

DRAFT

4MSI Common Approach: ACCEPTANCE OF ENAMELS AND CERAMIC MATERIALS USED FOR PRODUCTS IN CONTACT WITH DRINKING WATER

Part A – Methodologies for testing and accepting compositions to be included in the 4MSI Positive List of compositions for enamels and ceramic materials

Part B – 4MSI Positive List of compositions for enamels and ceramic materials

Part C – Procedure and methods for testing and accepting products or components made of enamels or ceramic materials

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France, Germany, the Netherlands, the United Kingdom and Denmark (4MSI) work together in the framework of the 4MS Common Approach as laid down in the Declaration of Intent (January 2011). This common approach aims for convergence of the respective national approval schemes for materials and products in contact with drinking water. It might also be used as a starting point for harmonized European requirements, which will have to be implemented under the revised Drinking Water Directive (DWD).

Part A of this document includes a common basis for accepting enamel and ceramic compositions as prerequisite for testing products.

Part B of this document includes a Positive List of enamel and ceramic compositions accepted in all of the 4MSI following the procedure described in Part A and a corresponding list of parameters to be investigated when products are tested according to Part C.

Part C includes a procedure and methods for testing and accepting products or components made of enamels or ceramics in a certifying or approval process.

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

Bundesministerium für Gesundheit (Deutschland)

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

Ministerie van Infrastructuur en Milieu (Nederland)

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

Miljøministeriet, and Trafik-, Bygge- og Boligstyrelsen (Denmark)

Principle of Acceptance

Enamels and ceramic materials are inorganic materials. They are defined by their composition of different elements. The acceptance of products or components made of enamels or ceramic materials (final materials) is based on the acceptance of possible compositions and a migration testing for certain constituents.

The acceptance of compositions is aimed to recognize the principle fitness of certain compositions and to identify the constituents to be determined for the migration test of products. In this process reference concentrations as acceptance criteria for the constituents or impurities are derived. As a result, the recognized composition is included in a Positive List for the specific material in Part B of this document.

The acceptance of products or components made of enamels or ceramic materials (final materials) in Part C of this document follows a risk-based approach. Products have to be in accordance with the 4MSI Positive List. Furthermore, migration tests have to be performed depending on the conversion factors to be applied.

Abbreviations

4MSI	Four Member States Initiative
C_{tap}	Calculated Concentration of a Substance at the Tap
CF	Conversion Factor in d/dm
DW	Drinking Water
DWD	Council Directive 98/83/EC - Drinking Water Directive
MS	Member State(s)
PL	Positive List
PWD	Products in Contact with Drinking Water
RC	Reference Concentration (Acceptance Criteria)

Definitions

Component:

is a finished component used for contact with drinking water either directly or after being assembled in another product.

Conversion factor (CF):

is a required component-specific factor, taking into account the experimental surface/volume ratio and the contact time used in the migration test to determine the maximum expected concentration at the tap (C_{tap}).

Enameller:

is the plant applying the vitreous enamel on work pieces to form a cohesive material.

Enamel manufacturer:

is the factory manufacturing the vitreous enamel.

Migration water:

is the test water after contact with the test specimen(s) according to specified contact conditions.

Product:

is a definitely identifiable, manufactured component in its final form, placed on the market by a manufacturer.

Reference concentration:

is the maximum concentration of an element in drinking water that is permitted to occur due to migration from enamels or ceramic materials.

Test water:

is fully demineralised water according to EN 12873-1 used for the migration test.

Part A - Methodologies for Testing and Accepting Compositions to be Included in the 4MSI Positive List of Compositions for Enamels and Ceramic Materials

1 Procedure to assess

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

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

2 Compilation of a 4MSI Positive List

For the acceptance of a composition or the modification of an accepted composition for enamels or ceramic materials it is required to perform a migration test according to EN 12873-1 (described in Part C) on test specimens which are representative of the material concerned and which displays relatively high contents within the allowed content range for relevant elements or substances.

Concentrations of constituents or impurities determined in migration waters have to comply with the reference concentrations given in Part B Table *Reference concentrations for the evaluation of enamels and ceramic materials* and Table *Reference concentrations for PAH*.

Following constituents of enamels and ceramic materials were evaluated and no reference concentration was seen necessary: Calcium, iron, fluorine, potassium, lithium, sodium, phosphorus, silicon, titanium dioxide, tin and zinc. Therefore, these elements are not included in Part B Table *Reference concentrations for the evaluation of enamels and ceramic materials* and Table *Reference concentrations for PAH*.

For elements or substances not listed in Part B Table *Reference concentrations for the evaluation of enamels and ceramic materials* and Table *Reference concentrations for PAH* or mentioned above, a reference concentration of 0.1 µg/l applies. The applicant might submit toxicological studies enabling assessment of the migrating element(s) or substance(s) in order to allow the establishment of corresponding reference concentrations.

The specified contents of enamel and ceramic materials (see Part B) are mandatory but may be modified on request.