

## **Decree of the Ministry of Social Affairs and Health**

### **on the notification of conformity assessment bodies for products in contact with domestic water and domestic hot water and the hygienic suitability of a product for use in water installations**

In accordance with the decision of the Ministry of Social Affairs and Health, the following is laid down pursuant to section 17b, subsection 7, paragraph 3 of the Health Protection Act (763/1994):

#### **Section 1** *Notifying authority*

The National Supervisory Authority for Welfare and Health acts as the notifying authority referred to in Article 4(1) of Commission Delegated Regulation (EU) 2024/370, hereinafter the *Commission Regulation*, laying down the conformity assessment procedures for products that are in contact with water intended for human consumption and the rules for the notification of conformity assessment bodies involved in these procedures, supplementing Directive (EU) 2020/2184 of the European Parliament and of the Council.

The National Supervisory Authority for Welfare and Health

- 1) establishes and implements the necessary procedures for the designation of conformity assessment bodies;
- 2) examines an application submitted by a conformity assessment body referred to in Article 7 of the Commission Regulation and adopts a decision on it;
- 3) notifies the Commission and other Member States of a body it has approved by using the electronic notification tool developed and managed by the Commission.
- 4) monitor that the notified body operates in accordance with the application and the decision referred to in paragraph 2.

The decision referred to in paragraph 2(2) may include conditions for approval that are necessary for the supervision of the notified body.

#### **Section 2** *Certificate of accreditation of a conformity assessment body*

The FINAS Finnish Accreditation Service unit of the Finnish Safety and Chemicals Agency accredits conformity assessment bodies after having assessed them as meeting the requirements laid out in standard SFS-EN ISO/IEC 17065:2017 and in Articles 5 and 6 of the Commission Regulation;

Proof of accreditation shall be attached to the application for notification referred to in section 1(2), paragraph 2.

Section 3  
*Suitability of the product for use in water installations*

A product that comes into contact with domestic water and domestic hot water and is used in new water system installations or in the reconstruction of existing installations shall comply with the specific minimum hygiene requirements laid down in the Commission's implementing acts adopted pursuant to Article 11(2) of Directive (EU) 2020/2184 of the European Parliament and of the Council.

Section 4  
*National product suitability requirements for use in water installations*

By way of derogation from Article 3, a product's hygienic suitability for use in installations where the product comes into contact with domestic water or domestic hot water may be demonstrated by means of a national certificate of conformity. This certificate must be valid on 31 December 2026.

Section 5  
*National certificates of conformity attesting the suitability of the product for use in water installations*

The national certificate of conformity referred to in section 4 means the type approval or other procedure for demonstrating suitability referred to in Chapter 2 of the Act on the Type Approval of Certain Construction Products (954/2012).

The other procedures for demonstrating suitability referred to in section 1 are:

- 1) an assessment certificate issued by an accredited independent party;
- 2) a declaration by the manufacturer, importer, seller or other operator who introduces to market products intended to come into contact with domestic water or domestic hot water, wherein it is stated that:
  - a) the product meets the requirements laid out in Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC;
  - b) the hygienic suitability of the product has been demonstrated experimentally in a State within the European Economic Area or in Turkey using a generally accepted procedure;
  - c) the product is approved for use in contact with domestic water and domestic hot water in a State within the European Economic Area or Turkey; or
  - d) it has been demonstrated in a manner other than the one referred to in paragraphs (a) to (c) that the product complies with the requirements laid out in section 17b, subsections 1 and 2 of the Health Protection Act.

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This Decree shall enter into force on [date] [month] 20xx.  
Articles 1(2)(1) and 2 of this Decree shall apply from 31 December 2026 at the latest.  
Article 3 of this Decree shall apply from 31 December 2032 at the latest.

Articles 4 and 5 of this Decree shall apply from 31 December 2026. The provisions shall remain in force until 31 December 2032, after which, in addition to the provisions of the Health Protection Act, the introduction of products to the market shall be governed by Article 2 of this Decree.

Helsinki xx xx 20xx

Minister Etunimi Sukunimi

Nimike Etunimi Sukunimi