A stronger Sweden with open systems

- a government assignment on how Swedish export can benefit from accreditation and standardisation

Preface

Swedish export is a cornerstone in Sweden’s economy that creates growth, employment and greater prosperity. On 24 September 2015, an export strategy was decided that was produced by the government in consultation with the business sector. The objective of the strategy is to increase exports, increase Sweden’s attractiveness for investment, skills and tourism, increase the proportion of exporting companies as well as increase the participation of Swedish companies in the global value chain. The government’s export strategy will contribute to the government’s overall objective that Sweden will have the lowest unemployment rate in the EU by 2020. The quality of products and services is a prerequisite for successful market access and is crucial to increasing revenues from export.

The Swedish Board for Accreditation and Conformity Assessment (Swedac) is the national accreditation body of Sweden. In this role Swedac verifies the competence of conformity assessment bodies which in turn verify compliance of products and services with quality and safety requirements in order to facilitate the free movement of goods and services across borders. Swedac is responsible for matters concerning conformity assessment, including accreditation and other aspects of conformity assessment procedures, as well as coordinating Swedish market surveillance. Swedac is also the regulating authority for legal metrology and the control of precious metal articles.

Swedac has been tasked by the government to analyse and report on how accreditation combined with standardisation can be used in order to promote Swedish export. Swedac will also submit proposals for how the conclusions of the analysis can be communicated to the companies affected. In this report we present examples of companies that have been successful in their use of accreditation and standardisation, as well as examples where the regulatory framework for the quality infrastructure does not work as intended. A main message is that there is a need for increased knowledge of the regulatory framework field as well as the benefits of accreditation and standards in promoting Swedish export. This requires cooperation and dialogue between different stakeholders at national, European and international level, and where Sweden can take a leading role.

The work in this report has been carried out by a working group comprising a project manager with main responsibility and as coordinator, two investigators as well as a lawyer; Peter Kronvall (project manager), Magnus Pedersen (investigator), Erika Palmheden (jurist) and Amina Makboul (investigator). In addition, other colleagues have also participated in the work. SIS has also contributed with data on standardisation for the relevant parts of the report.

Finally, we would like to thank the various parties we have been in dialogue with as work progressed. In particular, consultative contacts at the National Board of Trade, the Swedish Agency for Economic and Regional Growth, the Swedish Governmental Agency for Innovation Systems (Vinnova), and participants in the Swedish Standardisation Federation, as well as the companies, accredited bodies and professional associations which have been interviewed.

Borås, March 2018



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Interim Director General

Swedac

Summary

This report presents an analysis of how accreditation and standardisation can be used to promote Swedish export. The report also contains proposals for how the conclusions of the analysis can be communicated­ to the companies affected. The report is a result of a government commission to Swedac. An in-depth description is also provided of the quality infrastructure and conformity assessment­ system as well as their benefits in order to facilitate understanding of how accreditation and standardisation can be used to promote Swedish export. In addition, the report draws attention to a number of problems that need to be dealt with in order to make use of the intrinsic potential in accreditation and standardisation­ when they interact. The report also highlights a number of applications that can serve as good examples and guidance for both legislators and private enterprise.

Initially, the ambition of the report was to identify clear examples and connections between accreditation – standardisation and successful export. Similarly, another goal was to find clear examples of applications that should be avoided. This study now shows that reality is not so straightforward and it is difficult to identify successful or less successful examples in their strictest forms. In several of the examples studied we have found good applications together with poor applications. It is evident that several stakeholders lack knowledge about the quality infrastructure as a whole. Broad efforts are needed in this regard for information and training purposes. We note that the EU’s New Legislative Framework (NLF) brings about a well-functioning quality infrastructure. Here the rules and procedures are clear for the stakeholders and the proceedings ultimately lead to access to the European market. A further positive consequence of this European system is that it has an advantage when it comes to market access in many other markets of the world. Furthermore, Swedac finds it problematic that some legislative proposals deviate from the system heavily supported by the European Commission and sees a risk of an increased administrative burden as well as increased costs for private enterprise. The Swedish government should adopt a general and clear approach in this regard in future negotiations.

Situations in which the international system for conformity assessment fails to work are often characterised by one party placing additional requirements over and above the accepted standards. It may be a question of requirements on a product or service, or on the conformity assessment procedure itself. This leads to increased costs at all levels. Our study shows that larger and well-established companies, for the most part, accept other procedures. They accept the situation and conduct the testing and certification required for access to a market. For smaller companies, it may be more difficult to handle and, in the long run, reduces their export opportunities.

The examples also show that the companies that participate in standardisation see major advantages to it. This gives a company a unique opportunity to influence the development in its field. In several cases, the experience of the individual companies will become a direct input into the standardisation work. Other aspects that become evident include the perception of an advantage in having early knowledge and information about the content of new standards. In addition, several companies point out that standards are “best practice” and by using standards in their product development they have a certainty of meeting the relevant requirements for the product. This also applies where standards do not exist but the requirements are, for example, expressed in sector specific private requirements which are sometimes also called standards.

The examples studied also show great opportunities for improvement in the current applications, partly through a more consistent and exclusive way of using the tools, and partly in new areas and applications. In order to achieve a more consistent application of the international conformity assessment systems, it is important that specifiers, such as legislators or importers, focus on the requirements for the product/service and which requirements should be assessed and certified by conformity assessment bodies. With these two input values specified, it becomes clear as to which procedure is most appropriate: testing, inspection or certification.

We note that there is great potential for new areas. Extensive standardisation is underway in several different areas and applications where accreditation and conformity assessment can be used and therefore facilitate Swedish export.

Benefits of accreditation:

* Facilitates mutual acceptance within the framework of trade agreements.
* Ensures the quality in the business as well as the reliability of and confidence in the results.
* The client receives internationally recognised results showing that the product/service meets the set requirements.
* According to a questionnaire survey conducted, accredited bodies give a grade of 5.42 (out of 6) when it comes to the importance of accreditation to the activity, and a grade of 5.05 (out of 6) when it comes to accreditation facilitating international trade.
* The same questionnaire survey produced the following results on the most important benefits of accreditation:
  + Over 45% gave “accreditation shows that you meet the set requirements” as the most important benefit.
  + Over 14% gave “accreditation gives competitive advantages” as the most important benefit.
* Allows authorities to continuously ensure the quality of products and services.
* The state can assume responsibility that the quality assurance and systems are working in that accreditation is an exercise of public authority.
* Can be a supplement to regulatory surveillance.
* Regardless of which authority has responsibility for surveillance, accreditation works in an equivalent way and facilitates cooperation between regulatory authorities.
* Facilitates follow-up through recurrent inspection/surveillance.
* Creates a structure in the activity and promotes continuous improvement.

Benefits of participating in standardisation and using standards:

* Provides the opportunity for Swedish companies and organisations to influence Swedish, European and global[[1]](#footnote-1) standards.
* Makes it easier for innovations to quickly gain market access without losing their unique character.
* Strengthens Sweden’s competitiveness by ensuring that Swedish companies comply with well-established global standards in the export of their goods and services. This is a guarantee for their customers that Swedish products and services follow so-called “best practice” and thereby maintain good quality.
* Offers Swedish participants involved in standardisation work a unique and global network, giving Swedish companies and organisations a good insight into different markets and contacts throughout the world.
* Gives Swedish participants information in advance, on industry developments and emerging new products and services so that they have the opportunity to adjust their production and/or service development before the new standards are published.
* Facilitates regulation within the framework of trade agreements.
* Provides support for government regulations through technical requirements and their presumption of conformity with requirements.
* Provides tools for regulatory authorities to ensure safety, confidence and quality in products and services.
* Facilitates governance and monitoring of publicly funded activities.

Swedac takes the view that the government should consider the following in the continued work to promote Swedish export in the field of technical regulatory issues:

* Nationally, the government should
  + study which stakeholders should be included in the continued information efforts according to the conclusions presented in this assignment
  + promote the spread of knowledge to trade-promotion stakeholders
  + promote a strong national quality infrastructure that can contribute to promoting Swedish export
  + implement an overall coordination of the Swedish quality infrastructure and strengthen cooperation and coordination between the public authorities and the private bodies involved
  + consider whether the Forum for Technical Rules (FTR) can be developed and expanded so that all authorities with assignments in the commercial sector, companies, professional associations and other stakeholders are represented, with the aim of identifying concrete barriers to trade – both large and small, and exchange experiences and learn from each other
  + establish a forum for exchanging information and experiences between relevant authorities, state enterprises and other stakeholders in the innovation system. The forum should have representatives from public authorities, the business sector, consumers and other stakeholders in order to collect feedback and opinions important to export.
* At the European level the government should
  + act to ensure that the European Commission does not deviate from the previously agreed system in accordance with Regulation (EC) No. 765/2008 in the preparation of new laws and regulations and thereby eliminate the risk of an increased administrative burden and increased costs for private enterprise, as well as act to ensure that future negotiations on new legislation follow the legislative framework set out in the New Method and the provisions on accreditation in Regulation (EC) No. 765/2008.
  + within the framework for future free trade negotiations, work for clearer agreements that are easy to interpret in terms of impact and application (especially for private enterprise) and to have actual targets for greater direct market access through concrete measures for identified products or sectors
  + promote the spread of knowledge to trade-promotion stakeholders
  + ensure that Swedac is given greater opportunity to be a strong and clear stakeholder in the European Cooperation Body for Accreditation (EA) in order to promote a uniform interpretation and implementation of the provisions on accreditation.
* At global level, the government should work
  + for the promotion of a well-functioning quality infrastructure in future free trade negotiations
  + to actively participate in the WTO TBT committee in order to eliminate unnecessary barriers to trade and to promote good compliance with agreements entered into
  + for spreading knowledge to trade-promotion stakeholders
  + with the promotion of standardisation and the use of international standards on a global level.

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# 1 Introduction

In this chapter we give a brief description of the background to the government assignment and how the work has been carried out.

## 1.1 Background

Swedish export is a cornerstone in Sweden’s economy. It creates growth, employment and greater prosperity. On 24 September 2015, an export strategy was decided that was produced by the government in consultation with the business sector. The objective of the strategy is to increase exports, increase Sweden’s attractiveness for investment, skills and tourism, increase the proportion of exporting companies as well as increase the participation of Swedish companies in the global economy.

The government’s export strategy will contribute to the government’s overall objective that Sweden shall have the lowest unemployment rate in the EU by 2020. The quality of products and services is a prerequisite for successful­ market access and is crucial to increasing revenues from export. Swedac is Sweden’s national accreditation body with responsibility for matters concerning conformity assessment, including accreditation and other issues concerning conformity assessment procedures. Swedac coordinates market surveillance in Sweden and is the regulating authority for legal­ metrology and the hallmarking of precious metal articles[[2]](#footnote-2). Swedac is active in a large number of areas and contributes to confidence in everyday life. Swedac has international assignments in all of its areas of responsibility and also­ works with international development cooperation projects in order to promote the development of quality infrastructure in countries requesting development cooperation. Swedac’s activities are governed by instructions and appropriation directions from the government, as well as legislation and agreements­ within Europe and globally. Swedac falls under two departments; Ministry of Foreign Affairs and Ministry of Enterprise, Energy and Communications and reports to the Swedish Minister for EU Affairs and Trade.

In the appropriation directions for the financial year 2017, Swedac is tasked with providing the government with expertise and contributing to the implementation of the government’s export strategy by engaging in consultation with the Government­ Offices to produce analyses and decision data on how accreditation together with standardisation, as parts of a quality infrastructure, can be used to promote Swedish export. In March 2017, Swedac solicited additional funds for this work and reported the problem description in the area. Among other things, it was found that there is currently a knowledge gap in companies about the benefits of using standards in their products and services as well as the benefit of using accredited testing, inspection and certification in order to show that the set requirements have been met. In countries to which Swedish companies export there is sometimes also a reluctance to accept Swedish testing, inspection and certification, despite the global system of mutual recognition of results. Several examples of problem areas were identified. For example environmental and safety requirements or other requirements, i.e. regulatory­ requirements, are not harmonised in the global market; international standards are not used to a sufficient extent in Sweden and within the EU, and there is a lack of knowledge about the international system for conformity assessment in emerging economies, which makes exports more difficult and means that companies are forced to undergo extra testing and certification for other markets. This problem description is also confirmed in the report of the National Board of Trade; *“What are the obstacles to Swedish foreign trade?”, the National Board of Trade’s Companies Survey 2016* where 11 per cent of the companies state that they needed additional certification and testing in other EU Member States. The Board of Trade notes that this is a significant problem for smaller companies. Furthermore, it states that 25 per cent of the large companies responded that they encounter problems regarding testing and certification, which is also considered to be a significant problem as these companies account for the lion’s share of Swedish export[[3]](#footnote-3).

## 1.2 The assignment

On 17 August 2017, Swedac was tasked by the government to analyse and report on how accreditation combined with standardisation can be used in order to promote Swedish export. Swedac shall also submit proposals for how the conclusions of the analysis can be communicated to the companies affected. The assignment[[4]](#footnote-4) was to be carried out in consultation with the National Board of Trade, the Swedish Agency for Economic and Regional Growth, the Swedish Governmental Agency for Innovation Systems (Vinnova) and the Swedish Standardisation Federation, and reported not later than 30 March 2018.

## 1.3 Method

Swedac has carried out the assignment through discussions and meetings with several stakeholders for the collection of data. A workshop was held on 3 October 2017 with participants from the National Board of Trade, the Swedish Agency for Economic and Regional Growth, Vinnova[[5]](#footnote-5), SIS[[6]](#footnote-6), SEK[[7]](#footnote-7), ITS[[8]](#footnote-8) and Swedac in order to work on the issues raised in the government assignment (Appendix 2). In December, a supplementary quantitative study on the benefits of accreditation was conducted in the form of a questionnaire survey to 432 of bodies accredited by Swedac with a response rate of 41 per cent. The questions in the questionnaire are presented in Appendix 1. Researchers Frenz and Lambert’s report, drawn up in collaboration with the UK accreditation body, the United Kingdom Accreditation Service (UKAS), and the United Kingdom’s Department for Business Innovation & Skills (BIS), [[9]](#footnote-9) has been used as inspiration for the questionnaire survey. To supplement the collection of data, in December 2017 and January 2018 Swedac met with the trade association, Teknikföretagen (Association of Swedish Engineering Industries), and conducted telephone interviews with companies that currently use accreditation and standardisation in their activities. Swedac’s advisory council has also submitted proposals for areas to study in more depth within the framework of this assignment. Report proposals were referred to the consultation organisations and on 22 February 2018 a consultation meeting was held to discuss the comments received. SIS has contributed with data on standardisation for the relevant parts of the report. The examples presented in the report are not exhaustive.

## 1.4 Delimitations

Swedac has chosen to study in general how accreditation and standardisation can be used to promote Swedish export for as wide a range of applications as possible. There is therefore no geographical limitation as to­ which countries or regions whose markets should be prioritised. Egypt is, however, mentioned in Section 4.3 on international aid and development cooperation as one of the government’s priority­ markets within the framework for the export strategy. The EU’s free trade agreements with South Korea, Japan and Canada are also mentioned in Section 5.3 in the light of the fact that these markets have been assessed as being interesting by various stakeholders within the framework of this assignment with regard to accreditation, standardisation and conformity assessment. South Korea and Japan are also included in the government’s list of priority markets in the export strategy. Bolivia is covered in the report as one of the government’s pilot countries in the export strategy. When it comes to delimiting target groups for this report, the “companies affected” are mentioned in the second part of the assignment to provide proposals on how the conclusions of the analysis can be communicated. Based on Swedac’s ­interpretation, “companies ­affected” within the framework of this assignment consist of Swedish export companies, which constitute the primary target group for this report and which can use accreditation and standardisation to promote their exports. Chapter 5 on case studies presents several examples of such companies. However, Swedac considers that this report may also be of interest to other stakeholders in order to increase knowledge in the area. For example, during the work on this report the need for a broader approach emerged with regard to the target group for the *conclusions* of the analysis, such as several trade-promotion stakeholders who provide export advice to small and medium-sized companies (SMEs), various stakeholders who provide business advice to “start-ups”, authorities/specifiers, the educational system, the media, embassies and others, which are presented in Chapter 7. In addition, we note that the report paves the way for questions that have not been investigated in this report but which may need further investigation. Finally, we are aware that exports generate imports and vice versa, but we have chosen not to address the import perspective in this report.

## 1.5 Outline

The report is subdivided as follows.

Chapter 2 describes the quality infrastructure with accreditation, conformity ­assessment, testing, inspection, certification, standardisation, metrology and market surveillance, as well as the EU’s regulatory framework for goods.

Chapter 3 describes the benefits of accreditation and standardisation as well as previous research in the field.

Chapter 4 describes how accreditation and standardisation can promote Swedish export and gives examples of international development projects where both concepts are used to increase trade with the countries in question.

Chapter 5 gives examples of areas where accreditation and standardisation do and do not work, but also examples of new areas where accreditation and standardisation can play an important role. In addition to this, there is a brief description of three of the EU’s free trade agreements in the chapters covering technical barriers to trade. The agreements are interesting from an export­ perspective when it comes to accreditation, standardisation and conformity assessment.

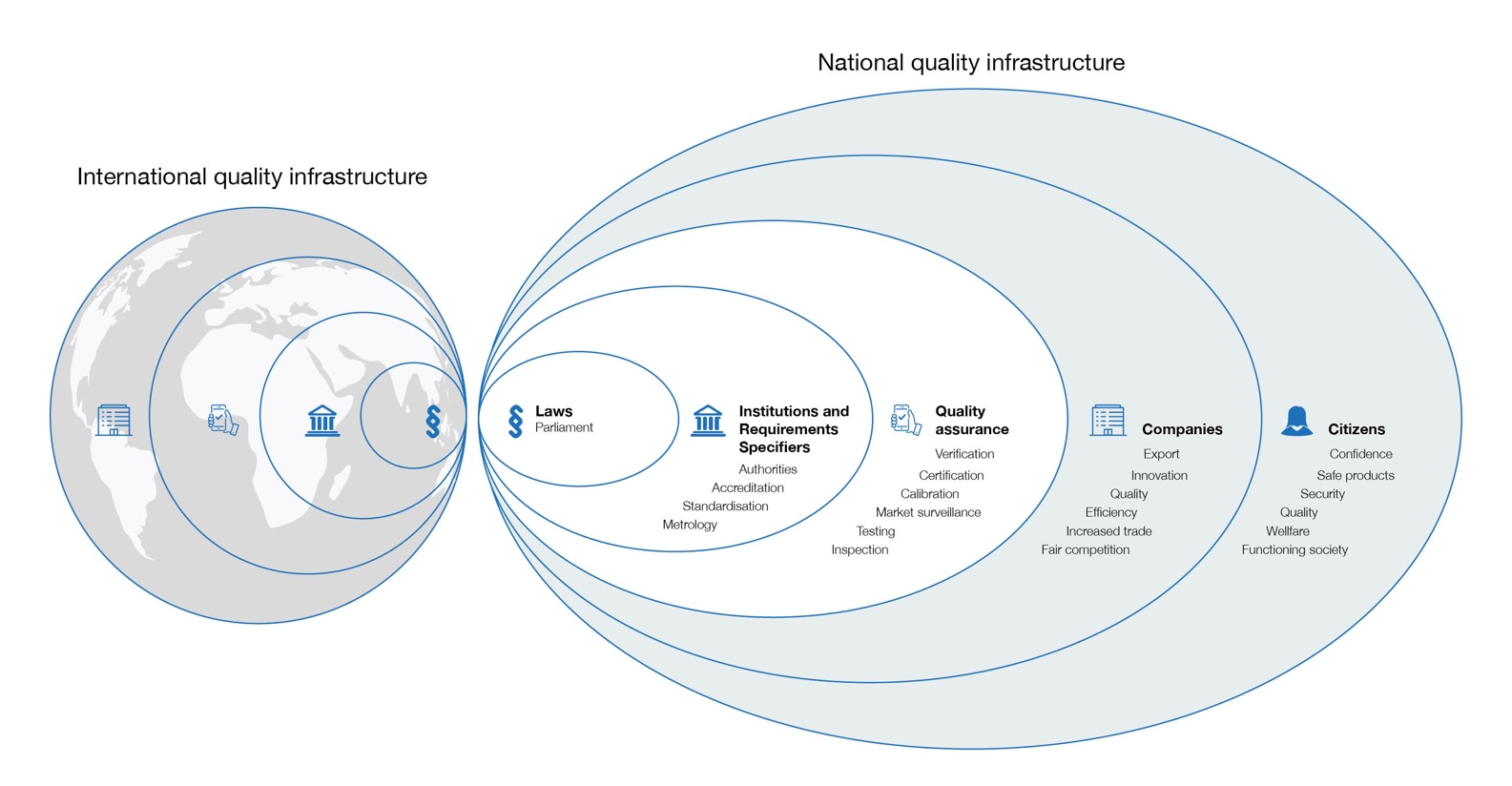
In chapter 6, we present analyses and conclusions.

Chapter 7 presents proposals for information initiatives for the companies affected and other target groups with regard to the conclusions of the report’s description of how Swedish export can be promoted by accreditation and standardisation.

2 Quality infrastructure and conformity assessment

Quality infrastructure[[10]](#footnote-10) refers to the institutions, systems and methods that a country needs in order to ensure that products and services meet requirements for safety and quality. Quality­ infrastructure is a global concept based on the World Trade Organisation (WTO) Agreement on Technical Barriers to Trade. All industrialised countries have a functioning quality infrastructure and the institutions it is comprised of cooperate globally. When this global system works, conditions are created for safety in everyday life, social ­benefits with more secure citizens, increased competitiveness in business and global free trade under fair competition.

In its capacity as national accreditation body, Swedac is coordinator for market surveillance and regulatory authority for legal metrology, and an important stakeholder in the Swedish quality infrastructure. Since 1992, accreditation in Sweden has been an exercise of public authority. The costs for accreditation are paid by the applicant and accredited conformity assessment bodies.

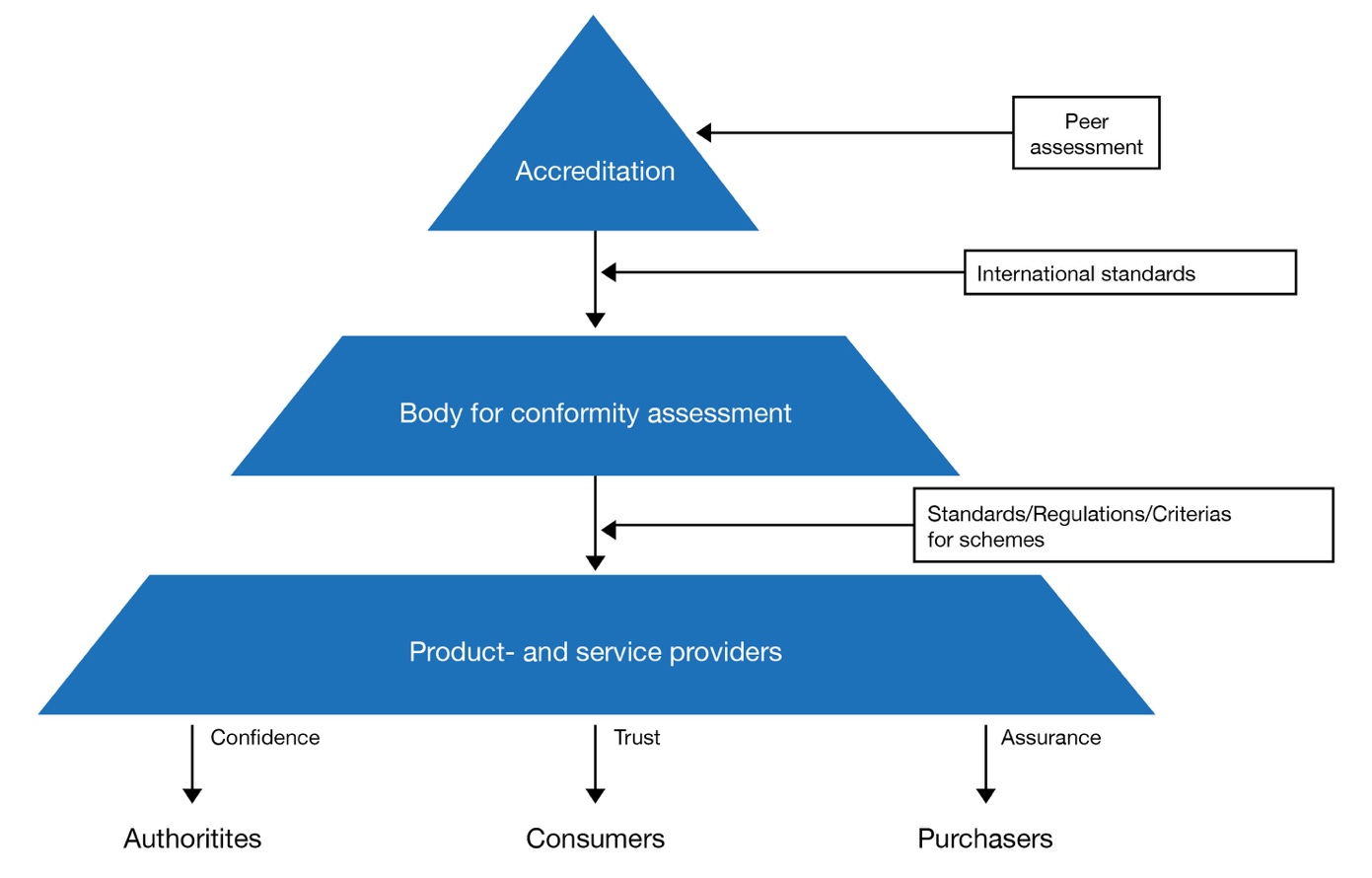
Illustration 1: International and national quality infrastructure.

## 2.1 Accreditation

Accreditation is a formal assessment of competence performed according to European and global standards. Accreditation is performed by an accreditation body. Accreditation is a method and a tool for assessing and approving companies which test, inspect, certify or verify goods, services, installations or systems. Accreditation can be used in areas which are regulated or which are completely voluntary.

The purpose of accreditation is to ensure that conformity assessment is performed in a reliable and uniform manner with the right competence by independent parties. Swedac uses accreditation to assess whether a body that offers testing, calibration, certification, inspection or verification has the competence and independence required for a particular task.

Illustration 2: Accreditation and connection to other stakeholders.



There are several objectives with accreditation. It contributes to sustainable development by improving the environment, health, safety and quality and facilitating trade.

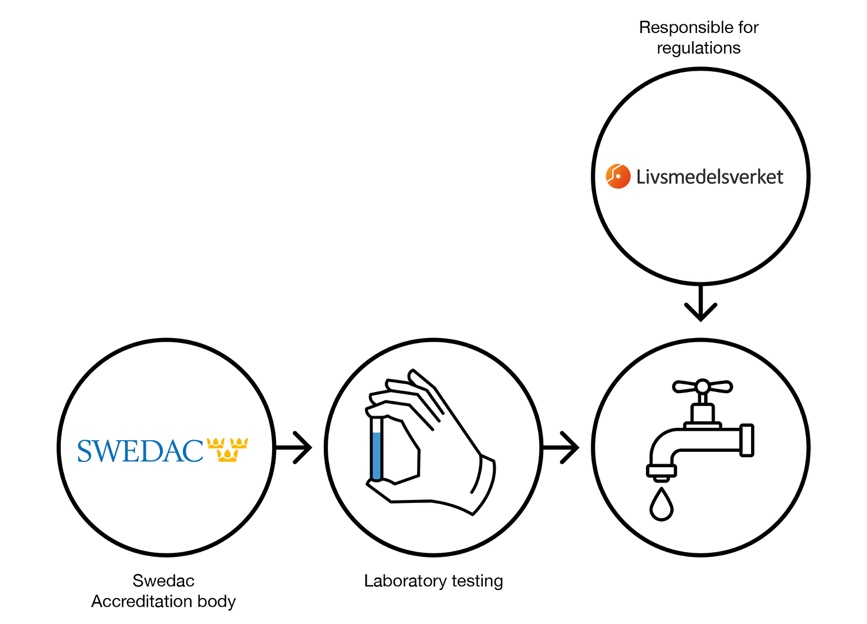
Becoming accredited involves the assessment of an organisation’s competence, procedures and methods to verify that all requirements are met according to a specific standard for the accreditation in question. The accreditation body also performs regular surveillance activities to ensure that the organisation continues to comply with the requirements for its accreditation.

Economic operators, normally companies but in some cases also individuals, that are legal entities and that perform conformity assessment can be accredited.[[11]](#footnote-11) It is not possible to accredit an entire hospital but, on the other hand, a laboratory that analyses blood samples can be accredited. It is not possible to accredit a fire extinguisher, but a certification body that confirms that the fire extinguisher meets the requirements of the relevant standards can be accredited. It is not possible to accredit a car, but all companies that are engaged in vehicle inspection must be accredited as an inspection body in Sweden.

Accreditation is a system that is used within a large number of societal areas. The system helps to ensure compliance with set rules and requirements. It creates opportunities for quality assurance on several levels and provides conditions for uniform surveillance.

Some everyday situations where accreditation is applied in Sweden is when you ride in an elevator, drink a glass of water straight from the tap, buy KRAV-certified organically grown produce or have your car inspected. Conformity assessment bodies accredited by Swedac are involved in all of these examples.

The illustration below gives an overview of how the system for accreditation works through a chain of different elements of an assessment character. Access to clean drinking water is a fundamental need for all people so there are therefore demands that the quality of the water is good. The Swedish National Food Agency (Livsmedelsverket) is the authority responsible for regulations on drinking water. Drinking water is inspected by accredited laboratories that analyse water quality. To ensure that the laboratories comply with the set requirements and that their work is carried out in the correct way, they are inspected by an accreditation body (Swedac). If the laboratory complies with the set requirements, it will become/remain accredited.

 Illustration 3: Inspection of drinking water.

The Regulation (EC) No. 765/2008[[12]](#footnote-12) of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (hereinafter referred to as Regulation (EC) No.765/2008) establishes a framework for accreditation within the EU with common principles for how accreditation should be organised and implemented. The EU Regulation codifies requirements found in international standards. Furthermore, it is ensured that all national accreditation bodies within the EU operate within a public judicial framework and that the activities of the national accreditation bodies is an exercise of public authority. Accreditation and the surveillance by accreditation bodies ensure the competence and independence of the conformity assessment bodies in accordance with standards and sector-specific requirements. In this way, the rules contribute to creating confidence in conformity assessment systems. They also contribute to the uniform application of the requirements within the EU.

Public authorities in both exporting and importing countries can reduce the burden on companies in conformity assessment by the leverage of existing systems and EU-internal and global voluntary agreements. By these means, public authorities can contribute to the objective of “one-stop-shopping” i.e. “tested, inspected, certified once and accepted globally”. Global acceptance of results from testing, certification and inspection is based on there being confidence in the results. This confidence is created by means of the competence of the parties performing the testing, inspection and certification being reviewed by a globally recognised accreditation body, and by means of the accreditation work using internationally harmonised standards at all levels, and thereby based on the same requirements in all countries. The global agreements on mutual recognition of results between accreditation bodies can therefore facilitate global acceptance of results, and thus promote the free circulation of goods and services.

An international system of common European legislation

Accreditation is an international system that is applied in a large number of the countries in the world. There is a highly developed cooperation between accreditation bodies in different regions.

As mentioned above, there is common legislation within the EU that establishes the requirements for accreditation. Regulation (EC) No. 765/2008 is the first legal framework for accreditation in the EU. The regulation­ ensures that accreditation takes place in a harmonised manner in all EU Member States. The Regulation ensures that national authorities recognise the equivalence of accreditation bodies in other Member States and accept certificates issued by the conformity assessment bodies that have been accredited by them. The main­ principles for accreditation in the Regulation are:

* One accreditation body per Member State
* Accreditation is an exercise of public authority
* No competition between national accreditation bodies, or between them and conformity assessment bodies
* Non-profit activity.

National rules for Sweden are included in, among others, the Accreditation and Conformity Assessment Act (2011:791) and the Accreditation and Conformity Assessment Ordinance (2011:811).

The importance of having an accreditation body

The absence of a functioning accreditation body can have serious consequences for a country from a trade perspective.

* Manufacturers dependent on accredited conformity assessment for conducting business are forced to turn to laboratories, inspection bodies and certification bodies in other countries, with increased costs, administration and competitive disadvantages as a result.
* The absence of accredited bodies for conformity assessment may mean that unreliable parties are given the opportunity to market their products and thereby distort competition.
* Companies risk losing revenue and market share in an international market.
* For countries within Europe, the absence of a functioning accreditation system means that requirements within the EU’s harmonised product areas are not met. This in turn means that companies and organisations are forced to move their activities to countries where there is a functioning system.
* Public authorities in the country do not receive the support they need to facilitate their surveillance through accredited testing, inspection and certification, thereby risking the absence of consumer and environmental protection.

An open system without discrimination

Accreditations are carried out in an open system. This means that each conformity assessment body with an accreditation can perform the specific tasks for which they are accredited. The accredited bodies operate in a competitive market, and all parties that so desire and that can comply with set requirements have the opportunity to establish themselves on the market. This creates an open and transparent system where there is no discrimination against any of the stakeholders. The structure of the system is based on the accredited bodies being competent, impartial, independent and free to operate in the areas within which they have been accredited. It is worth noting that different countries have made great strides in opening up areas or sectors for accreditation.

Requirements to be met during accreditation

Accreditation means that requirements are set in several areas. The requirements are detailed and comprehensive. Accreditation involves systematic reviews of set requirements within a wide range of different areas. It can be a question of technical equipment, staff competence and the management system of the organisation. The holistic approach involved in accreditation is one of the strengths of the system. The requirements cover:

*Competence*: Accredited bodies must have the experience and the competence required for the task.

*Independence*: Accredited bodies must be independent in relation to the organisation to which their services are directed.

*Impartiality*: Accredited bodies must not have conflicts of interest with the customer to which their services are directed.

Ways of working: Accredited bodies must have relevant routines, methods and procedures in order to perform their tasks.

*Equipment*: Accredited bodies must have the necessary equipment and ensure that it is operational and is operated properly.

*Management systems*: Accredited bodies must have a management system that ensures efficient and secure processes. Work methods and processes must be quality assured.

Accreditation – step by step

To become accredited is a long-term undertaking. The accreditation process from application to decision consists of the following steps.

1. Application

The application for accreditation is made via Swedac’s website using an application form which is sent to Swedac together with the other documents requested in the form.[[13]](#footnote-13) The type of conformity assessment, areas, industries and/or methods for which the applicant wants to be accredited shall be specified in the application. Swedac confirms that the application has been received and checks that it is complete. Based on the scope of the accreditation, Swedac issues notification of the cost and gives proposals for lead assessors, assessment team and a rough plan for the accreditation process. Swedac’s objective is to send a cost estimate within 4 weeks of receiving the complete documentation for the application. Thereafter, the applicant must accept the fee and accept the lead assessor and the assessment team.

2. Planning

Swedac plans the accreditation process in consultation with the applicant and employs experts as required.

**3. Assessment**

Assessment on site is made by the lead assessor, sometimes together with additional Swedac internal or external assessors. The assessment covers the applicant’s organisation, management systems and equipment, as well as the competence of the management and the personnel. In the accreditation of laboratories and certain inspection bodies, the assessment is supplemented by proficiency testing and calibration audits. For some accreditation procedures, Swedac participates as an observer when accredited bodies work on-site at their customers. Swedac’s objective is to carry out an on-site assessment within twelve weeks after the applicant has submitted all documentation and accepted the fee, the lead assessor and the assessment team.­

**4. Reporting**

The assessment is concluded with Swedac’s representatives describing the result of Swedac’s assessment of the activity and describing any non-conformities to the requirements.­ The assessment is documented in a report.

5. Corrective action.

Any non-conformities to the requirements must be closed through corrective actions by the applicant within four months. Swedac makes a decision on whether the corrective actions can be accepted. In the event of serious or extensive non-conformities, a return visit may be necessary. When all non-conformities have been closed, the lead assessor can recommend accreditation.

6. Decision

According to Section 5 of Swedac’s Regulations and General Guidelines (STAFS 2015:8) on Accreditation, a decision on accreditation is taken within two months of the necessary documentation being submitted to Swedac. The regulation also specifies what is meant by necessary documentation. The processing time can be extended only once by up to one month if this becomes necessary due to the investigation of the accreditation case.­ The decision on accreditation is taken by a supervising manager. Accreditation is not limited in time, but is open ended, on condition that the requirements are continuously met.

**7. Surveillance and reassessment**

Approximately six months after the accreditation has been granted, a supplementary surveillance visit is made to assess whether the accredited activity has started to be implemented according to the conditions for the accreditation. An accreditation decision is always followed up by regular surveillance visits, initially once a year. The purpose is to assess whether the activities continue to meet the requirements. The cost of the surveillance is charged in the form of an annual fee. A comprehensive evaluation, a reassessment, is made every four years. After the first reassessment, the surveillance interval for most accreditation areas is extended to 16 months if everything is working well. In the event of surveillance/reassessment, any non-conformities to the requirements must be closed by the accredited organisation within two months.

**8. Changing the scope of an accreditation**

An accredited conformity assessment body may apply for extension into one or more additional areas or request any other changes in the scope of the accreditation.

**9.** Withdrawing accreditation

If serious non-conformities are found during surveillance and corrective action is not taken to close the non-conformities, Swedac may withdraw the accreditation or limit the scope of the accreditation. Such a decision can be appealed to the Administrative Court in Jönköping. An accredited conformity assessment body which itself wants to have its accreditation withdrawn can submit a written notice of termination to Swedac, upon which Swedac withdraws the accreditation.

### 2.1.1 European Cooperation for Accreditation

The accreditation regulations within the EU require each Member State to appoint an accreditation body and that there should be a body at Community level for peer evaluation[[14]](#footnote-14) of the national accreditation bodies[[15]](#footnote-15). The European Cooperation for Accreditation (EA) has been recognised as such a body. The term “National accreditation body” refers to the single body of a Member State that has been tasked to perform accreditations.[[16]](#footnote-16) A precondition for recognition as a body under Article 14 of Regulation (EC) No. 765/2008 is that the EA has also entered into an agreement with the Commission. The agreement must contain a detailed description of EA’s tasks, financing regulations and provisions for the surveillance of EA as well as the possibility for the parties to terminate the agreement. The current agreement applies for the period 24 June 2014 - 24 June 2018 and there are also guidelines for the cooperation decided in 2009.[[17]](#footnote-17) [[18]](#footnote-18) [[19]](#footnote-19) These guidelines apply to the cooperation between the EA, the Commission, EFTA and the national accreditation bodies. A new cooperation agreement that will replace the current one is now under negotiation.

EA constitutes a body that is necessary for the functioning of the EU accreditation system and is a key pillar of the single market and the principle of mutual recognition. The activities for which the EA may be granted Community funding are described in Article 32 of Regulation (EC) No. 765/2008. The activities must be related to the application of the regulation. This applies to both the voluntary area and areas where accreditation is mandatory. On behalf of the EU, EA has, among other things, the task of drafting sector-specific accreditation programmes, participating in activities organised by international­ accreditation cooperations, drafting guidelines for accreditation and notified bodies, and assisting the Commission with expertise. EA’s activities are largely linked to the assignment that has been entrusted to the organisation by Community law, and they are an important part of the internal market­ and the application of harmonised Community legislation. Nevertheless, its assignment is also to promote international cooperation and to spread the accreditation model to other countries. Among other things, the guidelines for cooperation mentioned above also mean that EA must be involved in the EU negotiations with third countries on trade agreements when issues relating to conformity assessment­ are discussed.

### 2.1.2 International Laboratory Accreditation Cooperation and International Accreditation Forum

The International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) are international organisations for accreditation bodies and stakeholders and they provide and administer mutual recognition agreemeents for products and services that have been tested, inspected or certified by laboratories, inspection bodies or certification bodies that have been accredited by their members. IAF operates in the area of accreditation of certification bodies for products, persons and management systems. ILAC operates in the area of accreditation of inspection bodies and laboratories.

ILAC and IAF organise individual accreditation bodies and other stakeholders as well as regional cooperation bodies, such as the EA, and divide the members into several different categories. Swedac is a member of both ILAC and IAF in the capacity of accreditation body that has signed an agreement on mutual recognition, MRA[[20]](#footnote-20), but also indirectly as a member of the EA. ILAC and IAF base their MRA agreements on the regional MRA agreements. A region that has an MRA agreement within the ILAC or IAF activity areas may apply to become a recognised regional organisation in ILAC or IAF, depending on whether it concerns accreditation of laboratories and inspection bodies or accreditation of certification bodies. ILAC and IAF then conduct a peer evaluation of the procedures and decision-making process of the regional organisation, as well as witnessing peer evaluations conducted by the region as a basis for its decision to approve the regional organisation as a recognised regional organisation. Once a decision has been made at ILAC or IAF level, the individual accreditation bodies in the region may apply to become signatories to ILAC or IAF MRA agreements.

ILAC’s MRA agreement[[21]](#footnote-21) means that the signatories to the agreement recognise accreditation certificates issued by other signatories and also recognize the conformity assessment results of the accredited bodies. This means that trade is facilitated between states, since there is no need for further testing, calibration or inspection of the goods in the importing countries. The agreement is an assurance that the same standards are used by all contracting parties. Similarly, IAF has an agreement for mutual recognition, IAF-MLA,[[22]](#footnote-22) on the mutual recognition of accreditation certificates and the conformity assessments of the accredited certification bodies.

The signatories consist of accreditation bodies throughout the world. EA itself is not a signatory, but constitutes one of four recognised regional cooperation bodies[[23]](#footnote-23) which, through delegation­ within ILAC and IAF, have been assigned the task of evaluating the competence of accreditation bodies within their region. This takes place through peer evaluation of both recognised regional cooperation bodies and individual accreditation bodies. Peer evaluation is a process by which accreditation bodies and regional cooperation bodies are evaluated by their peers. However, there are a number of accreditation­ bodies that, for various reasons, are not part of a regional organisation. There are also regional organisations­ that do not yet have an MRA agreement, but where some of the members of the region have made great progress in their accreditation activities. In such cases, the accreditation bodies may apply to be peer-evaluated­ directly by ILAC or IAF, and then pay an extra fee in addition to the annual fee to finance the work involved in the individual peer evaluation.

Harmonisation of accreditation practices takes place mainly within ILAC and IAF. Documents relating to the application of the standards used and how peer evaluations should be conducted and reported are drawn up within ILAC and IAF. The recognised regions must comply with these documents but may, if necessary, draw up additional documents if there are local and regional requirements that need to be met­ and which are not covered by ILAC and IAF requirements. The requirements for accreditation bodies in (EC) No. 765/2008 are examples of such requirements. In order to meet the EU Commission’s requirements for accreditation bodies, EA has introduced these additional requirements into its statutes under membership terms.

## 2.2 Testing and calibration

Accreditation of laboratories may refer to laboratories that offer testing or traceable calibration. The former concerns laboratory testing that is carried out to check quality and reliability. For example, our drinking water should be clean and safe to drink, so the water quality is therefore analysed at accredited testing laboratories. Another example is blood samples used for medical diagnosis and decisions. In this case, it is also important that samples are handled and analysed in a safe way, which often involves the need for medical testing laboratories to be accredited. More examples of areas where there are accredited testing laboratories are within chemistry, biology, fire, air, food, electronics, software, fingerprints, doping and animal welfare.

Accreditation of a testing laboratory means that:

* The testing methods are valid and appropriate.
* The testing equipment is fit for purpose and is maintained in an appropriate manner.
* Test objects are collected, handled and transported in an appropriate manner.
* Test data are checked and quality assured.

The definition of testing[[24]](#footnote-24) is the determination of one or more properties in an object of conformity assessment according to a procedure. The results of a test are reported in a test report.

*Traceable calibration* means that measuring equipment must give accurate results. Measuring instruments must be reliable in order for the results they give to be the basis for sound and correct decisions. When calibrating a measuring instrument, calibration gives an exact picture of the accuracy of the instrument’s display. To maintain the reliability of measuring instruments, they should be regularly calibrated at an accredited calibration laboratory. The calibration laboratory compares the measuring instrument with a correct measurement. Measuring equipment can include speedometers, weighing machines, spectrometers, chronometers, radiation monitors, gas meters and electrical counters. Current examples of areas where accreditation takes place are for equipment that measures exhaust emissions, noise, soil mass, and air emissions.

Accreditation of a calibration laboratory means that:

* The calibration results are metrologically traceable.
* Procedures and documentation are traceable.
* The measurements are performed according to validated procedures.
* Standards and measuring instruments are reliable.

Swedac defines calibration[[25]](#footnote-25) as a comparison between a reference (measurement standard) and the instrument to be calibrated. The comparison determines how much the instrument deviates from the reference. The results of a calibration are reported in a calibration certificate.

The assessment of laboratories for the purposes of accreditation is based on the ISO/IEC 17025 and ISO 15189 standards.

## 2.3 Inspection

Accredited inspection bodies perform *inspections*. Among other things, the work of inspection bodies involves inspections of lifts and lifting devices. Accredited vehicle workshops work with vehicle inspection, and accredited inspection bodies also work in areas such as dangerous goods, building materials, pressure equipment and precious metals. Accreditation ensures that the inspection body is competent, that relevant methods are used for the inspections, and that the results are impartial.

The definition of inspection[[26]](#footnote-26) is the examination of a product design, product, process or installation and the determination of its conformity with specified requirements or, on the basis of professional judgement, with general requirements. The results from a completed inspection constitute a protocol.

The assessment of inspection bodies for the purposes of accreditation is based on the ISO/IEC 17020 standard.

## 2.4 Certification

Certification means that an independent party certifies that a specific organisation, product or person meets the requirements set in a standard or other sets of requirements. Special characteristics of certification include that the issuer of the certificate monitors and follows up that the certified party continuously meets the certification requirements, and that a certificate is time-limited, normally for between two and five years.

Certification is not a protected term, which may be unclear to the uninitiated, and which makes it more difficult to understand the reliability of a certificate. There are certification systems not under accreditation but which are nevertheless highly reliable and which have a place in the market. The opposite is also the case, there are certification systems which do not require accreditation and whose reliability can be questioned. Using accredited certification ensures that an independent third party performs the certification, that the certifying party is competent for the task and that the certificate is accepted both nationally and internationally. A certification body is accredited to perform one or more specific certifications.

In some areas, it is entirely voluntary for a certification body to become accredited, while in other areas there are legal requirements for accreditation. Another driving force for certification bodies to become accredited is customer demand for trustworthiness of the certificates. For example, in some areas involving welding, the personnel must be certified by an accredited certification body. However, in most cases there is no legal requirement that a company’s quality or environmental management system should be certified. In this case, it is rather the customer requirements that make accreditation a must in practice.

Certification is a collective name that includes three different main types of certification:

* Certification of products. Processes and services are also included in the concept of product. The assessment for accreditation is based on the ISO/IEC 17065 standard.
* Certification of persons. This refers to a person’s ability and competence to perform a task, such as welding. The assessment for accreditation is based on the ISO/IEC 17024 standard.
* Certification of management systems. There are several different types of management systems, but the most widely used are quality management systems in accordance with ISO 9001 and environmental management systems in accordance with ISO 14001. The assessment for accreditation is based on the ISO/IEC 17021-1 standard.

Among other things, accreditation means that the accreditation body assesses the ability of the certification body to perform specific certifications, that it has the necessary competence and equipment, and that it has an ability to perform certifications over time.

## 2.5 Notified bodies

The New Method (see section 2.9.1) means that manufacturers are wholly responsible for the products they release on the market, without any prior approval from national authorities. To demonstrate that the essential requirements have been met, the manufacturer is obliged to perform a conformity assessment procedure. A number of predefined procedures (so-called “modules”) are at the disposal of the legislator for drafting the legislation, and the legislator chooses the procedures that are deemed relevant to the product category in question. The manufacturer can perform some procedures entirely on its own, while the manufacturer is required to engage an independent third-party body for other procedures. The third-party bodies authorised to perform these tasks are notified to the EU Commission by the Member States and consequently they are referred to as notified bodies.

Testing, inspection and certification of products are currently conducted in an open system under competition by private parties whose competence has been evaluated and approved by the Member States.

Notified bodies have responsibilities in areas of public interest, and are therefore, in turn, accountable to the competent national authorities. To be appointed as notified body, the body must be a legal entity and must be established within the territory of a Member State and thus under the jurisdiction of the Member State. The Member States may themselves decide whether or not the bodies that meet the requirements of the relevant harmonised legislation should be notified. Notified bodies may operate or have personnel outside their own Member State and even outside the Union. However, certificates and other conformity assessment documents must be issued by the notified body and in its name.

Notified bodies must be a so-called “third party”, which is thereby independent of its customers and other interested parties. Whether the bodies are private or state-owned is irrelevant, provided that their independence and integrity are preserved and that they can be identified as a legal entity with associated rights and obligations. Notified bodies are obliged to participate in coordination activities. They must also participate directly or indirectly in European standardisation, or ensure that they are knowledgeable of the relevant standards.

Accreditation is the recommended method for assessing the competence of notified bodies. However, the Member States have the possibility to perform the evaluation in some other way. In order to ensure necessary confidence in the impartiality and technical competence of the bodies, as well as in the reports and certificates they issue, national authorities must provide detailed and exhaustive information on how they have assessed the notified bodies as being qualified to perform the tasks they have been notified for and how they meet the applicable criteria.

Notified bodies are notified by the notifying authorities of the Member States in the Commission’s electronic notification tool NANDO[[27]](#footnote-27). In the public section of NANDO, it is possible to see which bodies are notified for which tasks, and this is an important means by which manufacturers can find notified bodies eligible to participate in their conformity assessment procedures.

## 2.6 Standardisation

Standardisation is part of the quality infrastructure, and the main aim of European standardisation is to establish voluntary technical specifications or quality specifications with which existing or future products, production processes or services can conform. Standardisation can cover various aspects, such as the standardisation of different grades or sizes of a particular product, or technical specifications for product or service markets when it is essential for compatibility and interoperability with other products or systems.

European standards are of great importance to the internal market. For example, harmonised standards are used to show that products due to be made available on the market may be presumed to comply with the essential requirements for these products as laid down in the Union’s relevant harmonisation legislation.[[28]](#footnote-28) Each one of the current 20 000 European standards (mainly for products) has replaced potentially conflicting national standards.[[29]](#footnote-29) European standardisation is designed so that it gradually harmonises conflicting national standards, thereby removing technical barriers to trade while ensuring a high level of protection of public interests, such as health and safety in particular.

What is characteristic of the European standardisation system is that the Commission may request the European standardisation bodies to draw up a European standard or a European standardisation product for products and services as support for Union legislation and policies. Around 20 per cent of all European standards and European standardisation products have been added at the Commission’s request[[30]](#footnote-30), also known as harmonised standards, while the remaining 80 per cent have been drawn up through proposals from the industry or other standardisation stakeholders.[[31]](#footnote-31) The prerequisites for European standardisation are given in Regulation (EU) No. 1025/2012.[[32]](#footnote-32)

European standardisation is organised by the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) and the European Telecommunications Standards Institute (ETSI). These are legal entities under private law, like their ­international counterparts[[33]](#footnote-33). Their activities are based on principles that are recognised by the World Trade­ Organisation (WTO) in issues of standardisation, namely uniformity, transparency, openness, consensus,­ voluntary application, independence in relation to special interests and efficiency[[34]](#footnote-34). Their international­ global counterparts consist of the International Organisation for Standardisation (ISO), the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU). The EU works to promote cooperation between European and international standardisation­ organisations, as well as bilaterally with third countries[[35]](#footnote-35). The EU funds the European standardisation bodies, among other things, taking into account their need for secretariats and that the standards increase the opportunity to achieve compliance with Union legislation[[36]](#footnote-36).

Standard means a technical specification adopted by a recognised standardisation body for repeated or ongoing application, which is not mandatory and belongs to one of the following types:

* *International standard*: a standard that has been adopted by an international standardisation body.
* *European standard*: a standard that has been adopted by a European standardisation organisation.
* *Harmonised standard*: a European standard that has been adopted on the basis of the Commission’s request for the application of the Union’s harmonisation legislation.
* *National standard*: a standard that has been adopted by a national standardisation body.[[37]](#footnote-37)

The European standards are adopted by the European standardisation organisations CEN, CENELEC and ETSI. The work on developing the standards and amendments thereto is carried out by technical committees of CEN-CENELEC but the majority of the work is the responsibility of the national standardisation body­ that runs the secretariat belonging to each committee.

Standardisation is the creation of jointly agreed solutions to recurring problems. Standards exist in all areas: from the simplest nails and screws to data communication, industry, healthcare and the environment. Virtually all areas of our life are affected by standards. Standards are voluntary to apply and often function as a mandatory reference in different industries and application fields, such as in regulations from authorities, in procurement and in the communication between buyers and sellers in “business to business” affairs.

### 2.6.1 Standardisation work

A standardisation committee can be started on the initiative of one or more organisations. Anyone can contact the Swedish standardisation organisations with proposals for standardisation work. The reason is often a need within a particular area for clear guidelines and uniform requirements and procedures. The standardisation organisations decide to start the committee following an assessment of the national interest in the issue, as well as financing and resource needs. A committee is often formed in conjunction with the start-up of international standardisation efforts where Sweden wants to participate and influence.

It is open to all legal entities in Sweden to participate in the standardisation work, and it is important to accomplish as wide participation as possible. Representatives from companies, organisations, authorities, municipalities, non-profit associations and sole traders are examples of participants in Swedish standardisation committees. A number of invited experts also participate. In Sweden, small and medium-sized companies (SMEs) in particular are encouraged to participate in the work, as well as organisations that represent consumer interests as well as environmental and social interests.

A standardisation committee is organised on the basis of the objectives and purpose of the standard. The committee members together decide the content and scope of the work. Many committees are organised in order to have the capacity to effectively influence European and global standardisation efforts. Other committees work exclusively on a national basis. All standardisation work is characterised by consensus, openness, volunteerism and is stakeholder-driven.

A typical committee has 2-4 national meetings per year, either on-site at the standardisation­ organisations, as web/telephone conferences or at one of the participating organisations. In order to make it easier for groups with smaller economic resources to participate, the opportunity is always offered to participate via web conferences. In addition to this, international meetings can be held.

The objective and purpose of the committee work is to

* draw up national, European or global standards, guidance or technical specifications
* create legitimacy and acceptance through broad agreements
* create opportunities for information exchange and access to networks.

In most cases, the work within a committee results in standards, which in Sweden are defined by SIS, SEK or ITS. At EU level, they are defined by CEN, CENELEC or ETSI, and at global level they are defined by ISO, IEC or ITU. Many committees also produce other types of documents that make it easier to work efficiently, safely and in an environmentally friendly manner. For example, it may be a question of technical specifications, reports, checklists or manuals. The Swedish standardisation organisations have administrative responsibility and copyright on Swedish standards and draft standards in accordance with the international and European regulations in force.

Since the world is constantly changing, guidelines and common agreements must also be renewed and drawn up for new product areas. It is a constantly ongoing process. In today’s globalised world, it is important, if not crucial, to stay up-to-date with global standards. For this reason, the standardisation organisations and stakeholders together review all standards after 3-5 years. Through this process, the standardisation organisations ensure that the standards are constantly updated in all of the areas within which standards are developed.

In this way, organisations and companies that use standards increase the quality of their activities and their products and services, which leads to reduced risk of production errors, better communication with customers and suppliers, which contributes to a smoother establishment in different markets. Companies using standards also get help to comply with rules and legislation, and they also know that they are keeping pace with the development of technologies. Standards also constitute a basis for the research and development of technologies so that the parties developing an innovation can quickly gain acceptance on the market for new products and services.

Standardisation is important for Sweden on a purely socio-economic basis. In Swedish standardisation, experts come together in technical committees in order to participate in the development of standards taking place at the national, European and global level. The Swedish companies and organisations that participate in the standardisation­ work can influence Swedish, European and global standards in different areas. They have the opportunity to participate in global networks with experts, which provides early information on events on the market so that they can develop their scope of activities. Participants in standardisation activities also receive information and news updates about the market that they cannot otherwise get anywhere else.

All standards have been established, developed and quality assured through a standardisation process that looks the same throughout the world. The guiding principle in standardisation work is that consensus, stakeholder­ control, volunteerism, and transparency should prevail. This is also stipulated in the WTO’s TBT (Technical Barriers to Trade) agreement that Sweden has signed.

The standards drawn up are made available and sold in Sweden. In this way, it will be possible for all Swedish companies to become acquainted with “best practice” in order to develop their activities.

## 2.7 Market surveillance

The purpose of market surveillance is to ensure that products meet the applicable requirements that provide a high level of protection of the public interests while ensuring that the free movement of goods is not limited more than what is permitted by harmonised Union legislation or other relevant Union legislation. Market surveillance is also important for the interests of economic stakeholders since it helps eliminate unfair competition.

Market surveillance can be performed through information initiatives, planned inspections at the manufacturers, importers and dealers, or reactions to reported accidents, complaints from the public or warnings from authorities in other countries. Market surveillance does not include preliminary inspection, i.e. inspection during the drafting, design or manufacturing of products, nor inspection of products in use. Considering the rapid product development and the large amount of products available on the market, it is impossible to inspect all products. Market surveillance is therefore usually carried out in the form of random samples based on risk assessment.

EU Member States must ensure effective market surveillance. They must arrange and carry out inspection of the products that are placed on the market or imported. The Member States must take appropriate action to ensure compliance in the EU with the provisions of Regulation (EC) No. 765/2008 on accreditation and market surveillance, of Directive 2001/95/EC on general product safety and of other harmonisation legislation, as well as compliance with non-harmonised national legislation in force and must, in particular, prevent products that do not comply with the requirements and/or are unsafe from being placed on the market and used.

Market surveillance must contribute to ensuring that unsafe products, or products that do not meet the applicable requirements of harmonised Union legislation in some other way, are identified and seized, or withdrawn from the market, and that unscrupulous or even criminal actors are punished. This should also have a strong deterrent effect. However, for market surveillance to have the intended effect, it must be conducted uniformly throughout the Union. In order to be objective and impartial, market surveillance must be carried out by the authorities of the Member States. Cooperation and coordination of measures between national authorities is indispensable for achieving an effective and coherent surveillance of the internal market. The EU’s legal framework contains a number of tools in order to achieve this objective. These include a safeguard clause mechanism for transparency in restrictive measures and accompanying measures in other Member States, mutual assistance between market surveillance authorities in different Member States, administrative cooperation groups, the ICSMS[[38]](#footnote-38) product database and the Rapex system[[39]](#footnote-39) for rapid information sharing on products that pose a risk.

## 2.8 Metrology

Metrology is the science of measurement. It establishes a common definition of quantities and units that are crucial for a functioning society. Activities such as trade in goods, the ability to correctly diagnose diseases, and consumer confidence in buying goods and services, are all dependent on the confidence in the measurements made during these processes. This confidence is maintained by *defining and* *realising* internationally accepted units of measurement as well as *establishing traceability*, which means that it should be possible to relate a measurement result to the internationally accepted definitions of the units of measurement, via an unbroken chain of comparisons with stated uncertainties. Physical phenomena and properties that can be subject to measurements are called quantities. Examples of quantities are length, volume, mass and time. All measurements are based on producing quantitative data on quantity values. In principle, a measurement is the empirical determination of the relationship between the quantity of a unit and a selected reference of the same unit. The internationally accepted and uniform units of measurement are stated in the so-called “SI system”. The content of this is determined by the international metrological cooperation that has long been established within the framework of the so-called Metric Convention with member bodies, the General Conference on Weights and Measures (CGPM) and the International Bureau of Weights and Measures (BIPM).

Metrology, as part of the quality infrastructure, can be divided into general metrology and legal metrology. Within general metrology, units of measurement are established, new measurement methods are developed, measurement norms are realised and traceability is transmitted to other parts of society. Realising the internationally accepted units of measurement means that the definition of the unit of measurement is physically materialised, so that a reference (or measurement standard) thereof is obtained, against which a measurement comparison can be made. The National Metrology Institutes (NMI), in Sweden called National Standards Laboratories, have responsibility for the primary standards. Furthermore, general metrology includes the activity relating to measurement in manufacturing and other processes that aim to ensure the suitability of measuring instruments and their quality assurance through calibration and quality control.

Finally, legal metrology (regulated measurement technology) is the part of metrology that derives from statutory requirements. These requirements are often set when there is a need to safeguard health, safety, the environment, taxation, consumer protection and trade on equal terms. Countries also cooperate in this area within the framework of a convention. The convention is managed within The International Organisation for Legal Metrology (OIML[[40]](#footnote-40)). The European cooperation organisation in the field of legal metrology is Welmec[[41]](#footnote-41). In addition to the efforts to maintain confidence in measurements, the purpose of the two organisations is to harmonise the regulatory framework in the area and thus prevent the emergence of technical barriers to trade.

In terms of legal metrology in Sweden, the focus is on consumer protection and mainly comes from EU directives that include, for example, scales, petrol pumps and electricity meters. Rules also exist on the use of measuring instruments in order to ensure that the instruments continue to generate quality-assured­ measurement values. Swedac is the authority responsible for the regulations and surveillance in the area. The responsibility of authority also includes representing Sweden in the EU Commission’s working groups­ and committees, as well as OIML and Welmec.

## 2.9 The legal framework for goods

EU legislation on goods can be grouped according to certain principles. These consist of the so-called “Old Method” and the so-called “New Method”. The Old Method involves detailed regulation that contains all the necessary technical and administrative requirements. The New Method limits the legislation to essential requirements and provides the technical details through European harmonised standards. A European standardisation policy has been developed to support this method.

A legislative framework, the New Legislative Framework (NLF), provides the tools required for effective conformity assessment, accreditation and market surveillance, as well as the surveillance of products from countries outside the Union.[[42]](#footnote-42)

The old method of harmonisation meant that the product requirements were set out in legal documents, often in a detailed form. Vehicle approval constitutes such an area that is still regulated by a range of detailed legal documents.[[43]](#footnote-43) The legal documents consist of a framework regulation or framework directive with a range of related specific directives, regulations or UNECE provisions.[[44]](#footnote-44) The vehicle or components thereof are type-approved by a national authority after testing and inspection by a so-called technical service or by the authority itself.

### 2.9.1 The New Method

The New Method is based on the rationale that the requirements should be limited to essential requirements such as performance and function, and also that technical specifications for products should be laid down in harmonised standards. Products manufactured in conformity with harmonised standards are presumed to comply with the essential­ requirements of the legislation.

In principle, the application of harmonised standards or other standards is voluntary, which means that the manufacturers can apply other technical specifications in order to meet the requirements, but this means that they then have the responsibility to demonstrate the conformity of these technical specifications with the essential requirements.

European standardisation in support of Union harmonisation legislation is based on the New Method. The function of the harmonised standards and the responsibilities of the European standardisation­ organisations are defined in Regulation (EU) No. 1025/2012, together with the relevant harmonisation legislation at EU level. The principle that technical regulations should be based on standards has also been introduced by the World Trade Organisation (WTO), whose agreement supports the use­ of international standards as a basis for regulation intended to prevent unnecessary barriers to trade.

In parallel, conformity assessment tools have been developed for both regulated and non-regulated areas. Requirements for third-party conformity assessment bodies have been introduced using the New Method. This applies, for example, to the harmonised standards in the EN ISO/IEC 17000 series.

### 2.9.2 The New Legislative Framework

The New Legislative Framework, NLF, contains the basis for accreditation and market surveillance and regulates the notification procedure, accreditation, conformity assessment procedures (modules), CE marking and market surveillance.[[45]](#footnote-45) The new legislation takes into account all economic operators in the supply chain - manufacturers, manufacturer representatives, distributors and importers - and each of their roles in relation to the product. All these stakeholders are responsible to a varying extent for a product’s conformity when it is supplied, depending on their role. The level of requirements has increased in the new legislative framework, in particular when it comes to importers.

The “Goods Package” is the collective name for three EU acts: [Regulation (EC) No. 764/2008](https://www.kommers.se/Documents/dokumentarkiv/Verksamhetsomr%c3%a5den/Inre%20marknaden/F%c3%b6r%20myndigheter/Varuf%c3%b6rordningen%20myndigheter/forordning-764-2008-varuforordningen.pdf) laying down procedures for the application of certain national [technical rules](javascript:void(0)) for products lawfully marketed in another Member State, [Regulation (EC) No 765/2008](https://www.kommers.se/Documents/dokumentarkiv/Verksamhetsomr%c3%a5den/Handelsfr%c3%a5gor/Varupaktetet/F%c3%b6rordning%20EG%20765'2008%20krav%20f%c3%b6r%20ackreditering%20och%20marknadskontroll%20samt%20upph%c3%a4vande%20av%20f%c3%b6rordning%20EEG%20339'93.pdf) on requirements for [accreditation](javascript:void(0)) and [market surveillance](javascript:void(0)) in connection with the marketing of products and [Decision No. 768/2008/EC](https://www.kommers.se/Documents/dokumentarkiv/Verksamhetsomr%c3%a5den/Handelsfr%c3%a5gor/Varupaktetet/Beslut%20768'2008'EG%20gemensam%20ram%20f%c3%b6r%20saluf%c3%b6ring%20av%20produkter%20samt%20upph%c3%a4vande%20av%2093'465'EEG.pdf) on a common framework for the marketing­ of products. Regulation (EC) No. 765/2008 on accreditation and market surveillance requirements and Regulation (EC) No. 764/2008 laying down procedures for the application of certain national technical rules to products marketed in another Member State entered into force on 1 January 2010. On 20 December 2017, the European Commission submitted proposals for two new regulations to replace the market surveillance provisions of Regulation (EC) No. 765/2008 and, in addition, a new Regulation on mutual recognition, which then replaces Regulation (EC) No. 764/2008.

### 2.9.3 Technical service

A technical service is an organisation or body that has been approved as a testing­ laboratory and which has at the same time been notified to the EU and ECE[[46]](#footnote-46) respectively, in order to conduct testing­ in connection with type approval. A type approval procedure under the EC Directives requires the Member­ States to notify the European Commission and the other Member States of both the technical services that have been approved and the testing procedures for which they have been approved. A list of approved technical services can be found on the Commission’s website.[[47]](#footnote-47)

### 2.9.4 International application – WTO agreements and CAPs

Export to a new market means that exported products are adapted to local technical regulations and standards. In addition, exporters must demonstrate that the local product requirements are fully met by undergoing conformity assessment (hereinafter referred to as CAPs, Conformity Assessment Procedures), such as testing, inspection, or certification. CAPs give confidence to the regulatory­ authorities that the products - regardless of their origin – are compliant with national technical regulations and associated safety, environmental or health protection levels. At the same time, CAPs may potentially create major barriers to trade by increasing the trading costs of exporters.

Within the framework of the WTO agreements[[48]](#footnote-48), the members have the right to independently prescribe and choose the measures most suitable for compliance with national policies, taking into account, among other things, public health and safety, environmental protection, consumer information, etc., provided that these measures comply­ with member­ obligations under such agreements, in compliance with the “negative integration” process. By the same token, they are also free to choose the procedure that provides the best guarantee that products sold on their market meet their objective. As a result of this, there are a large number of different procedures between countries in addition to the already heterogeneous environment for regulatory policy.

For example, a simple product such as a toaster may be subject to identical technical regulations in two countries, but in one country it is considered a low-risk product, and in another country a high-risk product, due to serious domestic accidents caused by generally poor electrical infrastructure. As a result, the former country may require a simple declaration of conformity by the manufacturer, while the latter country may require the testing of a toaster sold on its market by one of its national laboratories that has a complete understanding of the weaknesses and risks specific to that country’s electrical infrastructure.

Despite very similar or even identical technical regulations, the diversity of CAP strategies in countries may potentially create major barriers to trade by increasing the trading costs of exporters. Duplication of CAPs across different markets may increase trading costs if a regulatory­ authority chooses not to accept the result of a foreign test or a foreign certification and requires importers to repeat these procedures. Trading expenses may also increase for foreign companies if domestic companies enjoy faster or customised CAPs. Compliance with CAPs in different export markets may be expensive simply because of the time and effort required to undergo several different procedures or because of any additional transport costs if products are not granted market access after undergoing mandatory CAPs.

The potential for CAPs to drive up trading costs unnecessarily is increased by the expansion in regional and global value chains and the consequent increasing spread and fragmentation of production. CAPs may need to be performed on each component along the value chain – e.g. to ensure interoperability or safety - and the impact of duplication or discrimination in CAPs increases the more the production is divided and distributed.

The WTO Technical Barriers to Trade (TBT) agreement provides a legal framework to ensure a balance between the needs of the importing member in order to receive a positive Declaration of Conformity­ with its regulations or standards and the need to ensure that procedures are not unnecessary or discriminatory barriers to trade. In turn, the WTO’s TBT committee offers WTO members a multilateral­ forum to discuss problems arising in the implementation of CAPs, taking into account both the costs estimated by traders on the one hand and the expected benefits of conformity proposed by the decision makers on the other. These open discussions help improve mutual understanding of measures, facilitate the exchange of best practices, and give the opportunity­ to highlight important relevant issues.

The main difficulties in CAP implementation can be identified by the members highlighting problems related to CAPs, facilitating increased regulatory cooperation where the greatest potential lies, in order to avoid unnecessary barriers to trade.

In the most fundamental sense, CAPs refer to procedures that give confidence that a certain requirement is respected. This means that the market, consumers, companies and regulatory authorities have confidence that products are e.g. safe, do not pose a risk to health, do not have a negative impact on the environment and that they function as expected.

The TBT agreement defines a CAP as “the procedure that is used directly or indirectly in order to establish that the relevant requirements of technical regulations or standards are met”. There are a number of ways to provide or show confidence with different stakeholders involved. The definition of the TBT agreement contains an explanatory comment showing examples of CAPs: “Conformity assessment procedures include, among other things, procedures for sampling, testing and inspection, evaluation, verification and declaration of conformity, registration, accreditation and approval as well as combinations of these”. In addition, two common procedures are defined that are not included in the TBT agreement elsewhere, namely certification, and supplier’s declaration of conformity.

The TBT agreement contains five articles covering the application of CAPs by central, local and non-governmental bodies (Articles 5, 7 and 8) as well as the cooperation between members to accept and recognise the results of CAPs from other members (Articles 6 and 9). These articles set out a number of core disciplines for CAPs that must be respected by WTO members, including: non-discrimination, avoidance of unnecessary barriers to trade, use of global standards and transparency. These disciplines run in parallel to those in the TBT agreement that apply to technical regulations (Articles 2 and 3), but are specifically adapted to the context and challenges of CAPs.

Article 5 contains obligations for the central authorities of the members with respect to CAPs. Article 5.1 begins with an overarching principle that establishes the application of these core prerequisites in situations where a member requires a “positive declaration” of conformity with CAPs. The introduction of CAPs therefore depends on the individual discretion of the members, in accordance with the legislation recognised by the members in the preface to the TBT agreement. As with Article 2 of the TBT technical regulations, the principles of national treatment and most favoured nation (MFN) apply equally to CAPs in Article 5.1.1, with particular focus on discrimination in procedures and availability of conformity assessment providers.

The provisions on avoiding unnecessary barriers to trade with CAPs are set out in Articles 5.1.2, where it states that, among other things, the CAPs of the members must not be “more stringent or applied more stringently than is necessary in order to give the importing member sufficient confidence” of the conformity. In relation to these provisions of Article 5 (1), Article 5 (2) sets out a number of process requirements for CAPs. For example, that the CAPs should be implemented “as soon as possible”, that confidential information on products originating in the territory of other Member States is respected, that the conformity assessment­ fees are limited to what is necessary and fair in relation to similar fees among other members, and that CAPs are generally transparent and respect customary processes.

Article 5.4 requires that in some situations members base their CAPs on relevant guidelines or recommendations issued by global standardisation bodies.

The members do not need to use relevant guidelines or recommendations if they are unsuitable for the member concerned and, in a non-exhaustive manner, Article 5.4 gives reasons that render inappropriate the relevant guidelines or recommendations issued by global standardisation bodies.

When members do not follow the guidelines or recommendations from global standardisation bodies and the proposed CAP, and this can have a significant impact on trade, members must meet a certain number of transparency requirements, very similar to the requirements of the technical regulations (Article 5 (6)). These include the obligation to publish a notice of the proposed CAP, notify other members of the proposed CAP and allow other members to comment within a reasonable time, respond to enquiries on notified measures, and provide a “reasonable interval” between the publication of the CAP requirements and their entry into force (Article 5.9).

In addition to these general principles for CAPs, the TBT agreement promotes cooperation between the members and the implementation of CAPs. Article 6 encourages members to mutually recognise CAP results “provided they are convinced that these procedures provide a declaration of conformity with applicable technical regulations or standards equivalent to their own procedures” (Article 6 (1)). In line with Article 5, Article 6 also gives members the possibility to act independently on the declaration of conformity with technical regulations or standards and emphasises that “prior consultation may be necessary to achieve mutual and satisfactory understanding”. In this context, the TBT agreement mentions accreditation and agreements on mutual recognition (Article 6 (3)) as possible means to ensure confidence in the reliability of the CAP results. Article 9 of the TBT agreement encourages the members to participate in, join, or devise and adopt international systems for CAPs in order to facilitate recognition and approval of CAP results, as long as these international systems comply with the provisions of Articles 5 and 6 of the agreement.

# 3 The benefits of accreditation and standardisation

## 3.1 Previous research

Few scientific studies have been conducted in the area of accreditation and standardisation and the benefits that these bring to companies. However, some European and national research can be mentioned within the framework of this assignment, primarily research that highlights the emergence of accreditation.

In their article *“Economics of Accreditation”* , the researchers Frenz and Lambert at Birkbeck University of London give an account of the economic benefit of accreditation from the perspective of economic theory. The reasoning is based on the researchers’ report, which was drawn up in collaboration with the UK accreditation body, the United Kingdom Accreditation Service (UKAS), and the United Kingdom’s Department for Business Innovation & Skills (BIS). The report from 2013 aimed to provide a detailed analysis of how the accreditation­ system contributes to innovation, entrepreneurship and economic value development. The purpose of the report was to help provide a general understanding of the benefits of using accredited conformity assessment and to help companies make informed decisions when procuring assignments and services that have undergone conformity assessment.

Frenz and Lambert consider that accreditation creates additional credibility in a complex quality infrastructure, but one that can work without accreditation. For this reason, the added value of accreditation needs to be identified by studying the impact of services within conformity assessment. By means of a type of self-declaration, companies can declare that their products or services meet a certain standard, but engaging a third party in the form of a conformity assessment body can provide a clear signal of credibility and quality to the users. Accreditation is an external validation of the independence and competence of conformity assessment bodies. Just as Lambert and Frenz claim, it is a question of inspecting the inspectors: “it is about assessing the assessors”. When it comes to standards, good empirical results show that standards have a significant role in economic growth, according to the researchers[[49]](#footnote-49). For example, an empirical study shows that accreditation of companies that certify in accordance with the ISO 9001 quality management system has a positive effect when it comes to promoting efficiency.

When it comes to the growth of accreditation, Frenz and Lambert return to the role of accreditation in, as well as its contribution to, the quality infrastructure and the relationship between buyer and seller, primarily in the form of reduced information asymmetry. Buyers can choose to rely on supplier reputation regarding quality and credibility, and a system of certified companies in accordance with standards may offer some form of guarantee of independence and competence. However, some uncertainty remains, and here accreditation plays a central role by providing additional credibility and reducing information asymmetry between buyer and seller. Frenz and Lambert claim that accreditation was developed as a way to deal with this problem, where credibility is created for goods and services with the support of certification bodies, which in turn are also subject to inspection in order to guarantee their independence and competence.

Finally, the researchers point out that the commercial added value of the accreditation of services by the UK accreditation body is hundreds of millions of pounds rather than tens of millions or billions, based on the results of a quantitative study of the UKAS accredited conformity assessment bodies. In addition, it is pointed out that accreditation also contributes to other economic and social added value, such as in international trade where previous research has shown the impact of standardisation and how this is further enhanced by accreditation.[[50]](#footnote-50)

In Swedish research, Ingrid Gustafsson’s thesis; *“Organisation of standards, certification and accreditation as a global control regime”* is interesting in this context. Based on the perspective of organizational theory, it studies how accreditation has emerged as part of a global control regime. Gustafsson begins with the same reasoning as Frenz and Lambert on how accreditation was developed­ as another way of creating credibility for the independence of the certification bodies. Every consumer wants the goods and services they buy to be safe. Uncertainty can be reduced by a third party inspecting the goods and services. Previously, the state had such a role through surveillance and review. After that, a global control regime was created with thousands of organisations that monitor compliance. The certification organisations act as the third party and the state no longer has the role of guarantor of the credibility of products or organisations. However, society also needs to be able to rely on the third party in order to reduce the uncertainty of consumers who do not have the opportunity of direct contact with the manufacturer. According to Gustafsson, accreditation has been created in order to solve this problem of uncertainty and thereby act as a fourth party. The starting point is that previous research has focused on the privately-owned and non-governmental and has therefore not discussed accreditation where the state has a role. The thesis therefore studies how the global control regime has been designed, which components build the control regime, and how the components are interconnected. In addition, it studies what role accreditation plays in the control regime, which also affects the responsibility and role of the state, not least when accreditation­ within the EU is the task of a public authority. The control regime is described as a network of organisations that organise themselves into a complex system. Among other things, the analysis shows that the organisations in the control regime are controlled through delegation of work and it is clear that they have different tasks. For example, a certification body cannot accredit, and an accreditation body cannot certify. Furthermore, the organisations are linked to each other like a chain via international organisations­ such as EA and IAF. Accreditation creates a coordination node in the control regime by the accredited­ bodies generating credibility in all the other organisations included in the control regime.

Finally, Gustafsson draws attention to four aspects in the design of the control regime. Firstly, the absence of a centre or periphery in the control regime by means of all being controlled, but none of them controlling all. Secondly, the difficulty in localising responsibility in the control regime due to the absence of a central hierarchy or authority. For example, accountability cannot be demanded of standardisation bodies, which also create the control tools, because standards are voluntary. The responsibility is therefore ambiguous; all parties are responsible for their own part but none of them for everything. Thirdly, the control regime has consequences for how the public sector is organised. The state has been woven into a well-organised global system, which contributes to a limitation to, and lack of clarity in, the state’s responsibility and the extent of its control. Gustafsson suggests that an “ISO fixation” on the part of authorities has developed. Fourthly, the control regime should be understood as an organised state by means of it being characterised by the same features such as work delegation, specialisation, authority, hierarchy, coordination, standardisation, rationalisation and formalisation. At the same time, in contrast to formal organisations, the control regime cannot be held accountable as a unit.

One conclusion drawn by Gustafsson is that the control regime was established in order to create less bureaucracy, but at the same time a bureaucracy is what the control regime mostly resembles. This is due to the complex system that the regime is a part of, where government agencies control and are controlled by others by means of standards but at the same time cannot be held accountable for these standards. In this way, internationalisation and privatisation can take place unnoticed without political or media debate and authorities are woven into international systems.[[51]](#footnote-51)

## 3.2 Accreditation

Accreditation is not a new phenomenon. Accredited conformity assessments have contributed to Swedish competitiveness and export since 1992. In the work to adapt the Swedish legislation to EC law, Swedac was tasked with being the Swedish accreditation body that would evaluate the competence of all conformity assessment bodies. It was decided to disband the monopoly of the state testing and inspection institutions. The concept of “open system” was introduced, the basic cornerstone of which was that both public and private bodies that meet the competence requirements must be able to participate in the system and compete for the assignments. Swedac’s role was to evaluate the competence of these bodies and thereby ensure a level playing field.[[52]](#footnote-52)

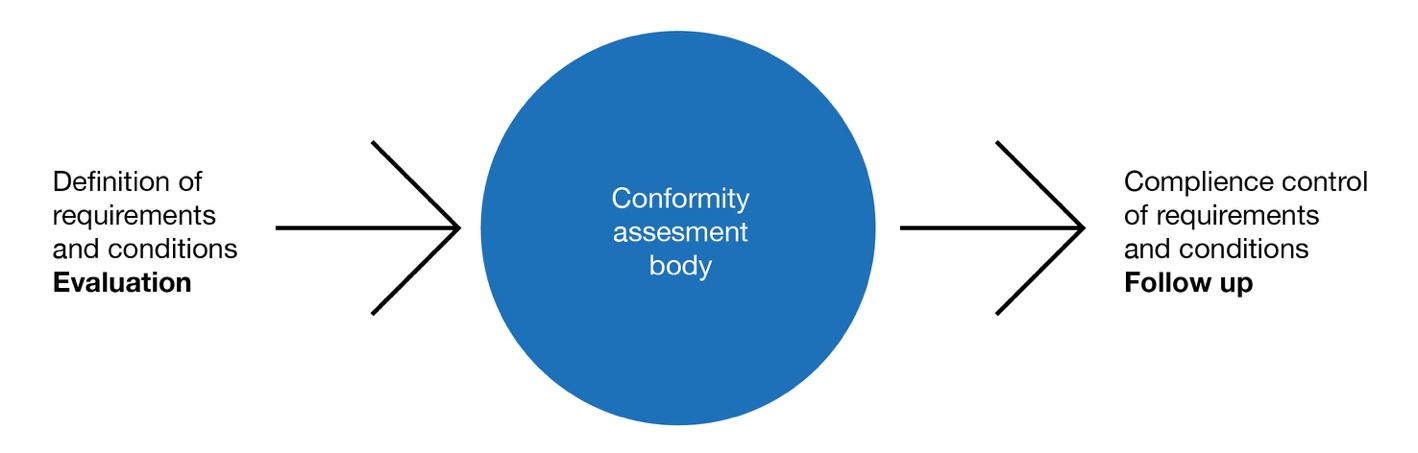
At the same time as the Act on Technical Control was drawn up, it was also established from the Swedish side that reciprocity in conformity assessment should apply as far as the bodies that would be subject to this principle met requirements in harmonised international standards. The principle of reciprocity had already been tested in the EC Court (1981) and established as valid even in non-harmonised product areas, and also in this court decision, provided that the bodies meet requirements in internationally harmonised standards.[[53]](#footnote-53)

Today, we can see that the correct application of accreditation and conformity assessment as a part of a functioning quality infrastructure creates the conditions for confidence in everyday life, societal benefit with more secure citizens, increased competitiveness in the business sector, and global free trade under fair competition. When both buyer and seller are aware that the international systems for conformity assessment and the mutual recognition of reports and certificates are in place, it is possible to achieve the “one stop shopping” principle, i.e. if products and services are approved in accordance with applicable rules and procedures, no new approvals need to be made. This reduces the costs for the companies as products do not have to undergo new testing, inspection and certification in order to gain access to other markets. This benefits all stakeholders in the chain. Accreditation is a method and a tool for doing things right from the start.

### 3.2.1 Benefits of accreditation

There are several benefits to be derived from accreditation and they are different for different stakeholders. Below is a brief description of how accreditation can create added value for the accredited parties, for the party that buys the services from the accredited body as well as for specifiers. For the party that wants to accredit its activities, an initial investment is required in the form of time and resources, but once accreditation has been achieved, it is subsequently an asset that contributes positively to the activities in several ways and can contribute to a reduced workload. Accreditation is a tool that facilitates at several levels.

Illustration 4: Accreditation facilitates at several levels.



Accreditation facilitates specifying and evaluation of conformity assessment­ bodies. It can be difficult to define which requirements and conditions should be aimed at individual conformity assessment bodies. Uncertainty or ambiguity about the requirements and conditions to be put on an organisation­ may lead to uncertainties over whether to use its services and financing decisions can become more difficult. In simple terms, it can be said that the definition of specific requirements can be replaced by a general requirement for the activities­ to be accredited.

Accreditation ensures that the activities meet the set requirements and that results are reliable­. Accreditation thereby provides support in the daily work.

Accreditation facilitates follow-up through recurrent surveillance that the requirements are met. Recurrent surveillance is a fundamental pillar of the accreditation system, which means that the scheduling and the subject of the surveillance will be clear.

Consequently, accreditation provides benefits not only for the activity covered by accreditation but also for other relevant stakeholders. The benefits for clients of the conformity assessment bodies, for individual conformity assessment bodies, and for authorities and specifiers are presented below.

Benefits for clients of the services of conformity assessment bodies

Increases confidence

Being accredited is one way of ensuring that the activity delivers high quality to its clients. This means that the activity can substantiate that it is working actively with quality, which can contribute to strengthening the client’s confidence in the activity.

Increases security

A client that employs an accredited conformity assessment body can have confidence that it is being run efficiently. This provides increased security for the clients of services from conformity assessment bodies.

Increases reliability

Accreditation helps improve the quality of the activity and to ensure that results will be reliable.

Produces an internationally recognised result

Accreditation is an international system. This means that the party employing an accredited conformity assessment body will receive a reliable result that is also recognised in other countries.

Benefits for individual conformity assessment bodies

Provides structure with assistance and support from standards

A key part of accreditation is the globally recognised standards. In very simple terms, a standard can be described here as a thorough checklist of requirements that are divided into different thematic areas. The standard is based on a holistic perspective and includes and sets requirements in a large number of areas that affect the activity. The standard is a support for e.g. a laboratory that can systematically ensure that the activity is run in accordance with all requirements. Among other things, the standard includes the following areas:

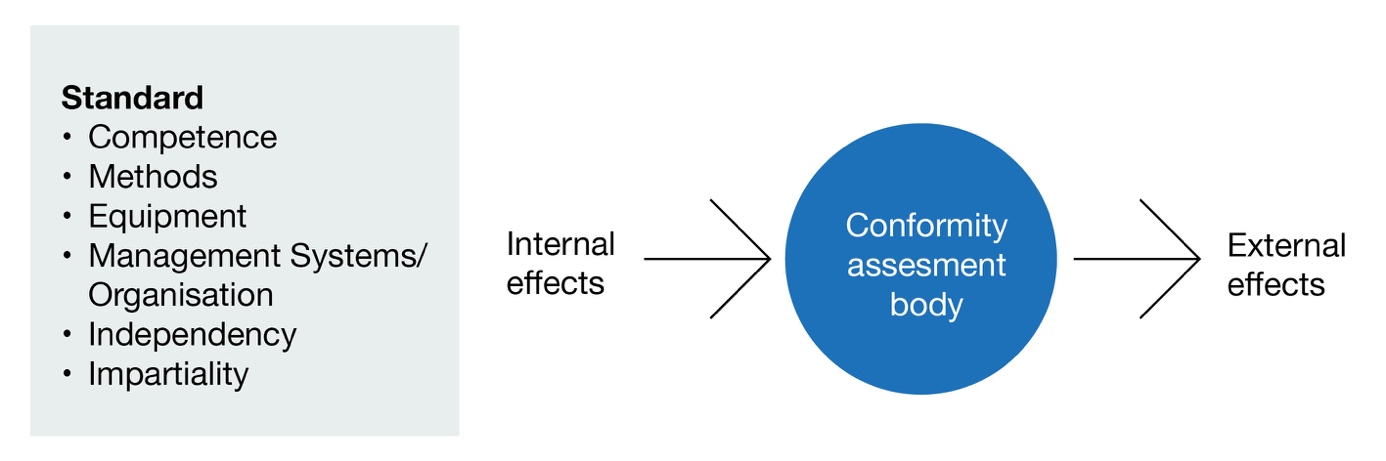
*Competence*: The standard sets requirements that the competence in the activity shall be appropriate and sufficient, and that the employees shall have the knowledge and skills required.

*Methods:* The standard sets requirements on work procedures and methods. In general, methods and procedures must be appropriate and satisfy the customer’s needs. Among other things, testing methods must be valid and applicable, test data must be checked and quality assured, and measurements must be performed according to validated procedures. The requirements also specify that implementation, results and documentation must be traceable.

*Management/organisation*: The standard sets requirements that the conformity assessment body must be organised in an appropriate manner and that there must be management systems that support and demonstrate, over time, conformity­ with the requirements for accreditation and ensure the quality of the work performed. The management­ system shall set overall objectives to be reviewed by the management.

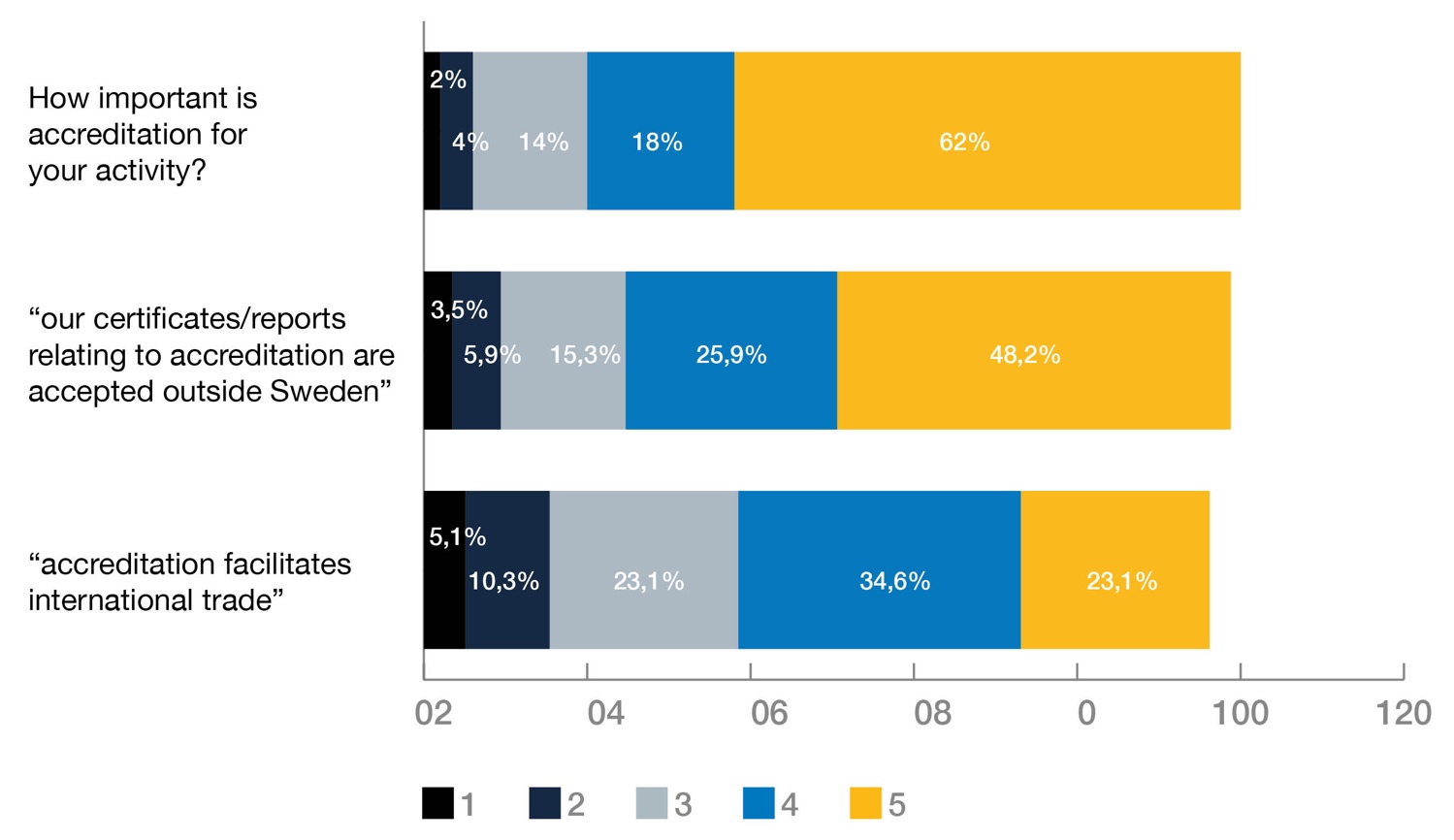
*Equipment*: The standard also includes requirements for the equipment that is used. The accredited party must have all the necessary equipment and it must be fit for purpose and maintained. Measuring instruments must be reliable. Furthermore, test objects must be collected, handled and transported correctly.

The accreditation process assesses that all requirements of the standard in question are met. The illustration below aims to show that it results in positive effects, both from an internal activity perspective and from an external perspective.

Illustration 5: Standards result in benefits in the form of internal and external effects.

The results from the questionnaire survey conducted in conjunction with the preparation of this report show that accredited bodies consider that accreditation is important for their activities. For the question “how important is accreditation for your activity?” the mean value is 5.42 on a six-degree scale. Similarly, for questions on whether accreditation facilitates international trade and whether certificates/reports relating to accreditation are accepted outside Sweden, the response values are high. For these three questions, the mean value is 5.05 on a six-degree scale.

Illustration 6: Results from questionnaire survey.



When it comes to the main benefits of accreditation (see table below), “meets customer requirements” is ranked highest. “Fulfilment of legal requirements” also ranks highly. Within the areas where mandated accreditation is common, this latter benefit is the most highly valued.

Another interesting but not particularly surprising observation is that certification bodies form the category whose participants most often respond that they gain new market access both within Sweden and internationally through their accreditation. Certification bodies, especially those active in management systems and products, are often active on the international market. Here, the link to the use of global standards such as ISO 9001 and ISO 14001 can be seen as a factor that contributes to an international market.

What is surprising is that the “economic benefits” factor ranks lowest in the survey, which does not correspond with the thesis of the researchers Frenz and Lambert. Their empirical study showed that the commercial value of the UK accreditation body’s accreditation amounts to hundreds of millions of pounds, based on the results of a quantitative survey of the UKAS accredited bodies/objects of surveillance.[[54]](#footnote-54) Swedac notes that it is difficult to draw any clear conclusions from this study, but that it would be interesting to study the issue in more depth.

Illustration 7: Ranking of the main benefits of accreditation according to the questionnaire survey.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Statement | Certification | Calibration | Inspection | Medicine | Testing | Others (more) | Total |
| Meets customer requirements | 23.7% | 23.8% | 19.0% | 27.9% | 26.6% | 25.0% | 25.5% |
| Meets legal requirements | 13.2% | 11.1% | 28.6% | 18.6% | 23.4% | 17.9% | 19.8% |
| Gives an advantage over competitors | 10.5% | 17.5% | 9.5% | 14.0% | 12.8% | 19.6% | 14.1% |
| Streamlines our internal work | 2.6% | 9.5% | 4.8% | 20.9% | 13.8% | 10.7% | 12.1% |
| It gives access to new customers/markets in Sweden | 18.4% | 15.9% | 14.3% | 7.0% | 8.3% | 8.9% | 10.5% |
| Marketing | 10.5% | 11.1% | 9.5% | 9.3% | 7.3% | 10.7% | 8.9% |
| It gives access to customers/markets outside Sweden | 18.4% | 7.9% | 4.8% | 0.0% | 6.9% | 5.4% | 7.1% |
| Economic benefits | 2.6% | 3.2% | 9.5% | 2.3% | 0.9% | 1.8% | 2.1% |
| Total | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |

Internal benefits for the accredited activity

Reinforces quality

Accreditation means the quality assurance of an activity and ensures that the organization has its house in order. Accreditation is a means by which independent and impartial organisations with specialist expertise can raise the quality of their activities.

Facilitates innovation

Accreditation also provides support for continuous improvement. Accreditation contributes to an innovative environment by enhancing the conditions for systematic work which in turn promotes innovation in the activity. In simple terms, it can be said that it is easier to develop and improve an activity by first ensuring that it is built on solid ground.

Reduces the risk of errors

By ensuring that everything is done right from the start, the risk of systematic errors that may affect quality is reduced. Accreditation results in a higher risk awareness and reduces the risk of costly mistakes. It also results in reduced costs linked with errors and deficiencies.

Reduces control mechanisms

Accreditation provides a presumption of conformity with standards and regulations. Consequently, the accredited party does not have to provide further documentation and the activity is simplified through the reduction or elimination of control mechanisms. Accreditation means that the activity can be improved, at the same time as the internal workload and effort can be reduced.

Better protection for personnel and equipment

Accreditation also covers protection of personnel and equipment. Ensuring that equipment is working, and is used correctly and appropriately, will be of benefit for the activity and its personnel.

Facilitates increased participation and commitment among employees

The holistic perspective involved in accreditation means that more employees can be involved in the work to develop and assure quality. The increased commitment means that accreditation contributes not only to the general development of the activities but also to potential positive effects for the work environment.

Increases efficiency

Accreditation means that the activities are run according to best practice. This results in more control over processes and procedures and increases efficiency. At the same time, the workload is reduced for the party ensuring that processes are complied with. Accreditation means that the activities and their governance can be run in a resource-efficient way.

External benefits for the accredited activity

Strengthens competitiveness

Having well-documented and effective quality control gives the activity a competitive advantage that can be used in, for example, marketing. Increased credibility and reliability strengthens the competitiveness of the activity.

A means of reaching new markets

Accreditation is a way to reach new markets as it enhances the opportunities to attract foreign customers. Accreditation works as a quality label and makes it easier for companies to conduct cross-border business. Accreditation creates security for customers from the knowledge that the accredited activity meets all requirements, as well as a stronger competitive situation for the activity in question. In this way, accreditation provides business opportunities, not least for service exporting companies such as laboratories that want to work internationally.

Benefits for authorities and specifiers

Accreditation is an aid for authorities

Accreditation provides an opportunity for authorities to promote quality assurance. At an overall level, accreditation means that the state can take responsibility that quality assurance works. Accreditation can be an aid for the authorities that have surveillance responsibility as it frees up time and resources for the ­authorities through independent parties being increasingly responsible for the inspection work. In this way, the regulatory authorities have reduced inspection workload and reduced need to use their own resources. Regulatory authorities can rely on the national accreditation body (in Sweden’s case Swedac) to assess the accredited bodies so that they perform their work in a systematic way and in accordance with the prescribed requirements. Regardless of which authority has responsibility for surveillance, accreditation works in an equivalent way and provides cooperation opportunities for authorities. Accreditation can also contribute to promoting the implementation of legislation since it works as evidence that confirms compliance with standards and relevant requirements.

Accreditation means credible assessments

Accreditation means that Swedac assesses the competence of the parties that will perform conformity assessment. Conformity assessment aims to establish whether e.g. a product or service complies with specific requirements. Accredited conformity assessments confirm that products and services comply with set requirements – legislation, standards and other applicable specifications. It is a question of being able to rely on assessments being made in an independent and competent way and that certificates and reports are reliable.

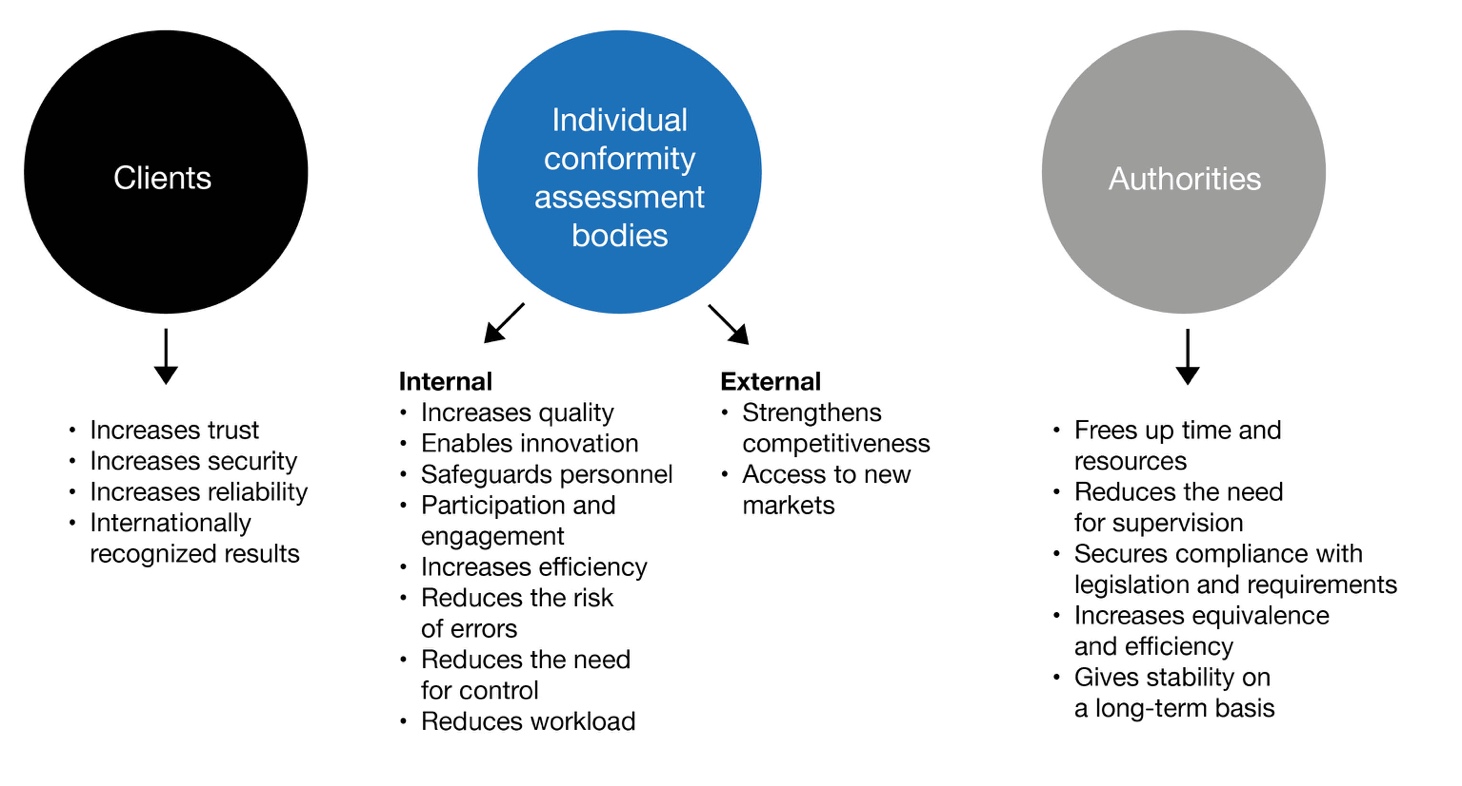
Accreditation contributes to equivalence and uniformity

Accreditation means that accredited bodies will perform conformity assessment in an equivalent way. The object under conformity assessment will be assessed equally, regardless of which accredited body is performing the assessment. As a result, fairness is created in the system, which provides security for the object of conformity assessment and the accredited bodies that can rely on the work being performed in an equivalent way. This also contributes to uniformity, which facilitates the work of the regulatory authorities. Swedac participates in consultation meetings with other authorities responsible for conformity assessment regulations in order to monitor application of the regulations.

Accreditation provides both short-term and long-term stability

Accreditation involves the surveillance of accredited bodies at regular intervals. Following the application for accreditation, there is a thorough evaluation of the applicant organisation by means of an on-site assessment at the premises of the applicant as well as a witness audit of the work performed. If an applicant body passes the assessment then it will be accredited. After that, Swedac performs regular surveillance activities in order to ensure that the accredited bodies continue to comply with the requirements. Swedac revokes accreditation decisions in the event of non-compliance with requirements. The regular surveillance of an accredited body creates both short-term and long-term stability, which contributes to establishing quality over time.

Illustration 8: Overview of the benefits for clients, individual conformity assessment bodies and authorities.



### 3.2.2 The benefits of management systems

A management system is a means of support for establishing and maintaining efficient processes as well as to lead, manage and improve an organisation’s activities. A management system makes it possible for the management to make sure that the right things happen at the right time, and in the right way. The main areas for management systems are quality and environment. Work environment is a growing area. Other areas include information security, road safety and energy. There are also standards for management systems that are directed towards special industries, including food safety, welding processes and medical devices.

A common element for all management systems is that they focus on continuous improvement. This involves the planning of objectives and processes, implementation of these processes, evaluation of results and analysis of deficiencies and then the planning of new measures.

It is usually voluntary for the organisation introducing the management system to certify the system. Nevertheless, many parties choose to certify their management systems as an acknowledgement that they meet the requirements and in order to keep the system alive. There may also be demands from customers or authorities that the management ­system should be certified. A certified management system gives confidence that there are processes in place for implementing the product/service as well as continuous improvement. Certification also shows that the processes are systematically implemented and meet applicable requirements.

ISO 9001 is the management system standard that is perhaps most relevant for exporting companies, for example, as it provides several benefits for activities that comply with it, such as

* engaging the management in the work on quality
* improving the business processes
* streamlining the activities
* increasing customer satisfaction
* improving the opportunity to win government contracts and strengthen the brand.

This is also in accordance with the thesis by Frenz and Lambert in which standards play a significant role when it comes to economic growth. For example, an empirical study shows that certification of companies in accordance with the ISO 9001 quality management system has a positive effect when it comes to promoting efficiency.[[55]](#footnote-55) A well-implemented quality management system that supports the way in which the activity works will help the organisation to achieve its strategic business objectives. The management system adds value. The values are both internal and external. Internal effects often highlighted are an orderly way of doing things, more efficient processes, systems for continuous improvement, more right and less wrong, etc. In simple terms, this leads to better resource utilisation and lower costs for quality deficiencies. These are normally factors that have a positive impact on the organisation’s finances, regardless of whether it is private or public sector. In terms of external benefits, a certificate issued by a certification body that is accredited by an accreditation body which is a signatory to EA’s or IAF’s MLA is an effective way of communicating externally that this is an organisation that inspires confidence. The Member States within the EU are obliged to accept such certificates. IAF’s MLA means that the certificates are recognised by its members at a global level. This means that certificates will not be called into question but will be recognised in the same way as a certificate issued by an accredited certification body in the country in question. IAF’s objective for free trade is “certified once, accepted everywhere”.

## 3.3 The benefits of standards in export promotion

Among other things, the correct application of standards contributes to a better functioning society, increased safety, improved environment and the promotion of trade and export. Sweden has an almost one hundred year long tradition of being one of the world’s strongest countries in the field of standardisation. Many large Swedish international companies have built their success over time precisely based on patents and standards. That’s why Sweden is strong despite being relatively small in size. However, international competition on quality is becoming increasingly tougher.

Global standardisation bodies have members in all industries from countries throughout the world due to the fact that there are standards for almost everything. The work is based on the principle of consensus, i.e. everybody participates. Global standards are well-known by all participating countries. When the requirements in global standards are met, the market knows what it gets. It will therefore be easier for Swedish companies and organisations to gain access to global markets if they use global standards. This is also why it is important for Sweden to have secretariats in subject areas of significance for Swedish industry, as well as industry participating in the standardisation work, see also in 4.2.

Companies that use standards strengthen their competitiveness by reducing costs and simplifying trade, among other things. It is important that Swedish companies participate in the standardisation ­work so that they can influence current and future European and global standards on the markets in which they operate. Companies that develop new products and innovations can gain faster market access. This drives efficiency and increases productivity.

By contrast, it can be costly for a company that lacks knowledge of current and future standards and that does not engage itself in standardisation work. The products and services from companies must match what is demanded and fit into the contexts for which they are intended, and this is specified in the European and global standards. The use of standards helps companies achieve the efficiency and competitiveness necessary for success on the market.

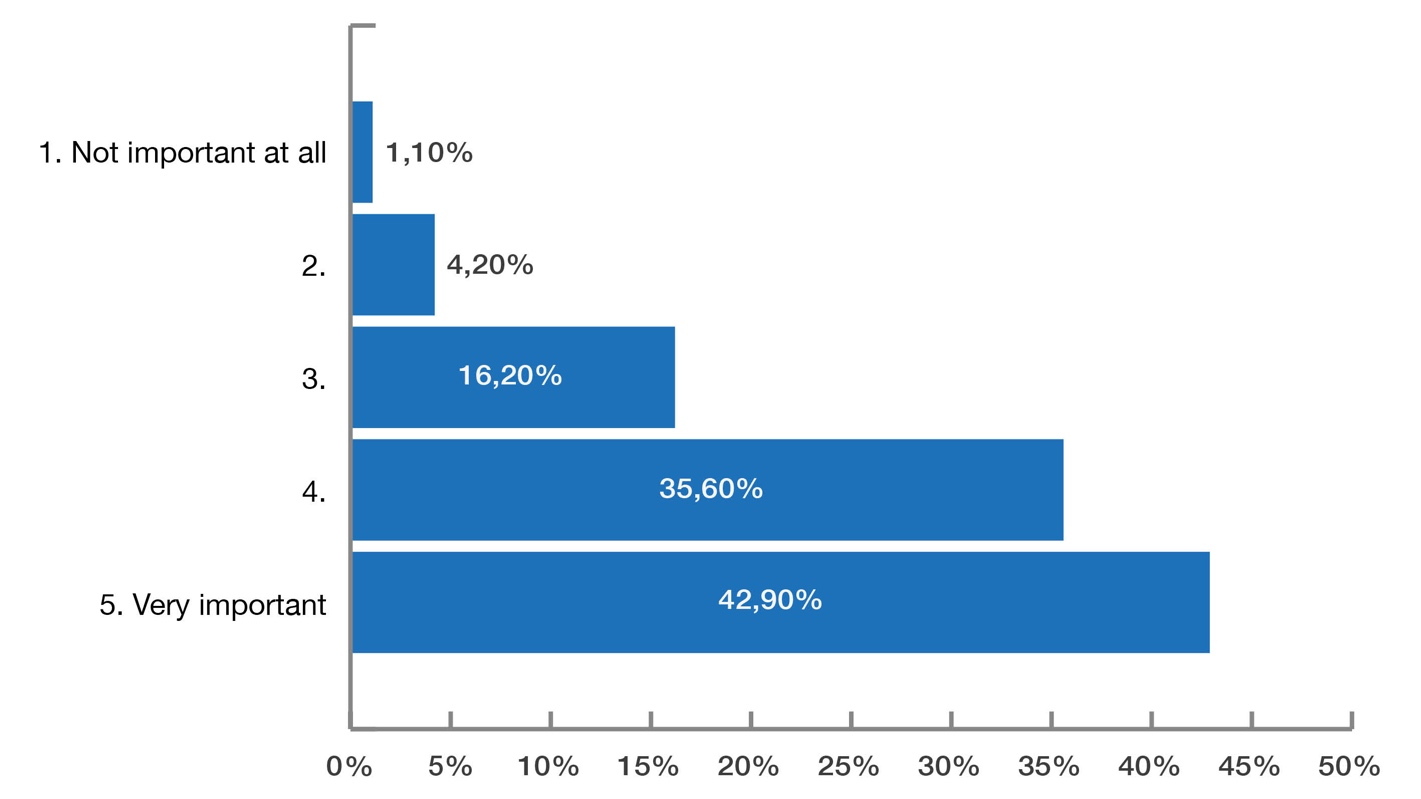
Countries such as China, South Korea, Japan and others are investing major resources in increased participation in the global standardisation activities, and countries that are traditionally strong in the area, such as Germany and the United Kingdom, are continuing to invest. If Sweden reduced its influence, this would harm Swedish industry, which would then have more difficulty in establishing new companies, products or services internationally.

Decisions have been taken at EU level on a comprehensive strategy and work programme for standardisation – Joint Initiative on Standardisation (JIS). JIS is an excellent example of how the legislator (EU Commission and Parliament) and the standardisation organisations cooperate to achieve the effective application of the law using standards. What is characteristic of the European standardisation system is that the Commission may request the European standardisation bodies to draw up a European standard or a European standardisation product for products and services as support for Union legislation and policies. The harmonised standards mean that the Commission does not need to set detailed requirements in the legislation, which creates a more efficient internal market.

### 3.3.1 The benefits of participating in standardisation work

In autumn 2016, SIS conducted a survey among 4954 committee participants from whom they received 1388 completed questionnaire responses, i.e. a response rate of 30.7%, and the questions included one on the importance of the international network they gain access to by participating in standardisation. The responses are distributed according to the following with an average rate of 4.15 on a 5-point scale where 1 = not at all important and 5 = very important.

Illustration 9: How important is the personal network you gain access to by participating in standardisation (nationally and/or globally)?



During the same period, SIS also conducted a survey among approx. 5000 people who purchase standards, courses or manuals. 1088 completed questionnaire responses were received, which is a response rate of 23.3%. Among other things, SIS used the survey to ask customers whether they had derived tangible benefits from using SIS products in their work. More than 92% replied that they had derived benefit from SIS products.

The customers were also asked whether they were certified to different standards, to which 64% answered “Yes”.

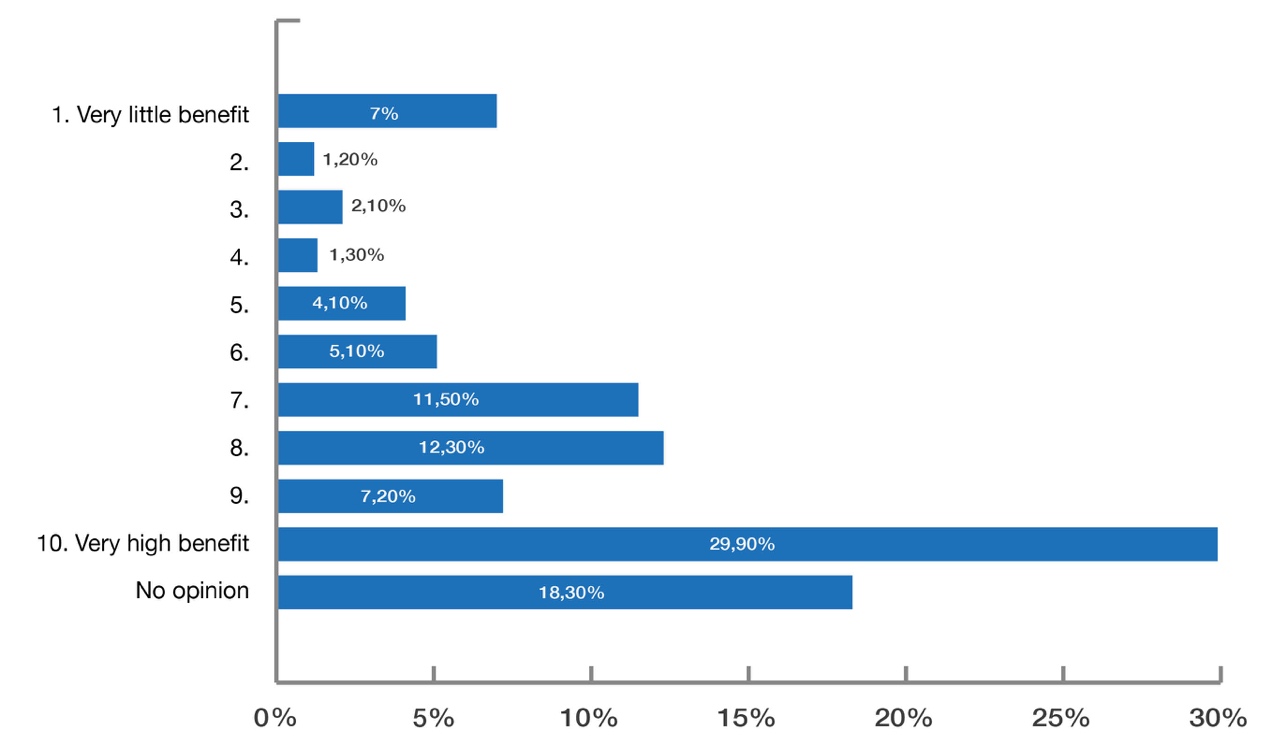
Illustration 10: Is your company/organisation certified in accordance with standards?

En bild som visar skärmbild

Automatiskt genererad beskrivning

The question on ranking the degree of benefit customers derived from being certified to different standards received an average score of 7.53 on a 10-point scale, where 1 was very little benefit and 10 was very high benefit.

Illustration 11: What benefit does your company/organisation derive from being certified in accordance with different standards?



### 3.3.2 Innovation

Sweden is reckoned to be one of the EU’s leading innovation countries, but for Swedish innovations to generate jobs and welfare, ideas and solutions need to spread. Correctly used, standards and standardisation can be tools that contribute to this, and for an export-dependent country like Sweden it is important that Swedish solutions are included in the work to establish the basis for new global standards. Market entry is facilitated when researchers and innovators take existing standards into account while developing their ideas.

If companies that develop new products and innovations take part in and influence the European and global standardisation work while they develop a new product, their product will have shorter “time-to-market”. This is because they will learn about the nature of the markets in different parts of the world and what requirements and measurement methods are involved in each market. They will also be able to strive to keep the functionality, etc., of their products in close conformity with the requirements of a standard. If their innovation is based on applicable and established standards, i.e. accumulated international knowledge, they will avoid repeating the development phases of the product that their competitors or colleagues had to undergo before them.

## 3.4 Opportunity for the public sector

The strategic work with Sweden’s established quality infrastructure by the business sector over almost 100 years has met with great success, making it an open process in which all stakeholders have the opportunity to participate in the work of drawing up guidelines and standards.

The implementation of such a scheme, within different publicly funded activities and based on standards and certifications, would make it possible for governmental authorities to focus on more risk-based surveillance, since the certification bodies handle the certification and thereby also continuous monitoring to ensure that the activities comply with the published standards.

This would lead to an increase in quality within publicly funded activities at a lower cost, primarily in the monitoring mechanisms. Using such a quality infrastructure would contribute to the quality assurance of the activities by the Government Offices and a more efficient use of the public resources and increased societal benefit.

Examples of areas with the potential to be developed according to the above are:

* Psychiatry – both residential and outpatient care.
* Refugee reception – cooperation between more authorities and more stakeholders.
* Clinical trials – process for developing clinical trials or studies.

Within the framework of the Joint Initiative on Standardisation (JIS), mentioned above, SIS has drawn up a proposal for a pilot project whose aim is to increase the use of and reference to standards within public procurement in Europe. It is currently the case that there is an absence of correct reference to standards within public procurement in Europe. The project can lead to simplifications and improvements for both contracting authorities and suppliers during the procurement process, with respect to both setting requirements and follow-up. There are also plans to publish a guide for referring to standards, aimed at contracting authorities as tenderers, as well as to make different types of efforts to disseminate knowledge on the issue. The project also aims to develop a standard in the issues of transparency and ethics in public procurement, and SIS will take the lead role in this work.

What are known as harmonised standards cover a range of areas that are regulated in EU legislation. Harmonised standards relate directly to the responsibility of the state for protecting the lives, health, environment and property of citizens. It can therefore cover a wide range from protective safety equipment and energy efficiency to the so-called Eurocodes for the construction sector.

# 4 Accreditation and participation in standardisation. The route to an international market.

## 4.1 Accreditation

As described earlier, accreditation is an international phenomenon. Accreditation bodies operate in a large number of the world’s countries and on all of the continents. The main influence of accreditation on export is the acceptance of the reports and certificates issued, for which the international agreements on mutual recognition form the groundwork. Recognition in and access to the markets of other countries is facilitated for companies that have their products or services tested, inspected or certified under accreditation by a body that is signatory to a European or international agreement on mutual recognition. Member States are obliged to accept reports and certificates within Europe, where accreditation is regulated in European legislation. This is a step further than the international agreements on mutual recognition in which the members are obliged to accept reports and certificates. Both agreements involve lower costs for testing, inspection and certification and reduce the risk of goods and services being rejected by international trading partners.

Accreditation also means that the accredited body has the opportunity to sell its services in an international market since accreditations are equivalent throughout the world. This does not mean that an accredited party needs to establish itself abroad, but can instead be an attractive alternative to the accredited bodies of other countries.

## 4.2 Swedish-run standardisation secretariats promote Swedish export

According to SIS, it is established that Swedish management of secretariats and working groups in European and global standardisation can lead to positive outcomes for Swedish companies. Having secretariats increases the opportunities to shape the content, and for experts from Sweden to take the initiative in the standardisation process. In this respect, there is therefore great development potential for Swedish competitiveness.

For Sweden to have the opportunity to take the lead role in new international secretariats in standardisation,­ there must be a mobilisation of companies, primarily small and medium-sized, and at the same time an increase in the interest to lead international standardisation projects.

2017 was the second successive year of the government’s special drive towards standardisation in export strategy, which meant much-needed financial support for Swedish-led secretariats, while other Swedish financiers have not yet managed to undertake a commitment. Germany, Canada, the United Kingdom and several South Asian countries maintain a prominent position when it comes to focusing efforts on European and global standardisation. Competition for secretariats is at times fierce.

### 4.2.1 Secretariats led by Sweden at the regional level, CEN, CENELEC and ETSI

Within CEN, the European standardisation organisation, the work is divided into three levels of secretariats:

* TC, Technical Committee
* SC, Sub Committee
* WG, Working Group

Only the TC level at the top of the structure is described below. Normally, there are several working groups under a TC.

SIS and Swedish stakeholders lead 12 TCs of almost 400, which represents approximately 3 per cent of all TCs in CEN. This 3 per cent represents approximately 1/28, which is in line with Sweden’s share. When it comes to working groups under TCs, the number is just over 1 500, of which approximately 50 are led by Swedish stakeholders. The rate of development for new TCs is an average of 6 per year (statistics for 2011-2017). The TC secretariats held by SIS are listed below:

* Thermal performance of buildings & building components (CEN/TC 89)
* Thermal energy meters (CEN/TC 176)
* Compressors, vacuum pumps and their systems (CEN/TC 232)
* Hand-held, non-electric power tools – Safety (CEN/TC 255)
* Assistive products for persons with disability (CEN/TC 293)
* Centrifuges (CEN/TC 313)
* Solid biofuels (CEN/TC 335)
* Health services - Quality management systems (CEN/TC 362)
* Service Chain for Social Care Alarms (CEN/TC 431)
* Quality of care for older people (CEN/TC 449)
* Patient involvement in person-centred care (CEN/TC 450)
* Methods of chemical analysis for iron & steel (ECISS/TC 102).

CENELEC, the European Committee for Electrotechnical Standardisation, has the primary responsibility to ensure that international standards from IEC are adopted in a coordinated and uniform way in the 34 member countries. The work is only carried out by CENELEC in the cases where European standards are needed and the work could not be transferred to IEC (see 4.2.2). These unique European standards make up only approximately 15% of the European standards from CENELEC. In line with this, there are not any Swedish committee secretariats in CENELEC and only around half a dozen working groups are led by Swedish stakeholders.

ETSI, the European Telecommunications Standards Institute, in which ITS is the Swedish national member, has a different structure, with the opportunity for companies to have direct membership. Several Swedish companies are active participants, and the chairperson for ITS is also on the ETSI board.

### 4.2.2 Secretariats led by Sweden at the global level, IEC and ISO

In the field of global standardisation, ISO, SIS and Swedish stakeholders have a disproportionately large share of just over 5 per cent, which means 13 TC secretariats from just under 250. This results in a seventh place in the overall ranking of ISO’s 160-plus member organisations, after large nations such as Germany, China, USA, and others.

The secretariats at global level held by SIS, together with Swedish stakeholders, are listed below:

* Rolling bearings (TC 4)
* Technical product documentation (TC 10)
* Quantities and units (TC 12)
* Compressors, pneumatic tools and pneumatic machines (TC 118)
* Powder metallurgy (TC 119)
* Thermal performance and energy use in the built environment (TC 163)
* Assistive products for persons with disability (TC 173)
* Small craft (TC 188)
* Geographic information/Geomatics (TC 211)
* Solid Biofuels (TC 238)
* Road traffic safety management systems (TC 241)
* Security and resilience (TC 292)
* Robotics (TC 299).

Global growth of TC secretariats within ISO is on average approximately 9 per year for the period of 2011-2017, which is equivalent to a growth of just over 3 per cent.

Swedish efforts in electrotechnical standardisation are primarily at international level, within IEC, where Svensk Elstandard (SEK) has been the Swedish member since 1907. International standards from IEC are normally also voted in parallel in CENELEC (see 4.4.1) and thereby also constitute approximately 85% of the European standards in the field of electrotechnology and electronics. SEK holds six secretariats in IEC, therefore just over 3% of the technical committees. This is on the level of the number of secretariats administered by China and South Korea respectively. SEK is also the representative in the technical board of IEC (SMB), and there is also a Swedish representative in the certification board (CAB). Swedish interests also lead four technical committees and almost forty working groups.

The Swedish secretariats in IEC are as follows:

* Information structures and elements, identification and marking principles, documentation and graphical symbols (TC 3)
* High-voltage switchgear and controlgear (TC 17)
* Switching devices (TC 17/SC 17A)
* Appliance couplers (TC 23/SC23G).
* Surface cleaning appliances (TC 59/SC59F)
* Environmental conditions, classification and methods of test (TC 104).

## 4.3 International aid and development cooperation

This section describes how accreditation and standardisation within the framework for international aid and development cooperation is beneficial to world trade and, in the longer term, also to Swedish export.

Egypt, in particular, is mentioned as one of the government’s 26 prioritised markets in the export strategy[[56]](#footnote-56).

### 4.3.1 Swedac’s work with international aid and development cooperation

Swedac’s international development projects contribute to building up an infrastructure for accreditation and associated legislation for testing, calibration, inspection and certification. Swedac’s development cooperation is based on the approach that a functioning quality infrastructure in countries with prioritised markets is beneficial to Swedish export. The aim of Swedac’s international development cooperation is that it should contribute to the implementation of Agenda 2030 with its objectives and interim objectives, with Sweden’s policy for global development as a tool.

The activities contribute to the following:

* Improved trade opportunities.
* Reduction of costs and time, by doing things right from the start.
* Strong competitiveness through:
  + Access to international markets
  + Strong consumer protection
  + increased safety.
* Increased sustainability through:
  + Enhanced environmental protection
  + Increased confidence
  + Reduced unfair competition.

The objectives of the international development cooperation are the following:

* To contribute to increasing knowledge of conformity assessment in open systems for harmonisation as well as safe products and services in world trade without barriers.
* To contribute to developing an efficient national infrastructure for accreditation and conformity assessment in the cooperation countries in order to facilitate participation in world trade.
* To be closely linked to Swedac’s national work and other international work – for mutual strategic benefit.
* To have a focus on Swedac’s unique competence and resources.

The conditions for Swedac’s participation can be divided into four parts: *demand, governance and financing, unique competence, and strategic benefit.* The importance of trade to economic growth and poverty reduction is clear. The developing countries have long made it clear that there is a need for increased trade-related aid, including increase to the ability of the countries to take advantage of trade opportunities and to accommodate any costs of adaptation as a result of liberalisation.

World trade without barriers is based on confidence that the goods and services moving across national borders and trading blocks are safe and meet the requirements set by authorities and markets. Proving this requires conformity assessment and assessment of compliance with standards that meet stringent requirements, and that these are performed in an equivalent manner around the world. At the same time, an efficient system for conformity assessment is important domestically, in order to ensure that products and services are safe for life, health and environment. Accreditation of the parties that perform testing and inspection creates such confidence.

The requests for support are usually directly from cooperation countries or organisations in need of development. They can also be made via Sida, EU, World Bank or some other financiers who may want to partner with Swedac in a development project. However, a basic prerequisite for successful development cooperation should be a clear ownership of the implementation­ by the cooperation partner in the developing country/region.

Ultimately, it is Sweden’s focus on the international development cooperation that governs Swedac’s efforts in the area. The development cooperation is externally financed, mainly through the budget for international aid via Sida, but also via the EU or other financing organisations.

As the Swedish International Development Authority, Sida is an important partner for Swedac for international aid activities. Sida is also the most important financier of Swedac’s aid activities. The focus of Swedac’s aid activities is to facilitate the participation in international trade by developing countries, which is closely in line with the current focus of Swedish development policy. Sida views Swedac as an important stakeholder in this sector of aid activities.

The participation by Swedish authorities in international development work constitutes a type of service export. The financial requirement is full cost recovery.

Swedac’s unique competence is in the role as national accreditation body and its experience as central authority for issues on accreditation and conformity assessment.

In order for international development cooperation to be seen as a natural part of Swedac’s national activities and other international activities, it is important to identify the strategic benefit to Swedac from participation. Some examples of such strategic benefit are as follows:

* The development cooperation contributes to increasing knowledge about, and internationally enhancing, the status of accreditation, as well as enhancing international awareness of and confidence in Swedac, both in Europe and in Sweden.
* The development efforts create good contacts with prospective members and signatories to the agreements signed in the international accreditation cooperations EA, ILAC and IAF.

The current appropriation directions do not specify any countries or regions that should be prioritised in Swedac’s development work. The only restriction is that the work should be aimed at countries that adapt to the rules of the EU or WTO, which should essentially include all developing countries.

There is a wide range of projects involving support for countries in essentially all continents. Swedac’s services are in demand from many countries and to a considerably larger extent than can be met by Swedac’s resources. For this reason, Swedac is forced to prioritise its efforts. The government’s bilateral strategies for development cooperation govern the opportunities for Swedac’s participation in the development cooperation. The exports of services is demand-driven, with the government’s strategies and the country’s needs as starting point.

Examples of international development projects

Egypt

Egypt is in the process of negotiating a so-called ACAA agreement[[57]](#footnote-57) with the EU. Such an agreement involves the EU’s contracting party, in this case Egypt, undertaking to implement EU product legislation in the sector or sectors covered by the agreement. This includes adopting the EU’s system for conformity assessment in the sectors in question. For its part, the EU undertakes to accept the products manufactured in accordance with the ACAA agreement and which are presumed to meet the requirements in applicable product directives from the EU.

An expert from Swedac has participated in a project led by the UK’s BSI[[58]](#footnote-58) aimed at modernising Egypt’s legislation concerning quality infrastructure, i.e. metrology, standardisation, accreditation, conformity assessment and market surveillance. Swedac’s expert has drawn up draft provisions on accreditation. In all material respects, the provisions are modelled on relevant requirements in Regulation (EC) no. 765/2008. Adapting Egypt’s legislation on accreditation to the regulations in force in the EU creates conditions that allow the EU to approve conformity assessments performed by bodies accredited in Egypt. This primarily applies to conformity assessments for products covered by Egypt’s impending ACAA, but subsequently within other sectors as well.

Agadir project

The Agadir agreement is a trade agreement between Morocco, Tunisia, Egypt and Jordan. The purpose of the agreement is to form a free-trade area between the four signatory states, which involves the elimination of customs duties between the member countries, as well as duties and taxes of equivalent effect. The objective is to increase trade between the member countries as well as between the member countries and the EU. Increased trade is expected to increase the productivity and living standards in the signatory states.

Eliminating customs duties is not sufficient to increase trade. Non-tariff barriers to trade also need to be eliminated, or at least reduced. This applies not least to so-called Technical Barriers to Trade (TBT). For some years now, Swedac has been conducting an aid project together with SIS and the Swedish National Board of Trade (Kommerskollegium) aimed at reducing the technical barriers to trade in accordance with what is stated in the Agadir agreement. The project has involved a number of seminars on-site in the Agadir countries with the objective to identify existing barriers to trade with regard to selected products and achieve a harmonisation of rules and mutual recognition. The project covers both mandatory technical rules as well as voluntary standards. Within the framework of the project, Swedac has also distributed information on accreditation. Accreditation would increase mutual confidence between the signatory states with regard to conformity assessment, which would create the conditions for increased trade internally between them and externally with the EU.

### 4.3.2 SIS’s work with international aid and development cooperation

SIS coordinates development cooperation efforts with countries in need of capacity building and institutional development in standardisation which will contribute to opportunities for these countries to integrate into the trade­ systems and thereby societal development. During 2017, SIS cooperated with 33 countries in specific projects, primarily supported by Sida, and during 2018, SIS entered South America with a project in Bolivia.

It would be advantageous for Swedish industry if Swedish efforts could be linked to a greater extent with Swedish investments in the country in which work is in progress. Implementation of recognised global standards is beneficial to the Swedish business sector. When both global standards and their significance for achieving quality, safety, etc., become well known and established in the country, demand can be redirected to more high-quality products­ and services that are normally delivered by Swedish companies. In procurements that take place in developing ­countries, Swedish companies bear witness to losing out on price to lower quality products and services that do not meet global standards.

The international aid and development cooperation (IU) of SIS is based on how the country in question uses standards, the degree of activity within ISO, as well as which standards are sold to or used by private and public stakeholders. This is supplemented by information about which standards are of particular interest to the participants from the countries, and this can be within existing or future export sectors.

Furthermore, this is matched against Sweden’s priorities and the development cooperation is shaped based on a common approach. Ensuring relevance in the chosen sector(s) guarantees interest, as well as relevance, for the private and public sector to be involved in the standardisation process, and subsequently in the practical application of the standard(s). Consequently, this strategy is not currently linked to Swedish export promotion, but rather to aid that is aimed at promoting export on behalf of the countries.

To promote Swedish export requires that the development cooperation is linked to Swedish interests and Swedish companies with activities in the countries (however, this does not have to mean concrete activities in a country but can also only comprise suppliers in a large value chain or similar). A joint review takes place of how the Swedish companies use the standard(s) in the area, i.e. whether they are participants in technical committee activities and/or are registered purchasers of the standard(s) (e-nav, etc.). If this is the case, it is even more relevant to promote an increased capacity in the area and that the application of the standard increases. It is possible to promote Swedish export in a more long-term perspective by linking Swedish activities to the countries with which Swedish standardisation cooperates.

Bolivia, which is mentioned above and which is a completely new cooperation country for SIS, belongs to one of the government’s pilot countries in the export strategy, with the aim to link trade with development aid. There are now many opportunities to act in a way that is beneficial to Swedish export to Bolivia. It is important that Business Sweden and the National Export Credits Guarantee Board (Exportkreditnämnden - EKN), parties tasked by the government to promote trade, are informed about this project which can probably contribute to export opportunities for Swedish companies. When planning development projects, Sida should invite these authorities and Swedish companies in the relevant sector for the dissemination of information and acquisition of knowledge. The importance of standards for a well-functioning trade system is established in WTO’s TBT rules.

Swedish companies will benefit in international procurements if the rules of play are well known in advance, i.e. by referring to the inclusion of existing global standards right from the start. In addition to referring to global standards, conformity assessment during accreditation should also be highlighted since this tool formalises the reciprocity principle when using global standards. The application of the same assessment criteria by accreditation bodies across the world for compliance with standardised requirements creates a well-functioning supply chain and increased world trade.

The more countries there are that receive support from Sweden in building capacity in accreditation and standardisation, the more markets there are that can become available to Swedish companies.

### 4.3.3 The work of Svensk Elstandard (SEK) with technical aid

Within IEC, International Electrotechnical Commission, the international organisation for standardisation in the electrotechnical field, there is the opportunity for countries will less experience of standardisation to become affiliated members. This means a less formal association with IEC with the opportunity to use IEC standards, to follow the work and also to participate in the work to a limited extent. A programme exists within IEC to support and introduce the affiliated members through cooperation with an established national committee with greater experience. For a couple of years, Svensk Elstandard (SEK) has participated in such a project to support the establishment of standardisation in Bhutan. The cooperation has involved discussions and support in conjunction with IEC meetings, and assistance and knowledge transfer on-site in Bhutan. There has been a very good outcome from this cooperation, which is why Svensk elstandard , SEK, has announced continued support within this IEC programme.

# 5 Case studies

Described below are a number of case studies where accreditation and standardisation are used to varying extents and in different ways. The cases studied are examples of applications as it has not been possible to cover all of the different scenarios.

## 5.1 Examples studied

### 5.1.1 IKEA

IKEA[[59]](#footnote-59) the company needs no further introduction. Some facts that may be of interest in the context are that in financial year 2017 there were 403 IKEA stores in 49 countries. The five countries with highest sales in 2015 were Germany, USA, France, United Kingdom and Italy. IKEA’s success in the world is well-known and there are naturally several factors that affect this. One fact is that IKEA uses accreditation and standards as part of its work to develop and manufacture products.

IKEA develops its own products, has the products manufactured on its behalf, puts the products on different markets and sells the products to end customers.

The first stage, product development, is largely performed in Älmhult, where the IKEA-owned IKEA Test Lab laboratory, which is a material and development laboratory, accounts for the majority of all testing performed. Here IKEA has chosen to have the laboratory accredited for fire testing, function testing, physical properties, climate and environmental resistance and material testing. 96 per cent[[60]](#footnote-60) of the accredited test methods are standard test methods. IKEA’s management has decided that its own laboratory should be accredited[[61]](#footnote-61) and meet the requirements in ISO/IEC 17025. IKEA considers it as one way of ensuring that testing is performed correctly in accordance with international requirement standards and that the management runs the activities in accordance with the laws and regulations in force. A driving force for IKEA is to do things right from the start and throughout the product development chain.

When a product is fully developed it is sent over to production. IKEA’s products are manufactured by a large number of suppliers located throughout the world. In order to ensure a high level of product quality and conformity with requirements and product specifications, IKEA has approximately 100 external laboratories across the world to test and verify that the requirements are met. These laboratories are not IKEA-owned but can be considered as suppliers and are engaged by the manufacturers of the products. As a basic requirement, these laboratories must comply with ISO/IEC 17025. In addition to this, IKEA has further requirements for the laboratories. These requirements also apply to all IKEA suppliers and are IKEA’s own requirements for suppliers and concern areas such as environment, social impact and working conditions, IWAY[[62]](#footnote-62). IKEA has its own organisation that evaluates the testing laboratories. In other words, the requirements for the testing­ laboratories are ISO/IEC 17025 and IWAY. Consequently, the laboratories which are accredited in accordance with ISO/IEC 17025 meet one of the basic requirements and do not need to be evaluated as to their compliance with ISO/IEC 17025. Focus is then put on the evaluation of the requirements in IWAY. In terms of size, 50 per cent of the approved laboratories are accredited in accordance with ISO/IEC 17025. The approved laboratories are added to a list of approved laboratories and can then be used by the suppliers that manufacture products and deliver them to IKEA.

IKEA is active in standardisation and is an active user of standards.[[63]](#footnote-63) During 2017, IKEA participated in around 60 working groups within SIS, CEN and ISO and subscribed to approx. 3500 standards from SIS. In addition to standards, IKEA draws up it own requirements for products when appropriate standards are not available. The suppliers that manufacture products and the approved laboratories are then given access to new requirements drawn up by IKEA in order to be able to use them in production and in the testing and verification of the products. Through its participation in standardisation work, IKEA’s experience in drawing up its own requirements for products can be used as an input for drawing up new standards.

Summary

IKEA ensures that it will “do things right from the start” by using an accredited testing laboratory straight away from the product development phase.

Evaluation and approval of suppliers for testing are based on the fulfilment of ISO/IEC 17025 and IKEA’s own requirements in IWAY. The supplier meets a number of requirements through accreditation and only additional requirements in IWAY need to be evaluated by IKEA.

Participation in standardisation provides IKEA with the opportunity to influence the contents of standards as well as having prior knowledge and information on the contents of new standards.

### 5.1.2 The CB Scheme

International Electrotechnical Commission (IEC) is the international organisation that develops and publishes global standards in all electrotechnical technology areas. IEC also develops and manages a conformity assessment scheme for electrical and electronic products and systems, commonly known as the CB Scheme.[[64]](#footnote-64) Electrical and electronic products are a major global commodity and, according to statistics from the UN, accounted for more than 15 per cent of overall trade value in 2015.[[65]](#footnote-65) Specific to electrical and electronic products is that they are the type of products that are assembled in different parts of the world before delivery to the sales supply chain and then to the consumer. This chain contains requirements from the final consumer, legal requirements and specific requirements from manufacturers. The requirements for electrical and electronic products usually relate to safety, function and quality. A prerequisite that the chain should work and remain intact is the existence of standards and that the requirements for products can be verified. This is the core of the CB Scheme of which IEC is the owner. Currently there are four global schemes within IEC for conformity assessment:

* IEC Scheme of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE), also manages the above-mentioned CB System.
* IEC Scheme for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres (IECEx).
* IEC Quality Assessment Scheme for Electronic Components (IECQ).
* IEC Scheme for Certification to Standards Relating to Equipment for Use in Renewable Energy Application (IECRE).

Sweden is a member of IECEE and IECEx through Svensk Elstandard (SEK). The IECEE scheme organises 53 member countries and IECEx organises 33 member countries.

As described earlier in this report, IAF’s MLA and ILAC’s MRA mean that the accreditation bodies that are signatories to the agreements are obliged to accept results from conformity assessment bodies from all other signatories to the agreements. The accreditation bodies are not members of any of the IEC schemes. However, there is a third-party agreement between ILAC-IAF-IEC to underpin good accreditation policy in relation to the various laboratories in the IEC schemes that choose to become accredited (which most of them do, although this is not a requirement from IEC).

IEC bases all of its schemes on peer assessment, where the members evaluate each other and it is easier for a party to pass a peer assessment if it is accredited. The intervals between peer assessments are also affected depending on whether or not a party is accredited. Peer assessment intervals for accredited laboratories are further apart, so most laboratories choose to be accredited. An approved conformity assessment body in the CB System is obliged to accept all results from all other approved conformity assessment bodies.

In practice, the proximity of the CB Schemes to standardisation means that rules and procedures drawn up for the implementation of testing and certification have a relatively shorter route to becoming incorporated into global standards. This applies to requirements originating within IEC as well as the national mandated requirements of individual countries.

Summary

Accreditation and standards form the basis of the entire system in the CB Schemes. In the same way as a customer evaluates a supplier regarding additional specific requirements, members of the CB Schemes evaluate each other using peer assessment procedures. This way, the members of the CB Scheme have confidence in each other and thereby accept each other’s work as equivalent. Swedac considers that an alternative procedure to peer assessment by the members regarding additional and specific requirements could be, as scheme owner for the CB Scheme, to include the additional and specific requirements in the requirements for becoming accredited for the CB Scheme. The latter procedure is common in other areas, such as in the food sector.

The CB Schemes give Sweden access to markets in other countries without the need to perform additional testing or certification. Accreditation is a complement to allow acceptance as member in the CB Schemes. The CB Schemes take into account the requirements from different types of stakeholder such as legislators, manufacturers and end customers, and are based completely on standards.

### 5.1.3 Baltic

Baltic Safety Products AB[[66]](#footnote-66) is a company that has manufactured life jackets since 1977. 48 per cent of the turnover is accounted for by export sales, primarily within Europe but also to other countries in the Middle East, Asia, Australia and New Zealand. The company has been active in standardisation since 1989. Current standards for the company’s products are included in the EN ISO 12402 series, standard for personal floatation devices, as well as EN ISO 12401, standard for deck safety harness and safety line.

In Europe, marine equipment, including personal floatation devices, must meet the requirements in the Directive 2014/90/EU on marine equipment. Among other things, the Directive requires most products to have a so-called EU Type Examination Certificate issued. To be entitled to mark a product with the “wheelmark”, the continuous production must be monitored by a notified body in accordance with one of the modules in the Directive. The European market is clear about which requirements are set for a company’s products to allow them to be sold. One problem that is highlighted by the company is the scope of market surveillance and the consequences, or rather lack of them, if a product does not meet the requirements.

In order to be successful in exporting to the international market outside Europe, products need to be certified in accordance with the relevant part of the EN ISO 12402 standard. The certifications are performed by certification bodies accredited by a signatory to IAF’s MLA. This is a scheme that works well for most countries that the company exports to. In this respect, it can be said that the system of standards, accredited certification and acceptance in other markets is working as intended. However, relatively recently this well-functioning scheme has been subject to some deviations. This primarily applies to exporting to Australia, where new requirements for products and a new certification procedure have been introduced. The new Australian requirements are based on approx. 90 per cent of the EN ISO 12402 series, supplemented by specific national requirements. Furthermore, only certifications performed by Australian certification bodies are accepted.

Regardless of the reasons for the new Australian scheme, it means a wider range of product variants, testing and certification, which in turn leads to increased costs for manufacturers of floatation devices. One way of handling additional requirements as in the Australian case could have been:

1. To set requirements based on the EN ISO 12402 series of global standards.
2. To define additional requirements and any non-relevant requirements in the EN ISO 12402 series in a separate requirements document.
3. The certification requirements would then consist of the EN ISO 12402 series in combination with the requirements document described in point 2.
4. To accept certificates issued by certification bodies that are accredited by a signatory to IAF’s MLA.

Additional requirements can be relevant to special markets. If this is the case, start from existing requirements in a relevant standard. Add relevant additional requirements and/or remove non-relevant requirements in a relevant standard and specify this in a requirements document. Set requirements for testing/inspection/certification by bodies that are accredited by a signatory to the relevant IAF MLA or ILAC MRA.

Summary

This example demonstrates several properly functioning applications. The EU’s legislative framework (NLF) has proven successful for Swedish industry with its entry into the entire European market. In addition, there are global standards with associated product certification that are accepted in most countries outside the EU. Unfortunately, the example also demonstrates applications where the international conformity assessment system is overridden by specific national requirements. Swedac’s understanding is that with the right resolve, and if the knowledge exists, then additional requirements can also be handled within the framework for the international conformity assessment systems.

### 5.1.4 Camfil

Camfil[[67]](#footnote-67) started in Sweden in 1963 and is currently a leading company in air filters for ventilation­ systems, with approx. 4000 employees around the world. It is based in the Nordic region and all of the filters (e.g. filters for ventilation, metal filters and clean-room filters/HEPA filters) are produced within the group. Camfil Svenska AB has two factories in Sweden that are certified in accordance with ISO 9001 and ISO 14001. Camfil has 28 factories around the world where production takes place for neighbouring markets. This is because filters are bulky­ and transportation costs can account for a considerable amount of the final price. Camfil has a market share of approx. 50 per cent in the Nordic region and approx. 30 per cent in Europe.

Camfil has worked on standards development for many years. The objective is to create relevant levels of requirements but also to create opportunities to set high quality requirements in order to demonstrate the high level of efficiency and the premium level of its own products.

Filter technology is difficult for a final consumer to understand, but the consumer wants to have “clean air”, which means that the filter industry is a confidence industry.

Work with standards in the area takes place on a global level. Despite this, there is still a strong local influence in setting requirements when it comes to ventilation systems and their filter solutions. This results in, for example, different products in southern/northern Europe and America.

In future standards development it would therefore be desirable to have greater involvement from representatives with a customer perspective. Creating purely technical testing standards can normally take place according to a good level of consensus. However, it is more difficult to create standards that have different levels or classifications of filters since this affects manufacturers, suppliers and their production methods as well as business arrangements to a greater extent. It is perhaps despite all this that customers demand to be able to make a conscious choice of filter level from a weight-of-evidence approach to filter capacity and power consumption.

Camfil currently has no standardised classification system for the classification of molecular filters, chemical filters and carbon filters.

Professional association Eurovent plays a central role in the filter industry.

Eurovent Certification certifies and classifies the performance of air conditioning filters in accordance with European and global standards.

Eurovent has a certification programme that is not implemented by an accredited certification body. The system is based on manufacturers affiliated with the system classifying their products and registering them with Eurovent. Eurovent lists products and also conducts random sample testing approximately once a year. Eurovent also has a number of designated laboratories that conduct testing, e.g. RISE[[68]](#footnote-68), VTT[[69]](#footnote-69), Cetiat[[70]](#footnote-70). Eurovent Certification uses laboratories accredited in accordance with ISO/IEC 17025.

Camfil is an advocate of independent third-party testing in order to maintain a high level of confidence in the industry’s products and stakeholders.

As an organisation, Eurovent has not participated in the development of the ISO 16890 series of standards from 2016 “Air filters for general ventilation”, but Eurovent’s members have participated in technical committees.

Summary

Camfil has been working with standards development for a long time to give it the opportunity to use standards in order to fulfil an appropriately high level of product quality. The filter industry uses accredited laboratories to test product performance. Swedac considers that the industry uses accredited laboratories in a relevant way, but that the industry has not gone the whole way using accredited certification bodies.

### 5.1.5 NCC

NCC[[71]](#footnote-71) is a one of the leading construction and property development companies in northern Europe with 17 000 employees. NCC is active throughout the value chain when it comes to creating environments for work, living and communication. NCC develops and builds housing, commercial property, industrial premises and public buildings, roads and installations, as well as other infrastructure. NCC also offers inputs for construction, such as crushed rock and asphalt, and is also responsible for the paving, operation and maintenance of roads. NCC’s main activities are conducted in the Nordic region.

NCC is involved in standards development for two main reasons:

1. Influence future standards.
2. Attend technology discussions on future requirements.

Participating in standards development is primarily important for the entities in the group that work with product development. On the service provider side, standards are a natural part of customer requirements.

Knowledge of future standards and ongoing standards development is an important aspect of being competitive and being prepared for the future.

There is a wide range of legal requirements within the construction sector. They are prerequisites for the effective operation of the international construction market and a means for achieving successful construction work. Since 1 July 2013, construction products covered by a harmonised standard, and where any transition period has expired, must have a declaration of performance and a CE marking to allow their sale within the EU, in accordance with the EU’s Construction Product Regulation. For example, for building framework materials, the European standards for dimensioning load-bearing supporting systems - Eurocodes - coordinate the calculation rules and requirement levels of the countries.

For products with key importance to safety, a further EU notified body must be involved in the work in order to verify the properties. In addition, there are a number of sector-specific codes (semi-authorisations, often not transparent) e.g. industry requirements for wet rooms. These requirements are considered as de facto requirements from the client’s side.

Various schemes are emerging within the environmental and sustainability fields. There are schemes that certify a building’s environmental and energy consumption performance. Factors such as occupant welfare are also being studied.

Once built, a building cannot be moved across the border to another country for obvious reasons, but the capital and ownership of a property can be moved. Therefore, the requirements on developers and designers of new buildings have increased. The reason for this is that future buyers and managers of a property will set requirements for environmental and energy performance.

Future requirements that will increase include the system for environmental declarations, Environmental Product Declaration (EPD), which is an information system to factually describe the environmental properties of products and services in a life-cycle perspective. Market-driven requirements within this area will probably increase, but legal requirements will always be the basis.

At international level, development is also in progress of standards and certification procedures for example, for handling cooperation in a construction project. Partnering is a structured form of cooperation in the construction industry, where the developer, consultants, contractors and other key stakeholders jointly complete a construction assignment.

Summary

NCC is involved in standards development as the intention is to influence future standards as well as attend technology discussions on future requirements. Swedac’s assessment is that the company has had good grounds for meeting the EU’s product legislation and that the EU’s legislative framework (NLF) facilitates product development with clear requirements for notified bodies and CE marking.

### 5.1.6 Scania

Scania[[72]](#footnote-72) is a world leader in the transport sector. Scania has approximately 46 000 employees in more or less 100 countries and is part of Volkswagen Truck & Bus.

Scania works with both national and international standards. Normally, an appointed Scania expert participates in each technical committee. This also creates opportunities for their experts to create networks. To actively participate in standards development also results in benefits for product development by creating “shorter time to market”. However, it is important that standards are always technologically neutral and not obstructive to technological developments.

Scania has a wide range of Scania specifications (approx. 900) that are usually based on global standards but which have been supplemented by special requirements from Scania. Scania’s specifications can consist of product specifications or requirements for a specific process. Specifications can also consist of Scania’s specific interpretations of a global standard e.g. “ISO 26262 Road vehicles - functional safety for electrical and electronic (E/E) systems”.

Scania considers that there is a lack of standards in certain areas, for example:

* Connectivity functions
* Secure program codes
* Confirmation that the vehicle is not “hacked”

Scania has ambitious objectives in the area of sustainable transport. In this regard there is a lack of standards in:

* Sustainable fuel
* Charging systems for electrical operation.

Naturally, there are always legal minimum requirements when it comes to requirements for a vehicle.

For example, Scania uses either the Dutch authority for testing vehicles, RDW[[73]](#footnote-73), or the Spanish body, IDIADA[[74]](#footnote-74). Scania has to use entities outside Sweden since whole vehicle type approval cannot be performed in Sweden. Some component testing is performed in Sweden by an approved technical service.

Scania also conducts its own tests under the supervision of an authority, e.g. RDW or the Swedish Transport Agency.

Legal requirements differ between different regions/countries, and there is a tendency for these differences to increase. The development is advancing rapidly, and setting requirements in each area must therefore keep pace. Some of the countries with rapid development, such as China, are also faster at increasing their legislative requirements. For a long time now, Scania has been working with its module system for building vehicles. In order to adapt to requirements in certain regions, certain modules are therefore not sold in these regions.

When it comes to the procurement of buses, for example, every city often sets its own requirements and levels, which creates sub-optimisation.

Scania considers that requirements for regular independent testing should be addressed. European classification of vehicles with regard to pollutant emissions has existed for some time. Some cities already set high classification requirements for allowing a vehicle to drive in certain areas. It is anticipated that more cities/countries will follow suit.

Monitoring of suppliers and their products takes place through the Production Part Approval Process (PPAP), and quality assurance is handled by the Automotive Industry Action Group (AIAG) (previously also requirements in ISO/TS 16949). Scania considers that this closed system makes access more difficult for suppliers.

Summary

Scania works with standards development on both a national and international basis. Scania often uses foreign testing institutions since whole vehicle type approval is not performed in Sweden. Some component testing is performed in Sweden by an approved technical service. Scania also conducts its own approval tests under the supervision of an authority, e.g. RDW or the Swedish Transport Agency.

### 5.1.7 Epiroc (Atlas Copco)

Atlas Copco[[75]](#footnote-75) was established in 1878 and currently has customers in more than one hundred and eighty countries. The group of companies has a total of 45 000 employees. The separation of the company into two divisions was initiated during 2017. Atlas Copco will continue to focus on industrial customers while Epiroc will focus on the mining, installations and raw materials sectors. The decision on separation was due at the annual general meeting in spring 2018. Epiroc would then consist of approximately 12 500 employees. More than 95 per cent of the output from Epiroc and its Swedish manufacturing is exported.

Epiroc is positive about the use of standards. Epiroc is active in standards development, both within the EU and globally. There is also a sector-specific standards programme within the industry, the Earth Moving Equipment Safety Round Table (EMESRT), which also includes criteria and requirements for procurement. However, Epiroc is calling for forums in which competence at a global level can handle future requirements and challenges in the field, which currently takes place more at a regional level.

Within the EU, harmonised standards are used to meet, for example, the machinery directive (2006/42/EC) in order to ensure the correct CE marking of products. Notified bodies perform the tasks prescribed by each directive and harmonised standard.

Legally, there is a difference between regions and countries. However, it can be noted that if a product meets European requirements then, as a rule, the requirements of other countries/regions are met.

An example of specific requirements is in Australia, where a system of inspectors is used who assess whether the country’s requirements have been met, which results in a certain degree of uncertainty for a supplier. Another example is China, which issues specific state requirements. This means that Epiroc must provide more technical documentation and reports with each delivery, although there are no requirements for an independent third party to be involved.

Looking ahead, an emerging trend can be seen of general growth in the area of safety, which is beneficial for Swedish companies as it has long been an area of strong focus in Sweden.

Epiroc has currently organised its research and development so that it includes the entire chain from design/development via prototyping and testing to final verification. This is in order to ensure that customer requirements and legal requirements are met.

Throughout the years, Atlas Copco and Epiroc have recognised the importance of testing. They perform a large proportion of product and component testing themselves. Only a small amount is performed by external parties, e.g. Research Institutes of Sweden (RISE), whose laboratories are accredited for many different activities. The Epiroc group also has its own central function with a focus on metrology. Accredited third-party bodies in Denmark or Sweden are used when it comes to specific testing of cabins in order to meet the applicable requirements.

Requirements are set for purchasing components, such as for CE-marked pressure vessels (where notified bodies have been involved). In addition, the company has its own process for approving suppliers and components. There are rarely any explicit requirements for independent testing but there is always value in a new supplier being able to provide independent reports.

Summary

Epiroc is active in standards development, both within the EU and globally. The use of notified bodies for CE marking takes place centrally. Epiroc performs a substantial amount of tests itself but in some cases it uses accredited laboratories for special tasks. Swedac is able to establish that requirements met in Europe are also viable in other parts of the world.

### 5.1.8 Sandvik

Sandvik[[76]](#footnote-76) is a global industrial group with around 43 000 employees. It works in the following main areas:

* Tools and tooling systems for metal processing
* Machines, tools, service and technical solutions for the mining and process industry
* Advanced stainless steel and specialist alloys, as well as products for industrial heating.

Sandvik carries out its activities within three business areas:

* Sandvik Machining Solutions
* Sandvik Mining and Rock Technology
* Sandvik Materials Technology.

Sandvik gives high priority to issues relating to environment, health and safety as well as sustainability. The group has an internal requirement that its units with more than 25 employees must be certified by accredited certification bodies to ISO 14001 Environmental management system, and OHSAS 18001 Occupational health and safety management system (will become ISO 45001 when it is introduced). Sandvik has an internal recommendation for certification to the ISO 9001 quality management system standard which has resulted in approximately 80 per cent of the units being certified to ISO 9001. Certifications are handled at national level and, in some cases, as group-wide certificates.

Sandvik also works with 24 internal standards which describe how the organisation should handle, for example, incident reporting and leadership development.

The Sandvik Supplier code of conduct applies to procurement and requirements for suppliers. There are also basic requirements such as compliance with ISO 9001, ISO 14001 and OHSAS 18001.

Sustainability issues have been more in focus at Sandvik in recent years. Each business area is currently working with a sustainability strategy. Work is in progress in the Crushing & Screening product area to support customers in order for them to also work with sustainability. A strategic focus has been created since there are no standards in the area.

Sandvik is focused on selling the “environment, health and safety” concept to its customers so that they get more out of their products. There are also efforts to sell complete services to the customer, where the requirements include a certain delivery of crushed quantity per unit of time, which then also includes service.

One area where Sandvik highlights a lack of accepted methods is EPD (electrophoretic deposition). International marking systems could also make it easier for customers to order products with a certain performance rating.

*Summary*

When it comes to the certification of management systems, Sandvik gives high priority to issues relating to environment, health and safety as well as sustainability. The group has an internal requirement that its units with more than 25 employees must be certified by accredited certification bodies to ISO 14001 Environmental management system, and to OHSAS 18001 Occupational health and safety management system. Swedac notes that working in a structured way with its management systems creates added value for the organisation.

### 5.1.9 Datacenter

Teknik i Media Datacenter Stockholm AB[[77]](#footnote-77) was established in 1997 and is now a turnkey supplier of IT services to companies and organisations with high requirements for security and accessibility. The company has 37 employees.

Datacenter is certified by an accredited certification body to ISO 27001, ISO 9001 and ISO 14001. The company believes it has gained new customers with international connections through these certificates.

The company recognises two benefits in particular from information security management systems.

Customer requirements for information security often correspond with the requirements in ISO 27001 and ISO 27002. When Datacenter can demonstrate that a certificate is issued by an accredited certification body, a new customer does not need to carry out any type of audit itself on-site. It is also difficult for a customer to identify from its own audit that its requirements have been met. Before Datacenter was certified and could show a certificate, customers often wanted to make their own assessment of the company. This involved very time-consuming task for Datacenter.

The company also recognises the internal benefits of meeting the requirements of the standard. Datacenter considered that it already had a high level of security before work on introducing ISO 27001 was started. After GAP analyses and risk assessments, there was a recognition that several measures needed to be taken before the certification audit could be started. ISO 27002 also provides good practical guidance. Actively working with these standards has also raised the company’s own security awareness.

The certification audit report from the accredited certification body is produced for customers on request. This procedure has allowed Datacenter to have a transparent dialogue with its customers.

A certificate can be used as a strong marketing ­argument in contacts with prospective new customers. The certificate demonstrates that the appropriate level of security is achieved and that the accredited certification body performs follow-up audits on a regular basis (at least once per year) in order to confirm continued compliance with the requirements.

An ISO 27001 certificate is also a big help to the client who can set requirements in a straightforward and relevant way, since many clients have a lack of knowledge in the area. The company points out that there are others in the industry saying they work according to ISO 27001, but their own experience shows that a great deal of security measures needs to be introduced before the requirements are met and certification can be granted.

The company also emphasises the benefits of the standard: “ISO 27002 Information technology - Security techniques - Code of practice for information security controls”. It provides a lot of good information on how to achieve “best practice”.

Now that the EU’s new data protection regulation - Regulation (EU) 2016/679 General Data Protection Regulation (GDPR) - is in force, it is desirable for the standardisation bodies to initiate an update so that standards are in line with the new regulation.

Summary

Datacenter is certified by an accredited certification body to ISO 27001, ISO 9001 and ISO 14001. The company believes it has gained new customers through these certificates. Actively working with these standards has also raised the company’s own security awareness. Here too, Swedac notes that working in a structured way with its management systems creates added value for the organisation.

## 5.2 Other applications of accreditation and standardisation

There are examples of areas where the system does not function as intended and where schemes emerge that are not in line with the global systems for mutual acceptance of testing, inspection and certification, and which contain undesirable additional requirements in relation to Regulation (EC) No. 765/2008. These schemes with additional requirements involve unnecessary administrative burdens and increased costs for companies, authorities and consumers.

### 5.2.1 Example of additional requirements in a regulatory framework from the United States Environmental Protection Agency

The United States Environmental Protection Agency (EPA) and the California Air Resources Board (CARB) have drawn up the “Formaldehyde Emission Standards for Composite Wood Products Regulation”, a regulatory framework for product certification and testing of formaldehyde in composite wood.

The regulatory framework is designated “EPA Toxic Substances Control Act (TSCA) Title VI Third-Party Certification Programme”, 40 CFR Section 770 (Code of Federal Regulations)[[78]](#footnote-78).

The regulatory framework contains limit values for formaldehyde in composite wood (plywood and MDF, etc.) which is often used in e.g. furniture, kitchen cabinets, floors, picture frames and wooden toys for children. Products that comply with the requirements must be marked as specified in the regulatory framework.

Furthermore, there are rules on how to prove that the products comply with the set requirements, in 40 CFR Section 770, through a third-party assessment. The products must be certified by an accredited certification body and the laboratories that perform testing must be accredited.

So far the regulatory framework is in line with the global systems for mutual acceptance of testing, inspection and certification. Requirements that certification should be performed by accredited certification bodies and that testing should be performed by accredited laboratories create confidence and facilitate acceptance of the results, thereby promoting the free circulation of the goods and services involved.

However, the EPA’s regulatory framework contains provisions that set further requirements for the different participants in the chain. These provisions require that the EPA examines applications from and performs surveillance of both accreditation bodies (e.g. Swedac) and the accredited conformity assessment bodies (for example certification bodies). The global systems for mutual acceptance of testing, inspection and certification and the reliable scheme applied in Europe through Regulation (EC) No. 765/2008 are therefore overridden by these additional requirements. Through its system of testing and surveillance, the EPA ultimately determines which accreditation bodies and which accredited conformity assessment bodies may operate on the market and which may not.

The regulatory framework from the EPA involves a doubling of the requirements for both approval and surveillance and it operates on two levels since both the accreditation bodies and the parties accredited by the accreditation bodies must also be approved directly by the EPA and concede to ongoing surveillance by the EPA.

Requirements set by the EPA for accreditation bodies and accredited certification bodies:*[[79]](#footnote-79)*

* Accreditation bodies must be approved by the EA in accordance with Regulation (EC) No. 765/2008 (or equivalent outside the EU), and must be signatories to the IAF MLA (product certification) and the ILAC MRA (testing).
* Accreditation bodies and accredited certification bodies must have a local agent in the USA, an entity on American territory that can receive legal documents on behalf of the accreditation­ body or the certification body. The EPA considers this necessary for legal reasons and that there are solutions available at a relatively low cost.
* Accreditation bodies must apply for approval directly from the EPA. Following approval by the EPA, accreditation bodies must enter into a “recognition agreement” with the EPA that is valid for three years. This can be renewed following application and evaluation every three years.
* Accredited certification bodies must apply for approval directly from the EPA. An approval from the EPA is valid for two years and can be renewed following application and evaluation every two years.
* Accreditation bodies must perform surveillance of the accredited certification bodies and laboratories in the manner specified by the EPA and at least every two years. Among other things, accredited bodies must draw up and use a checklist for each assessment of certification bodies that covers the requirements in the EPA’s regulatory framework and the essential elements of ISO/IEC 17065.
* Accreditation bodies and accredited certification bodies must report certain items of information to the EPA, in some cases within 72 hours.
* Accreditation bodies and accredited certification bodies must submit annual reports to the EPA.
* Accredited bodies must have meetings with the EPA, at least every two years.
* Accreditation bodies and accredited certification bodies must allow the EPA to make site visits, inspect premises, etc.
* The EPA can revoke or amend the approval of accreditation bodies and accredited certification bodies.
* The EPA has specified a fine of up to 37 500 USD per infringement and day that may be applicable to a party breaching the regulatory framework. In terms of damages, Section 770.5 Prohibited Acts prescribes that sanctions in accordance with both civil law and criminal law may be applicable to a party breaching the regulatory framework.

Summary

The scheme that emerges from the EPA’s requirements contains several extra stages in the chain before testing and certification can take place. These extra stages could have been avoided if the EPA had instead made use of the existing systems, according to which, laboratories and certification bodies would be accepted if they were accredited for the task according to the EPA’s regulatory framework by accreditation bodies that are approved by the EA in accordance with Regulation (EC) No. 765/2008 (or equivalent outside the EU), as well as signatories of the IAF MLA and the ILAC MRA.

The surveillance that the EPA aspires to perform in accordance with the regulatory framework, leads to questions on whether authorities in Sweden or Europe, for example, can concede to the jurisdiction of foreign authorities. Questions also arise about damages and penalties in accordance with American law due to the requirement that accreditation bodies and certification bodies must have a local agent in the USA for legal reasons. This must be taken into account by the accreditation bodies and certification bodies that intend to offer their services in the area and may prevent manufacturers, importers and dealers from putting their products on the market.

### 5.2.2 Example of additional requirements in a regulatory framework from the United States Federal Communications Commission - requirements for the USA market when it comes to the testing and certification of radio and telecommunications equipment.

With respect to electromagnetic compatibility (EMC) and the requirements set for radio and telecommunications equipment, there are major differences and special national requirements in specific countries and parts of the world. Even if differences can be justified to a certain extent in terms of technical requirements, there should be opportunities to simplify processes for companies through increased usage of the global systems for conformity assessment. The current agreement on mutual recognition between the EU and the USA covering telecommunications equipment, among other things, includes specifications on which procedures for conformity assessment should be applied.[[80]](#footnote-80)

The United States Federal Communications Commission (FCC) has drawn up a regulatory framework for the testing and certification of radio and telecommunications equipment, the Electronic Code of Federal Regulations, Title 47 Telecommunication.[[81]](#footnote-81)Products covered by FCC’s regulatory framework are, for example, mobile phones, computers, microwave ovens, radio receivers and wireless transmitters.

According to the FCC’s regulatory framework, the requirement for placing electrical products on the USA market is either verification, or self-declaration by the manufacturer that the requirements have been met on the basis of a test report (Supplier Declaration of Conformity), or certification through a Telecommunication Certification Body (TCB). Certification is required for most types of radio transmitter and self-declaration may be appropriate only for electrical equipment that does not contain a radio transmitter. All test reports must be issued by an FCC recognised laboratory that is accredited in accordance with the ISO/IEC 17025 standard.[[82]](#footnote-82)

Accreditation bodies must be approved by the Commission’s Office of Engineering and Technology (OET) in order to be able to accredit testing laboratories in accordance with the FCC’s regulatory framework. Accreditation bodies must apply for approval at OET which evaluates whether the requirements have been met and conducts ongoing assessments to ensure that the accreditation bodies continue to meet the FCC’s requirements. Accredited testing laboratories in a country with MRA agreements with the USA must be approved by an “FCC recognised designating authority” in the country, see e.g. EU MRA[[83]](#footnote-83) and APEC TEL MRA[[84]](#footnote-84). Information on “FCC recognised designating authorities” and approved accreditation bodies is published on OET’s website.

In Sweden, Swedac has been appointed as both Test Firm Accrediting Body and TCB Designating Authority.[[85]](#footnote-85)

The certification bodies (TCB) must be accredited product certification bodies in accordance with ISO/IEC 17065 and accredited laboratories in accordance with ISO/IEC 17025 with a scope of accreditation that includes the FCC’s regulatory framework. Approved TCBs are listed on the FCC’s website.[[86]](#footnote-86)

In addition to the requirements of the FCC, companies intending to place electrical products on the USA market must also comply with the requirements for electrical safety that are set by, among others, the Occupational Safety and Health Administration (OSHA). For some equipment, certification by an OSHA-recognised body is required.[[87]](#footnote-87)

### 5.2.3 ENERGY STAR – an example of a regulatory framework from the US EPA that is implemented in the EU

ENERGY STAR is an American service mark programme for energy efficiency that is run by the EPA and the US Department of Energy (DoE). It is a voluntary labelling programme that has been developed to reduce the costs of energy consumption and to reduce the climate impact by using energy efficient electrical appliances. For electrical appliances to qualify for the service mark, ENERGY STAR in USA, they must be tested and certified by a third-party body in accordance with the EPA’s regulatory framework.[[88]](#footnote-88)

A cooperation between the EU and the USA on a joint programme to promote energy efficient office equipment based on the American ENERGY STAR energy labelling system was initiated in 2001, and agreements have been entered into between the government of the USA and the EU on the coordination of programmes for energy efficiency labelling of office equipment.[[89]](#footnote-89) Participants in the programme in the EU (manufacturers, importers, dealers, etc.) have to register with the EU Commission.

The provisions of the agreement are implemented in the EU through Regulation (EC) No. 106/2008 of the European Parliament and of the Council of 15 January 2008 on a Community energy-efficiency labelling programme for office equipment.[[90]](#footnote-90) According to Article 6, for the procurement of office­ equipment, central governmental authorities must set energy efficiency requirements of at least ENERGY STAR level.

Product groups included in the EU and USA cooperation programme for ENERGY STAR are, among others: computers, monitors, printers, photocopiers and scanners. There is no limitation to these product groups in the USA.

The laboratories which test the appliances for ENERGY STAR in accordance with EPA’s requirements must be accredited. Swedac is one of the accreditation bodies approved by the EPA and can also accredit certification bodies according to the regulatory framework. Information on approved certification bodies and laboratories can be found on the ENERGY STAR website.[[91]](#footnote-91)

Despite the cooperation agreement between the EU and the USA on ENERGY STAR, there are differences over what is required for labelling in the EU and in the USA and how the logotype may be used. The EU does not require a third-party assessment in order to consider that the requirements have been met, while a so-called “Self-certification” is permitted. However, the EPA does set the requirement for third-party assessment and that testing and certification in the USA must have been performed by laboratories and certification bodies that have been approved by the EPA. If a product is labelled in accordance with the EPA’s requirements for ENERGY STAR in USA, the logotype may be used globally as well as in the EU. However, if a product is labelled and meets the requirements for ENERGY STAR in the EU, the logotype must only be used within the EU and is not accepted on the global market. The implementation of the regulatory framework in the EU can be questioned since it risks leading to misunderstanding over the meaning and value of the European logotype in the light of the fact that the participants on the market must still apply for approval from the EPA.

## 5.3 Certifications and labelling

Currently we do not see any signs that the system of certification under accreditation is generally being abused or used incorrectly. However, there is a large array of certifications and labelling schemes not linked to official standards or accreditation in accordance with Regulation (EC) No. 765/2008. This often creates confusion among entrepreneurs and consumers. The main difference between the systems is that accreditation based on official standardisation builds upon transparency, consensus and is a fully open system, which is not the case for the private labelling and/or certifications. SIS works actively to promote certification and accreditation by developing certification schemes together with the committees that draw up requirements standards.

Unfortunately, there are examples where both authorities and companies realise at a late stage that they should have participated and influenced the content of the standards that affect them. An example of this concerns the Swedish Transport Administration that is briefly described below. The example is taken from SOU (2017:106) New Start for Construction Standardisation through Strong Cooperation, interim report by the Committee for more modern building rules.

The Swedish Transport Administration did not actively participate in the drafting of the harmonised standard on geotextiles. This means that an important characteristic required for Nordic conditions, referred to as stretching, was not included. The consequence was that the amount of geotextiles available on the market with the stretching characteristics essential for Swedish conditions was considerably limited, resulting in increased costs. A conservative assessment made by the Swedish Transport Administration was that the price of geotextiles increased by ten per cent. With a turnover of approximately SEK 100 million, this means a cost increase to the Swedish Transport Administration’s activities of SEK 10 million per year.

The Swedish Transport Administration did not actively participate in the drafting of the bitumen standard either. This meant that the important characteristics of breakpoint and viscosity required for Nordic climate conditions were not included in the standard. The consequence of not being able to specify these required characteristics in Sweden was a shortened service life of road surfaces in the Northern part of the country. A conservative assessment by the Swedish Transport Administration was that the service life of paved roads would be shortened by one year. With an annual paving volume of SEK 500 million, this would involve an annual economic loss of SEK 25 million. In both these cases, the Swedish Transport Administration worked retrospectively for three to five years in order to have the characteristics required included in the standards.

## 5.4 Free trade agreements

This section will give a short description of three of the free trade agreements entered into by the EU: the trade agreement with Canada, the partnership agreement with Japan and the free trade agreement with South Korea. These are interesting from an export perspective in terms of the chapters in the agreements on technical barriers to trade. The distinction of these three trade agreements is due to the fact that these agreements have been assessed as interesting by various stakeholders within the framework of the work in this assignment with regard to accreditation, standardisation and conformity assessment.

It can also be mentioned in this context that South Korea and Japan are included in the government’s list of priority markets within the framework for the export strategy[[92]](#footnote-92). According to Swedac’s findings, these are examples of free trade agreements that promote the international quality infrastructure in order to increase trade between trade partners of the agreement. A report from January 2018 by the National Board of Trade and UNCTAD[[93]](#footnote-93): *The Use of the EU’s Free Trade Agreements, Exporter and Importer Utilisation of Preferential Tariffs* studied the extent to which the EU’s free trade agreements are used by both the EU’s exporters and exporters in the partner country. The relationship between exports and imports is also studied, but is not mentioned here. The conclusions include findings that two-thirds of the EU’s exports to partner countries use the free trade agreements while the corresponding figure amounts to 90% of the partner country’s exports. The figures are based on the value of the exports in the form of reduced customs duties and, according to the report, there can still be a number of small companies that do not fully utilise the benefits of the free trade agreements. Furthermore, it is considered that the value of the exports using the free trade agreements is greater for the EU exporters than for the exporters in the partner country. The difference amounts to 33 billion euros. At the same time, the value of the exports where free trade agreements are not used is higher for the EU than for the partner countries with a difference of 60 billion euros. According to the report, this represents lost opportunities or future potential for EU exporters. At the same time, according to the Board of Trade, it does not need to be a problem that partner countries utilise the agreements to a greater extent than the EU as is sometimes described. Examples of countries where the EU has entered into free trade agreements but which are not used to a great extent among EU exporters are Tunisia, Morocco, Egypt, Lebanon and Mexico. However, the EU’s free trade agreement with South Korea is used extensively.[[94]](#footnote-94)

Egypt, Morocco and Tunisia are particularly interesting within the framework for this assignment in the light of Swedac’s ongoing development work in the region to promote trade by building up a well-functioning quality infrastructure (see Section 4.3). This work is also of benefit in the long term for Swedish and European export, hopefully contributing to more utilisation of the export potential with these countries based on the conclusions in the Board of Trade’s report. What is positive, however, according to the report, is that effective use is made of the EU’s free trade agreement with South Korea, described briefly below. As mentioned above, Swedac’s starting point is that free trade agreements promote the international quality infrastructure in order to increase trade between contracting parties. It will be interesting for future reports to study whether it is immediately evident that the use of the EU’s free trade agreement with South Korea by EU exporters can be directly traced back to the joint use of international standards, technical regulations and conformity assessment procedures in a certain sector, which characterises the agreement’s chapter on technical barriers to trade.

CETA

The EU’s trade agreement with Canada, “Comprehensive Economic and Trade Agreement” (CETA), entered into force provisionally on 21 September 2017 but certain parts do not become applicable until all parliaments in the EU’s Member States have ratified the agreement. The agreement contains a chapter on technical barriers to trade which encourages cooperation regarding technical rules and standards in order to avoid unnecessary international barriers to trade.[[95]](#footnote-95) Despite reference to voluntary cooperation, in the sense that both parties retain what is known as the “right to regulate”, CETA represents a broad free trade agreement with considerable opportunities for trade. According to the Commission, the agreement offers new export opportunities for European companies regardless of size, and it is estimated that the agreement involves savings in the region of 590 million euros per year, not least through the abolition of almost all customs tariffs.[[96]](#footnote-96)

The trade agreement includes a special protocol regarding conformity assessment, “Protocol on the Mutual Acceptance of the Results of Conformity Assessment”, (CETA Protocol). The protocol is based on a mutual recognition of the accreditation bodies and conformity assessment bodies of the parties through mutual acceptance of conformity assessment results for certain products. However, the protocol does not include mutual recognition of the product rules of the parties, but some differences can be bridged by using standards even though national legislation prevails and determines the extent to which this is possible. Canada’s standardisation institute; “Standards Council of Canada” (SCC) operates in the framework for the protocol as a national accreditation body. In practical terms, the protocol allows conformity assessment bodies in the EU to test EU products for export to Canada in accordance with Canadian requirements and vice versa. From an export standpoint, this is beneficial for Swedish companies and European companies in that a product for export to Canada does not need to undergo conformity assessment again. The breadth of the product sectors covered by the protocol indicates a high export potential; electrical and electronic equipment, radio equipment, electromagnetic compatibility, toys, building products, machines, measuring instruments, hot-water boilers, products for use in explosive environments, equipment used outdoors linked with noise as well as recreational craft. The parties have also agreed on a number additional sectors that can be considered for future inclusion.[[97]](#footnote-97)

In order to create mutual confidence in the accreditation bodies and conformity assessment bodies of the parties, a bilateral cooperation agreement was signed in June 2016 between EA and the SCC. The cooperation agreement sets up conditions and procedures for cooperation. Among other things, EA and the SCC will exchange information on issues related to the protocol as well as information on criteria for the assessment and accreditation of conformity assessment bodies that apply for notification under the protocol. Within the framework for the cooperation agreement, pilot projects are also being conducted for certain products covered by the protocol with the evaluation of European and Canadian procedures for assessing conformity assessment bodies using experts from both parties.[[98]](#footnote-98) It should also be mentioned in this context that it will take time before the practical application of the provisions of the free trade agreement in the regulatory area and the international regulatory cooperation. It takes time to develop a cooperation between European and Canadian accreditation organisations, and systems other than accreditation and standardisation are required in order to create an operational organisation. These systems are often not ready and operational when the agreement is signed.

EU-Japan

The EU has entered into a partnership agreement with Japan; “EU-Japan Economic Partnership Agreement” and the negotiations were concluded in December 2017. It is hoped that the European Parliament and the parliaments in the Member States will approve the agreement so that it can enter into force during 2019.

In parallel, the EU is also negotiating with Japan on a strategic partnership.[[99]](#footnote-99) When it comes to the chapters on technical barriers to trade in the agreement, it can be mentioned that the parties undertake to ensure that technical requirements, standards, and conformity assessment procedures do not create unnecessary barriers to trade.[[100]](#footnote-100) As a highly regulated country, Japan undertakes to ensure that standards and technical requirements are based on global standards to as large an extent as possible. In the field of motor vehicles, Japan has accepted to adapt its standards to the UNECE[[101]](#footnote-101) regulatory framework. Consequently, European vehicles will be subject to the same requirements in both Japan and the EU and do not need to be tested or certified again for export to Japan. The cost for certifying European medical devices exported to Japan will also be reduced in that Japan adopted the global standard for quality management systems for medical devices in 2014.[[102]](#footnote-102) When it comes to drugs, Japan has accepted reference to standards and guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).[[103]](#footnote-103)

EU-South Korea

The EU has signed a free trade agreement with South Korea, which entered into force provisionally in July 2011 and was formally ratified in December 2015. In the chapter on technical barriers to trade, the parties recognise the ­International Organisation for Standardisation (ISO), the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU) as the competent global standardisation bodies for aspects concerning electromagnetic compatibility and safety in electronics products. The agreement establishes that where there are relevant standards drawn up by ISO, IEC and ITU, the parties shall use these standards or relevant parts of them as the basis for all standards, technical regulations and conformity assessment procedures. Furthermore, the parties will ensure that their standardisation­ bodies participate in the development of global standards in ISO, IEC and ITU and undertake to hold consultations­ with a view to arrive at a common understanding. When it comes to conformity assessment, unless otherwise stated, the parties will accept products in their respective markets, and where one or more procedures are to be considered as an explicit declaration of conformity with their respective technical regulations on EMC and safety. In precise terms, this means that the EU’s rules on low-voltage equipment, electromagnetic compatibility and radio equipment in accordance with the agreement are equivalent to the South Korean rules and thus relevant products have access to the South Korean market.

In addition to electronics, the agreement also covers motor vehicles, drugs and medical devices, as well as chemicals, but there the provisions do not concern accepting each other’s products but establish certain principles on transparency and cooperation. However, as regards motor vehicles and parts, the parties will refrain from introducing new national regulations that deviate from the UNECE regulations.[[104]](#footnote-104)

## 5.5 Ongoing developments within accreditation

### 5.5.1 Test-beds

Test-beds are strategically important for promoting innovation and strengthening Swedish competitiveness. The ambition to strengthen the availability and scope of Swedish test-beds is in line with the government’s new industrialisation strategy and export strategy. In the latest research ­bill[[105]](#footnote-105), the government declares that Sweden will be a leading knowledge nation and one of the world’s foremost research and innovation countries. To make this possible, the development of testing and demonstration­ environments is judged to be a key element. Furthermore, the government previously mobilised the Test-bed Sweden initiative in order to encourage the testing of new innovations. Test-bed Sweden includes several different undertakings. The government has also allocated increased funding to Vinnova in order to develop and invest in existing environments as well as stimulate start-ups of testing and demonstration environments, both in private and public sector activities. The overall picture is that test-beds constitute a priority area from a national perspective.

There are currently great hopes and expectations for test-beds. Significant investments in the area have been made or are planned. One challenge in the context is that it can be difficult to assess how requirement profiles must or should be designed, as well as on which grounds funding decisions should be made. A further dimension is follow-up and how compliance with requirements should be monitored. Swedac’s view is that increased use of accreditation would make a positive contribution to meeting these challenges.­ Swedac shares the assessment that test-beds are important for promoting innovation and strengthening Swedish competitiveness. Out of necessity, test-beds are experimental by nature, but need to be surrounded by a system for quality assurance in order to ensure the reliability of the results and raise the general level of quality in the activity.

One option for improving quality assurance is to use accreditation to a larger extent. This does not just provide increased reliability of results but can also create added value for the parties which need to test products, services or processes. In addition to that, it can strengthen the competitiveness of test-beds by means of further improving their activities. Test-beds can be operated in different forms and have varying ownership structures. The possibility for accreditation works independently of whether the operation of and responsibility for a test-bed activity takes place in the business sector, academia, research institutes or other organisations.

At present, Swedac envisions two approaches for improved quality assurance of test-beds through accreditation:

1. That laboratories used within test-beds should be accredited.
2. That the suppliers who operate and offer services within the area of test-beds should have certified quality management systems.

Test-beds can be divided into three main categories:

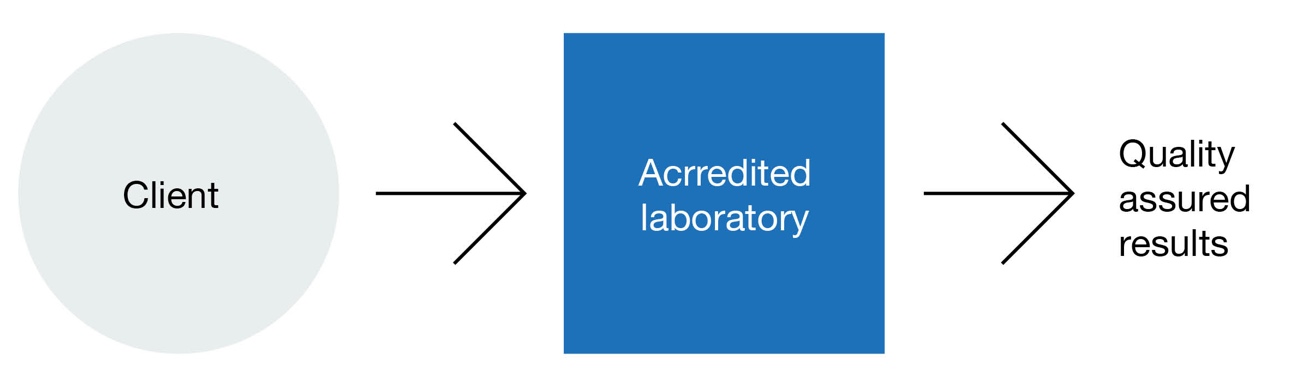
* Laboratory environment
* Isolated test environment
* Real-world environment.

The government’s assessment is that test-beds in real-world environments have the greatest development needs as well as potential where, among other things, the well-functioning public sector and many developed system­ solutions provide good conditions for creating a unique solution.[[106]](#footnote-106) A reflection from Swedac is that the development needs for quality assurance are probably greatest for test beds in a real-world environment.

Laboratory environment

For a customer choosing to use a laboratory, the reliability of the results increases if the laboratory is accredited. Among other things, accreditation means that the equipment, competence and procedures have been assessed, which guarantees quality assurance and confirms that the laboratory actually meets the set requirements and that the results are reliable.

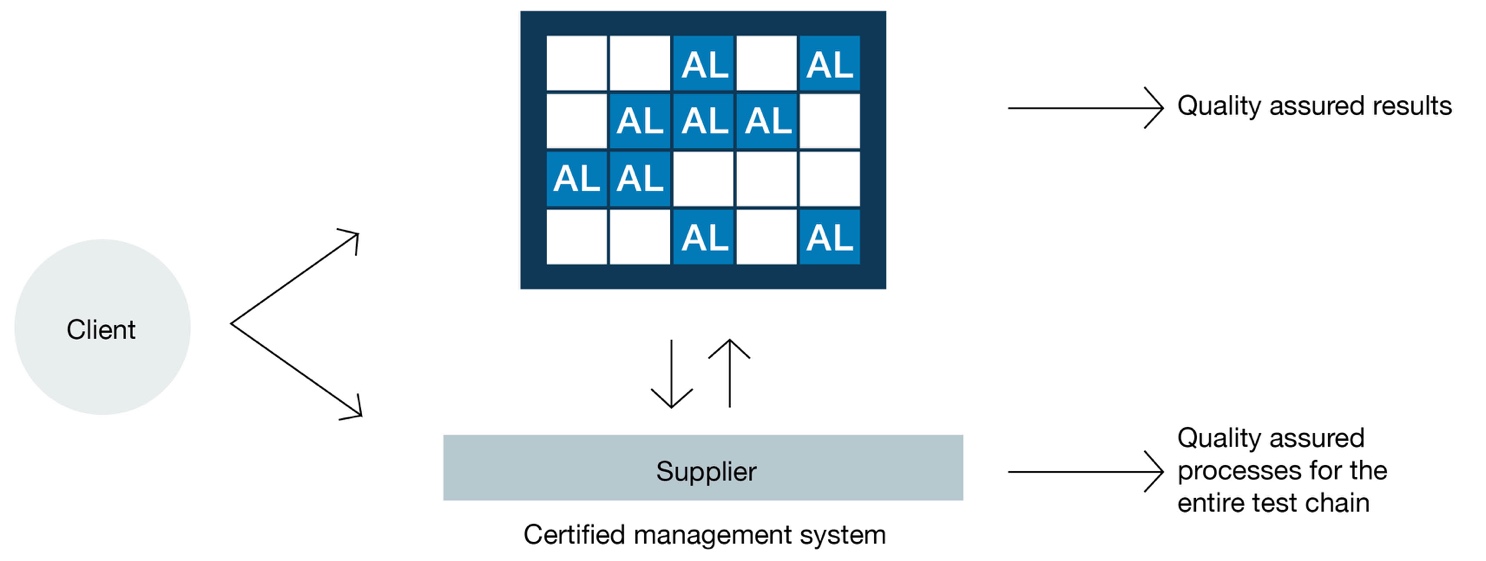
Illustration 12: Quality assurance in a laboratory environment.



Comment: AL stands for Accredited laboratory.

Isolated environment

A test-bed in an isolated environment is physically delimited and can consist of several different parts. For example, in addition to accredited laboratories, there may be laboratories and other types of activities that test characteristics and performance. In the illustration, the test-bed is represented by the dark-blue box. In this context, the quality assurance can be strengthened in two main ways. The first is that laboratories should be accredited, which strengthens the reliability of the laboratory results. The second is that the supplier with responsibility for the overall activity of the test-bed should have a management system that is certified under accreditation. The illustration shows that the customer can choose to contact the supplier or make direct contact with one part within the test-bed. The choice will probably depend on the prior knowledge and needs of the customer. A certified management system ensures that the organisation works in an appropriate way to meet the needs and problems of the customer and that the organisation will be able to propose adequate measures to resolve these. In this way, the supplier can enhance its scope of business and become greater that the sum of the parts of the activities included in the test environment that provides a range of different testing options.

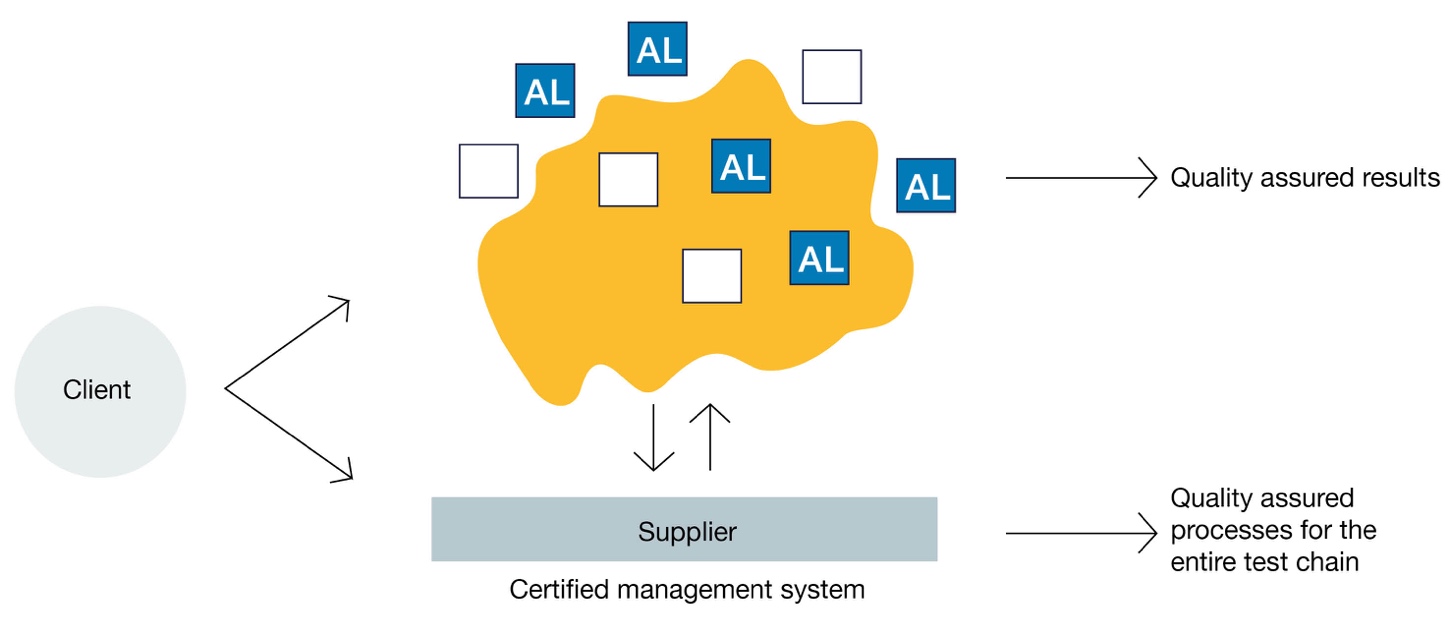
Illustration 13: Quality assurance in an isolated environment.

Comment: AL stands for Accredited laboratory.

Real-world environments

A test-bed in a real-world environment has no clear geographical delimitation and can consist of several different parts. For example, in addition to accredited laboratories, there may be laboratories and other types of activities that test characteristics and performance out in the real-world environment. As in the example of isolated environments, in this context, the quality assurance can be enhanced in two main ways. The first is that laboratories should be accredited, which strengthens the reliability of the laboratory results. The second is that the supplier with responsibility for the overall activity of the test-bed should have a management system that is certified under accreditation. The illustration shows that the customer can choose to contact the supplier or make direct contact with one part within the test-bed. The choice will probably depend on the prior knowledge of the customer. A certified management system ensures that the organisation works in an appropriate way to meet the needs and problems of the customer and that the organisation shall be able to propose adequate measures to resolve these. In this way, the supplier can enhance its scope of business and become greater than the sum of the parts of the activities included in the test environment that provides a range of different testing options. Not least in the light of the fact that it can be difficult for a customer to get an overview of and understand the available scope in a real-life test environment, it would be useful if the supplier could contribute with support and advice.

Illustration 14: Quality assurance in a real-life environment.

Comment: AL stands for Accredited laboratory.

From an export perspective, accreditation of test-beds would provide their users with a quality-assured result that is accepted by the Member States. Through accreditation, the test-beds will also be of interest to foreign customers and the opportunity to export their services will increase.

### 5.5.2 Civil drones (Unmanned aircraft)

There is a new proposal for European regulation for civil drones (unmanned aircraft) from the European Aviation Safety Agency (EASA). The new proposal for a legal act contains provisions on certification. One ambiguity in the proposal is that the provisions on certification do not refer to accreditation in accordance with Regulation (EC) No. 765/2008 for all proposed areas. Taking into account the principle of open systems for testing, inspection and certification, as well as independent, impartial and equivalent assessment within the entire EU, certification should take place by certification bodies that are accredited in accordance with Regulation (EC) No. 765/2008. The proposal includes several areas suitable for certification under accreditation:

* Certification of persons (remote pilot)
* Product certification (functional requirements of the drone)
* Certification of management systems (UAS[[107]](#footnote-107) operator certificate).

If the proposal for a new regulation develops in the direction of a system in accordance with Regulation (EC) No. 765/2008, there will be good prospects for a European market with harmonised regulations. Based on the certification schemes highlighted in accordance with the above, conditions will be created to allow for the following:

* Swedish accredited bodies can offer their services on a European market.
* Certified persons will have evidence of their competence that is accepted in the Member States.
* Drones which have been certified will be accepted by the Member States.
* Operators with a management system certification will be accepted by the Member States.

This grants access to the European market.

## 5.6 Development opportunities

As mentioned earlier, there is great potential in strengthening Swedish competitiveness and export by running and having responsibility for European and global secretariats within standardisation. Influencing the standards of the future results in favourable conditions for avoiding the need for re-adaptation of goods and services for export, since a common standard is in place and participation in the standardisation work has resulted in favourable conditions for insights into what the standard will contain at an early stage. This means not only the opportunity to strengthen Sweden’s competitiveness, but also greater opportunity to influence European and global issues in the areas where Sweden is at the forefront, e.g. within environment.

Sweden has traditionally been strong within industrial standardisation, which is an area Sweden intends to continue maintaining, although development is heading towards increased digitalisation and service standardisation - areas that cut across traditional standardisation.

### 5.6.1 Health and social care

There is strong commitment from organisations, companies, authorities and patients in health and social care since standards are a way of enhancing and developing quality in order to achieve safe and secure health and social care.

eHealth

SIS is project leader for a range of national, European and global efforts that in a variety of ways provide and have great potential to provide practical and long-term support for Vision e-Health 2025.

eHealth is a cross-cutting technology area and cuts across a range of areas, which means that standards and standardisation work need to be taken into consideration. Such dependencies and considerations are complex, difficult to develop and take time to refine and relate to. SIS has declared its intention to be an outspoken partner in the concrete progress of Vision eHealth 2025. The sooner SIS can become involved, the greater the benefit that can be derived.

There are far more areas that are affected by the development in eHealth than is evident at first sight. Some areas are self-evident, such as standards for health informatics, information­ security, medical technologies, laboratory medicine, medical imaging and management systems. Less self-evident, but equally important, are standards linked to accessibility and biomedicine. The entire hospital and ­healthcare sector, as well as health and social care, will be affected and will have great need for operational standards if Sweden is to be successful in the change and development we are currently experiencing. Examples of SIS’ priority areas:

* Offer support for Vision eHealth 2025 through traditional and long-term standardisation­ work that involves the management, development and revision of standards and technical specifications.
* Provide support through existing standards and education to the hospital and healthcare sector in order to meet regulatory requirements of GDPR[[108]](#footnote-108), MDR[[109]](#footnote-109) and IVDR[[110]](#footnote-110).
* Monitor and influence the development of standards through its experts in its international work, primarily in health informatics and medical technologies.
* Offer a good platform to Swedish experts in the work with standardisation and standards.
* Act as a hub in Sweden for standards in eHealth.
* Take responsibility for an international outlook and monitoring of the area.
* Maintain international commitment through support, and also develop this support within eHealth by holding the ISO secretariat and financing the participation of experts.

Assistive devices

The assistive devices and disability area is undergoing dramatic change. Partly as a consequence of successful international work from the Swedish side, but also as a consequence of the strong development underway in digitalisation and welfare technology. Currently the assistive devices area deals not only with physical assistive devices and products, but also with accessibility issues in a larger perspective, such as cognitive aspects.

There is a great need for continued standardisation in the area. Naturally, it is a question of continued­ work in the product area, but also in the services area and community building area. SIS has a strong ambition to maintain and strengthen the position it has built up since 1978, and SIS also leads a global (ISO) secretariat as well as a European (CEN) secretariat in the area.

Pharmacy market

The assessment is that a special quality management system for pharmacies would probably provide support in the work to embrace the development towards risk-based surveillance and make it easier for pharmacies to achieve good legislative and regulatory compliance as well as meet other sector-specific requirements as agreed. In order to increase the quality of self-care advice and more simply specify the level and standard the advice must or should have, guidelines or a services specification would be helpful.

The government inquiry into the area states that “The municipalities need guidelines on what the operational surveillance assignment for the sales of medicinal products outside of pharmacies means.” In consultation with municipalities and other stakeholders, SIS could develop proper support for the surveillance assignment. The significance of self-assessment should not be underestimated. Support, through guidelines or specifications, for self-assessment of authorised sellers of medicinal products not subject to prescription and outside of pharmacies, can contribute to increased quality of self-assessment, and thereby lead to enhanced safety and simpler surveillance.

A national service standard that describes a lowest acceptable level for the pharmaceutical service could potentially be of benefit for equivalence in the service at a national level, and also an opportunity to set the level for what the service should offer to consumers and patients.

Quality in welfare

In contrast to the Welfare inquiry, which does not make the assessment that what is done in health and social care is essential, SIS finds that what is done in health and social care can very well be essential and sometimes absolutely essential for the right quality and safety. What is done may have its basis in what should be considered necessary in order for a certain service or measure to be considered as able to lead to the right quality, and to make it possible to follow up and measure. In addition, what should be done is a component of exceptional importance for procurement, i.e. requirements on the content of a certain service and naturally for follow-up.

There is a need to look more closely at how the existing quality infrastructure in Sweden can contribute to enhanced quality development in welfare. By means of standards and possible accreditation and certification of healthcare providers and operators, the quality infrastructure should align well with the work on developed and strong quality and safety within the welfare sector. Among other things, SIS holds a European secretariat that draws up standards to ensure quality in sheltered accommodation and home care services.

### 5.6.2 Industry

There are several interesting industrial applications where Sweden is traditionally strong.

Smart industry

SIS works actively with the coordination of Swedish interests in smart industry and has created the conditions for influencing global standardisation in the area. In the years ahead, interest for smart industry and thereby the interest for standardisation in the area are expected to increase.

In relation to the global standardisation work, SIS has already ensured a strong Swedish involvement in ISO’s all-embracing Smart Manufacturing Coordinating Committee, where 4 of 21 places are currently held by Swedish representatives. Through this work, SIS can ensure that Swedish interests are taken into account. One example of this is to ensure that account is taken of the life-cycle perspective in ISO’s basic reference model for the area, something that is a cornerstone of the Swedish strong point, the circular economy.

In addition, SIS continues to be proactive in the cooperation with academia, industry and different public stakeholders in smart industry. SIS also invites persons in leading positions for consultation meetings in order to identify common interests for joining forces.

Like may others, SIS has identified a great need for coordination and standardisation in preparation of when the digital industry becomes interconnected, at which point it must be possible for individual ecosystems of products, activities and information to be included in comprehensive systems.

In order to ensure this interconnection, work is underway with open solutions within ISO, IEC and others, as well as proprietary solutions in both individual companies and different consortia.

Future of transport

Historically, the transport and vehicle sector occupies an important place and during 2017, the focus was on drawing up standards for testing methods, among other things, in active safety. At a global level, the important work within ISO/TC 22/SC 33/WG 16 Active Safety test equipment can be mentioned.

Looking ahead, there will be a need to take a systems perspective of vehicles and society and the standards that will be needed in the future. The vision for the future of the transport sector has an extreme impact on society in a positive sense.

In recent years, SIS has been involved in development at the activity level, since standards development has been close to the core activity of a specific stakeholder. SIS has also had dialogues with parties within the collaboration programmes and various innovation programmes, a collaboration that clearly shows the future need for standardisation in the area.

SIS is planning to be proactive over the next few years in collaboration with academia, industry and various public stakeholders regarding future transport solutions. SIS also invites persons in leading positions for consultation meetings in order to identify common interests for joining forces. Since much of the standardisation required for future transport is of the basic type, i.e. agreements that affect very many but in which few have enough self-interest to drive development, it must be ensured that standards are developed that support the work in this societal challenge.

The steel industry

Existing steel standardisation does not take into account the excellent stainless steel produced in, for example, Sweden. A new standard for stainless steel led by Sweden would lead to increased margins in an export ­context and is expected to also result in increased export in terms of volume. SIS is currently working on separating stainless steel from the more general steel standardisation, with the aim of being able to create new higher requirements that Swedish special steel can meet today. After the work is completed, Swedish steel will not be compared with significantly worse and unclean steel as it is today. This would increase exports, and the pricing for Swedish steel would be more favourable for the Swedish industry.

An opportunity to raise the issue once again can currently be seen within the CEN standardisation. Previously, other steel-producing countries opposed the Swedish proposal because it favours Sweden but not the majority of other countries. If Sweden can show more commitment to the issue, there is a greater opportunity to exert influence in favour of Swedish interests.

Forest industry

Products from forest raw materials have great potential for export and often compete, for example, with international plastics companies. The assessment is that standardisation can contribute to increasing the market internationally and to enabling consumers around the world to make smart choices of materials in, for example, for packaging.

### 5.6.3 Community building

The trend towards more sustainable building is continuing and growing. One area of growth is to build (high) in wood, where Sweden has a unique chance to become a world leader with our long-standing traditional­ methods in combination with domestic research. SIS focused on this issue during the spring of 2018 and gathered stakeholders in a business council to jointly identify and position Sweden internationally***.***

Eco City also continues to grow with “urban farming”, where areas such as roofs, courtyards, balconies and terraces are used for food production. “Vertical farming” is also growing, where buildings are clad with vegetation both internally and externally. A beneficial side effect is that these activities also capture some of the precipitation and therefore reduce the amount of waste water that the drainage­ system would otherwise have to deal with.

In Eurocodes, [[111]](#footnote-111)standardisation is a prerequisite for an efficient international construction market. In turn, this increases competition and increases the supply of skills and labour. In addition, a common conceptual basis at a scientifically high level facilitates the international R&D work, which is why the Eurocodes increase the competitiveness of the European construction sector. When it comes to the extensive work on the Eurocodes that will be revised by 2020, SIS is currently leading the work on wood standardisation, where the main task is to influence the development of standards within CEN.

Digitalisation

SIS took over the Geodata Secretariat (ISO/TC 211) from Norway in 2017. The BIM[[112]](#footnote-112) Alliance and the combination of geodata and SIS agreements with Lantmäteriet (Swedish mapping, cadastral and land registration authority) will be linked together more closely. Several standards in the geodata area are included in the agreement with Lantmäteriet with regard to prepaid standards. SIS is strong in geodata and wants and needs to take a more prominent position within the BIM Alliance. SIS runs an important global ISO secretariat “Construction Documentation”. However, it is difficult to find the funding in Sweden. Most parties engaged in this important issue are small consulting companies.

Traditional construction materials, such as concrete (Digitong) will also be digitised for the verification of properties in connection with delivery and self-diagnostics in finished construction.

Property management services account for approximately 90 per cent of the life cycle costs of a building and are currently an area with a low level of digitisation in which sensors and data processing will make the management more efficient and cost-effective. Standards will be needed here as there is currently a low degree of standardisation.

### 5.6.4 Consumer

CEN’s standardisation advisory function in the service sector (SAGS), in which SIS participates, delivered the results of ongoing CEN/service sector feasibility studies in 2018, identifying sectors in which service standardisation is possible. SIS is taking a leading role in segments that are relevant to the Swedish market. During 2018-2019, SIS is creating a forum for dialogue with the Swedish service sector.

Participants on the Swedish market use ISO as a tool for exporting Swedish know-how in work environment and consumer safety, with the aim of opening up markets in developing­ countries, for example, in which Swedish stakeholders have not previously had access and where legislation and regulations are not yet sufficiently developed.

Work environment

The launch in 2018 of Work Environment ISO 45001, the very first ISO standard for work environment, and legislation, will lead to a new and greater need for cross-cutting standardisation in the work environment sector.

### 5.6.5 Environment

Environment is a large and general area with many special applications.

Plastic and environmental aspects

In the plastic and environmental aspects area, SIS has started a working group with the aim of exerting influence internationally on the ISO standardisation that started in September 2017. There are a number of countries in global standardisation that participate with a large number of experts and work hard for their own agendas. Their views on problems and opportunities do not always agree with those of Swedish stakeholders. The National Committee and the working group planned to develop a couple of standards proposals in 2018 and the number of proposals will continue to increase over several years.

In principle, the development of standards concerns microplastics, biobased plastics, biodegradable plastics, recycling, carbon dioxide footprints and what to do in order to achieve a circular economy.

Packaging

In order to influence the economics of recycled materials in a positive way, the costs of recycling must be reduced and customers for recycled materials must be able to rely on a steady flow of recycled materials. To be able to digitalise and automate the sorting of waste for recycling, the inflow into sorting must be more steady and predictable.

The question is whether a jointly agreed flow process description from collection to delivery of recycled material can secure the necessary investment in new technology. Re-using and recycling packaging material is an increasingly growing focus area. The packaging industry is facing greater demands for resource optimisation and is striving to become more sustainable. The Commission’s circular economy package and the updated packaging directive will bring about changes in the industry from the expected stricter requirements for recoverability rates. Challenges for the packaging industry are mixed materials in sorting/recycling. There are also requests for clearer labelling of the properties of the materials in the packaging.

Innovation-critical rare earth metals

One area that has become increasingly relevant is the availability of special metals. Sometimes they are referred to as rare earth metals, sometimes in other terms. Another example is innovation-critical metals. What they have in common is that they are critical to certain production processes that are essential to important societal development. Renewable energy sources, communication equipment and the further development of digitalisation in general are other areas. From a Swedish perspective, this is very important because we have limited resources to mine and have to rely largely on better recovery. It is therefore also appropriate to consider the recoverability of metals.

There is a special committee within ISO that deals with these issues, ISO/TC 298 Rare earth. Sweden does not monitor the work of this committee. China holds the Secretariat. SIS wishes to create a Swedish mirror committee, and wishes also to participate with experts in the international TC 298. Stimulating innovation and a sustainable society are of great importance, and standardisation can play a crucial role in this area for the Swedish situation.

Textiles

With the automation of textile sorting in recycling processes as their objective, stakeholders will unite behind the RFID[[113]](#footnote-113) labelling of, for example, clothing in which the amount of relevant information can be more than what can be given on a label and can be automatically scanned in the sorting process. This can contribute to creating a more balanced inflow and automatic sorting at the waste stage. This can apply to textiles, plastics and other products such as electronics. A Swedish initiative can lead to the increased export of products, but also to the opportunity for recycling companies to export recycling processes and services.

Nano and graphene

There is strong growth in the global market for nano-reinforced materials including graphene. There is a lot of research in this area, while at the same time there is a delay in the regulation of security levels, and academia seems to have difficulty agreeing on which levels can be considered to be “safe”. A global initiative within ISO is now underway and is supported by major industry stakeholders on the global market. Sweden and SIS are seeking funding in order to retain a balanced voice in the debate and to influence what is considered most important from a safety and environmental point of view.

Sustainable finances

The Swedish Financial Supervisory Authority (FI) has been tasked by the government to investigate how it can meet the issues and needs that may arise in companies working to develop new, innovative financial services. Sweden has made considerable progress within Fintech and Swedish standardisation could be at the forefront when it comes to presenting new proposals for standards and actively taking secretariat responsibility.

During the UN Climate Change Conference in Paris 2015, it was decided that global warming should be limited to 1.5 degrees. In order to draw closer to achieving that target, the UN’s climate committee, the UNFCCC, wants better monitoring of the link between financial activities and climate impact. ISO has been commissioned to develop a global standard for financial operators. In Sweden, SIS is starting a working group so that Swedish stakeholders can participate in and influence the design of the standard.

On 1 December 2016, a new legal requirement for sustainability reports was introduced in Sweden for all companies. A standard in the area could further contribute in several ways. There are also opportunities to standardise overall frameworks for analysis and reporting in order to create transparency and comparability.

### 5.6.6 Further proposals/list of new areas

Listed below are areas where SIS has indications that stakeholders want to start standardisation and where there are good chances that Sweden, through Swedish stakeholders, can also take the lead at European or global level. All areas need in-depth knowledge and stakeholder consultation:

* Municipal inspections on building sites (inspection supervisors for building permits, monitoring that building work is progressing correctly can be done by accredited bodies instead, environmental surveillance)
* Restaurants (municipal surveillance on behalf of the Swedish National Food Agency)
* Eurocodes - the national annexes can become standards instead of regulations (Boverket - Swedish National Board of Housing, Building and Planning)
* Security guards (Swedish Police Authority)
* Psychiatry (National Board of Health and Welfare).
* Accommodation for asylum seekers (Swedish Migration Agency)
* Schools (Swedish Schools Inspectorate)
* Medicinal products not subject to prescription in stores (Municipal inspections on behalf of the Medical Products Agency (Läkemedelsverket)
* Translation services
* Biotechnology
* Clinical trials
* High wood houses
* Transportation of the future
* Infrastructure - standard for traffic solutions
* Self-driving vehicles
* Interfaces in public transport
* Sustainable consumption
* Artificial intelligence
* Virtual reality
* Medical robots

### 5.6.7 Electrical standardisation

Smart electricity grids

The emergence of what we call smart electricity grids requires more than a coherent landscape of standards for communication, measurement, control and automation - from data elements to system design. The obvious combination with an increased proportion of renewable electricity production in the narrower branches of the electricity grid also imposes new and changed requirements on the conventional components for the grids, such as transformers and tap changers - requirements formulated in standards, together with appropriate testing methods. Naturally, the new and future products must also be specified and tested in an agreed and useable way - for example, solar panels, energy stores, smart meters.

Interference levels, efficiency, electromagnetic fields and other special phenomena and aspects are treated as before in standards jointly developed by specialists around the world. In an ageing electricity system, the issues related to condition monitoring and maintenance planning, as well as asset management, will also become increasingly important. Here, too, network owners and entrepreneurs can benefit from each other’s knowledge, through standards and common specifications. Recognised guidelines can be used as early as in the planning stage of new plants and also in the evaluation of new plants and the monitoring of old ones. Knowledge in these areas is also assimilated in international standards.

By participating in various technical committees for Svensk Elstandard (SEK TK) and directly in working groups within IEC, Swedish specialists participate actively in various projects and system areas that are of significance to the growth of smart electricity grids.

### 5.6.8 IT standardisation

Internet of things (IoT)

The technology to enable communication between different products and systems, the Internet of Things or IoT, is evolving at a frantic pace and is in many ways dependent on the development of different types of standards. This applies to both the communication itself, where much of the work takes place in different consortia, primarily for short distance wireless communication, and within ETSI, where it is largely the new networks, called 5G and other systems, that will take wireless communication to a new level. The application of IoT, in industry, infrastructure, health care and within several other areas, also requires standards in order to ensure safety and function, both in the various devices themselves and as components of larger systems. In addition to the new IoT Committee ISO/IEC JTC 1 SC41, for which Svensk Elstandard (SEK) runs the Swedish Mirror Committee, IoT-related work is ongoing in several international technical committees, e.g. IEC TC 5, Industrial process measurement, control and automation, IEC TC 119, Printed electronics, and IEC TC 124, Wearables.

# 6 Analysis and conclusions

Application of the European and international system for conformity assessment

Based on the examples examined, Swedac’s assessment is that the most important parameter for Swedish companies to be successful in their export activities is for them to have products and services that are in demand and can compete with other suppliers. What is clear when we look at the examples we have highlighted in the report is that there are different ways to use the international system for conformity assessment. It is also clear that in certain areas, the application is more in line with how it is intended to work, and in certain areas there is more to be desired. The examples show that in most cases, the EU’s New Legislative Framework (NLF) has been successful­ for Swedish industry, with clear requirements for notified bodies and CE marking. Product legislation that follows NLF has clear rules for the interested parties, there is an accepted and established system, and the products are granted access to the EU’s internal market. One bonus in this context is that products that meet the European requirements often have an advantage when it comes to acceptance on the international market. When they work as intended, accreditation and conformity assessment based on standards are good methods and tools for introducing products and services into other markets.

However, we note that there are also situations where the international system of conformity assessment does not work as intended.[[114]](#footnote-114) It is often the case that one party sets new requirements over and above the accepted standards. It may be a question of requirements on a product or service, or on the conformity assessment procedure itself. One example is the additional Australian requirements for life jackets as reported in Section 5.1.3. This usually leads to increased costs at all stages. Functioning conformity assessment, where reports and certificates are mutually recognised, reduces the costs of testing and certification. In a functioning market, conformity assessment bodies are also exposed to competition, and pricing is driven by market­ forces. Our study shows that larger and well-established companies, for the most part, accept a different procedure. They quite simply conduct the testing and certification required for access to a market. For smaller companies, it may be more difficult to handle and, in the long run, reduces their export opportunities.

From looking specifically at the US regulatory framework mentioned in the report, and attempting to understand why the regulatory framework of the EPA and FCC and applicable MRAs in the area are designed as they are, the following observations can be made. Firstly, it can be noted that the testing performed prior to certification in accordance with the EPA’s regulatory framework for formaldehyde in composite wood or ENERGY STAR, is no more technically complicated than can be performed at a normal testing laboratory. Technical weaknesses should therefore not be the explanation for the appearance of additional requirements in the EPA’s regulatory framework. Nor can the design of the FCC’s regulatory framework be explained by technical difficulties. Secondly, what is mentioned in the FCC’s area can be justified by certain differences in terms of technical requirements, but the current system for global conformity assessment could still be applied and make things simpler for all stakeholders at all stages. Instead, a likely explanation for the specific requirements contained in the regulatory framework of the authorities is that there is no fundamental confidence in the global system for conformity assessment. Thirdly, in most cases, states rely on other states but not always directly on IAF and ILAC. The clarity in the MRAs between states makes them relatively easy to compare, while there may be a problem in that there is no standardised way of specifying the scope of accreditations, and they can then be difficult to compare. MRAs between states also have functions to stop recognising testing, etc. over which the states have control. Fourthly, global acceptance of results from testing, inspection and certification is based on there being confidence in the results. This confidence is created by means of third-party auditing of the parties that carry out the testing, inspection and certification in terms of their competence by a globally recognised accreditation body, and by means of the use of European or globally harmonised standards in all parts of the accreditation work, which is thereby based on the same requirements in all countries. Knowledge of how this works needs to be disseminated. Hopefully, increased knowledge dissemination can lead to the scope of the specific national requirements being reduced. Effective market surveillance is prioritised in particular instead of specific requirements, and is then a good tool for monitoring and ensuring that the system is working (see Section 2.7).

The examples studied also illustrate great opportunities for improvement in current applications. Partly through a more consistent and exclusive way of using the tools, and partly in new areas and applications. In order to achieve a more consistent application of the international conformity assessment system, it is important that specifiers focus on the requirements for the product/service and which requirements should be assessed and certified by conformity assessment bodies. With these two input values specified, it becomes clear as to which procedure is most appropriate: testing, inspection or certification. To be able to reach this level, more knowledge on conformity assessment is needed among specifiers. A suitable route to achieve this is the further dissemination of knowledge and information on conformity assessment and a wider spread of experience from practical applications. Two examples of sources for the practical applications of conformity assessment are the two websites “public sector assurance”[[115]](#footnote-115) and “business benefits”[[116]](#footnote-116) which present examples of how legislators use the system for conformity assessment in their applications and how businesses can benefit from using standards and conformity assessment.

Accreditation and standardisation are important to Swedish companies

Accreditation is important. When the international systems for accreditation, conformity assessment­ and the mutual recognition of reports and certificates are applied correctly, it is possible to achieve the “one stop shopping” principle, i.e. if products and services are approved in accordance with applicable rules and procedures, new approvals are not needed. This reduces the costs for the companies as they do not have to undergo new testing, inspection and certification in order to gain access to other markets. This benefits all stakeholders in the chain.

The examples also show that the companies that have engaged in standardisation see major advantages to it. This gives a unique opportunity to influence the development in the field. In several cases, the experience of the companies will become a direct input into the standardisation work. Other benefits that become evident include the perception of an advantage in having early knowledge and information about the content of new standards. In addition, several companies point out that standards are “best practice” and by using standards in their product development they have a certainty of meeting the relevant requirements for the product. This also applies where standards do not exist but the requirements are expressed in for example, private, sector specific requirements.

Requests for a system of product marking or product classification

Requests from various stakeholders have emerged from the case studies, or the examples examined, for a system of product marking or product classification from an environmental sustainability perspective. What is highlighted as a good example of this, and something that can serve as a model for new systems, is the EU’s labelling of white goods that has been a driver of the development of energy-efficient products. There are other similar systems in which Swedac, among others, grants accreditation. The system is called Environmental Product Declaration (EPD) and deals with a declaration of a product’s environmental impact during its entire life cycle. More organisations, both specifiers and producers, need to raise their awareness of the EPD system. This presents a good opportunity for Swedish companies to take an overall responsibility.

Use of management systems

Swedac considers that a certified management system is beneficial to exporting and in “business to business” relationships, as well as access to new markets. Certification of management systems against global standards gives confidence that processes are in place for product or service realisation, confidence that these processes are carried out systematically and meet applicable requirements, and confidence that processes for continuous improvement are in place.

Need for collaboration between different stakeholders for knowledge, resources and innovation in the area

The government’s export strategy has involved much-needed financial support for global standardisation in order for Sweden to be internationally competitive compared to countries such as China and South Korea in terms of leading global secretariats. This has given Sweden the opportunity to take on global secretariat responsibilities in geodata, elderly care and robotics, to implement a “workshop agreement” on social responsibility, as well as a feasibility study on drones (unmanned aircraft), to name but a few new initiatives.

Together with the government’s innovation council and the strategic collaboration programmes in Vinnova, key market participants could help strengthen the link between standardisation and competitiveness, but also increase knowledge and ensure that Sweden makes use of the opportunities and tools offered by European and global standardisation. There is also a need for close dialogue on these issues between the government and the organisations within the Swedish Standardisation Federation.

There is also a need to increase knowledge about how standardisation and standards can facilitate market access for innovations, primarily among future researchers and innovators at our universities and colleges. Accreditation also has a role to play here when it comes to product development and putting new products on the market. For this reason, authorities with responsibility for higher academic education should be commissioned to investigate which courses should include knowledge requirements regarding standards and standardisation, as well as the benefit of standards, accreditation and conformity assessment.

Vinnova and other authorities with innovation assignments and/or assignments to strengthen Sweden’s competitiveness should take stock of areas in new technology and innovation where Sweden is well ahead from an international perspective. The authorities should be commissioned to help initiate new standardisation work in these areas, as well as work towards Sweden and Swedish stakeholders taking a key role when European and global standards are drawn up.

Stakeholders in quality infrastructure, in particular standardisation organisations, conformity assessment bodies and accreditation bodies, can also be commissioned to offer short training courses on standards, standardisation, conformity assessment and accreditation for the researchers and innovators who receive state support through Vinnova and other state promotion organisations.

In order to be successful in translating innovations into new future standards, state and private stakeholders must collaborate in a strategic way. Participation and involvement in European and global standardisation work is critical to the commercialisation and international implementation of new products and services. This favours Swedish competitiveness, development of the business sector and public sector, job creation and welfare. Collaborations with the Research Institutes of Sweden, RISE, and other important stakeholders in the area are vital to be able to make full use of the opportunities to promote Swedish export.

There is also a lack of knowledge in the educational system and in the innovation environments about the opportunities for using standardisation strategically in order to achieve export benefits. This means that Sweden is currently losing ground in several areas, primarily newer areas that have not traditionally worked with official standardisation.

There is a considerable lack of knowledge about how a patent or rights to an innovation can and should be best handled in relation to standards. In collaboration with Swedac and the Swedish Patent and Registration Office (PRV), the standardisation organisations should be commissioned by the government to create a helpdesk, which researchers and innovators could contact for help to determine the benefit of standards, accreditation, conformity assessment and/or patents in order to achieve maximum market access.

The importance of authority participation in standardisation work that arises from a mandate, i.e. after drafting a bill, cannot be overemphasised. The authorities participate in the legislative work at European level, but the majority of authorities do not participate when the time comes to develop a suitably adapted standard that complies with the directive or regulation. The loss of Swedish expertise in the development of harmonised standards is negative for Sweden, which loses influence in this important phase.

In international bodies, standards are drawn up in collaboration between industry and authorities. It is costly­ to participate in European or global standardisation­ work, in particular for SMEs. There is therefore a need for enhanced resources to increase Swedish participation within CEN and ISO, and other types of activities may also be necessary to strengthen Sweden’s role in European and global standardisation. This can be achieved with additional effort aimed at SMEs to increase their participation in the technical committee work.

Trade benefits from an increased and correct application of the quality infrastructure.

A well-implemented and properly applied quality infrastructure means that all stakeholders have knowledge of the content, function and use of the structure, as well as confidence in the results it produces. These conditions are created through involvement and relevant knowledge. Knowledge leads to insights that in turn lead to the proper application and which give confidence in its use. One starting point for Swedac is that free trade agreements promote the international quality infrastructure with the aim of increasing trade between contracting parties (see Section 5.4). The problem with free trade agreements, for example, is that it takes time before their provisions in the regulatory area, and international regulatory cooperation, can be applied in practice. Nor do free trade agreements always include mutual recognition of the product rules of the parties, even though some differences can be overcome by using standards. However, national legislation is decisive, which makes it difficult to determine the extent to which this is possible. This is rarely discussed but needs to be clarified in order to provide companies as good conditions as possible to succeed with their exporting.

Listed below are insights and focus areas that we assess as being vital for a continued enhancement and correct application of the quality infrastructure.

* Properly used, the systems of accreditation and conformity assessment based on standards work satisfactorily.
* Sweden should work towards a strong quality infrastructure at national, European and global levels.
* Knowledge of conformity assessment, accreditation and standardisation must increase within several different areas and for different types of stakeholder, in particular with:
  + Trade promotion stakeholders, such as Swedish and foreign Chambers of Commerce in Sweden, Swedish Chambers of Commerce abroad, Swedish embassies, etc.
  + Legislators, authorities and other specifiers
  + Companies, both large and SMEs
  + Researchers and innovators
  + Educational bodies for higher education
* Standardisation is important for Sweden and Swedish export:
  + It is important for Sweden to have secretariats in standardisation for the areas of significance for Swedish industry and that industry participates in the standardisation work.
  + It is also important that SMEs can participate in and assimilate the results of standardisation.
* It is important that Sweden can have a strong presence within the international cooperation­ organisations for accreditation, IAF and ILAC.
* In addition to Swedish export companies, communication efforts should also be directed towards other stakeholders, such as authorities/specifiers, professional associations, decision-makers in individual companies, the educational system, media and embassies, in order to increase knowledge in the area.
* An action plan should be drawn up for how the conclusions of the analysis, but also the report in its entirety, can be disseminated to SMEs at regional level. It is also of great importance to use the available channels comprising, e.g. embassies, regional Chambers of Commerce, and even Small Business Standards (SBS)[[117]](#footnote-117).

# 7 Information and communication efforts

This chapter presents proposals for information and communication efforts on how the conclusions of the analysis can be used in order to promote Swedish export, which constitutes the second part of the government­ assignment. In the Introduction, it was found that there is currently a knowledge gap in companies about the ­benefits of using standards in their products and services as well as the benefit of using accredited testing, inspection and certification bodies in order to show that the set requirements have been met. Work on issues relating to accreditation and standardisation should be coordinated since it relates to different industries and sectors that are linked to different state departments. The companies involved should benefit from accreditation and standardisation in order to promote and develop Swedish export. Our assessment is that there is a general interest in building up greater knowledge of accreditation and standardisation­ and what they can achieve, in terms of increased competitiveness, increased societal­ benefit, trade, exploitation of innovations and increased quality. The conclusions of this report should be presented in a strategic way both in traditional channels and in new digital channels. New networks should be developed, as well as participation in platforms and arenas where target groups, existing and potential partners and media can be found. Swedac believes that the report constitutes a tool to reach out to the companies affected as well as relevant trade journals, while at the same time, there is a requirement that other stakeholders in the quality infrastructure on a national, European and international level contribute to the promotion work. Our starting point is therefore that a national perspective from the Swedish export point-of-view is needed, but also a European and international perspective in which Sweden takes the leading role and works towards a strong quality infrastructure

Target groups

Our assessment is that the target group for the *conclusions of this report* consists of Swedish export companies. As mentioned in Section 1.4, they form the primary target group for this report and one which can use accreditation and standardisation to promote their exports. However, as pointed out earlier, the report is also of interest to other stakeholders, such as authorities/specifiers, professional associations, decision-makers in individual companies, the educational system, media and embassies in order to increase knowledge in the area. In order for the conclusions of the report to be beneficial to Swedish export­ companies, efforts are required from trade promotion stakeholders which provide export counselling at a regional and national level to SMEs as well as various stakeholders that provide business­ advice to “start-ups” with a potential to become export companies.

We view it as appropriate for the media to gain insight into and enhanced knowledge within the area. Similarly, it is desirable that higher education institutions for economics, law and technology have access to the material, both as basic knowledge on the quality infrastructure and as inspiration to research in the area.

Channels

There are several channels that can be used to disseminate the conclusions of the analysis and the report. Our assessment is that the next stage should be to adapt the selected channel to each target group and message, and for it to be part of the action plan proposed below.

## 7.1 National efforts

Swedac proposes that the government should establish an interdepartmental working group (IDA group) to coordinate work and disseminate knowledge on accreditation and standardisation within the Government Offices. Furthermore, we propose that the government, in consultation with Swedac and the respondents, should identify which stakeholders should be included in the continued information efforts according to the conclusions presented in this assignment, and work towards a strong national quality infrastructure that can contribute to the promotion of Swedish export. Within the framework for this government assignment, Swedac has consulted a number of stakeholders which should also be included in the continued work. It is proposed that professional associations that bring together a wide range of companies affected by the technical regulatory issues should be given the opportunity, in collaboration with Swedac and the respondents, to present the benefits of a strong quality infrastructure.

Networks and collaborations

There is a great need to reach out to export companies at an early stage in connection with advice on potential­ markets and regulatory frameworks. Swedac’s consultative group has determined that the export­-promotion networks and channels of the Swedish Agency for Economic and Regional Growth are appropriate means for reaching the target groups of SMEs and (regional) export promotion stakeholders. The assignment of the Swedish Agency for Economic and Regional Growth is to promote sustainable business sector development and regional growth, as well as to implement Structural Fund programmes. Since 2016, work has been underway within the framework for Sweden’s export strategy to develop regional export cooperation. For example, in 2018, the Swedish Agency for Economic and Regional Growth assisted all regions in the country to develop regional export cooperation together with regional development managers. The work was carried out together with Business Sweden, Swedish Export Credit Corporation (SEK), Swedish Export Credit Agency (EKN), Almi and Enterprise Europe Network (EEN). The assignment to set up regional export centres meant cooperation between several business promotion organisations within their region to make it easier for companies to get the right support in their internationalisation process. In parallel with this assignment, the Swedish Agency for Economic and Regional Growth developed the website verksamt.se with regional pages as well as internationalisation information for SMEs. Swedac therefore proposes that the government should consider whether it is appropriate for the Swedish Agency for Economic and Regional Growth to be commissioned to draw up an action plan together with Swedac and the respondents for how the conclusions of the analysis, but also the report in its entirety, can be distributed to SMEs at regional level. It is also of great importance to use the channels comprising, e.g. embassies, regional Chambers of Commerce, and even Small Business Standards (SBS)[[118]](#footnote-118).

Swedac has undertaken the Kvalitetslandet (Quality Country) initiative[[119]](#footnote-119), a platform for dialogue and collaboration between stakeholders who want to work for Sweden to maintain its position as a nation of quality. Kvalitetslandet is still in its infancy but Swedac’s assessment is that it will be able to work well as a tool to contribute to increased knowledge on standardisation and accreditation.

There should be a body that can receive information on certain problems in connection with ­standardisation, accreditation and conformity assessment. Examples of some such problems have been presented within the framework for this assignment. These and future similar problems should receive attention­ at a higher level, e.g. within the EA, as these constitute barriers to cross-border trade. Export­ promotion stakeholders can have such information and can assist in the continued work to demonstrate the benefits of accreditation and standardisation, in particular when they have access to many contact networks and other bodies where the target group consists of export companies. It is worth noting in this context that, among other things, EEN has the assignment to identify problems that have a negative impact on trade between Member States and to report these barriers to the National Board of Trade, which can then in turn pass the issues on to the European cooperation network SOLVIT[[120]](#footnote-120).

Furthermore, the consulting organisations should highlight the report in their normal networks. Swedac also proposes the formation of a new permanent forum by participating consultation organisations. There should be participation here by the stakeholders identified by the government for inclusion in the continued information efforts.

## 7.2 European efforts

At European level, the government should in general actively work to ensure that future negotiations on new legislation­ follow the legislative framework in the New Method, as well as the provisions on accreditation­ in Regulation (EC) No. 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products. As mentioned earlier in various contexts, Swedac finds it problematic that some legislative proposals deviate from the system heavily supported by the European Commission and sees a risk of an increased administrative burden as well as increased costs for companies. The government should adopt a general and clear approach in this regard in future negotiations. Furthermore, at European level, and within the framework for future free trade negotiations, the government should work for clearer agreements that are easy to interpret in terms of impact and application (especially for companies) and to have actual targets with greater direct market access through concrete measures for identified products or sectors.

## 7.3 International efforts

Swedac proposes that Sweden should also work at the international level to promote a well-functioning quality infrastructure, not least in future free trade negotiations, but also through active participation in the WTO TBT committee in order to remove unnecessary barriers to trade as well as work towards good compliance with agreements entered into. Work on promoting standardisation, which is an important component in the quality infrastructure, is also required at the global level. In the same way as it is important for Sweden to hold secretariats in standardisation for areas of significance to Swedish industry and for industry to participate in the standardisation work, it is also important that Sweden can have a strong presence in the international cooperation organisations for accreditation, IAF and ILAC. It is partly a question of a normal ability to influence as an active member, but primarily the opportunity to occupy the leading positions within each organisation. Leading positions within IAF and ILAC lead to opportunities to establish direct contact with other international organisations such as WTO, OECD and UNECE.

# Appendices

## Appendix 1. Questionnaire.

|  |  |
| --- | --- |
| Questions on Swedac’s assignment within accreditation, standardisation and export | |
| Swedac has been tasked by the government to produce supporting documents on how accreditation and standardisation can be used to promote Swedish export. As part of information gathering and documentation, we are contacting you as accredited bodies in order to get your view on the area.  Your feedback is important to us and we hope that you have the opportunity to contribute to this important work. | |
| 1. What is your main activity as an accredited body? Select all applicable areas.  (Please select more than one option if applicable) | |
|  | Calibration |
|  | Testing |
|  | Certification of management systems |
|  | Certification of products and processes |
|  | Certification of persons |
|  | Medical laboratory |
|  | Verification |
|  | Inspection body |

|  |  |  |  |
| --- | --- | --- | --- |
| 2. How many employees work in the accredited activity?  (Please select only one option) | | | |
|  | | | 1-9 | | |
|  | | | 10-49 | | |
|  | | | 50-249 | | |
|  | 250 or more | | |
| 3. Of your total turnover, what percentage is accounted for by the accredited activity?  Please give an estimated percentage for the accredited activity on a scale from 0% to 100%.  (Allocate in total: 100%) | | | | | |
|  | | |  | | |
| Calibration | | | \_\_\_\_\_\_\_\_ % | | |
| Testing | | | \_\_\_\_\_\_\_\_ % | | |
| Certification of management systems | | | \_\_\_\_\_\_\_\_ % | | |
| Certification of products | | | \_\_\_\_\_\_\_\_ % | | |
| Certification of persons | | | \_\_\_\_\_\_\_\_ % | | |
| Medical laboratory | | | \_\_\_\_\_\_\_\_ % | | |
| Verification | | | \_\_\_\_\_\_\_\_ % | | |
| Inspection body | | | \_\_\_\_\_\_\_\_ % | | |
| Other non-accredited activity | | | \_\_\_\_\_\_\_\_ % | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 4. Do your accredited activities have higher or lower prices compared with the non-accredited services?  (Please select only one option per question) | | | | | | | | | | | |
|  | | More than 10% higher price | | Up to 10% higher price | | No difference in price | | Up to 10% lower price | More than 10%  lower price | Not applicable | | |
| Calibration | |  | |  | |  | |  |  |  | | |
| Testing | |  | |  | |  | |  |  |  | | |
| Certification of management systems | |  | |  | |  | |  |  |  | | |
| Certification of products | |  | |  | |  | |  |  |  | | |
| Certification of persons | |  | |  | |  | |  |  |  | | |
| Medical laboratory | |  | |  | |  | |  |  |  | | |
| Verification | |  | |  | |  | |  |  |  | | |
| Inspection body | |  | |  | |  | |  |  |  | | |
|  | | |  | |  | |  | |
| **5. How important is accreditation to your business?**  **Please answer on a scale of 1-6 where 1 is not important and 6 is very important. (Please select more than one option if applicable)** | | | | | | | | | | |
| 1 | 2 | | | 3 | | 4 | | 5 | 6 | |
|  |  | | |  | |  | |  |  | |
| Comment | | | | | | | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **6. What are the main benefits of accreditation for your business? Select all applicable benefits. (Please select more than one option if applicable)** | | | | | | | |
| Meets customer rrequirements | Gives an advantage over competitors | Streamlines our internal work | It gives access to new customers/ markets in Sweden | It gives access to customers/ markets outside Sweden | Marketing | Economic benefits | Meets legal requirements |
|  |  |  |  |  |  |  |  |
| Other (please specify)   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **7. How well do you agree with the following statements?**  **Please answer on a scale of 1-6 where 1 is Strongly disagree and 6 is Strongly agree,  option not applicable (Please select only one option per question)** | | | | | | | | | |  | 1 | 2 | 3 | 4 | 5 | 6 | Not applicable | | “Accreditation facilitates  international trade” |  |  |  |  |  |  |  | | “Our certificates/reports under accreditation  are accepted outside Sweden” |  |  |  |  |  |  |  | | | | | | | | |

|  |  |
| --- | --- |
| 8. If you selected 1 - Strongly disagree to the previous question, please answer a) and b) | |
| 8. a) Where are your certificates/reports not accepted? |
| 8. b) What areas/products/services does this apply to? | |

|  |
| --- |
| 9. Do you see any new product or service areas and/or any new geographical areas/economies where accreditation may be requested within five years? |

|  |
| --- |
| 10. What can be done to increase knowledge of the benefits/opportunities of using accredited bodies? |

## Appendix 2. Questions and participant list at the consultation meeting of 3 October 2017.

1. Are there good examples from industries, products/services or geographical areas that have benefited from available standards and/or accreditation/certification in order to facilitate Swedish exports?
2. Are there bad/less successful examples from industries, products/services or geographical areas where Swedish exports have had difficulties due to the lack of standards and/or accreditation/certification?
3. How can accreditation combined with standardisation be used to promote Swedish export?
4. Is there a lack of knowledge in exporting Swedish companies about the benefits of using standards and accreditation in order to show that set requirements have been met?
5. Is there a reluctance in some countries to recognise Swedish certification, testing and inspection under accreditation despite the global system of mutual recognition?
6. In what areas are there foreign requirements for exporting Swedish service providers that are incompatible with Swedish legislation/EU legislation?
7. In what areas could Sweden increase its share of the world market by offering services under accreditation?
8. In what areas is there a lack of standards and otherwise limited prospects for using conformity assessment?
9. How can the conclusions of the project be communicated to the companies and stakeholders affected?

**Participant Organisation**

Karin Rydén Swedish Agency for Economic and Regional Growth  
Hiba Zeydi National Board of Trade  
Anders Karlsson National Board of Trade  
Bianca Dochtorowicz Vinnova  
Camilla Åberg SIS  
Fredrik Göthe SIS  
Thomas Korssell SEK  
Thomas Borglind ITS  
Erika Palmheden Swedac  
Åsa Tysklind Swedac  
Magnus Pedersen Swedac  
Peter Kronvall Swedac

## Appendix 3. Agenda and participant list at the consultation meeting of 22 February 2018.

Agenda for consultation meeting on how accreditation and standardisation can be used to promote Swedish export, report for consultation.

1. Purpose and objectives of the consultation meeting
2. Swedac presents completed activities and completed work.
3. Around the table: each consultation organisation summarises its main points on the report.
4. Comments and discussions about the views expressed.
5. Discussion on Chapter 7 Information and communication efforts.
6. Summary
7. Closing

**Participant Organisation**

Maria Helle Swedish Agency for Economic and Regional Growth  
Camilla Åberg SIS  
Fredrik Göthe SIS  
Amina Makboul Swedac  
Erika Palmheden Swedac  
Peter Kronvall Swedac

Written consultation has supplemented the consultation meeting above.

In addition, comments on proposals for the report have been received from the Swedish Agency for Economic and Regional Growth, National Board of Trade, Vinnova, SIS, SEK and ITS.

1. The word “global” is used to describe international standards/standardisation in order to distinguish between European standards/standardisation and international standards/standardisation. [↑](#footnote-ref-1)
2. Swedac’s assignment is stated in instructions, appropriation directions and the Accreditation and Conformity Assessment Act (2011:791) and the Accreditation and Conformity Assessment Ordinance (2011:811) [↑](#footnote-ref-2)
3. *What are the obstacles to Swedish foreign trade?, the National Board of Trade’s Companies Survey 2016* https://www.kommers.se/Documents/dokumentarkiv/publikationer/2016/Publ-f%c3%b6retagsunders%c3%b6kningen-webb.pdf [↑](#footnote-ref-3)
4. See the Government Decision of 17 August 2017 UD2017/13340/HI. [↑](#footnote-ref-4)
5. Governmental Agency for Innovation Systems (Vinnova) [↑](#footnote-ref-5)
6. Swedish Standards Institute [↑](#footnote-ref-6)
7. Svensk Elstandard (SEK) [↑](#footnote-ref-7)
8. Swedish Information and Telecommunication Standardisation (ITS) [↑](#footnote-ref-8)
9. Frenz, Marion and Lambert. 2013 *“The Economics of Accreditation*” https://www.ukas.com/download/general\_documents/Economics%20of%20Accreditation%20Final%20Report.pdf [↑](#footnote-ref-9)
10. Quality and compliance infrastructure, United Nations Industrial Development Organisation (UNIDO), website: unido.org [↑](#footnote-ref-10)
11. CERTIF 2012-04 REV4 [↑](#footnote-ref-11)
12. The Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 [↑](#footnote-ref-12)
13. https://www.swedac.se/tjanster/ackreditering/ansok-om-ackreditering/ [↑](#footnote-ref-13)
14. http://www.european-accreditation.org/peer-evaluation-process [↑](#footnote-ref-14)
15. Articles 4 and 14 of Regulation (EC) No. 765/2008 [↑](#footnote-ref-15)
16. Article 2 of (EC) No. 765/2008 [↑](#footnote-ref-16)
17. Framework Partnership Agreement, Framework Agreement Number 30-CE-0647816/00-85, Ref. Ares (2014)2282914 - 09/07/2014 [↑](#footnote-ref-17)
18. Under the terms of the agreement, the agreement is valid for four years from the date it was signed by the last signing party which, according to the agreement, took place on 24 June 2014. The agreement is therefore valid until 24 June 2018. [↑](#footnote-ref-18)
19. For the cooperation between the European Cooperation for Accreditation (EA), the European Commission, the European Free Trade Association (EFTA) and the competent national authorities (2009/C 116/04) [↑](#footnote-ref-19)
20. Mutual Recognition Arrangements [↑](#footnote-ref-20)
21. See, for example, ILAC Mutual Recognition Arrangement (Arrangement), ILAC-P5:10/2013 [↑](#footnote-ref-21)
22. Multilateral Recognition Arrangements [↑](#footnote-ref-22)
23. Asia Pacific Laboratory Accreditation Co-operation (APLAC), European co-operation for Accreditation (EA), Inter-American Accreditation Cooperation (IAAC) and The Arab Accreditation Cooperation (ARAC) [↑](#footnote-ref-23)
24. SS-EN ISO/IEC 17000:2005 §4.2 [↑](#footnote-ref-24)
25. Swedac doc 04:2 [↑](#footnote-ref-25)
26. SS-EN ISO/IEC 17000:2005 §4.3 [↑](#footnote-ref-26)
27. Nando (New Approach Notified and Designated Organisations) Information System [↑](#footnote-ref-27)
28. Reason 5 of (EU) No. 1025/2012 (Standardisation Regulation) [↑](#footnote-ref-28)
29. Report from the Commission to the European Parliament and the Council on the implementation of Regulation (EU) No. 1025/2012 for 2013-2015, Brussels 1.6.2016, COM2016 212 final [↑](#footnote-ref-29)
30. When it comes to standards adopted by CEN, the percentage is 30% according to CEN’s website [↑](#footnote-ref-30)
31. Report from the Commission to the European Parliament and the Council on the consequences of the procedure established by Article 10 of Regulation (EU) No. 1025/2012 on the timetable for issuing a request for standardisation, in accordance with Article 25 of that Regulation, Brussels, 13.5.2015 COM (2015) 198 final [↑](#footnote-ref-31)
32. Regulation (EU) No. 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation and amending Council Directives 89/686/EEC and 93/15/EEC as well as the Directives of the European Parliament and of the Council 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC and on the repealing of Council Decision 87/95/EEC and Decision No. 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12) [↑](#footnote-ref-32)
33. Some European standardisation bodies exist within the country’s administrative organisation (information from SIS) [↑](#footnote-ref-33)
34. Recital 1 and 2 of Regulation (EU) No. 1025/2012 [↑](#footnote-ref-34)
35. Recital 6 of (EU) No. 1025/2012 [↑](#footnote-ref-35)
36. Recital 40 and 43 of (EU) No. 1025/2012 [↑](#footnote-ref-36)
37. Article 2.1 of (EU) No. 1025/2012 [↑](#footnote-ref-37)
38. <https://webgate.ec.europa.eu/icsms/> [↑](#footnote-ref-38)
39. https://ec.europa.eu/consumers/consumers\_safety/safety\_products/rapex/alerts/?event=main.listNotifications [↑](#footnote-ref-39)
40. https://www.oiml.org/en?set\_language=en [↑](#footnote-ref-40)
41. https://www.welmec.org/ [↑](#footnote-ref-41)
42. https://ec.europa.eu/growth/single-market/goods/new-legislative-framework\_sv [↑](#footnote-ref-42)
43. Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 on establishing a framework for the approval of motor vehicles and their trailers and of systems, components and separate technical units intended for such vehicles (“Framework Directive”)

    Regulation (EU) No. 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles

    Regulation (EU) No. 168/2013 of the European Parliament and of the Council of 15 January 2013 approving and market surveillance of two or three-wheel vehicles and quadricycles [↑](#footnote-ref-43)
44. annexed to the revised agreement of 1958 [↑](#footnote-ref-44)
45. Regulation (EC) No. 765/2008 and Decision No. 768/2008/EC [↑](#footnote-ref-45)
46. <https://www.kommers.se/verksamhetsomraden/Handelspolitik/Organisationer/UNECE/> [↑](#footnote-ref-46)
47. http://ec.europa.eu/DocsRoom/documents?tags=technical-service-auto&pageSize=30&sortCol=title&sortOrder=asc [↑](#footnote-ref-47)
48. https://www.wto.org/english/docs\_e/legal\_e/17-tbt\_e.htm [↑](#footnote-ref-48)
49. In this context, it can be mentioned that SIS is working on a Nordic study of standardisation from a macroeconomic perspective, see www.sis.se [↑](#footnote-ref-49)
50. pp.42-50 Frenz, Marion and Lambert, Ray in *The Economics of Accreditation*, The Journal of Measurement Science, volume 9, number 2, 2014. [↑](#footnote-ref-50)
51. Gustafsson, Ingrid (2016). Organisation of standards, certification and accreditation as a global control regime, School of Public Administration, University of Gothenburg. [↑](#footnote-ref-51)
52. Prop. 1991/92:170 Appendix 11 [↑](#footnote-ref-52)
53. 272/80 Public Prosecutor/French-Dutch Society for Biological Products BV. [↑](#footnote-ref-53)
54. see section 3.1 [↑](#footnote-ref-54)
55. See section 3.1 [↑](#footnote-ref-55)
56. p.7 Sweden’s export strategy, 28 September 2015 [↑](#footnote-ref-56)
57. Agreement on Conformity Assessment and Acceptance of Industrial Products. [↑](#footnote-ref-57)
58. British Standards Institute. [↑](#footnote-ref-58)
59. Interview on 5 December 2017 with Stefan Bertilsson, Deputy Head and Quality Manager of IKEA Test Lab. [↑](#footnote-ref-59)
60. Swedac’s scope of accreditation, 13 January 2017 [↑](#footnote-ref-60)
61. Swedac Newsletter, no. 3 2017 [↑](#footnote-ref-61)
62. The IWAY Standard defines the minimum requirements for suppliers that they need to fulfil. [↑](#footnote-ref-62)
63. Information from SIS [↑](#footnote-ref-63)
64. Interview on 6 December 2017 with Thomas Korssell, Managing Director of Svensk Elstandard (SEK). [↑](#footnote-ref-64)
65. Ulrich Spindler, Vice President of IEC and Chair of Conformity Assessment Board [↑](#footnote-ref-65)
66. Interview on 15 December 2017 with Per Frode, Managing Director of Baltic Safety Products. [↑](#footnote-ref-66)
67. Interview on 14 December 2017 with Anders Sundvik, Vice President for Research and Development. [↑](#footnote-ref-67)
68. Research Institutes of Sweden [↑](#footnote-ref-68)
69. Technical Research Centre of Finland [↑](#footnote-ref-69)
70. [Centre Technique des Industries Aérauliques et Thermiques (Cetiat)](http://www.cetiat.fr/) [↑](#footnote-ref-70)
71. Interview on 28 December 2017 with Jan Byfors, Chief Technology Officer of NCC. [↑](#footnote-ref-71)
72. Interview on 8 January 2018 with Erik Dahlberg, Senior Manager, Regulations & Standards, and on 21 December 2017 with Lina Orbéus, Head of Corporate Standards (YDRC). [↑](#footnote-ref-72)
73. https://www.rdw.nl/ [↑](#footnote-ref-73)
74. http://www.applusidiada.com/en/ [↑](#footnote-ref-74)
75. Interview on 8 January 2018 with Anders Hedqvist, Vice President Research & Development, Underground Rock Excavation Division, Epiroc Rock Drills AB - Part of the Atlas Copco Group. [↑](#footnote-ref-75)
76. Interview on 3 January 2018 with Anders Åkesson, Global EHS Manager EHS / QM Manager, site Svedala.

    Crushing & Screening Sandvik Mining & Rock Technology [↑](#footnote-ref-76)
77. Interview on 3 January 2018 with Lars Granström, CEO Teknik i Media Datacenter Stockholm AB [↑](#footnote-ref-77)
78. 40 CFR Section 770:

    <https://www.law.cornell.edu/cfr/text/40/part-770>

    <https://www.law.cornell.edu/cfr/text/40/770.7>

    <https://www.law.cornell.edu/cfr/text/40/770.5> [↑](#footnote-ref-78)
79. See “Small Entity Compliance Guide For Accreditation Bodies and Third-Party Certifiers”

    <https://www.epa.gov/sites/production/files/2017-06/documents/small_entity_compliance_guide_for_accreditation_bodies_and_third_party_certifiers.pdf> [↑](#footnote-ref-79)
80. <https://ec.europa.eu/growth/single-market/goods/international-aspects/mutual-recognition-agreements_sv> [↑](#footnote-ref-80)
81. EMC (electromagnetic compatibility) and radio requirements for the USA market

    <https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title47/47tab_02.tpl>

    <https://www.law.cornell.edu/cfr/text/47/part-2/subpart-J> [↑](#footnote-ref-81)
82. The guidance document “TCB PROGRAMME ROLES AND RESPONSIBILITIES” can be downloaded via the following link:

    <https://apps.fcc.gov/oetcf/kdb/forms/FTSSearchResultPage.cfm?id=44683&switch=P>

    The guidance documents “ACCREDITED TESTING LABORATORY PROGRAMME

    ROLES AND RESPONSIBILITIES” and “OET PROCEDURES FOR THE RECOGNITION OF

    LABORATORY ACCREDITATION BODIES” can be downloaded via the following link:

    <https://apps.fcc.gov/oetcf/kdb/forms/FTSSearchResultPage.cfm?switch=P&id=44684> [↑](#footnote-ref-82)
83. <https://www.fcc.gov/general/equipment-authorization-eu-mra> [↑](#footnote-ref-83)
84. <https://www.apec.org/Groups/SOM-Steering-Committee-on-Economic-and-Technical-Cooperation/Working-Groups/Telecommunications-and-Information/APEC_TEL-MRA.aspx> [↑](#footnote-ref-84)
85. FCC Office of Engineering & Technology Active TCB Designating Authority (TDA) List <https://apps.fcc.gov/tcb/TcbHome.do> [↑](#footnote-ref-85)
86. <https://apps.fcc.gov/oetcf/tcb/reports/TCBSearch.cfm> [↑](#footnote-ref-86)
87. <https://www.osha.gov/law-regs.html> [↑](#footnote-ref-87)
88. How to apply for EPA approval:

    <https://www.energystar.gov/index.cfm?c=third_party_certification.tpc_labs> [↑](#footnote-ref-88)
89. EUT L 63, 6.3.2013, p. 7, <https://www.eu-energystar.org/downloads/legislation/Agreement_USA-EU_20121210.pdf> [↑](#footnote-ref-89)
90. <http://eur-lex.europa.eu/legal-content/SV/TXT/PDF/?uri=CELEX:32008R0106&rid=1>, <http://eur-lex.europa.eu/legal-content/SV/TXT/PDF/?uri=CELEX:02008R0106-20130326&qid=1515580603276&from=SV>

    EUT L 39, 13.2.2008, p. 1 [↑](#footnote-ref-90)
91. EPA-Recognised Certification Bodies (CBs) and Laboratories <https://www.energystar.gov/index.cfm?fuseaction=recognized_bodies_list.show_RCB_search_form> [↑](#footnote-ref-91)
92. p.7 Sweden’s export strategy, 28 September 2015 [↑](#footnote-ref-92)
93. http://unctad.org/en/Pages/Home.aspx [↑](#footnote-ref-93)
94. The Use of the EU’s Free Trade Agreements, Exporter and Importer Utilisation of Preferential Tariffs, National Board of Trade and the United Nations Conference on Trade and Development (UNCTAD), January 2018 https://www.kommers.se/Documents/dokumentarkiv/publikationer/2018/Publ-The-use-of-the-eus-ftas.pdf [↑](#footnote-ref-94)
95. Chapter Four on technical barriers to trade, Council of the European union; “Comprehensive Economic and Trade Agreement between Canada, of the one part, and the European Union and its Member States, of the other part”, 14 September 2016, 10973/16, Interinstitutional file 2016/0206. [↑](#footnote-ref-95)
96. The Commission’s press release; “EU-Canada trade agreement enters into force”, 20 September 2017 [↑](#footnote-ref-96)
97. Council of the European Union, Council of the European union; “Comprehensive Economic and Trade Agreement between Canada, of the one part, and the European Union and its Member States, of the other part”, Protocol on the mutual acceptance of results of conformity assessment, 14 September 2016, 10973/16, Interinstitutional file 2016/0206 [↑](#footnote-ref-97)
98. The EA’s press release; “EA supporting trade accord between Canada and the European Union”, 29 June 2016 and the EA’s brochure; CETA Agreement and Conformity Assessment **-** *Accreditation, a tool to enhance trade between the European Union and Canada.* [↑](#footnote-ref-98)
99. The Commission’s press release, “EU and Japan finalise Economic Partnership Agreement”, 8 December 2017. [↑](#footnote-ref-99)
100. The Commission’s document; “EU-Japan EPA – The Agreement in Principle”, 6 July 2017 [↑](#footnote-ref-100)
101. The United Nations Economic Commission for Europe [↑](#footnote-ref-101)
102. The Commission’s Fact Sheet; Key elements of the EU-Japan Economic Partnership Agreement”, 6 July 2017 [↑](#footnote-ref-102)
103. The Commission’s document; “An introduction to the EU-Japan Economic Partnership Agreement,

     Regulatory cooperation and non-tariff measures”. [↑](#footnote-ref-103)
104. Chapter 4 on Technical Barriers to Trade and Annexes 2b-2E. The Official Journal of the European Union, L127, 14 May 2011 [↑](#footnote-ref-104)
105. 2016/17:50 Knowledge in Collaboration – for societal challenges and enhanced competitiveness) [↑](#footnote-ref-105)
106. 2016/17:50 Knowledge in Collaboration – for societal challenges and enhanced competitiveness) [↑](#footnote-ref-106)
107. Unmanned Aircraft System [↑](#footnote-ref-107)
108. General Data Protection Regulation [↑](#footnote-ref-108)
109. Medical Devices Regulation [↑](#footnote-ref-109)
110. Invitro Diagnostics Regulation [↑](#footnote-ref-110)
111. Europe-wide dimensioning rules for load-bearing supporting systems for buildings and facilities (construction works), such as bridges and houses [↑](#footnote-ref-111)
112. Building Information Models or Building Information Modelling [↑](#footnote-ref-112)
113. Radio Frequency Identification [↑](#footnote-ref-113)
114. <http://tbtims.wto.org/en/PredefinedReports/STCReport> [↑](#footnote-ref-114)
115. http://www.publicsectorassurance.org/ [↑](#footnote-ref-115)
116. http://business-benefits.org/ [↑](#footnote-ref-116)
117. http://www.sbs-sme.eu/ [↑](#footnote-ref-117)
118. http://www.sbs-sme.eu/ [↑](#footnote-ref-118)
119. https://kvalitetslandet.se/ [↑](#footnote-ref-119)
120. http://ec.europa.eu/solvit/index\_sv.htm [↑](#footnote-ref-120)