Assessment of Cementitious Products in Contact with Drinking Water

4MS Common Approach

France, Germany, the Netherlands and the United Kingdom (4MS) work together in the framework of the 4MS Common Approach. This common approach aims for convergence of the respective national approval schemes for materials and products in contact with drinking water.

The 4MS have adopted this document as a common basis for implementing the concept of assessing cementitious materials in their national regulations. The document is subject to revisions agreed by the 4MS.

As a next step, the 4MS will prepare common Positive Lists for organic and inorganic substances and a List of Recognised Generic Constituents.

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

Bundesministerium für Gesundheit (Deutschland)
Ministère du Travail, de L’Emploi et de la Santé (France)
Ministerie van Infrastructuur en Milieu (Nederland)
Department for Environment, Food and Rural Affairs (United Kingdom)
Abbreviations

AoC Attestation of Conformity (as laid down in the CPD/CPR)
CAP Constituent Approval Procedure
CEN European standardisation body (Comité Européen de Normalisation)
CEN TC CEN Technical Committee responsible for standardisation work in a particular field
CF Conversion Factor (based on the S/V and contact time in a migration test to assess the toxicology impact in the operating situation) in d/dm
DW Drinking water
DWD Drinking Water Directive (98/83/EC)
DWPL Drinking water positive list
DWPLL Drinking water positive list limit
EC European Commission
EFSA European Food Safety Authority
EG-CPDW Expert group formed by the Commission to advise on construction products in contact with drinking water
EMG Enhanced microbial growth
FTU Formazine Turbidity Unit (see EN ISO 7027)
GC-MS Gas chromatography-Mass spectrometry
JMC 4MS Group Joint Management Committee
MTC_{tap} Maximum Tolerable Concentration at the tap
MS Member State of the European Union
PDW Product coming into contact with drinking water
PL-CM Positive List – Cementitious Materials
PL-OM Positive List – Organic Materials
SG-CM 4MS JMC Sub Group Cementitious Materials
SG-EMG 4MS JMC Sub Group Enhancement of Microbial Growth
S/V Surface to volume ratio (surface area of product/material to volume of water in contact)
TOC Total Organic Carbon
TFN Threshold Flavour Number (see EN 1622)
TON Threshold Odour Number (see EN 1622)
## Definitions

<table>
<thead>
<tr>
<th><strong>Term</strong></th>
<th><strong>Definition</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Accepted generic constituent</td>
<td>Constituent where all organic and inorganic substances are listed as generic constituents in Table 2 columns 1 and 2 of this document</td>
</tr>
<tr>
<td>addition</td>
<td>Finely divided material used in concrete in order to improve certain properties or to achieve special properties. EN 206-1 “Concrete – Part 1: Specification, performance, production and conformity” deals with two types of inorganic additions: - nearly inert additions (type 1) - pozzolanic or latent hydraulic additions (type 2)</td>
</tr>
<tr>
<td>admixture</td>
<td>Material added during the mixing process of concrete in small quantities related to the mass of cement to modify the properties of fresh or hardened concrete</td>
</tr>
<tr>
<td>aggregate</td>
<td>Granular mineral material suitable for use in concrete. Aggregates may be natural, artificial or recycled from material previously used in construction. NOTE. Source material would need to be assessed for recycled material to ensure no introduction of contamination.</td>
</tr>
<tr>
<td>approved constituent product</td>
<td>Constituent product tested and approved in accordance with Part C of this document</td>
</tr>
<tr>
<td>approvals body</td>
<td>Notified Body and/or regulator representative authorised to take decisions on testing requirements and product/constituent approvals</td>
</tr>
<tr>
<td>cementitious material</td>
<td>Material that contains a hydraulic cement in sufficient proportion to act as the main binder by forming a hydrate structure which governs the performance of the material</td>
</tr>
<tr>
<td>cementitious product</td>
<td>Factory made unit containing a cementitious material supplied in the hardened state with a formed surface prior to its incorporation into the construction works</td>
</tr>
<tr>
<td>certificate of drinking water conformity</td>
<td>Statement of approval given to manufacturers for constituent products successfully tested for contact with drinking water. (See Section C)</td>
</tr>
<tr>
<td>constituents (and constituent products)</td>
<td>Minerals or preparations used to make a cementitious material or product and are defined in a technical specification. NOTE. Most constituents are classified as construction products under the Construction Products Directive</td>
</tr>
<tr>
<td>drinking water positive list (DWPL)</td>
<td>List of substances that have been assessed with respect to their toxicological characteristics and can be used for the manufacture of a constituent from which a cementitious product is (partly) made</td>
</tr>
<tr>
<td>microbiological characteristic of a product, material or constituent</td>
<td>Ability of the product, material or constituent to enhance microbial growth on the surface and in drinking water</td>
</tr>
<tr>
<td>Notified Body</td>
<td>Organisation which has been designated by Members States for tasks to be carried out for the purpose of conformity assessment. (According to the CPD, Certification bodies are Notified Bodies - when relevant supervising the work of accredited testing laboratories and inspection bodies.</td>
</tr>
<tr>
<td>organoleptic characteristic of a product, material or constituent</td>
<td>Ability of a product, or constituent to affect the odour, flavour, colour or turbidity of drinking water</td>
</tr>
<tr>
<td>substance (and primary substance)</td>
<td>Chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. NOTE: Definition taken from the REACH Regulation.</td>
</tr>
</tbody>
</table>
Background

1. Introduction

The 4MS (France, Germany, the Netherlands and UK) have committed themselves to work towards common practices for the assessment and approval of products in contact with drinking water. Principles have been established for use with metallic materials and for the organic materials by control of constituent substances and risk-based testing of finished products against defined acceptance criteria. These principles have been applied – insofar as they are relevant - to cementitious products and are based on an analysis of established national practices.

2. Scope and Coverage

The aim is to reach a position where assessment and approval in one country allows a product to be accepted in the other three MS without further testing. Thus common practices are required for products which are placed on the market within the 4MS. They are expected to cover factory made products (but not specialist items intended only for one particular use in one MS) and coatings and packaged products for site application. Users of such products will rely on third party testing and certification to demonstrate that they meet national regulatory requirements. Materials prepared on site from primary constituents, or ready-mixed off-site and transported to the point of use, will not be the subject of common regulatory practices at this time. National regulators will continue to specify the requirements to be met by such materials, and it will be the responsibility of the constructor and the client to make the arrangements needed to ensure compliance. There will be elements of the arrangements for factory made products that will also be relevant for site prepared materials e.g. use of approved constituents. It will be for each MS to decide on the extent of their use in relation to site prepared materials.

3. Further Development Work

This Report sets out the general approach to the assessment and acceptance of cementitious products that will be adopted by the 4MS, but further work is required on some aspects of practice before a common working procedure can be put into operation.

- The proposals made in this report show that test methods will need to be available for site applied products and proxy samples when prepared. This will require re-activating the CEN work on parts 2 and 4 of EN14944.(TC164/WG3)
- Draft of the Positive Lists will be prepared by the JMC SG-CM based on present national practice, which will then need to be validated. A procedure will be proposed for making additions.
- More work is required on the proposals for the assessment of metal release. Research is being put in hand by Germany on behalf of the JMC on the use of content level limitations for metals linked to testing requirements
- More time is needed to decide how to apply the test methods currently being produced by CEN for Enhancement of Microbial Growth (EMG) and GC-MS. These topics will be reviewed by SG-CM in the light of any proposals from the JMC SG-EMG, and experience on the introduction of the new test method standards.
Overview

At the level of principles the assessment approach for cementitious products will follow that adopted for other materials. However, a feature of the preparation of cementitious products is that they comprise some combination of constituents, which can themselves be mixtures (preparations) of primary substances and minerals. There will be controls on the substances and constituents that can be accepted for use. Final products will be subject to compliance testing. It is accepted that prior approval of constituents produced as products by manufacturers can allow the testing of the final product to be reduced. This Report therefore distinguishes the various elements of assessment that can be involved in product certification.

1) Control of Primary Substances
Substances that are acceptable in manufactured cementitious constituents and products will be itemised in Positive Lists, distinguishing between organic and inorganic substances. Part A of the report deals with the establishment of such Lists and the requirements for compliance. Part A of the report deals with the establishment of such Lists and the requirements for compliance. The potential for release of metals is also a matter of concern as regards the impact on drinking water, and provisions related to content levels and test requirements are set out in Part C.

2) Control of Constituents
The constituents of cementitious products comprise a variety of substances, not all of which can, or need to, appear on Positive Lists. The 4MS Common Approach accepts that constituents themselves can be assessed for their suitability for drinking water applications. The control approach acknowledges that:
   a. There are constituents that can be described and accepted at a generic level. (Accepted Generic Constituents)
   b. Manufacturers can create and place on the market constituents from mixtures of substances and minerals, and these Constituent Products can themselves be tested to establish satisfactory performance in contact with drinking water. (Approved Constituent Products)

   a. Accepted Generic Constituents
   The Common Approach accepts that it will be helpful for manufacturers if regulators schedule generic constituents which, based on past experience, will be accepted for use in cementitious products. Part B of the report identifies these constituents and introduces the specifications to be met to allow acceptance in final products

   b. Approved Constituent Products
   The report goes on to detail in Part C the arrangements that can be made for individual manufacturers’ constituent products to be granted a certificate of (drinking water) conformity. Possession of such a certificate will be taken into account in the testing of the final product. Under the Common Approach product conformity certificates granted in one country can be used in any of the 4MS countries, but no central list of the certificates will be maintained.

3) Product Testing and Approval
The tests that are relevant for cementitious products are:
   - Organoleptic effects (colour, odour, taste, turbidity, foaming)
   - Migration of metals
   - Migration of organics by TOC
   - Migration of PL substances
   - GC-MS
   - Enhanced Microbial Growth (EMG)

Part D describes the acceptance criteria for approval of both constituents and final products. It shows that tests are related to the nature of the constituents in the final product.
4) **Restrictions on use of cementitious PDW in certain water compositions**

The use of a product in contact with drinking water must be safe over its expected lifetime and under all reasonable conditions of use. However, it may be necessary to restrict the use of cementitious PDW in certain water compositions (soft/aggressive water in particular) in the European Union. Based on their long-term experience of use of certain materials, Member States may need to impose restrictions depending on the local drinking water composition.
PART A - CONTROL of PRIMARY SUBSTANCES

A1 Positive Lists for Cementitious Materials

The control of input substances to cementitious products will be by way of Positive Lists – Cementitious Materials (PL-CM), scheduling organic and inorganic substances.

Substances used for cementitious products have to be mentioned on these Positive Lists. However some elements or substances found in the ingredients of accepted generic constituents (see Part B) may not be suitable to appear on Positive Lists (e.g. Ca, Al, Si).

The same general approach for organic substances will apply as is used in the 4MS Common Approach for Organic Materials. That is the toxicological evaluation of the substance under the circumstances of its use, and the setting of a limit value for the presence of that substance (or its reaction/degradation products) in drinking water.

As with the Organic Materials PL, a recognised route to approval for organic substances is via acceptance by the European Food Safety Authority. However, it is accepted that only a minority of products intended for use in cementitious products will be subject to food safety controls (perhaps around 30%). Even where an EFSA approval exists it will need to be reviewed to establish that it is relevant for use with cementitious products. For other substances the principles of the EFSA assessment will be used by MS regulators, again subject to recognising the specific situation of cementitious products.

Applications for the approval of non-EFSA substances will be made to one of the 4MS regulatory bodies, who will carry out the required toxicological and limit evaluation, and offer their “Opinion” to the other 4MS countries for endorsement.

Note: Organic substances used in non-cementitious sealants and coatings will appear in the PL-Organic Materials even if they are only used in conjunction with cementitious products

A review will be made of inorganic substances currently subject to controls in the 4MS, and proposals will be developed for the evaluation and acceptance of such substances.

A2 Transitional Arrangements

The current MS positive (and equivalent) lists will be consolidated in a Combined List as the starting point for the transition to common lists. The first step will be to identify substances that appear in current lists that it is agreed can be transferred to a common “Core List”. After that items on existing lists must be either validated by a toxicological evaluation (and then transferred to the Core List), or eliminated as no longer acceptable.

This will not be such a demanding exercise as it is for organic materials, since the lists are likely to have something under 400 entries.
PART B - ACCEPTED GENERIC CONSTITUENTS

B1 List of Accepted Generic Constituents

The experience of regulators is that a range of constituents are acceptable for drinking water applications and they can be defined and described. Table 2 sets out in the first and second columns the technical specifications for these Accepted Generic Constituents. Conformity with these specifications is necessary for a product to be accepted.

The List of Accepted Generic Constituents (Table 2) indicates for each constituent the nature (organic and/or inorganic) of substances for which compliance with the PL-CM has to be controlled and which tests have to be performed when a constituent product (Part C) or a final product (Part D) is assessed.
PART C - APPROVAL of MANUFACTURERS’ CONSTITUENT PRODUCTS

C1 Rationale
Whilst constituents must conform to the generic specification in Table 2, testing of the final product is still required to establish compliance with actual performance requirements for contact with drinking water. However it is accepted that a particular constituent produced by a manufacturer can be tested in its expected conditions of use in the form of test specimens to determine its acceptability for use with drinking water. There is then no need to repeat the relevant constituent test when the final product containing it is presented for approval.

A pre-approval of manufacturers’ constituent products allows the final testing of the product to be reduced (Part D below). This can benefit both the producer of the final product and the constituent manufacturer. Manufacturers will need to decide whether it is to their advantage to offer certificated constituent products which will help the approval of the final product.

Set out below are the protocols to be used in assessing each constituent by an approvals body in order for the manufacturer to be given an individual constituent drinking water certificate of conformity.

C2 Constituent Approval Procedure (CAP)
The manufacturer of a cementitious constituent shall provide the approvals body with full details of the formulation and a dossier of relevant information corresponding with specifications in Table 2 column 2 and the intended use of the constituent including the type of final products made from the constituent.

On the basis of the information provided in the manufacturer’s dossier, the approvals body shall decide what testing if any will be required. The testing shall be:
- Based on the parameters detailed in Table 2 for acceptance of constituents
- Constituent products shall be sampled and test specimens prepared according EN 14944-2 and 4 either by the manufacturer (or their nominated contractor) under the supervision of the test laboratory, or by the test laboratory. In each case in strict accordance with manufacturer’s instructions for use.
- Test specimens shall be prepared at the manufacturers maximum recommended dose for PDW applications
- Test details are given in Table 4. The migration tests shall be performed according to EN 14944-3 and EN 14944-4 at an S/V ratio which is not smaller than the S/V ratio in service conditions for which the constituent shall be used. Details for the S/V ratio will be given in these standards. Information regarding the S/V ratio and CF for which the constituent has been tested and approved shall be given in the certificate of conformity.
- Compliance requirements where applicable are detailed in Table 4.
- The testing shall be undertaken at AoC level 1+.

Further consideration is to be given to the use of GC-MS testing for certain cementitious products or constituents products. GC-MS may be required to check for reaction/degradation products as part of the toxicology prior to inclusion on the PL-CM and also for cementitious products having regard to the formulation when organic constituents are present.

C3 Compliance with Generic Constituent Specifications and with the PL-CM
Any constituent of a cementitious product must be declared and must comply with the requirements of the Accepted Generic Constituent List. Otherwise, the constituent cannot be used in the preparation of a PDW. This List also indicates where organic and inorganic substances within the constituent must comply with the relevant PL-CM (see Table 2).
Note: At this moment, none of the 4MS apply PL requirements to grinding aids used in the preparation of cements. The content of these substances are always < 0.5 % and usually < 0.2 % by mass of the constituent. However for the assessment of organic products, any substance even at very low concentration has to be included in the organic section of the PL-CM.

**C4 Constituent Approval for Organic Preparations and Products**

Any constituent that contains an organic substance is covered by this requirement. It includes organic admixtures, polymer modifiers, polymer fibres, bundling aids for steel fibres, surface coatings and where applicable release agents and curing agents.

Organic substances of the constituent shall be listed in the organic section of the PL-CM which may include a DW Positive List Limit (DWPLL- MTC\text{tap}). (See 4MS document on Positive Lists for Organic Materials for definitions of DWPLL, MTC\text{tap}, etc.)

The manufacturer’s constituent product shall be sampled, prepared at its maximum recommended dosage for DW applications in the reference concrete and tested, all in accordance with the appropriate part of EN 14944 for:

- Compliance with organoleptic properties: prEN 14944-2 and Table 4 of this document.
- Compliance with microbiological properties: Further consideration is to be given to which of the three available EMG test methods should be used for cementitious products.
- Migration of organic substances by TOC and, if required by the approvals body, specific substance determination – EN 14944-4 and Table 4 of this document.

As appropriate, the results of the migration test shall be used to determine compliance of the constituent with the DWPLL or MTC\text{tap} for its component substances using the conversion factors set out in Table 1.

If these requirements are all satisfactory, a Drinking Water Certificates of Conformity can be issued to the manufacturer of that constituent by the approvals body.

If any organic substance is contained in the constituent it shall:

- Be tested and approved as an organic constituent according to clause C.4.
- Or tested for migration in the cementitious product according to Part D and Table 4 (Migration modelling might be used when possible.)

If a grinding aid present at less than 0.2 % in the constituent (cement or inorganic addition), and no other organic substances are present, no migration testing is required for this substance incorporated in the constituent. This is an interim arrangement reflecting current practice, and will be subject to further review when the PL-CM has been established in use. In any other case any constituent containing organic substances has to be tested and approved in accordance with the relevant clause.

Note: Harmonised test standards are needed (EN 14944 part 2 and part 4 still pending in TC 164/WG3 work programme).

However, apart from the preparation of test samples which has to be specifically developed, the test procedures should not differ significantly from standard procedures for factory-made cementitious products described in EN 14944-1 (organoleptic parameters) and EN 14944-3 (general migration).

The procedure needs to be extended to cover formwork release agents and curing compounds.

**C5 Constituent Approval – Metals in Preparations and Products**

The potential for release of metals is a matter of concern for impacts on drinking water. Metal migration will have to be tested according to Table 4.

Current practice accepts that migration testing for metals is not necessary if the content in cement plus additions is below critical levels. Examples of current limit values are given in Table 3.
Research is being commissioned to validate these levels, and also extend the list of metals covered.

Content of the following metals in cement and additions shall be determined by:

i. Complete digestion according to EN 13656 (subject to review linked to the metals research project)

ii. Metal analysis according to one of the following methods

- As (EN ISO11969, EN ISO 11885, or EN ISO 17294)
- Cd (EN ISO 5961, EN ISO 11885, or EN ISO 17294)
- Cr (EN 1233, EN ISO 11885, or EN ISO 17294)
- Ni (EN ISO 11885, or EN ISO 17294)
- Pb (EN ISO 11885, or EN ISO 17294)

Reduced testing for migration of metals can be applied only if (for each metal) the sum of the content of the metals in the cement plus any additions is less than the values given in Table 3. Otherwise the final cementitious product shall be fully tested in accordance with Part D and Table 4.

Note: Content testing is not a valid control for aluminium migration but experience shows that while aluminium may be at or close to the permitted value of 20 ug/l (10% of DWD parametric value for Al) for some cements after 3 migration cycles, it always falls within this value before 10 cycles.

The content of these metals by mass of cement or addition shall be given on the Drinking Water Certificates of Conformity for the cement or addition.

**Test method references:**

EN 13656:2002. Characterisation of waste – Microwave assisted digestion with hydrofluoric (HF), nitric (HNO₃) and hydrochloric (HCl) acid mixture for subsequent determination of elements in waste


PART D – FINAL PRODUCT TESTING & APPROVAL

D1 Rationale

All factory made cementitious products shall undergo appropriate testing in order to assess their impact on the quality of the drinking water.

Where manufacturer’s constituents have a drinking water certificate of conformity from an approvals body, testing of the final cementitious product would normally be reduced. In case all constituents are certified the testing of the final product is reduced to organoleptic parameters and TOC migration.

D2 Approval procedure

The manufacturer of a cementitious product shall provide the approvals body with a dossier of information including the maximum intended S/V at which the product will be used, composition, full details of the constituents and any drinking water certificates of conformity for the constituents.

On the basis of the information provided in the manufacturer’s dossier, the approvals body shall decide what further information is required (e.g. details of organic substances present in generic constituents) and what testing is to be carried out by the approved test laboratory. The testing shall be:

- Based on the constituents and the parameters detailed in Table 2
- Samples and test specimens shall be sampled and prepared according to EN 14944-1 & 3 either by the manufacturer (or their nominated contractor) under supervision of the approved test laboratory, or by the test laboratory. In each case in strict accordance with manufacturer’s instructions for use.
  
  NOTE: EN 14944-1 & 3 only apply to (hardened) factory made products. This does not cover products like, e.g. pre-packaged mortar which are not in a hardened form when put on the market. Provisions should be included either in EN 14944-2 and 4 or in future revisions of EN 14944-1 & 3 to cover the preparation of proxy samples for these products
- If a series of different products is made from the same raw and ancillary materials under the same manufacturing process (a so-called product family) and the product with the largest in use S/V is assessed and approved, then the whole series of products is allowed to be used for all application areas within the product group without further testing
  A clause will be required in certificates and product approvals to indicate the CF used and its implications for the conditions of use.
- The acceptance procedure for final products shall follow sections C3 - C5.
- Test details are given in Table 4.
- If all constituents hold a Certificate of Conformity the testing is reduced to organoleptic parameters and TOC migration.
- Compliance requirements where applicable are detailed in Table 4.
- The certification shall be undertaken at AoC level 1+.

Further consideration is to be given to the use of GC-MS testing for certain cementitious products. (See also C2)
Figure 1: Procedure for approving factory made cementitious products

Control of constituents (for each individual constituent)

- Product description (S/V in use, application...) & detailed formulation
- Compliance with Generic Constituents specifications (Table 2)
- List of testing parameters for product testing (according specification for each individual constituent)
- Product testing (EN 14944)
  - TON-TFN + TOC always required as a minimum (See Table 1 for Conversion Factors)
- Compliance to requirements (Table 4)

Certified constituent (See Figure 2)

Is the certificate valid for this product? (CF in certificate ≥ CF of product)

- Compliance with Generic Constituents specifications (Table 2)
  - Compliance with PL-CM\(^1\)
    - yes
    - Rejected
    - no
  - yes
  - no

- Yes
- No

1 Positive List – Cementitious Materials
Figure 2: Approval of manufacturers’ constituent products

Description:
Application conditions (max concentration in product, product type, product CF…)
Detailed composition

Compliance with Generic Constituents specifications (Table 2)

Compliance with PL-CM

Constituent testing (EN 14944)
At maximum dosage & CF ≥ CF max in use

Compliance to requirements (Table 4)

A certificate is issued to the manufacturer (including max concentration in product and S/V or CF max)

Rejected
### Conversion Factors

Table 1

For cementitious products and constituents, the following CFs shall apply to substances determined during testing for general migration according to Table 4

<table>
<thead>
<tr>
<th>Product group</th>
<th>CF in d/dm*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pipes and their linings:</strong></td>
<td></td>
</tr>
<tr>
<td>• 80 mm ≤ ID &lt; 300 mm (service piping)</td>
<td>10</td>
</tr>
<tr>
<td>• ID ≥ 300 mm (mains piping)</td>
<td>5</td>
</tr>
<tr>
<td><strong>Storage systems:</strong></td>
<td></td>
</tr>
<tr>
<td>• In domestic installations, buildings</td>
<td>4</td>
</tr>
<tr>
<td>• In water supply</td>
<td>1</td>
</tr>
<tr>
<td><strong>Repair products for storage systems</strong></td>
<td></td>
</tr>
<tr>
<td>In domestic installations, buildings:</td>
<td></td>
</tr>
<tr>
<td>• products covering the total surface or a substantial part of that (e.g. coatings)</td>
<td>4</td>
</tr>
<tr>
<td>• products covering &lt; 1 % of the total surface in contact with drinking water</td>
<td>0.04</td>
</tr>
<tr>
<td>In water supply:</td>
<td></td>
</tr>
<tr>
<td>• products covering the total surface or a substantial part of that (e.g. coatings)</td>
<td>1</td>
</tr>
<tr>
<td>• products covering &lt; 1 % of the total surface in contact with drinking water</td>
<td>0.01</td>
</tr>
</tbody>
</table>

*Days per decimetre.

The PL-CM details substances approved for the production of cementitious products in contact with drinking water. For the listing of a substance an assessment of the substance including its toxicological evaluation and its possible reaction products is required. As a result of the assessment some substances may be restricted in the form of a Positive List Limit (DWPLL) or MTCtap as a limit value of the substance in the drinking water at the tap.

Laboratory based migration testing provides a value for the substance under the prescribed test conditions. It is necessary to apply a Conversion Factor (CF) to this value in order to obtain a value at the tap. The conversion factor takes into account surface to volume ratio and retention time. Full details can be found in Part B of the 4MS document “Positive List for Organic Materials”
## List of Accepted Generic Constituents – Specifications and Testing

<table>
<thead>
<tr>
<th>Constituent</th>
<th>Technical specifications (1)</th>
<th>PL-CM requirements</th>
<th>Testing parameters</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>YES</td>
<td>X</td>
<td>X(2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For organic substances used in cement preparation (e.g. grinding aids)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cement</td>
<td>• (h) EN 197-1 (common cements)</td>
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<tr>
<td></td>
<td>• (h) EN 197-4 (low early strength blast furnace cements)</td>
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<td></td>
<td>• (h) EN 413-1 (Masonry cement)</td>
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<td></td>
<td>• (h) EN 14216 (Very low heat special cements)</td>
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<tr>
<td></td>
<td>• ETA-07/0019 and NF P15-314 (Ciment Prompt naturel)</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>• Calcium alumina cement (h) EN 14647 for raw water applications only</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inorganic additions</td>
<td>• (h) EN 450-1 (Fly ash for concrete)</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>• (h) EN 13263-1 (Silica fume)</td>
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<tr>
<td></td>
<td>• (h) EN 15167-1 or BS 6699 (Ground granulated blast furnace slag)</td>
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<tr>
<td></td>
<td>• BS 7979, NF P 18-508 or LNEC E 466 (Limestone additions)</td>
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</tr>
<tr>
<td></td>
<td>• NF P 18-509 (Siliceous additions)</td>
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<tr>
<td></td>
<td>• DIN 51043 (Trass)</td>
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<tr>
<td>Aggregates</td>
<td>• (h) EN 12620 (Aggregates for concrete)</td>
<td>No</td>
<td></td>
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<tr>
<td></td>
<td>• (h) EN 13139 (Aggregates for mortar)</td>
<td></td>
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<tr>
<td></td>
<td>• (h) EN 13055-1 (Lightweight aggregates for concrete, mortar and grout) (?)</td>
<td></td>
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<tr>
<td>Constituent</td>
<td>Technical specifications (1)</td>
<td>PL-CM requirements</td>
<td>Testing parameters</td>
<td>Note</td>
</tr>
<tr>
<td>--------------------------------</td>
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<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Mixing water</td>
<td>• EN 1008 (Mixing water for concrete)</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admixtures</td>
<td>(h) EN 934-2, 3, 4 or 5 (Admixtures for concrete, mortar and grout)</td>
<td>YES</td>
<td>Inorganic and organic substances</td>
<td>X  X  X  X</td>
</tr>
<tr>
<td>Fibres</td>
<td>(h) EN 14889-1 (Steel Fibres for concrete)</td>
<td>YES</td>
<td>For organic substances</td>
<td>X  X  X  X</td>
</tr>
<tr>
<td>polymer modifiers</td>
<td>(h) EN 14889-2 (Polymer fibres for concrete)</td>
<td>YES</td>
<td>For organic substances</td>
<td>X  X  X  X</td>
</tr>
<tr>
<td>Formwork release agents</td>
<td>To be proposed by SG-CM</td>
<td>YES</td>
<td></td>
<td></td>
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<tr>
<td>Curing compounds</td>
<td>Not applicable to factory made products. MS requirements for site applied products will vary</td>
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</tbody>
</table>

(1) Currently accepted in at least 1 of the 4 MS
(2) For the CAP, metals in cement and inorganic additions shall be declared on the basis of content not migration. Where the combined content of a metal in a cementitious product is below the level given in Table 3, migration testing in the final cementitious product may not be required as agreed by the approvals body.
(3) Recycled concrete aggregates (RCA) derived from concrete that has not been used (e.g. surplus pre-cast units or returned ready mixed concrete), has previously been approved for contact with DW, and has not been contaminated in storage, will not require further testing. Other sources of RCA and recycled aggregates will need testing for metals, admixtures and other organic substances.
(4) Not required if the organic substance is only a grinding aid at less than 0.2% by mass of the constituent (See C4)
Research is being commissioned to confirm that the use of content limits can eliminate the need for testing, to confirm limit values and also extend the number of metals covered. (Other metals to be studied include Sb, Hg, Se and V)

<table>
<thead>
<tr>
<th>Metal</th>
<th>Limit by content on cement plus inorganic additions (% by mass)</th>
</tr>
</thead>
<tbody>
<tr>
<td>As</td>
<td>&lt; 0.01 %</td>
</tr>
<tr>
<td>Cd</td>
<td>&lt; 0.001 %</td>
</tr>
<tr>
<td>Cr</td>
<td>&lt; 0.05 %</td>
</tr>
<tr>
<td>Ni</td>
<td>&lt; 0.05 %</td>
</tr>
<tr>
<td>Pb</td>
<td>&lt; 0.05 %</td>
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<tr>
<td>Assessment test</td>
<td>Testing procedure</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td>Composition rules</td>
<td>Part B, Table 2</td>
</tr>
<tr>
<td>Organoleptic parameters</td>
<td>EN 14944-1 for Products prEN 14944-2 for constituents (Note 1)</td>
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<tr>
<td>General Migration</td>
<td>EN 14944-3 for Products prEN 14944-4 for constituents (Note 1)</td>
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<tr>
<td>Enhanced Microbial Growth</td>
<td>For future review by SG-CM</td>
</tr>
</tbody>
</table>
NOTE 1:

EN 14 944-1 and 3 include options for some “regulatory” aspects of the test procedure: disinfection option, chlorinated and/or chlorine-free test water, number of replicates, testing at elevated temperature.

Regarding these options, specifications for application of these standards for approval of products/materials are as follows:

- **disinfection procedure** (clause 8.3.3 of EN 14944-1 & 3) is not required (justification: see co-normative research report (2002/2003))
- **Chlorinated and/or chlorine-free test water**: chlorine-free test water is always required. Test with chlorinated water are required in addition for applications and Member States where the product/material is intended to be used for contact with chlorinated water (Tests with chlorinated water may not be necessary for parameters on which chlorine has no impact, e.g. migration of metals…)
- **Number of replicates**: duplicate testing is required as defined in the standard – i.e. a duplicate test for each test water
- **Number of leaching periods**: first three migration periods, extended if required to a maximum of ten
- **Testing at elevated temperature**: procedures are described in normative annexes of EN 14 944-1 & 3. The test temperature needs to be specified in product standard or national regulation.

NOTE 2: EMG –see C4. Further work being done on selection of test method from the alternatives available by the SG-CM in the light of any work on the application of EMG tests to products.