

Principles for the cooperation between FINAS and national authorities

Policy document A6/2024

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1 Foreword

This FINAS policy document is originally drawn up by a working group appointed by the Advisory Committee for Conformity Assessment Matters, Subcommittee for Accreditation Matters (VANK-P). The new version A6/2024 replaces the previous version A6/2021. This version takes into account new practices.

The purpose of the policy documents is to clarify the application of accreditation requirements in practice. The policy documents have been drawn up in accordance with principles agreed within the international cooperation organizations of accreditation bodies (European co-operation for Accreditation (EA), the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF)).

Accreditation criteria in force are presented in FINAS's Decision P1. Information about policy documents and mandatory guides can be found at FINAS website (www.finas.fi).

2 Background

The European Parliament and Council issued in the year 2008 a Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products (765/2008/EC) as part of the NLF (NFL = New Legislative Framework). In 2019 (20.6.2019) the Regulation on Market Surveillance and Conformity of Products ((EU) 2019/1020) was separated from the regulation 765/2008/EC for its own regulation. In addition in year 2008, the European Parliament and Council issued a Decision on a common framework for the marketing of products (768/2008/EC). The Decision will be applied when drafting new EC legislation or when amending existing legislation. Among other things, the Decision includes requirements concerning notified bodies. In Finland, the Decision has been taken into account in the new general Act on Notified Bodies (2016/278) and in the NLF package's directive-specific enforcement acts.

The Regulation has been applied since 1 January 2010, and after 2019 Regulation 2019/1020 has been taken into account. It contains rules about accreditation, market surveillance, external border controls (products within the sphere of application of EC legislation), and CE marking. The rules on accreditation apply to both statutory and compulsory accreditation. By virtue of the Regulation, all national accreditation systems within the EU operate according to the same principles. The starting point of the Regulation is to consolidate

the role of accreditation when assessing the competence of conformity assessment bodies.

In June 2006, the European co-operation for Accreditation (EA) launched a project to prepare for the New Legislative Framework (NLF) of the European Union. The EA project was completed in November 2007 with the publication of the guide “Accreditation Body Communication with National Regulators – Best Practice Guide”. The guide is intended to assist the EA and the EA accreditation body members in developing, maintaining and strengthening cooperation with the regulators, at the European and national level. The guidance has been updated and published in 2020 as EA-INF/07:2020.

These recommendations and principles concerning cooperation with the authorities are based on the EA guide.

3 General principles

The objective of FINAS Finnish Accreditation Service is to develop accreditation so that it meets the needs of various sectors as well as possible. FINAS promotes the use of accreditation in different sectors and disseminates information about the benefits of accreditation. FINAS cooperates with the national authorities and follows the developments taking place within the EA. FINAS’s goal is to ensure that uniform requirements are applied in all sectors.

4 Co-operation and Exchange of Information

4.1 Co-operation

The Ministry of Employment and the Economy is directive ministry for FINAS. FINAS promotes issues related to accreditation with different ministries. FINAS contacts directly to ministries or through Tukes if needed.

The legislation has defined that the Advisory Committee for Accreditation Matters (VANK-P) can serve as an advisory committee for FINAS but during the publication phase of this policy document the Advisory Committee is not nominated. In this point tasks of the Accreditation Board have been increased when its has taken some tasks from the Advisory Committee.

The Ministry of Employment and the Economy is hoping to promote recognition of accreditation and appropriate application. Also, Ministry must inform to FINAS its needs and goals concerning accreditation.

On FINAS website, FINAS updates and supplements the information on

Multilateral Recognition Arrangements (MLA) and its coverage.

FINAS maintains a list of bodies responsible for the national implementation of EU legislation associated with accreditation and assessment of competence.

In order to ensure efficient operation, FINAS and the authorities should jointly see to it that FINAS is kept informed of the latest guidelines and interpretations. FINAS's participation in the joint meetings of the authorities and/or conformity assessment bodies and other such events is one way of accomplishing this.

4.2 Preparation of legislation

In keeping with its own practices, the EA collects information on the preparation of EU legislation. Through EA committees, FINAS follows how the preparation is proceeding. Whenever necessary, FINAS keeps the EA up to date of the preparation of Finnish legislation.

As early as possible, FINAS is informed of legislative projects or preparation of guides that include sections concerning accreditation or assessment. Information comes from Tukes or directly from Ministry or authority. At its discretion, FINAS takes part in such preparation.

5 Process for Assessing Conformity Assessment Bodies

Both Regulation 765/2008 and Decision 768/2008 consider accreditation to be the primary procedure for proving the competence of conformity assessment bodies. In general, the process for assessing actors in the regulated sector is uniform with voluntary accreditation processes. However, when performing assessments in the new regulated sector, FINAS contacts the competent authority already during the application phase in order to determine the scope of accreditation needed and any special features that there might be. At the same time, it may be agreed that representatives of the authority participate in some specific stages of the assessment process. Information on contact persons in various sectors is kept up to date for liaison between FINAS and the competent authority. Any problems or other similar issues arising during the assessment process are solved between the contact persons named.

In accordance with the prevailing practice, FINAS supplies all assessment reports and decision documents to the party assessed, which then transmits the necessary information to the authority.

Whenever needed, an authority may ask FINAS for more information through a information request. It can be agreed between the authority that they should

provide FINAS with information on its approval decision, including any obligations that may be attached to the decision.

The authority must see that FINAS is kept informed of the latest guidelines and interpretations.

In its dissemination of information, FINAS complies with the confidentiality principles of accreditation activities.

References

EA-INF/07:2020 National Accreditation Body Communication with National Regulators - Best Practice Guide

Regulation (EC) No 765/2008 of the European Parliament and of the Council

Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products

Regulation (EU) 2019/1020 of the European Parliament and of the Council on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011

Changes to the previous version

Changes 28.02.2024

Chapter	Change
4 Cooperation and Exchange of Information	Updated in line with current cooperation and taken into account change with VANK cooperation.
5 Process for Assessing Conformity Assessment Bodies	Updated as regards the information to be disclosed to the authorities.
6 Assessment of Assessment Bodies	Chapter moved and part of the text is moved to chapter 4.
7 Summary of Recommendations for the Various Parties	Chapter moved and part of the text is moved to supplement other chapters.