can be measured in a Biomass Production Potential (BPP) test. This testing method is described in standard NVN (Dutch pre-standard) 1225:2004 (EN). However, at the present moment, evaluation criteria to be met by these products in order to obtain an authorisation have not been defined. As soon as the criteria will be defined, the BPP will be one of the assessment aspects to obtain an authorisation for a product.

3.6 Annex E: General and specific data to be provided for the toxicological evaluation of products, other than metallic products

Annex E lists the data to be submitted with the application for the assessment of finished products and the raw materials and auxiliary materials used. The data are derived from Chapter 4 and Annex 5.1 to part A of the Inspection Guideline and the Note for Guidance to list substances in the Regulation 10/2011/EC (see also paragraph 2.3).