



Enamel Industry position on the assessment of the hygienic suitability of enamel materials in contact with drinking water

Design of delegated and implementing acts under Article 11 of Directive EU 2184/2020 (EU Drinking Water Directive)

This position paper aims to provide inputs from EEA, representing European Enamel Industry, to the EU Commission, as well as other regulators and stakeholders, involved in the process of specifying the provisions of the Article 11(2)(b) DWD (Implementing Acts) and Article 11(2)(c) DWD (Implementing Acts), which will describe requirements for:

European positive lists of starting substances, compositions and constituents

Implementing Acts to establish “procedures and methods for testing and accepting final materials as used in a product made from materials or combinations of starting substances, compositions or constituents on the European positive lists.

Art. 11§2(b) - European positive lists of starting substances, compositions and constituents

In the draft document of the EU commission AP7 (b)_Draft 2.IA_annexes, we noticed that HfO_2 , a by-product in the used raw material zirconium oxide, is not included in the European positive lists of compositions of enamels, ceramics and other inorganic materials (Table 10 of Annex 4). We would like to inform that a request for the introduction of hafnium oxide (HfO_2) is currently being assessed at UBA on the request of our German member DEV. Consequently, EEA also requests its implementation in the European acts.

We also noted that the release limits for the elements Bi, Ce, Hf, Mo, Pr, Sr, Ti, Y, Zr are indicated as "not available" in the Table 11 in the Annex 5. We would appreciate the meaning and reason for this.

Art. 11§2(c) - Procedures and methods for testing and accepting final materials as used in a product

We have several comments on the draft document of the EU commission AP10 (d)_Draft 4.IA_annexes and especially on its Annex IV: Final enamels, ceramics materials and other inorganic materials (including glass):

- Testing of the composition: enamel can be found in different forms during the manufacturing process of enameled components (frit, formula, enamel layer). Depending on the form of the



material used for testing, the repeatability of the chemical analysis may be poor. It seems necessary to define the matrix to be used to test the composition of the material. We recommend to carry out the assessment directly on the final enamel layer intended to be in contact with drinking water.

- Composition review: The draft documents mention that “for the final materials the complete composition with the range for all constituents exceeding 0.02 % (m/m) is required”. A set limit without considering the risk group is not relevant. Consequently, we recommend to use a similar approach than the one described for final organic materials in Annex 1: “the cut-off value, below which details of the formulation (i.e. the chemical composition of starting substances or impurities) are not required, expressed as mass percentage in the formulation is:
 - o for one substance: 0.02% for RG1, 0.05% for RG2 and 0.1% for RG3 materials and
 - o for the sum of all such substances: 0.1% for RG1, 0.2%for RG2 and 0.5% for RG3.”

As enamel is mainly within the risk group RG2, we ask to use 0.05% limit for one substance and 0.2% for the sum of all such substances.

- Temperature of testing: EEA ask to apply test conditions of the Table2 of the 4MSI Common Approach: ACCEPTANCE OF ENAMELS AND CERAMIC MATERIALS USED FOR PRODUCTS IN CONTACT WITH DRINKING WATER.

Table 2: Test conditions for components

Component group	Test conditions
Components intended exclusively for cold-water use	Cold water test at 23 °C ± 2 °C
Components normally in contact with both warm and cold water (e.g. mixing blocks on a tap)	Warm water test at 60 °C ± 2 °C
Components for drinking-water heaters	Warm water test at 60 °C ± 2 °C
Components for drinking-water heaters that normally dispense hot water near the boiling point	Hot water test at 85 °C ± 2 °C

EEA is available to justify this position if required.