

Principles for the cooperation between
FINAS and national authorities

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Background

The European Parliament and Council issued 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. In addition, 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.

The Regulation has been applied since 1 January 2010. 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 voluntary 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 2011 as EA-INF/07:2011.

These recommendations and principles concerning cooperation with the authorities are based on the EA guide. Under sections 3–6, the principles describe how the recommendations given in the EA guide can be implemented in Finland. The principles have been drawn up by the Advisory Committee for Accreditation Matters (VANK-P).

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.

Cooperation and Exchange of Information

The Ministry of Employment and the Economy is responsible for coordination and acts as a liaison between the various ministries.

The Advisory Committee for Accreditation Matters (VANK-P) serves as an advisory committee for FINAS. In line with the requirements set for an accreditation body, the Committee should represent a sufficiently wide range of stakeholders.

On its website, FINAS updates and supplements the information on Multilateral Recognition Arrangements (MLA), taking into account the principles of the NLF Regulation. FINAS informs the Advisory Committee for Conformity Assessment Matters (VANK) of the results of peer evaluations.

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

Preparation of legislation

Dissemination of information on new Directives or Directives under amendment is a standard item on VANK-P meeting agendas. Information is disseminated in both directions.

As early as possible, FINAS is informed (through VANK or directly) of legislative projects or preparation of guides that include sections concerning accreditation or assessment. At its discretion, FINAS takes part in such preparation.

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.

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 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. The same procedure also applies when an amendment is sought for the scope of accreditation. 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.

If they so wish, authorities may also receive the information directly from FINAS, provided that an agreement to this effect has been made between the party as-

essed, the authority and FINAS. In that case, the authority should provide FINAS with information on its approval decision, including any obligations that may be attached to the decision. The authority's decision should include a clause stating that the authority is entitled to obtain information related to accreditation and necessary for surveillance directly from FINAS. The contact persons of the authority and FINAS agree to what extent FINAS provides information for the authority. FINAS is required to inform its clients of any data that it gives directly to the authorities.

With respect to information that, by law, must be kept confidential, the authority must first ensure that it has the legal right to obtain the information in question from FINAS. It is recommended that the authorities go through the regulations pertaining to their own sector and ensure that the rules concerning disclosure of information are in order.

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

Assessment Schedule and Surveillance of Assessment Bodies

With respect to the assessment schedule and surveillance in the regulated sector, FINAS adheres to normal accreditation practices. The authorities may set additional requirements for the surveillance.

The maintenance of accreditation includes the accredited body's obligation to provide information on any significant changes that have taken place in accredited operations. In their own decisions, the authorities also define what information the accredited body needs to supply. In Finland, the party accredited is generally itself responsible for supplying information to the supervisory authority. FINAS and the authority may agree on practices whereby FINAS informs the authority, in particular, of any major changes having a bearing on the decision, such as suspension of accreditation or a reduction in the scope of accreditation.

In order to ensure efficient surveillance, 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.

Summary of Recommendations for the Various Parties

Ministry of Employment and the Economy:	Coordinates and acts as a liaison between ministries.
	Sees to it that the VANK-P committee represents a sufficiently wide range of stakeholders in line with the requirements set for an accreditation body.

The authority:	Informs FINAS, through VANK or directly, of legislative projects or preparation of guides that include sections concerning accreditation or assessment.
	Determines, together with FINAS, the scope and special features of each assessment.
	Participates in the assessment process, as needed.
	Informs FINAS of its approval/appointment decisions (FINAS is on the distribution list of the decision).
	In the approval/appointment decision, sets requirements for the provision of information.
	Goes through the rules pertaining to disclosure of information in its sector and ensures that it is entitled to receive information directly from FINAS (especially information that must be kept confidential).
	Provides the approval/appointment decision with a clause stating that the authority is entitled to obtain information related to accreditation directly from FINAS.
	Agrees with FINAS on practices whereby FINAS informs the authority, in particular, of any major changes having a bearing on the decision.
	Sees to it that FINAS is kept informed of the latest guidelines and interpretations.
FINAS:	On its website, maintains information on Multilateral Recognition Arrangements and their scope.
	Informs VANK of the results of peer evaluations.
	Maintains information on EA contacts and a list of bodies and persons responsible for the national implementation of EU legislation associated with accreditation and assessment of competence.
	Maintains a list of contact persons in various sectors.
	At its own discretion, participates in the preparation of national legislation.

	Through EA committees, follows the preparation of EU legislation.
	Informs the EA of the preparation of national legislation, as needed.
	Determines, together with the authority, the scope and special features of each assessment.
	Informs its clients of data that it supplies directly to the authorities.
	Agrees with the authority on practices whereby it informs the authority, in particular, of any major changes having a bearing on the decision.
	Participates in the joint meetings of the authority and/or conformity assessment bodies, as needed.
VANK-P:	Serves as an advisory committee for FINAS.
	Meeting agendas have dissemination of information on new Directives and Directives under amendment as a standard item.

FINAS Policy Documents

This FINAS Policy Document was drawn up by an ad hoc working group (2008–2010) appointed by the Advisory Committee for Accreditation Matters (VANK-P). The working group comprised the following persons:

Vaittinen Kalevi, Chairman	Ministry of Employment and the Economy
Karjalainen Sanna-Mari	Safety Technology Authority
Nieminen Janne	Customs Laboratory
Kuoppasalmi Kimmo	National Public Health Institute
Wallin Harriet	Finnish Food Safety Authority
Janas Antti	Ministry of Social Affairs and Health
Kajander Pekka (expert)	Finnish Vehicle Administration
Rantanen Varpu (expert)	FINAS
Kaartinen Harri, Secretary	FINAS

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, International Laboratory Accreditation Cooperation and International Accreditation Forum).

Further information about policy documents is available from FINAS – Finnish Accreditation Service:
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