

Principal impacts

1. Impacts on Public Finances and the Duties of Authorities

National Supervisory Authority for Welfare and Health (Valvira)

Acting as the notifying authority would be a new task for Valvira.

An applicant seeking to become a conformity assessment body would have to submit an application to Valvira, in which the applicant specifies the products, product groups, or methods for which it wishes to act as an assessment body. Valvira should process the application, issue an approval decision, and enter the relevant information concerning the approved applicant into the Commission's NANDO system (New Approach Notified and Designated Organisations, <https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies>).

The decision to approve a conformity assessment body and to notify the approved body in the NANDO system may be made starting from 31 December 2026, when Commission Delegated Regulation (EU) 2024/370 begins to apply. In the future, Valvira should also monitor the activities of recognised conformity assessment bodies, for example by requiring an annual report from the body in its recognition decision. Supervision would mainly consist of document review.

The processing of applications and the drafting of the decision are estimated to require, on average, 1.5 person-days of resources per assessment body. This would be a one-off assignment. The approval of annual reports for supervision and the provision of guidance to assessment bodies are estimated to require one person-day of resources per notified body per year. In addition, cooperation with the Commission and with notifying authorities in other countries is estimated to take a few person-days per year. It is assumed that there will be 2–5 applicants for conformity assessment body status in Finland, so from 2027 onwards, handling the task would require at most the equivalent of 0.5 person-months of resources annually at Valvira. Prior to this, working time would be spent on, among other things, preparation, familiarisation, and the design of the application and supervision processes.

The task does not require additional human resources for Valvira. Pursuant to section 4(1)(3) and (5), section 4(2), and section 6(1) of the Act on Criteria for Charges Payable to the State (150/2012), a fee must be charged for the approval of conformity assessment bodies and for inspections relating to their supervision, corresponding to the total costs incurred by the State in providing the service. Thus, Valvira would not incur any additional costs due to the task.

FINAS Accreditation Service (FINAS)

The accreditation of conformity assessment bodies would be a partly new task for FINAS. The assessment bodies to be accredited are the same as those which FINAS already accredits under Regulation (EU) No 305/2011 of the European Parliament and of the Council, on harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, so this would amount to an extension of accreditation.

The task does not require additional human resources. Since accreditation is a chargeable activity for the operator, the task would not give rise to additional costs for FINAS.

2. Impact on the business economy

Conformity assessment bodies

Under the Act on Criteria for Charges Payable to the State, the one-off fee for a decision to be designated as a notified body is estimated at around EUR 1 500. The annual supervisory

inspection is estimated to cost the notified body approximately EUR 950. The maintenance of the accreditation is estimated to cost the notified body between EUR 3 000 and EUR 5 000 per year. The identified operators applying to become notified conformity assessment bodies are large companies with a turnover exceeding EUR 10 million. Therefore, the additional costs incurred by the operators can be considered minor.

Operators placing products on the market

Section 5 of the Regulation would define what is meant by a national certificate of conformity. The section comprehensively compiles the procedures currently in use for verifying that a product is suitable for use in water supply installations. The costs for operators placing products on the market are therefore estimated to be minor.

Water supply facilities

There are currently no documents defined in Finland for products used in water supply installations that could be considered as national certificates of conformity. The Act on the Approval of Certain Construction Products (954/2012), hereinafter *Product Approval Act*, does not apply to products used in the drinking water production chain of water utilities, except for products that are the same as those used in building water installations.

Water utilities use various criteria in their procurement of materials to demonstrate that products are suitable for drinking water use. These criteria have included, for example:

1. that the product complies with the legislative requirements for materials in contact with food;
2. that the suitability of the product has been demonstrated in a reliable manner (such as through a certificate issued by an accredited independent party or by meeting the requirements of relevant EN or ISO standards) within the European Economic Area; or
3. that the product has been approved in another EEA member state.

The procedures currently used by these utilities to demonstrate a product's suitability for use in water installations are compiled in subsection 2 of Section 5 of the draft Regulation. In addition to the European Economic Area, the section also refers to Turkey, with which the European Economic Community concluded an Association Agreement in 1963 to deepen economic cooperation (the so-called Ankara Agreement).

Defining a national certificate of conformity in legislation can be seen as clarifying the criteria by which water utilities select products that are hygienically suitable for their installations, thereby partly reducing the administrative burden on the utilities and, consequently, their costs.

Impacts on households

For products used in building water fittings, the current hygienic and technical requirements are governed by the Product Approval Act. Under the Product Approval Act, the suitability of a construction product can be demonstrated through type approval as referred to in Chapter 2 of the Act. Type approval would be considered a national certificate of conformity, so the current procedure for demonstrating the suitability of products for use in building water installations would not change. Therefore, the proposed amendments would not result in additional costs for households.

3. Impacts on the Environment and Human Health

The proposed amendments are not expected to have any impact on the environment.

The proposed amendments can be seen as strengthening the high level of protection of human health, as the legislation would clarify which products are hygienically suitable for use in water installations.

4. Impacts on the Internal Market

The proposed amendments do not have an impact on the internal market. A national certificate of conformity would be granted based on a declaration by the manufacturer, importer, seller, or other operator placing on the market products intended to come into contact with drinking water or domestic hot water, stating that the product's hygienic suitability has been demonstrated experimentally in a member state of the European Economic Area or in Turkey using a generally accepted procedure, or that the product has been approved for use in contact with drinking water and domestic hot water in a member state of the European Economic Area or in Turkey.