

Report

Functioning of accreditation in Europe



2019

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1. Introduction

More than 10 years ago, the European Commission published Regulation (EC) No 765/2008 with the aim to ensure that products benefiting from the free movement of goods within the Community fulfil requirements providing a high level of protection of public interest such as health and safety in general, health and safety at the workplace, protection of consumers, protection of the environment and security, while ensuring that the free movement of products is not restricted to any extent greater than that which is allowed under Community harmonisation legislation or any other relevant Community rules.

In order to reach these objectives, it was necessary to establish an overall framework of rules and principles in relation to accreditation, conformity assessment and market surveillance.

Regulation (EC) No 765/2008 provides a comprehensive framework for accreditation and to lay down at Community level the principles for its operation and organization.

The particular value of accreditation lies in the fact that it provides an authoritative statement of the technical competence of bodies whose task is to ensure conformity with the applicable requirements providing a high level of protection of public interest.

Moreover, transparent accreditation, as provided for in Regulation (EC) No 765/2008, should be considered by the national public authorities as the preferred means of demonstrating the technical competence of conformity assessment bodies (CABs).

Due to the new accreditation system set out in Regulation (EC) No 765/2008, the number of European legislations with reference to accreditation and conformity assessment has been increased significantly. Accreditation is also the preferred tool to demonstrate the competence of CABs in trade agreements with third countries with the aim of mutual acceptance of conformity assessment results and with that avoiding technical barriers to trade.

Accreditation is also the appropriate means that consumers (end-users) can have trust directly in certificates and reports issued by accredited conformity assessment bodies.

The European Commission confirmed in its report on the implementation of Regulation (EC) No 765/2008 ¹, that the European accreditation infrastructure created by Regulation (EC) No 765/2008 has provided added value, not only for the single market but also for international trade.

Accreditation has wide support from European industry and the conformity assessment community for ensuring that products meet the applicable requirements, removing barriers for CABs and helping entrepreneurial activities to flourish in Europe. The Regulation established a trustworthy and stable accreditation system in all Member States, as well as EFTA countries and Turkey.

¹ Report, dated 19th of December 2017, from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the implementation of 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

But how accepted is accreditation in Europe and used by the European and national authorities as well as private scheme owners/users as the preferred means to demonstrate competence of CABs and how robust is the accreditation system?

EA has been requested by the European Commission to provide specific indicators, which shall provide information about the functioning of accreditation in Europe. This information shall be provided regularly in future and shall complement the information presented in the Commission's report on the implementation of Regulation (EC) No 765/2008.

2. Accreditation of conformity assessment bodies

Accreditation of CABs is defined in Regulation (EC) No 765/2008 and in ISO/IEC 17011.

The international standard ISO/IEC 17011:2017 Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies defines accreditation as follows:

Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

Conformity assessment activities, being performed by CABs, are for instance testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification.

According Regulation (EC) No 765/2008 '*accreditation*' shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity.

The harmonised standards for accreditation are published in the Official Journal of the European Union (OJEU).

There are the following harmonized standards applied for the accreditation of CABs:

EN ISO/IEC 17025:2017	<i>General requirements for the competence of testing and calibration laboratories</i>
EN ISO 15189:2012	<i>Medical laboratories - Requirements for quality and competence</i>
EN ISO/IEC 17020:2012	<i>Conformity assessment - Requirements for the operation of various types of bodies performing inspection</i>
EN ISO/IEC 17065:2012	<i>Conformity assessment - Requirements for bodies certifying products, processes and services</i>
EN ISO/IEC 17021-1:2015	<i>Conformity assessment - Requirements for bodies providing audit and certification of management systems -- Part 1: Requirements</i>
EN ISO/IEC 17024:2012	<i>Conformity assessment - General requirements for bodies operating certification of persons</i>

EN ISO 14065:2013	<i>Greenhouse gases - Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition</i>
EN ISO/IEC 17043:2010	<i>Conformity assessment - General requirements for proficiency testing</i>
EN ISO 17034:2016	<i>General requirements for the competence of reference material producers</i>

If we are talking about accredited CABs, then we have to look always to the scope of accreditation. In some cases, the CAB is not accredited for the whole conformity assessment activities which are offered by this CAB to the market, but only for a part of these activities.

Definition of scope of accreditation (ISO/IEC 17011:2017, clause 3.6)

Specific conformity assessment activities for which accreditation (see above) is sought or has been granted.

For more information about accreditation and conformity assessment, please visit EA's website <https://european-accreditation.org/>.

3. Survey on the functioning of accreditation in Europe

EA launched a survey in June/July 2019 to all 50 EA National Accreditation Bodies (36 EA Full² and 14 Associate³ members) with the aim to receive information about:

- Number of accreditations (by end of 2018)
 - Number of accreditations in the regulated sector
 - Number of accreditations in the non-regulated (voluntary) sector
- Number of accreditations per activity (by end of 2018)
- Main sectors/legislations with the most number of accreditations
- Suspension/withdrawal of accreditation
- Complaints/appeals
- Acceptance of accreditation
- Challenges

This information shall be used for the analysis of the functioning of accreditation in Europe.

² EA Full members: NABs legally appointed as referred to in Regulation (EC) No 765/2008 in:

- a member state of the EU; or
- a member state of the EFTA; or
- a country which has been formally identified by the EU or EFTA as a candidate country for membership in the EU or EFTA.

³ EA Associate members: NABs legally appointed as such by countries or economies being:

- identified by the EU or EFTA as potential candidate countries or economies for EU or EFTA membership; or
- identified by the EU in the European Commission's European Neighbourhood Policy as countries or economies of particular importance.

EA received responses from 34 Full members and 11 Associate members:

AA, Austria	ACCREDIA, Italy	ARMNAB, Armenia
ATCG, Montenegro	AZAK, Azerbaijan	BATA, Bosnia & Herzegovina
BELAC, Belgium	BSCA, Belarus	CAI, Czech Republic
COFRAC, France	CYS-CYSAB, Cyprus	DAK, KOSOVO (under the UNSC Resolution 1244/1999)
DAkS, Germany	DANAK, Denmark	DPA, Albania
EAK, Estonia	EGAC, Egypt	ENAC, Spain
ESYD, Greece	FINAS, Finland	GAC, Georgia
HAA, Croatia	IARNM, Republic of North Macedonia	INAB, Ireland
IPAC, Portugal	ISAC, Iceland	ISRAC, Israel
LA, Lithuania	LATAK, Latvia	MOLDAC, Republic of Moldova
NA, Norway	NAAU, Ukraine	NAB-Malta, Malta
NAH, Hungary	OLAS, Luxembourg	PCA, Poland
RENAR, Romania	RvA, The Netherlands	SA, Slovenia
SAS, Switzerland	SNAS, Slovakia	SWEDAC, Sweden
TUNAC, Tunisia	TURKAK, Turkey	UKAS, United Kingdom

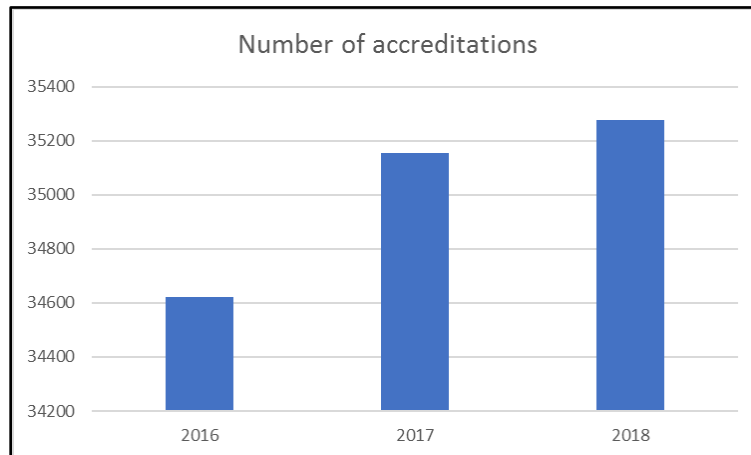
2 Full member and 3 Associate members, which have responded to the survey, are not signatories to the EA MLA.

For more information about the EA Multilateral Agreement for Recognition (MLA) and about EA members and their MLA signatory status please visit the EA website <https://european-accreditation.org/>.

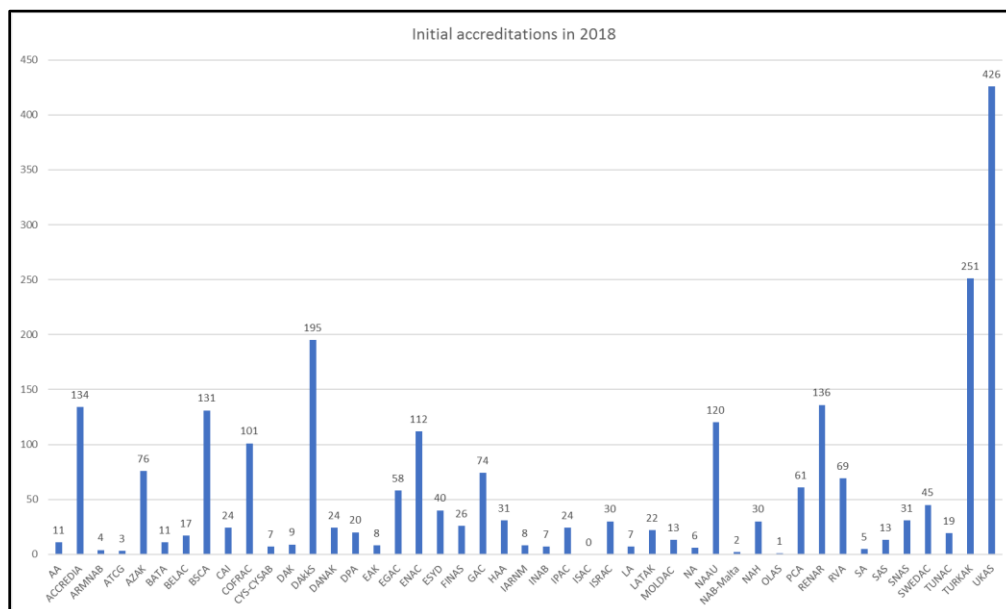
4. Results

4.1 Total number of accreditations by the end of 2018

The total number of accreditations under the EA MLA continues to rise. By the end of 2018, more than 35.250 accreditation have been granted in total by all EA National Accreditation Bodies (NABs) compared to 35.100 by the end of 2017 and 34.600 by the end of 2016.



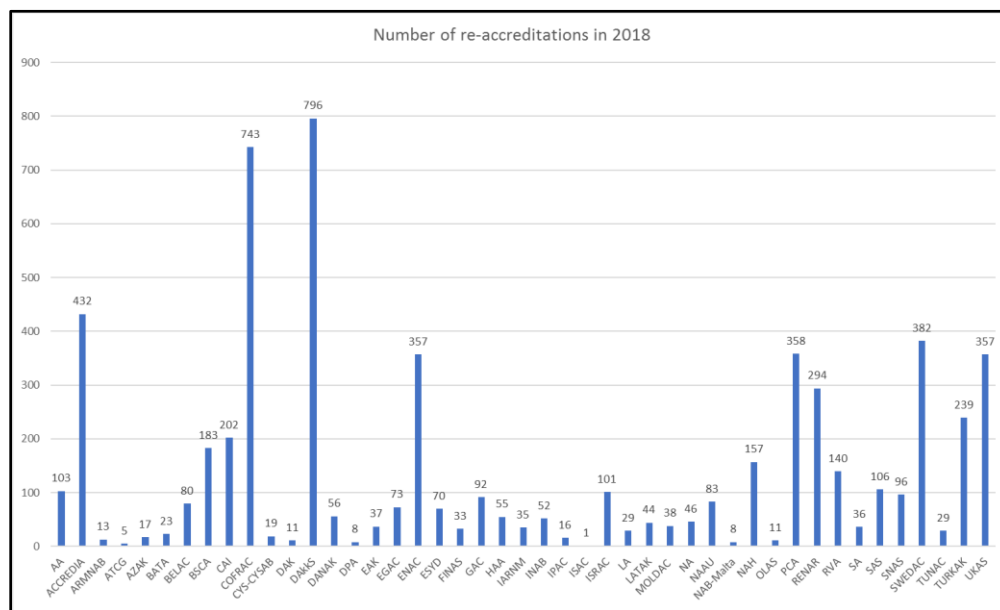
The total number of accreditations granted by the NABs, which responded to this survey, is 34.064. The number of accreditations is equivalent to the number of issued accreditation certificates. But some conformity assessment bodies hold more than one accreditation, because in general the NABs issue for each activity (e.g. testing according ISO/IEC 17025 or product certification according ISO/IEC 17065) an accreditation certificate. That means that the number of accredited CABs is slightly lower than the number of granted accreditations.



The EA NABs issued more than 2.400 new accreditations in 2018.

The increasing number of accreditations demonstrate the confidence in accreditation and in certificates and reports issued by accredited CABs.

The process of accreditation is defined in ISO/IEC 17011 (see above item 2). The NAB shall apply an assessment programme for assessing the CAB activities during the accreditation cycle to ensure that the conformity assessment activities - representative of the scope of accreditation at the relevant locations - are assessed during the accreditation cycle.



The assessment programme shall also ensure that the requirements of the international standards (see above item 2) and other normative documents containing requirements for CABs and the scope of accreditation shall be assessed taking risk into consideration. A sample of the scope of accreditation shall be assessed at least every two years. The time between consecutive on-site assessments shall not exceed two years. The re-assessment shall take place after 5 years at the latest of the previous initial or re-assessment. It shall confirm the competence of the conformity assessment body and cover all the requirements of the standard(s) for which the conformity assessment body is accredited.

The outcome of the re-assessment is the so-called re-accreditation or renewal of the accreditation based on a positive decision by the NAB.

In 2018, the EA NABs have issued in total more than 6.000 re-accreditations.

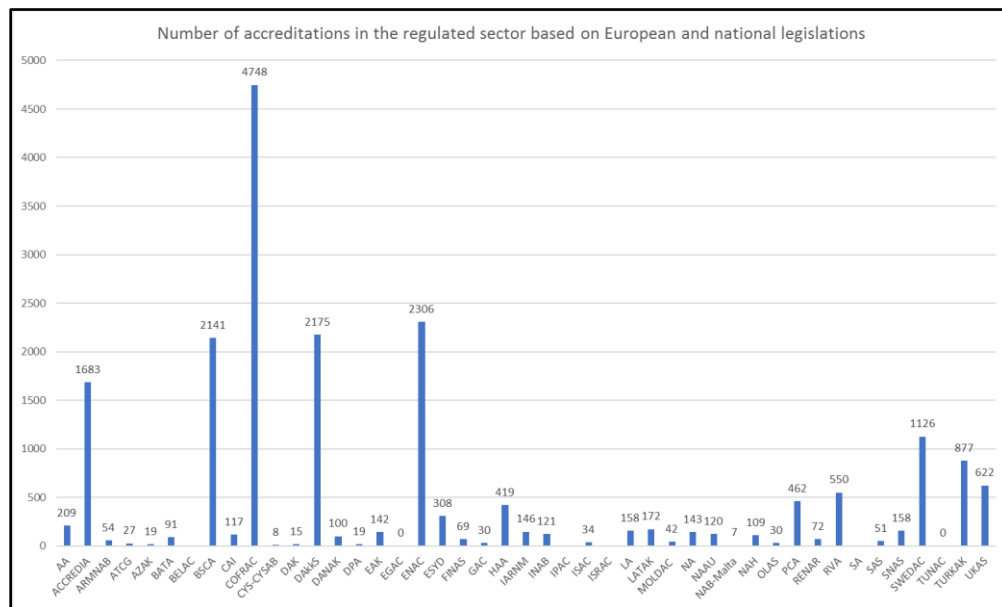
4.2 Total number of accreditations by the end of 2018 in the regulated sector based on European and national legislations

In many European and national legislations regulators make use of accreditation as the preferred means to demonstrate the competence of CABs.

Examples of those European legislations are the Directive 2014/68/EU on pressure equipment, the Regulation (EU) No 305/2011 on construction products and the Regulation (EC) No 882/2004 on official controls in the agri-food sector.

Currently, there are more than 100 European legislations with reference to accreditation and conformity assessment. Additionally, the national regulators make use of accreditation too.

The NAB shall provide information on the accreditation to the accredited CAB. The scope of accreditation shall be part of the accreditation information, which shall include among others the scope of accreditation. Normally the accreditation information is being provided in an accreditation certificate.



The scope for accreditation, expressed in one accreditation certificate, can cover activities which are dedicated to the regulated and non-regulated sector (see below item 4.3) as well as different regulated and non-regulated sectors. Therefore, the number of accreditations for specific scopes can be (significantly) higher than the total number of accreditations, counted as the number of issued accreditation certificates (see above item 4.1).

Many years ago, the vast majority of accreditations were related to the non-regulated (voluntary) sector (see below item 4.3). But now, due to the new European Accreditation system established with the Regulation (EC) No 765/2008, the European Commission and the national regulators make more and more use of accreditation. As a consequence, the EA NABs have issued more than 20.000 accreditations in the so-called regulated sector by the end of 2018. That means that the number of accreditations in the regulated sector is comparable with the number of accreditations in the non-regulated sector.

Notes: BELAC didn't provide the total number of accreditations in the regulated sector, but noted that with the exception of calibration laboratories, proficiency test providers and reference material producers, almost all accreditation certificates include a significant part of activities in the regulated sectors.

IPAC didn't provide the total number of accreditations in the regulated sector but estimated that around 75% of the issued accreditations are related to the regulated sector (approximately 600 accreditations).

ISRAC didn't provide the total number of accreditations in the regulated sector.

SA didn't provide the total number of accreditations in the regulated sector but noted that most of Slovenian CABs apply for accreditation (need accreditation) due to legal obligations.

In some regulated sectors, the CABs need to be notified or recognized by the national authorities in order to perform conformity assessment activities. Examples of those regulated sectors are the Union harmonisation legislations and the Comprehensive Economic and Trade Agreement (CETA) between the EU and Canada.

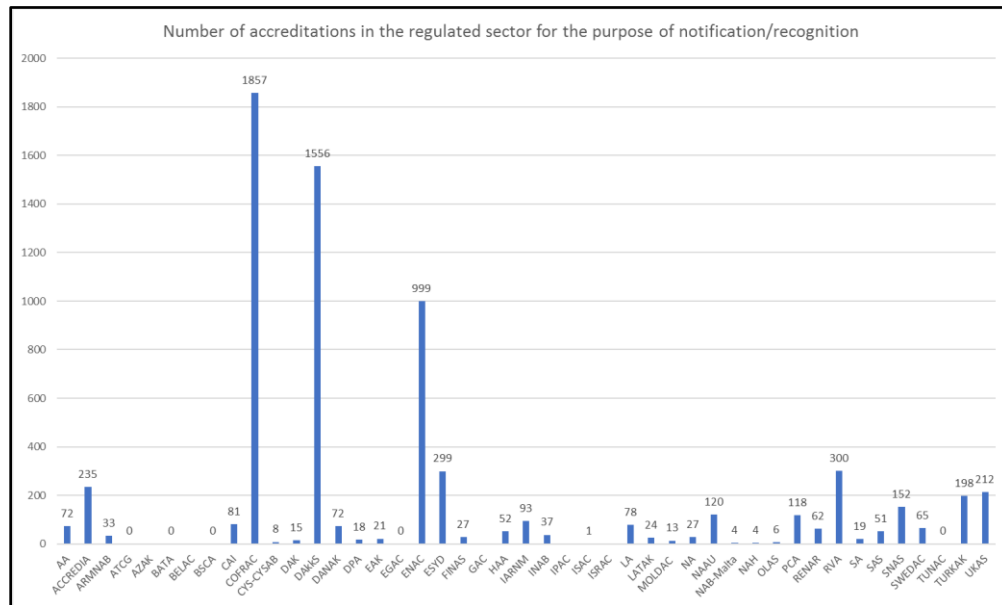
Notified bodies are conformity assessment bodies which have been officially designated by their national authority and notified to the European Commission and the other EU Member States to carry out the procedures for conformity assessment within the meaning of applicable Union harmonisation legislation when a third party is required. They are called 'notified bodies' under EU legislation.

The assessment of a conformity assessment body seeking notification determines if it is technically competent and capable of carrying out the conformity assessment procedures in question, and if it can demonstrate the necessary level of independence, impartiality and integrity.

According to Regulation (EC) No 765/2008, accreditation should be considered by national notifying authorities as the most favored technical basis for the assessment of conformity assessment bodies so as to reduce differences in the criteria applied for notification.

For more information about Notified Bodies see the Blue Guide on the implementation of EU products rules 2016 published in the OJEU C272 Volume 59.

All EU Member States decided to make use of accreditation for notification purposes, but with different extent. In some Member States accreditation is used for notification for one or two Union harmonisation legislations only and consequently there are a couple of accredited notified bodies only. In some other Member States accreditation is used for all legislations and all notified bodies have to demonstrate their competence by accreditation. In general, the number of accredited notified bodies continues to rise.



Notified bodies must be established on the territory of the notifying Member State.

EU and EFTA countries as well as other countries with which the EU has concluded Mutual Recognition Agreements (MRAs) and Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products (PECAs) have designated Notified Bodies for Union harmonisation legislations. That means, that not all EA NABs can be involved in the accreditation of notified bodies. Accordingly, those NABs, mainly EA Associate members, don't have any accredited notified body.

Furthermore, in order to have the benefit of accreditation in the notification process, the accreditation shall be issued by an EA NAB who is signatory to the (relevant) EA Multilateral Agreement for Recognition (MLA). Any other accreditation, including accreditations by non-EA members, are not considered as accreditation in the meaning of Regulation (EC) No 765/2008. If an EA member is not a signatory to the relevant MLA scope, the Member State shall demonstrate that the assessment of the notified body has been performed in a competent manner, similar to the accreditation of an EA NAB signatory to the EA MLA.

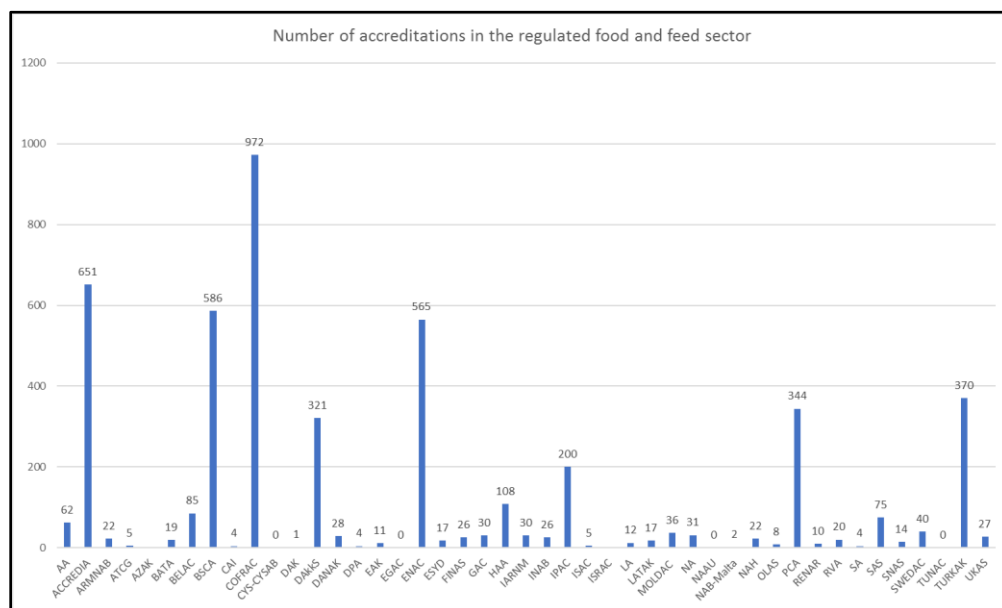
Lists of notified bodies can be searched on the NANDO (New Approach Notified and Designated Organisations) website <https://ec.europa.eu/growth/tools-databases/nando/>.

It is important to emphasize that not all accredited bodies seeking notification or recognition are related to notified bodies. In some countries, there are requirements from the national regulators that the CABs need an official recognition by the national authority in order to perform certain conformity assessment activities under specific national legislations. Those accreditations are also covered in the total number of accreditations - more than 7.000 - in the regulated sector for notification or recognition purposes.

Notes: BELAC noted that the number of accredited notified/recognized bodies would not be available.

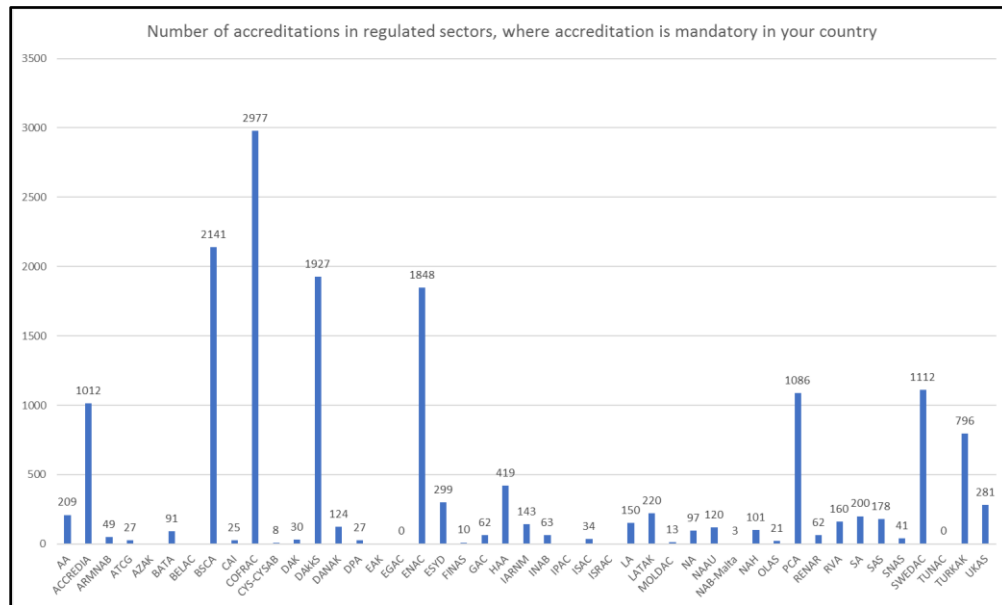
IPAC noted that the number of accredited notified bodies would not be available. But IPAC estimated that more than 95% of the notified bodies are accredited.

The regulated food and feed sector is not covered under the Union harmonisation legislations. But nevertheless, there are different European and national legislations which makes use of accreditation and conformity assessment. One example is the Regulation (EC) NO 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.



Even if the European Commission and national authorities make use of accreditation in legislations as the preferred means to demonstrate the competence of CABs, that doesn't mean that accreditation is mandatory for the CABs. In few cases the national authorities have their own system to demonstrate the CAB's competence, although Regulation (EC) No 765/2008 encourage national authorities to make use of accreditation.

However, in many cases the national authorities prefer to make accreditation mandatory in order to ensure in a harmonized way that the CABs are competent. But on the European level there are also sectors, where accreditation is mandatory. One example is the EU Emissions Trading System (EU ETS) and the related Regulation (EU) 2018/2067 on the verification of data and on the accreditation of verifiers (further information see https://ec.europa.eu/clima/policies/ets_en).



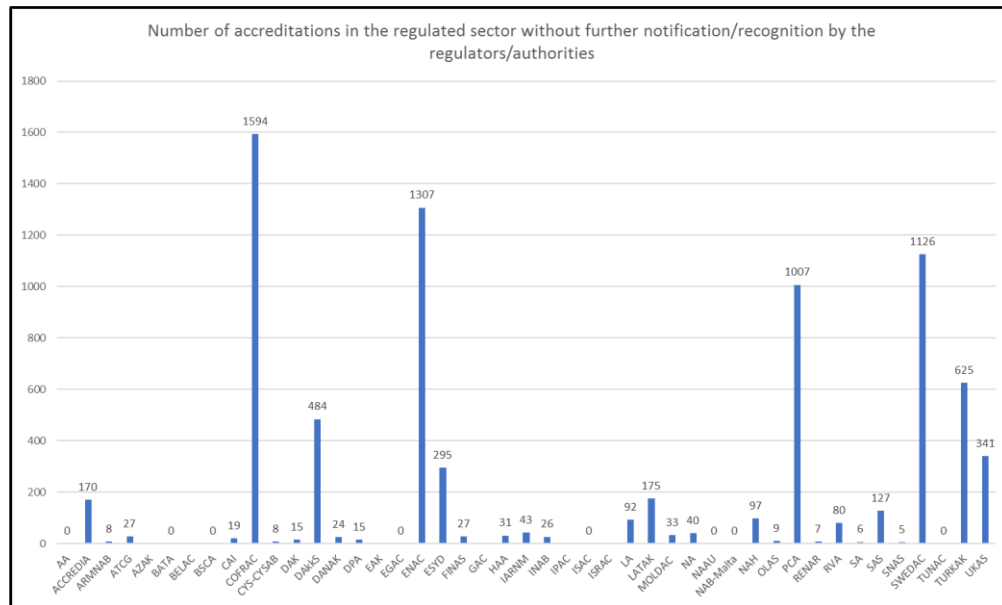
In total, the NABs have issued more than 16.000 accreditations in regulated sectors, where accreditation is mandatory either stipulated by the European Commission or the national authority.

Notes: BELAC noted that the number of mandatory accreditations would not be available.

EAK noted that they don't have this information on mandatory accreditations available.

IPAC noted that the number of mandatory accreditations would not be available. But IPAC estimated that more than 75% of the accreditations are mandatory for the CABs.

Another detail is the number of accreditations in the regulated sector (by the end of 2018) without further notification/recognition by the authorities. In these cases, a CAB can perform the relevant conformity assessment activity under the condition only, that the CAB is accredited by its NAB. But the authorities will accept certificates and reports only, if the certificates and reports are issued by a CAB who is accredited by its NAB signatory to the relevant EA MLA. Examples are the EU ETS (see above) and the General Data Protection Regulation (GDPR).



Notes: BELAC noted that the number of accreditations in the regulated sector without further notification/recognition would not be available.

EAK noted that they don't have this information available.

IPAC noted that the number of mandatory accreditations would not be available. But IPAC estimated that more than 75% of the accreditations would be in the regulated sector without further notification/recognition.

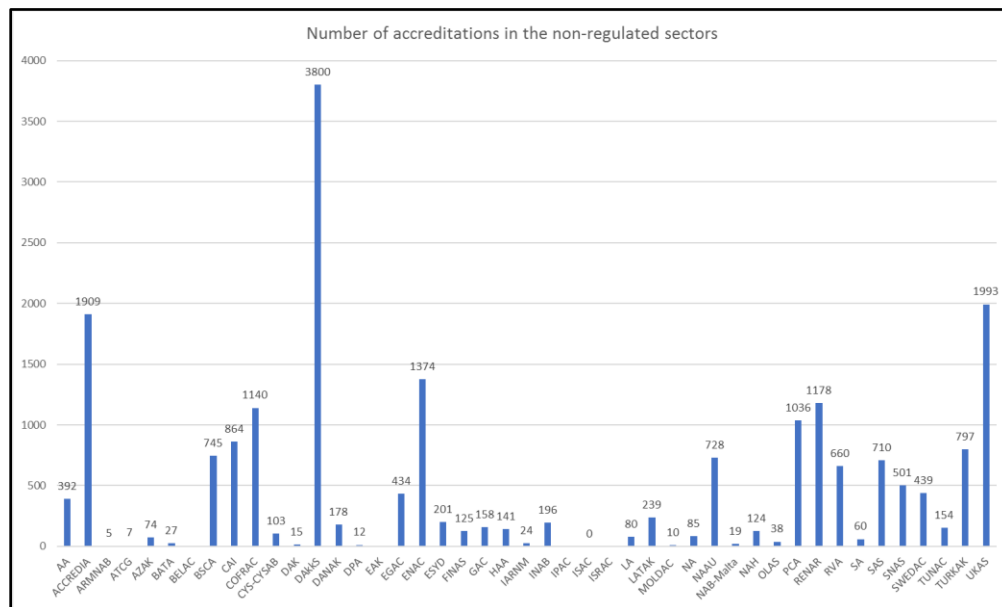
4.3 Number of accreditations in the non-regulated (voluntary) sector by the end of 2018

Regulation (EC) No 765/2008 shall apply to accreditation, used on a compulsory (mandatory) or voluntary basis, relating to conformity assessment, whether that assessment is compulsory or not, and irrespective of the legal status of the body performing the accreditation.

Therefore you can argue, that accreditation in Europe is always in the regulated sector.

However, accreditation is not only for regulators and authorities the preferred means to demonstrate the competence of CABs, but also in the so-called non-regulated sectors - that are the sectors where we don't have a legislation that refers to accreditation - accreditation is important for the (private) market, scheme owners, consumers and other clients of CABs in order to have confidence in certificates and reports and finally in conformity assessment results.

Therefore, in many non-regulated sectors the market requires conformity assessment activities which are underpinned by accreditation.

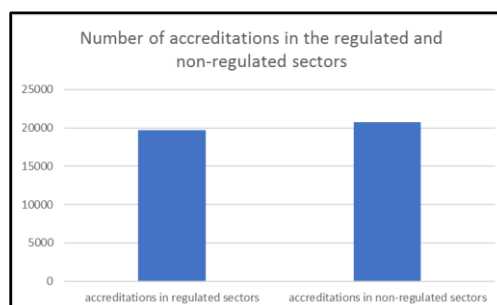


Notes: BELAC noted that with the exception of calibration laboratories, proficiency test providers and reference material producers, almost all accreditation certificates include a significant part of activities in the regulated fields, at the national or European level.

EAK noted that they do not collect such data and do not differ between voluntary and regulated sectors.

IPAC noted that the number of voluntary accreditations would not be available. But IPAC estimated that less than 25% of the accreditations (approximately 180 accreditations) would be issued in the non-regulated sectors.

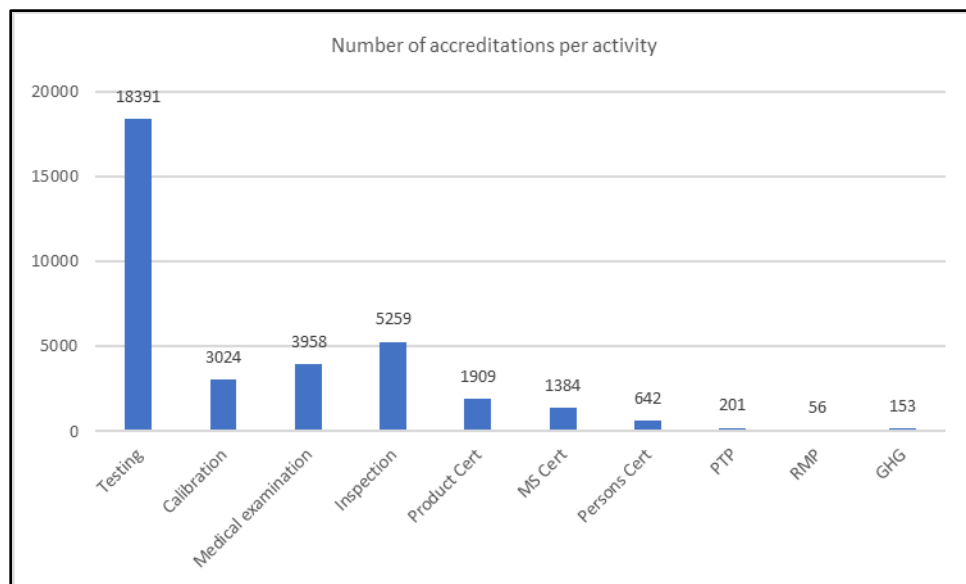
The total number of accreditations in the non-regulated sectors is almost at the same level as the number of accreditations in the regulated sectors. 10 years ago, before Regulation (EC) No 765/2008 came into force, accreditations in the non-regulated sectors overweighed considerably the number of accreditations in the regulated sector.



4.4 Number of accreditations per activity by the end of 2018

Almost 35.000 accreditations have been issued in total by the 45 EA NABs, which responded to the survey (see above item 3).

More than 50% of all accreditations have been issued for testing activities. The lowest number of accreditations have been issued for the activity production of reference materials (RMP).

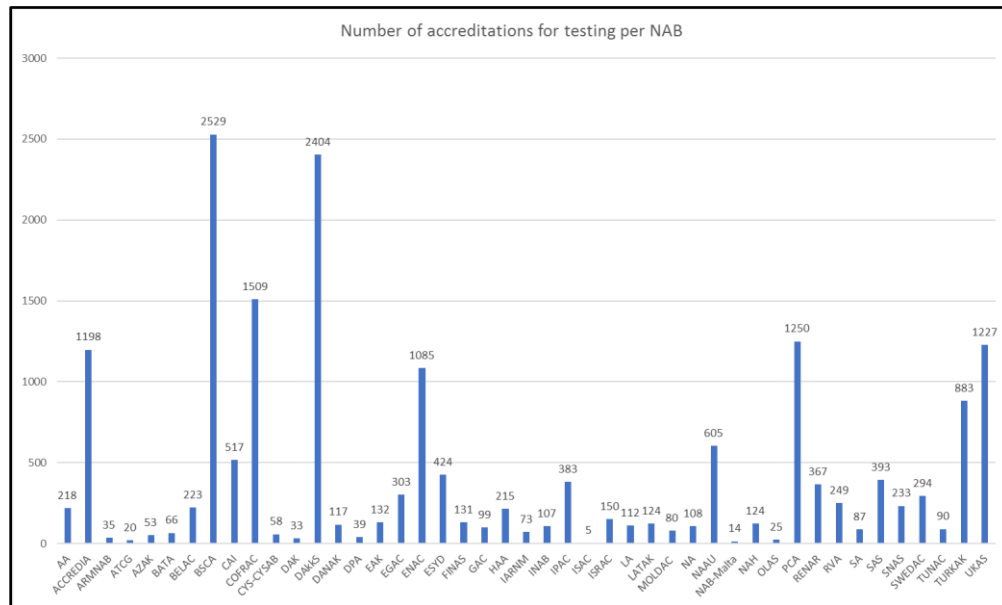


4.4.1 Number of accreditations ISO/IEC 17025 (testing)

The applicable harmonized standard for the accreditation of testing laboratories - bodies performing the conformity assessment activity testing - is ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*.

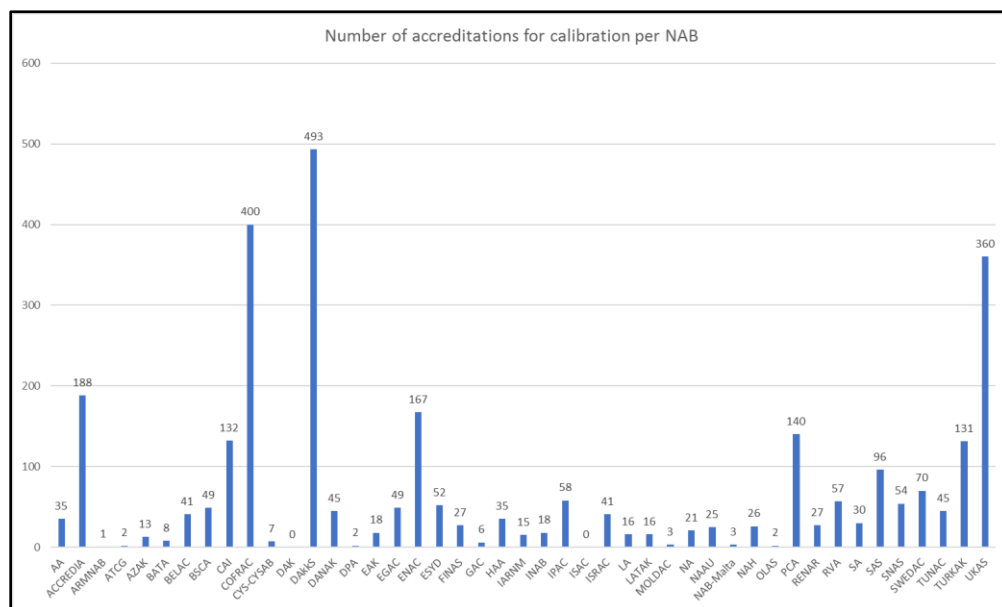
ISO/IEC 17025:2017 specifies the general requirements for the competence, impartiality and consistent operation of laboratories and is applicable to all organizations performing laboratory activities (testing), regardless of the number of personnel.

You find more information about the international standard ISO/IEC 17025:2017 on the ISO website <https://www.iso.org/standard/66912.html>.



4.4.2 Number of accreditations ISO/IEC 17025 (calibration)

ISO/IEC 17025:2017 is the applicable standard also for the accreditation of calibration laboratories. ISO/IEC 17025 includes specific technical requirements relevant for calibration laboratories. That are especially specific requirements regarding the traceability of results to the SI units and the related estimation of the measurement uncertainty.

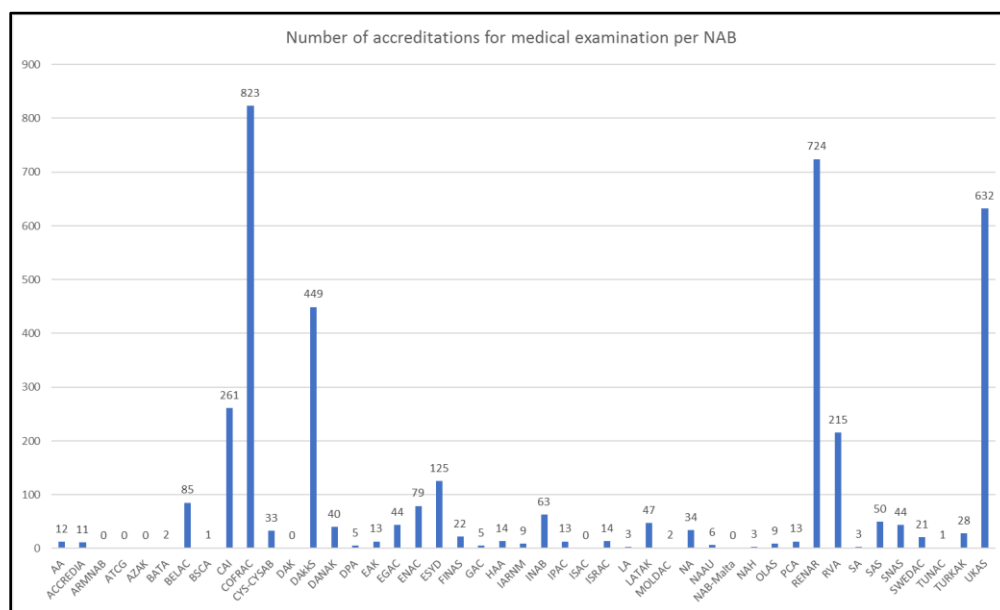


4.4.3 Number of accreditations ISO 15189 (medical examination)

A Medical laboratory performs for the biological, microbiological, immunological, chemical, immuno-haematological, haematological, biophysical, cytological, pathological, genetic or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, management, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation

ISO 15189:2012 specifies the requirements for quality and competence in medical laboratories.

You find more information about the international standard ISO 15189:2012 on the ISO website <https://www.iso.org/standard/56115.html>.

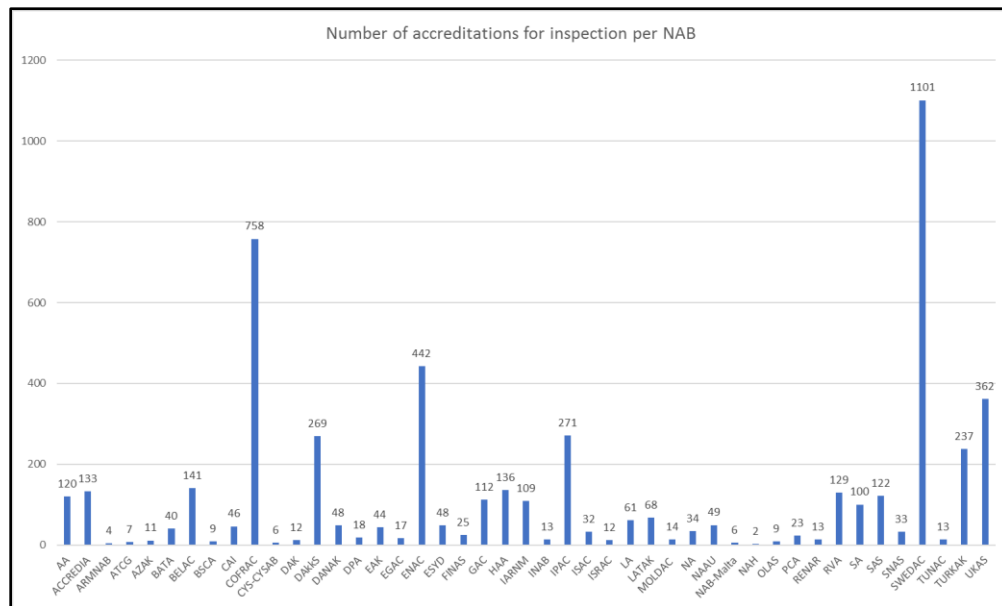


4.4.4 Number of accreditations ISO/IEC 17020 (inspection)

NABs accredit inspection bodies according ISO/IEC 17020:2012 *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*.

This International Standard covers the activities of inspection bodies whose work can include the examination of materials, products, installations, plants, processes, work procedures or services, and the determination of their conformity with requirements and the subsequent reporting of results of these activities to clients and, when required, to authorities.

Inspection can concern all stages during the lifetime of these items, including the design stage. Such work normally requires the exercise of professional judgement in performing inspection, in particular when assessing conformity with general requirements.



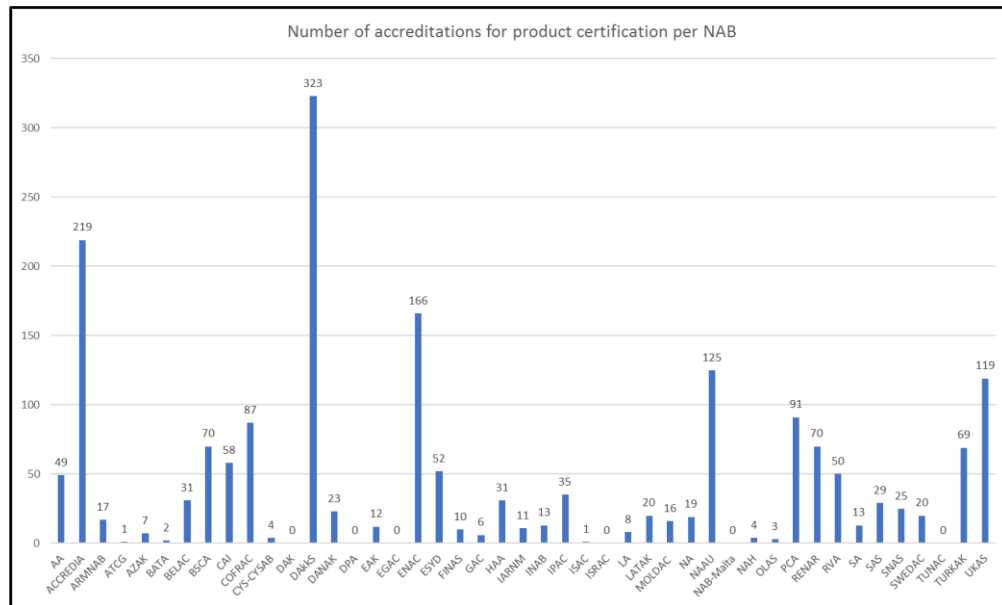
You find more information about the international standard ISO/IEC 17020:2012 on the ISO website <https://www.iso.org/standard/52994.html>.

4.4.5 Number of accreditations ISO/IEC 17065 (product certification)

ISO/IEC 17065:2012 *Conformity assessment - Requirements for bodies certifying products, processes and services* contains requirements for the competence, consistent operation and impartiality of product, process and service certification bodies. Certification bodies operating to this International Standard need not offer all types of products, processes and services certification. Certification of products, processes and services is a third-party conformity assessment activity.

ISO/IEC 17065 is the preferred harmonised standard applied for the accreditation of CABs seeking notification regarding many Union harmonization legislations and related conformity assessment procedures (so-called modules).

You find more details about the preferred harmonized standards for accreditation of CABs seeking notification on EA's website <https://european-accreditation.org/wp-content/uploads/2018/10/ea-accreditation-for-notification-project-afn-final-report-23-sep-16.pdf>.



On the ISO website <https://www.iso.org/standard/46568.html> you find more information about the international standard ISO/IEC 17065:2012.

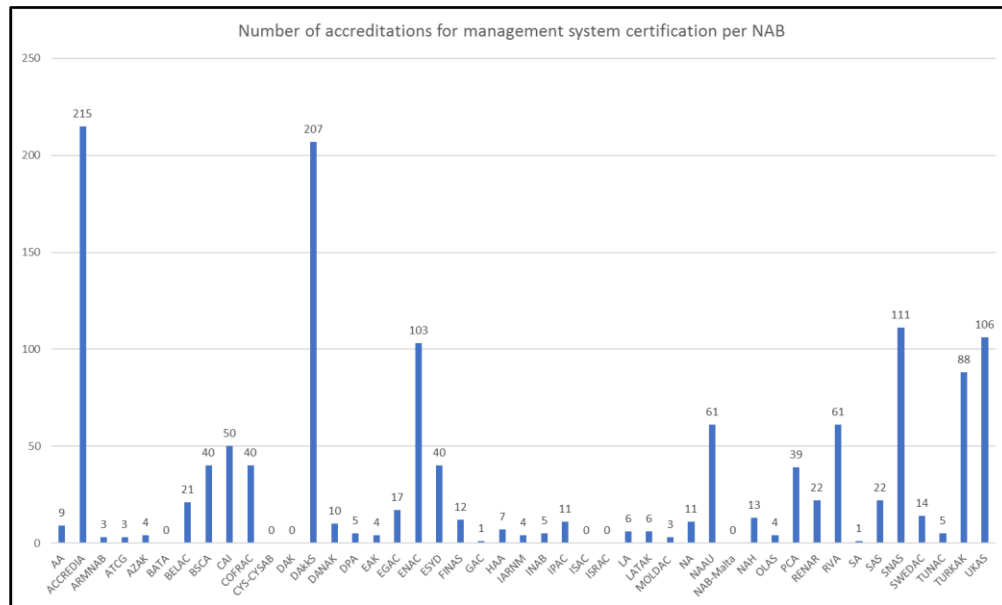
4.4.6 Number of accreditations ISO/IEC 17021-1 (management system certification)

ISO/IEC 17021-1:2015 contains principles and requirements for the competence, consistency and impartiality of bodies providing audit and certification of all types of management systems. Certification bodies operating to ISO/IEC 17021-1:2015 do not need to offer all types of management system certification.

Certification of management systems is a third-party conformity assessment activity and bodies performing this activity are therefore third-party conformity assessment bodies.

One of the worldwide best-known standards is ISO 9001:2015. This international standard sets out the criteria for a quality management system. It can be used by any organization, large or small, regardless of its field of activity. In fact, there are over one million companies and organizations in over 170 countries certified to ISO 9001.

ISO 9001:2015 is based on a number of quality management principles including a strong customer focus, the motivation and implication of top management, the process approach and continual improvement. Using ISO 9001:2015 helps ensure that customers get consistent, good quality products and services, which in turn brings many business benefits.



The number of management system standards has increased enormously in the last 20 years. Certification bodies certify today companies and organizations according environmental, energy, IT security, food and plenty other management system standards.

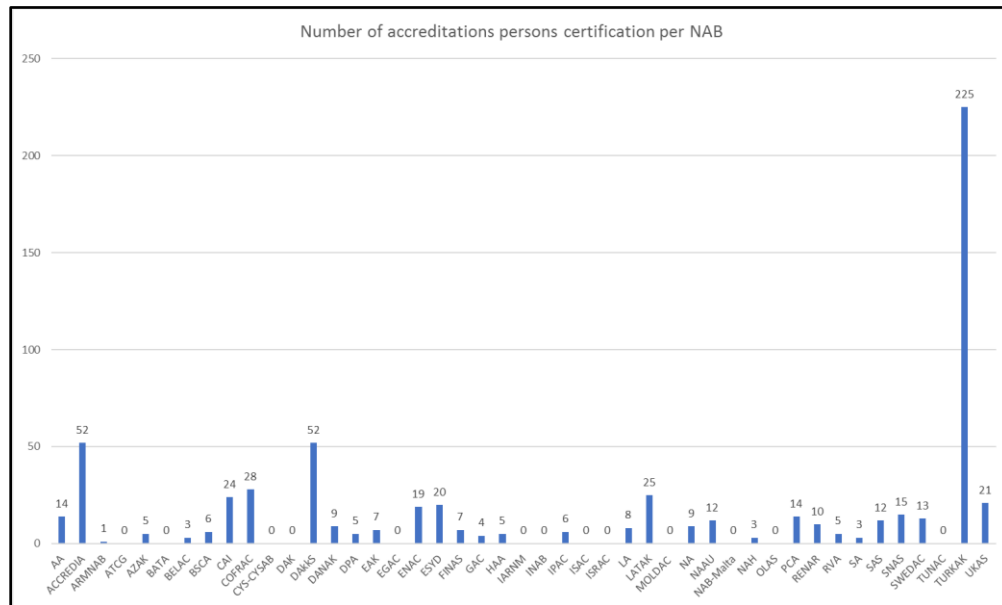
You find more information about the international standard ISO/IEC 17021-1:2015 on the ISO website <https://www.iso.org/standard/61651.html>.

4.4.7 Number of accreditations ISO/IEC 17024 (persons certification)

ISO/IEC 17024:2012 contains principles and requirements for a body certifying persons against specific requirements and includes the development and maintenance of a certification scheme for persons.

The key concepts in certification of persons are

- Identification of the specific tasks and the related knowledge, skills and abilities (competencies) required to perform a job;
- Systems to assess whether an individual possesses these competencies; and
- Independent third-party verification to the public that an individual has successfully demonstrated he/she possesses the defined competencies.



More information about certification of persons see

https://www.unido.org/sites/default/files/files/2018-07/Guidelines_on_Conformity_Assessment.pdf
and <https://www.iso.org/standard/52993.html>.

4.4.8 Number of accreditations ISO/IEC 17043 (proficiency testing providers)

ISO/IEC 17043:2010 specifies general requirements for the competence of providers of proficiency testing schemes and for the development and operation of proficiency testing schemes. These requirements are intended to be general for all types of proficiency testing schemes, and they can be used as a basis for specific technical requirements for particular fields of application.

According ISO/IEC 17043 proficiency testing is defined as the evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

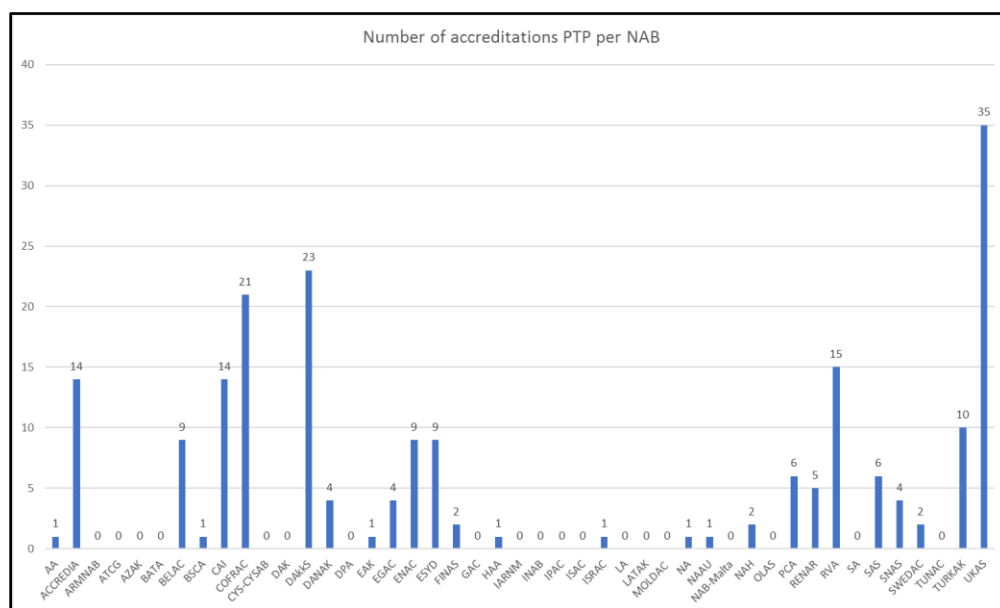
For the purposes of this International Standard, the term “proficiency testing” is taken in its widest sense and includes, but is not limited to:

- quantitative scheme - where the objective is to quantify one or more measurands of the proficiency test item;
- qualitative scheme - where the objective is to identify or describe one or more characteristics of the proficiency test item;
- sequential scheme - where one or more proficiency test items are distributed sequentially for testing or measurement and returned to the proficiency testing provider at intervals;
- simultaneous scheme - where proficiency test items are distributed for concurrent testing or measurement within a defined time period;
- single occasion exercise - where proficiency test items are provided on a single occasion;

- f) continuous scheme - where proficiency test items are provided at regular intervals;
- g) sampling - where samples are taken for subsequent analysis; and
- h) data transformation and interpretation - where sets of data or other information are furnished and the information is processed to provide an interpretation (or other outcome).

Some providers of proficiency testing in the medical area use the term “External Quality Assessment (EQA)” for their proficiency testing schemes, or for their broader programmes, or both. The requirements of ISO/IEC 17043 cover only those EQA activities that meet the definition of proficiency testing.

Types of proficiency testing schemes are described in Annex A of ISO/IEC 17043.



You find more information about ISO/IEC 17043:2010 on the ISO website

<https://www.iso.org/standard/29366.html>.

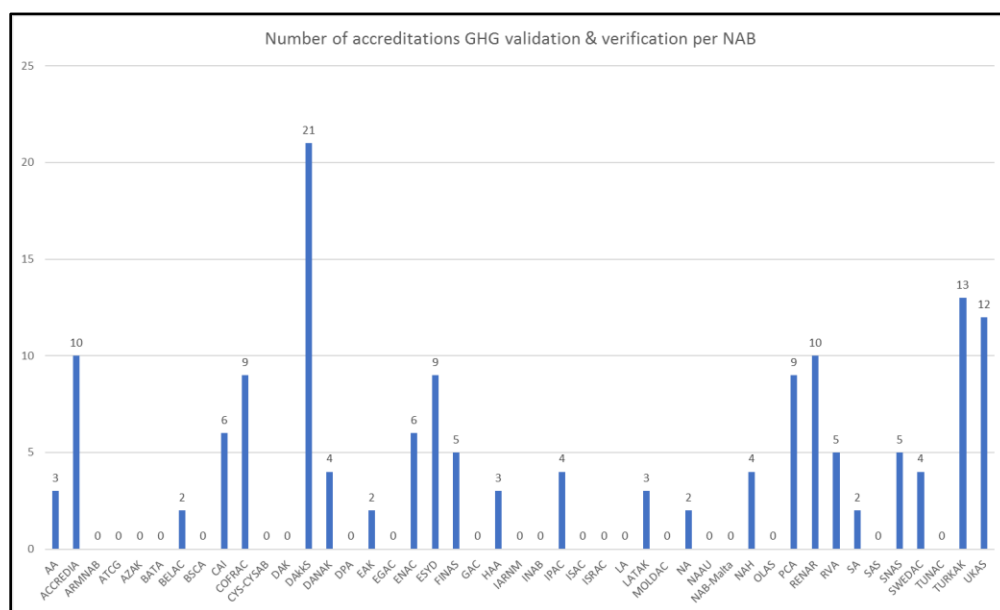
4.4.9 Number of accreditations ISO 17034 (reference material producers)

ISO 17034:2016 specifies general requirements for the competence and consistent operation of reference material producers. The International Standard sets out the requirements in accordance with which reference materials are produced. It is intended to be used as part of the general quality assurance procedures of the reference material producer. ISO 17034:2016 covers the production of all reference materials, including certified reference materials.

The EU ETS is such a specific GHG trading scheme/ programme, and the AVR (Commission Regulation No. 600/2012 of 21 June 2012 on the verification of greenhouse gas emission reports and tonne-kilometre reports and the accreditation of verifiers pursuant to Directive 2003/87/EC) contains the EU ETS specific requirements on the verification process as well as on the competence and impartiality of the different parties involved in the verification.

You find more information on the AVR and the relation to ISO 14065 under

https://ec.europa.eu/clima/sites/clima/files/ets/monitoring/docs/kgn_8_relation_avr_iso_14065_en.pdf



Due to the fact that the EU ETS is the most important GHG trading scheme and applies to EU Member States, all accreditations in this sector are delivered by EA Full members.

You find more information about EU ETS under the accreditation of verifiers on the European Commission's website https://ec.europa.eu/clima/policies/ets/monitoring_en.

For more information to ISO 14065:2013 see <https://www.iso.org/standard/60168.html>.

4.5 Main sector/legislations

Many years ago, the first accreditations of CABs were mainly related to testing and calibration in sectors like environment, food and material testing. Nowadays CABs being accredited in almost all sectors and for all products, including processes and services. New examples are data protection, cybersecurity or GHG validation & verification.

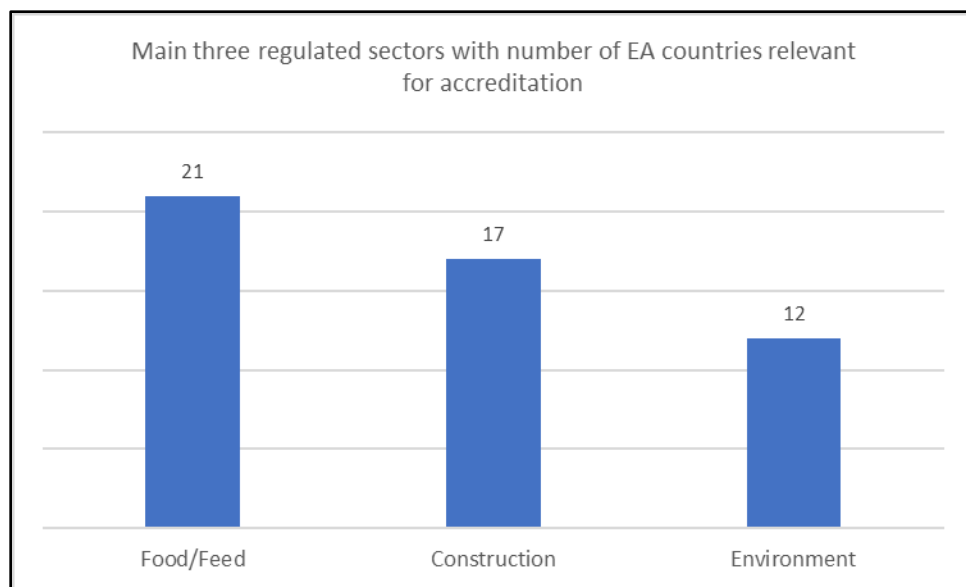
That demonstrates the acceptance of accreditation, especially the accreditation system in Europe.

4.5.1 Regulated sectors with the most numbers of accreditations

The use of accreditation in the regulated sectors varies significantly between the countries (see also above 4.2). In some countries the national authorities take recourse to accreditation for almost all sectors where CABs shall demonstrate their competence. In other countries the national authorities are performing the assessment of CABs by themselves, with the negative impact that in these cases the authorities shall demonstrate that their assessment is equal reliable as accreditation by the NABs.

Accordingly, it may happen, that in some countries the national authorities take recourse to accreditation in specific sectors (legislations), where the regulators in other countries do not use accreditation.

The European Commission and/or the national regulators make use of accreditation mainly in the Food/Feed, Construction and Environment sectors.



In the following table you find the three regulated sectors per National Accreditation Body (NAB) with the highest numbers of accreditations.

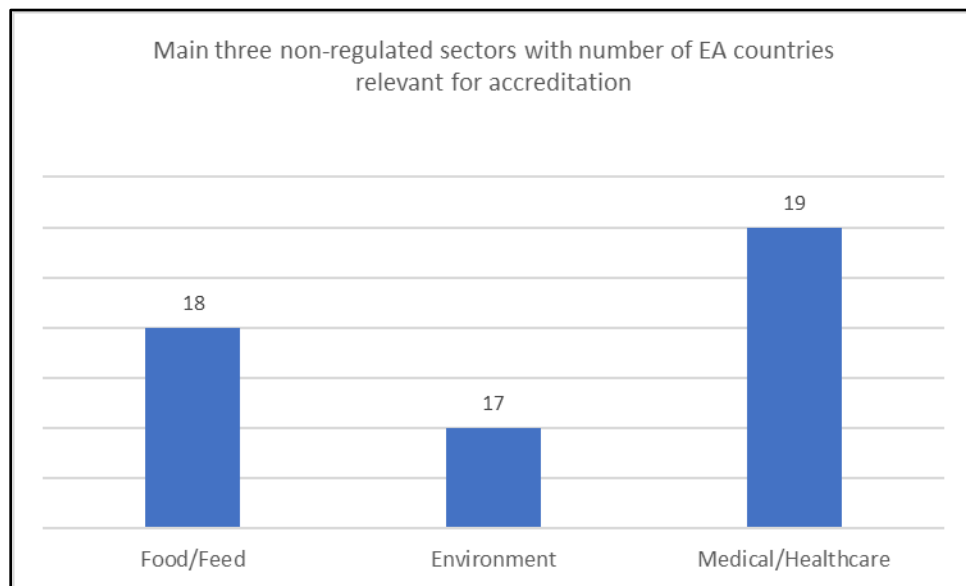
NAB	Main regulated sector 1 (Number of accreditations, if provided)	Main regulated sector 2 (Number of accreditations, if provided)	Main regulated sector 3 (Number of accreditations, if provided)
AA	Food/Feed (37)	Construction (34)	Hygiene bath (29)
ACCREDIA	Elevators (100)	food testing (800)	Food designation of origin (34)
ARMNAB	Food/Feed	Electrical equipment	
ATCG	Food	Environment	Construction
AZAK			
BATA	Legal metrology	Environment	Food/Feed
BELAC	Food (85)	Medical testing (85)	Construction (52)
BSCA	Food	Environment	Workplace safety
CAI	Construction (15)	Machinery (1)	
COFRAC	Medical examination (799)	Water analysis (245)	Legal metrology (189)
CYS-CYSAB	Lifts (2)	Transportable Pressure Equipment (1)	Construction (2)
DAK	Lifts	Oil	
DAkKS	Drinking water	Environment	Construction
DANAK	Construction	Environment	Measuring instruments
DPA	Pressure Equipment	Lifts	Electrical systems
EAK	Electrical safety (50)	Construction (8)	Welding (17)
EGAC			
ENAC	Safety of industrial products and installations (132)	Food (483)	Car inspection (102)
ESYD	Lifts	Pressure Vessels	Hotels/Apartments
FINAS	Pressure Equipment	Construction	Health building
GAC	Food	Car inspection	Lifts
HAA	Feed (52)	Legal metrology (41)	Food (40)
IARNM	Inspection of analog and digital tachographs	Food/Feed	Car inspection
INAB	Traceability of blood and blood products	Construction	Food/Feed
IPAC	Car inspection	Environment	Food
ISAC	Vehicle (3)	Ship inspections (3)	Electrical inspections (3)
ISRAC	Food	Environment	Construction
LA	Construction	Transport	Legal metrology
LATAK	Environment	Food	Measuring instruments
MOLDAC	Food (8)	Construction (7)	Industrial products (6)
NA	Food and drinking water (33)	Pressure Equipment (17)	Fish farming (15)
NAAU	Machinery	Low-voltage equipment	Road vehicles
NAB-Malta	Lifts inspection		
NAH	Environment	Drinking water	Food/Feed
OLAS	Food/Feed (8)	Medical examinations (6)	Occupational safety & health (5)
PCA	Occupational safety and health	Environment	Food
RENAR	Construction	Pressure Equipment	GHG
RvA	Legionella in water (40)	Soil environment (32)	Construction (27)
SA	Legal metrology (37)	Pressure Equipment (27)	Transport (24)

SAS	Technical safety (70)	Food/Feed (75)	Health, Medical (85)
SNAS	Emissions (29)	Metrology (14)	Pressure Equipment (10)
SWEDAC	Car inspection	Pressurization with Gas	Tank inspection
TUNAC			
TURKAK	Lifts	Food	Construction
UKAS	Forensics (70)	Construction (59)	Transportable Pressure Equipment (32)

4.5.2 Non-regulated sectors with the most numbers of accreditations

Food/Feed, environment and medical/healthcare are the non-regulated sectors with the highest number of accreditations.

Food/Feed and medical/healthcare are those sectors with the highest number of accreditations in the regulated sectors too. That means that accreditation is used in both sectors to a high extent. It also demonstrates that there are many CABs (mainly laboratories) in these sectors offering their services to the market and the regulated and non-regulated market requires accredited CABs.



In the following table you find the three non-regulated sectors per National Accreditation Body (NAB) with the highest numbers of accreditations.

NAB	Main non-regulated sector 1 (Number of accreditations, if provided)	Main non-regulated sector 2 (Number of accreditations, if provided)	Main non-regulated sector 3 (Number of accreditations, if provided)
AA	Environment	Food	Construction
ACCREDIA	Environment (600)	Mechanical (100)	Textile (40)
ARMNAB	Calibration	Management systems	Personal
ATCG	Pressure vessel in use	Safety valve	Electrical installation
AZAK			
BATA	Mechanical testing	Textile and leather	Medical examination
BELAC			
BSCA	Electric Testing	Optical testing	
CAI	Healthcare (250)	Water (158)	Construction (104)
COFRAC	Temperature calibration (73)	Metallic material testing (70)	Testing petroleum products (47)
CYS-CYSAB	Medical	Chemical	Microbiology
DAK	Construction	Water	
DAKKS	Environmental analysis	Food analysis	Medical diagnostics
DANAK	Calibration	Healthcare	Tailing
DPA	Environment	Food	Fuels
EAK	Medical examination (13)		
EGAC	Food	Water	Pharmaceuticals
ENAC	Food (246)	Environment (309)	Industrial products (324)
ESYD	Food	Environment	Healthcare/Medical
FINAS	Environment	Food	
GAC	Food	Environment	Medical examinations
HAA	Calibration (37)	Construction (25)	Medical examinations (14)
IARNM	Low voltage electrical installations	Textile	Fuels and Engine Coolants
INAB	Healthcare (250)	Veterinary testing	
IPAC	Environment/Noise	Engineering materials	Mass & pressure calibration
ISAC			
ISRAC	Calibration	Medical	Electricity
LA	Construction	Road tests	Healthcare
LATAK	Medical examination	Environmental testing	Food testing
MOLDAC	Food (5)	Construction (7)	Electric products (3)
NA	Medical examination (38)	Physical testing (21)	
NAAU	Food	Perfumes and cosmetics	Construction
NAB-Malta	Construction	Fuel testing	Food
NAH	Environment	Drinking water	Food/Feed
OLAS	Medical analysis (10)	Industrial products (9)	Environment (8)
PCA	Food	Environment	Mechanical
RENAR	Medical examination	Food	Construction
RvA	Healthcare (223)	ISO 9001 certification (48)	Occupational health, safety management system certification (35)
SA	Mechanical testing (17)	Microbiology (10)	Medical examination (3)
SAS	Construction (126)	Calibration (96)	Health/Medical (85)

SNAS	Environment (40)	Health (54)	Food/Feed (33)
SWEDAC	Environment	Healthcare/Medical	Calibration
TUNAC	Food	Environment	Textile
TURKAK	Chemistry	Electricity	Mechanical
UKAS	Healthcare (741)	Construction (404)	Food/Feed (205)

4.5.3 Sectors/areas where NABs do not have know-how

Accreditation is used in all regulated and non-regulated sectors/areas where the competence of CABs shall be demonstrated.

According Regulation (EC) No 765/2008 a CAB shall apply for accreditation by its NAB due to the principle that a NAB shall not compete with other NABs. However, a CAB may request accreditation by another NAB in any one of the following situations:

- (a) where the Member State in which it is established has decided not to establish a national accreditation body and has not had recourse to the national accreditation body of another Member State;
- (b) where the NABs do not perform accreditation in respect of the conformity assessment activities for which accreditation is sought;
- (c) where the NABs have not successfully undergone peer evaluation by EA in respect of the conformity assessment activities for which accreditation is sought.

These principles of non-competition and cross-border accreditation have been implemented in EA policies in order to make these principles mandatory for all EA members, including those which are not directly concerned by Regulation (EC) No 765/2008.

Normally, the NABs try to provide all services to their CABs by themselves and to build up the competence needed according Regulation (EC) No 765/2008, ISO/IEC 17011 and EA policies. That includes the competence for the accreditation of notified bodies according the Union harmonization legislations.

In some cases, there is an exchange of (technical) assessors in order to support other EA NABs in order to enable the local NAB to perform the assessment and to make the accreditation decision.

But there are some NABs, in particular from small Member States, which do not offer the accreditation of CABs for all relevant scopes. In those cases, the CAB can apply by another NAB for accreditation (see above).

Ireland is the only Member State who takes recourse to another NAB (RvA) for a specific scope of accreditation (ISO 14065 / EU ETS). INAB was successfully peer evaluated and accordingly signatory of the MLA for this scope, but due to no verifiers in Ireland INAB decided to withdraw from the MLA. However, as a result of Brexit, INAB will now offer this scope for accreditation and relies on another NAB for a period of 3 years to allow time to be evaluated for the EA MLA again.

4.6 Suspension/withdrawal of accreditation

The accredited CABs have to demonstrate on a permanent basis their competence to the NABs by providing evidence that they comply with the rules for accreditation (see above).

The accreditation shall be suspended, withdrawn or reduced when an accredited CAB has failed to meet the requirements of accreditation or to abide the rules for accreditation or has voluntarily requested a suspension, withdrawal or reduction.

Definition of reducing accreditation (ISO/IEC 17011:2017, clause 3.17)

Cancelling part of the scope of accreditation.

Definition of suspending accreditation (ISO/IEC 17011:2017, clause 3.18)

Putting temporary restrictions in place for all or part of the scope of accreditation.

Definition of withdrawing accreditation (ISO/IEC 17011:2017, clause 3.19)

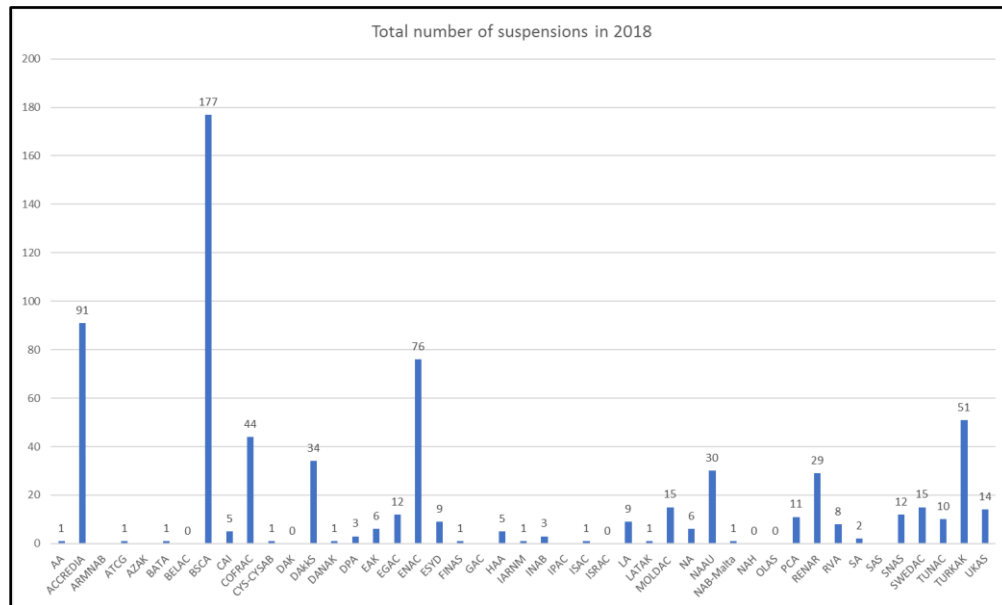
Cancelling accreditation for the full scope.

In case that a CAB doesn't meet the requirements for specific technical activities (scopes), then the scope for accreditation shall be reduced and the CAB cannot claim accreditation for this scope as long as the reason for this reduction has been solved and the NAB has decided to include this scope again in the scope for accreditation. The reduction of scopes takes place more often than the complete suspension or withdrawal of accreditation. But the reduction of scopes was not subject of this survey.

The number of suspensions/withdrawals should be compared in relation to the number of issued accreditations. Normally, NABs that have issued many accreditations may have more suspensions/withdrawals than NABs with a low number of accreditations.

4.6.1 Number of accreditations which have been (completely) suspended in 2018

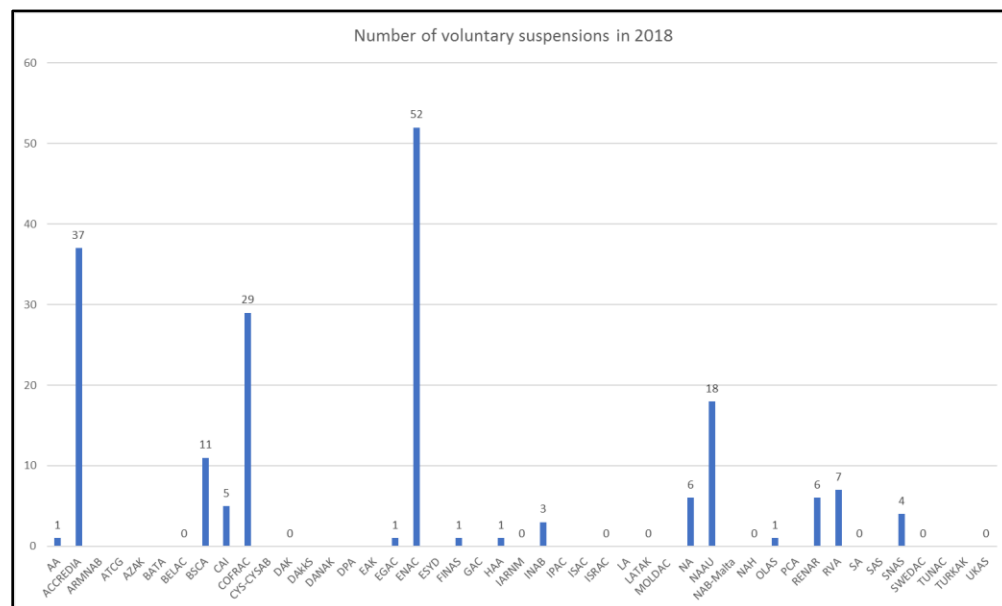
In 2018, 687 accreditations have been suspended. That's around 2% of all issued accreditations.



5 NABs were not able to provide numbers about suspension of accreditations.

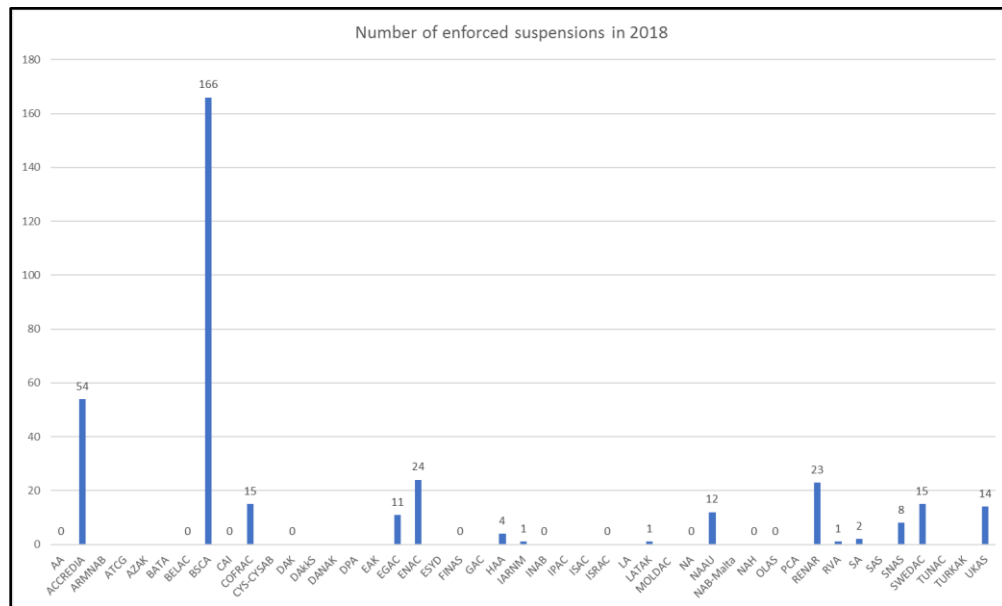
The suspension of a CAB can be initiated voluntary by the CAB itself or enforced by the NAB. The reasons for the voluntary suspension of the accreditation by the CABs themselves can be very different. Examples are:

- temporarily stop of the conformity assessment activity,
- change of personnel,
- economic problems.



183 accreditations have been suspended in 2018 based on the request by the CABs.

20 NABs were not able to provide numbers about voluntary and enforced suspensions. Accordingly, the numbers of voluntary and enforced suspensions are lower than the total number of suspensions.



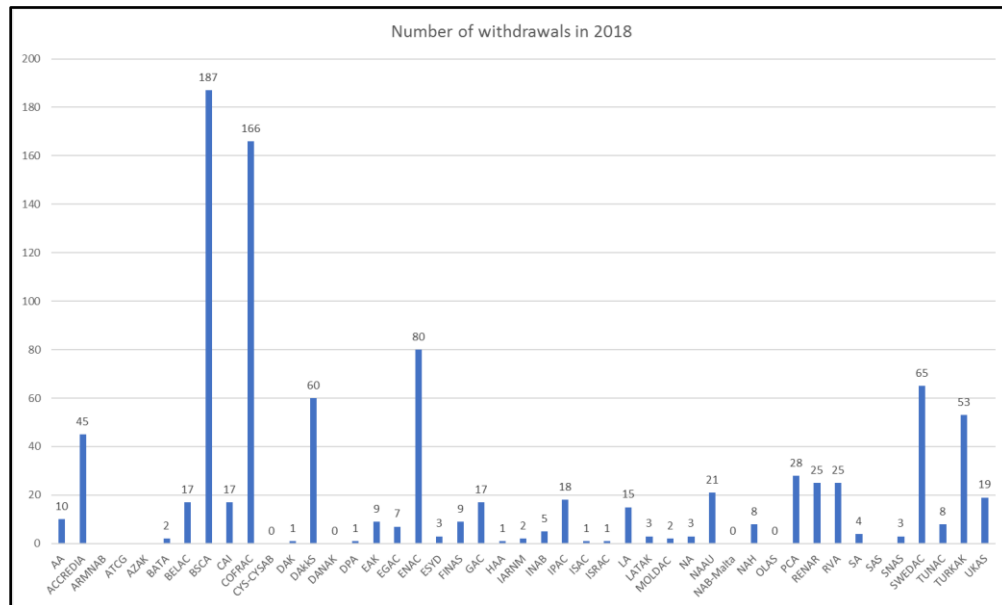
In 2018, there are 351 enforced suspensions of accreditation. Examples of reasons for enforced suspensions are:

- Lack of technical competence,
- Non-closure of non-conformities,
- Negative results in Interlaboratory Comparisons,
- Non-payment of fees.

Around 1% of all issued accreditations have been suspended in 2018, enforced by the NABs.

4.6.2 Number of accreditations which have been (completely) withdrawn in 2018

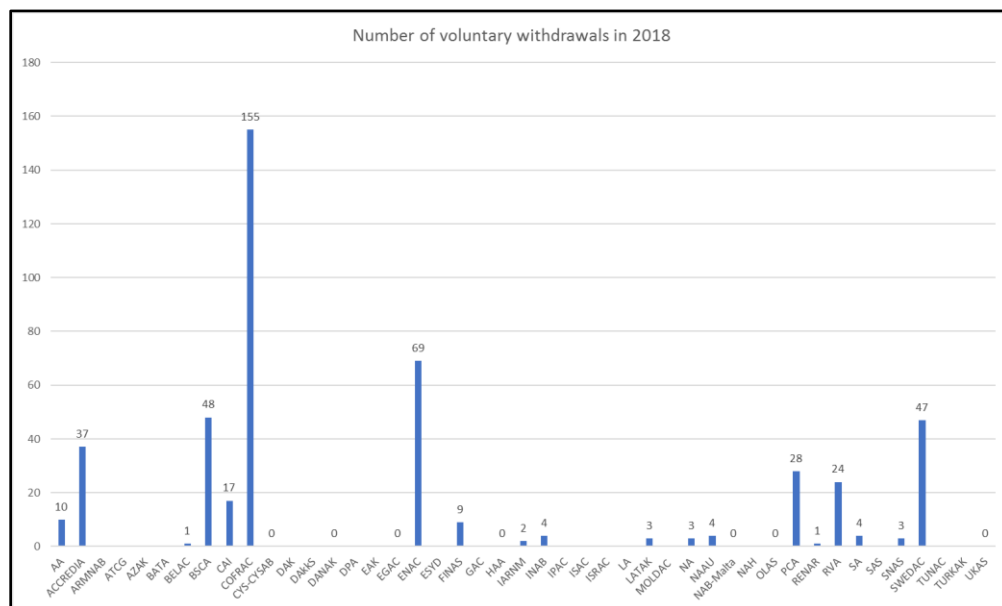
In 2018, 941 accreditations have been withdrawn. That's more than 2% of all issued accreditations.



4 NABs were not able to provide numbers about withdrawals of accreditations.

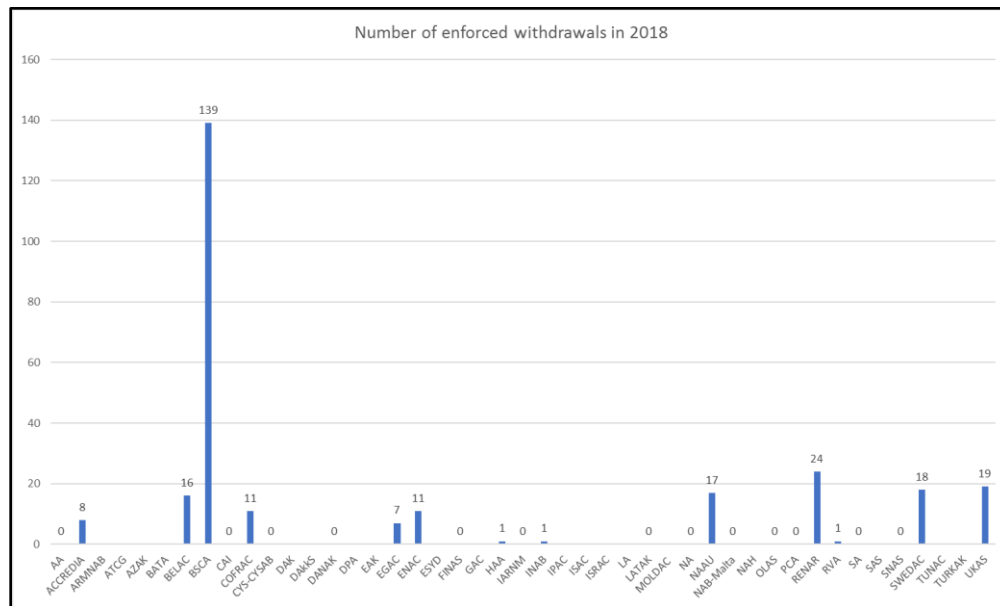
The withdrawal of the CAB's accreditation can also be initiated voluntarily by the CAB itself or enforced by the NAB. The reasons for the voluntary withdrawal of the accreditation by the CABs themselves can be very different. Examples are:

- merger of CABs and transfer of accreditation,
- bankruptcy,
- economic problems.



469 accreditations have been withdrawn in 2018 based on the request by the CABs.

19 NABs were not able to provide numbers about voluntary and enforced withdrawals. Accordingly, the numbers of voluntary and enforced withdrawals are lower than the total number of suspensions.



In 2018, there are 273 enforced withdrawals of accreditation. Examples of reasons for enforced withdrawals are:

- exceeding the maximum time of the suspension period,
- Ongoing non-closure of non-conformities,
- Negative results in Interlaboratory Comparisons,
- Non-payment of fees.

Summarizing the numbers of suspension and withdrawals, 1628 accreditations have been suspended and/or withdrawn in 2018. That are around 4.5 % of all issued accreditations.

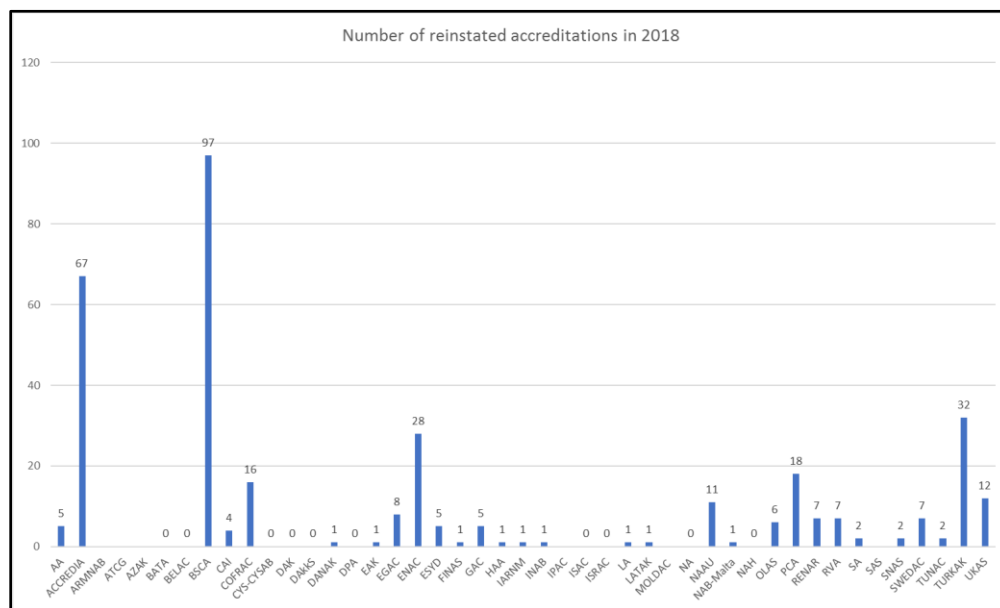
At least 624 suspensions and withdrawals have been enforced by the NABs, considering that not all NABs were able to provide numbers about voluntary and enforced withdrawals of accreditation.

4.6.3 Number of accreditations which have been reinstated (lifting suspension/withdrawal) in 2018

In case that the accreditation is withdrawn, the CAB shall normally apply for a new accreditation to its NAB. A suspended accreditation can be reinstated, if the CAB can demonstrate that the reasons for the suspension have been solved and the CAB meets the accreditation requirements.

Depending from the suspension date, the lifting of the suspension can take place the following year. That means that an accreditation suspended in 2017 can be lifted in 2018.

In 2018, 350 accreditations have been reinstated. With the assumption that the number of suspensions/withdrawals but also the number of reinstated accreditations would be evenly spread over the years, then around more than 1300 suspended/withdrawn accreditations 2018 will not be reinstated.



4.7 Complaints/Appeals

Definition of complaint (ISO/IEC 17011:2017, clause 3.20)

Expression of dissatisfaction, other than appeal (see below), by any person or organization, to an accreditation body, relating to the activities of that accreditation body or of an accredited conformity assessment body, where a response is expected.

Definition of appeal (ISO/IEC 17011:2017, clause 3.21)

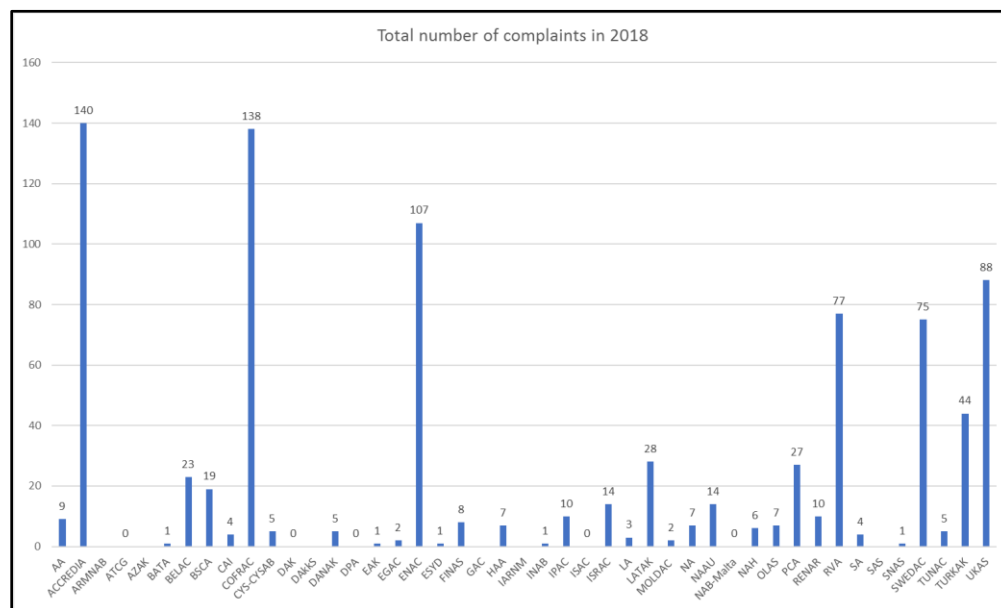
Request by a conformity assessment body for reconsideration of any adverse accreditation decision related to its desired accreditation status.

According ISO/IEC 17011, the NAB shall implement procedures for the handling of complaints and appeals. The description of the handling processes for complaints and appeals shall be available to any interested party.

4.7.1 Complaints

897 complaints have been received by 39 NABs. 6 NABs were not able to provide the information about complaints.

The number of complaints per NAB must be compared in relation to the number of accreditations that has been issued by this NAB. It is obvious, that those NABs which have issued many accreditations may receive more complaints than those NABs with a low number of accreditations.

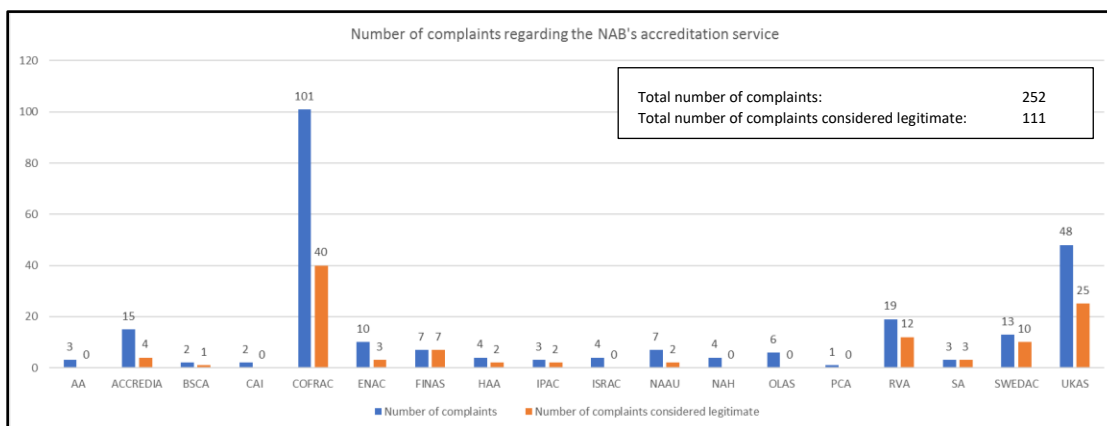
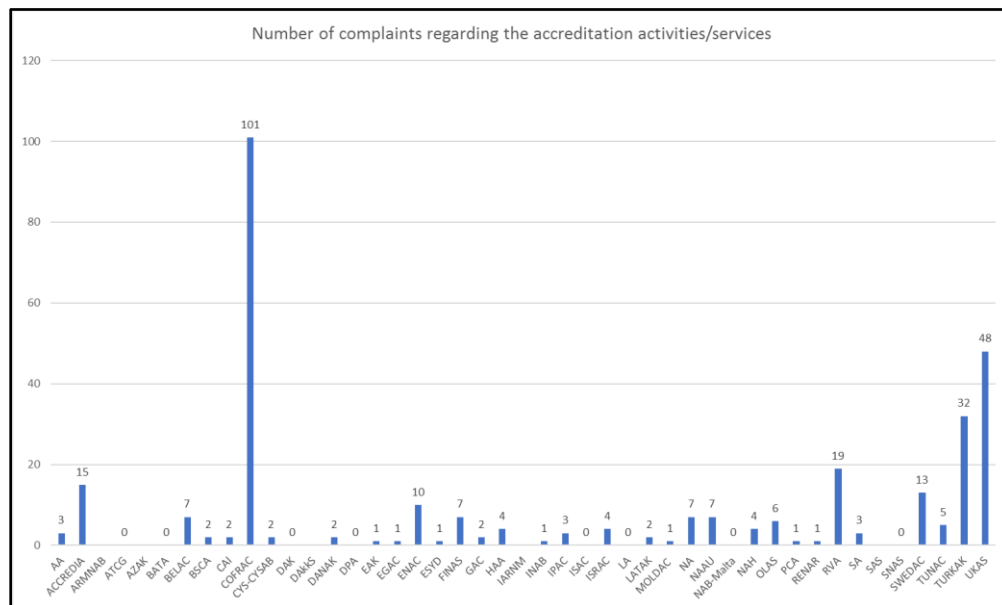


16 NABs reported also the number of (total) complaints considered as legitimate. In total 328 complaints have been graded by these 16 NABs as legitimate.

According the definition, a complaint is the expression of dissatisfaction to an accreditation body relating to the activities of that accreditation body or of an accredited conformity assessment body, where a response is expected.

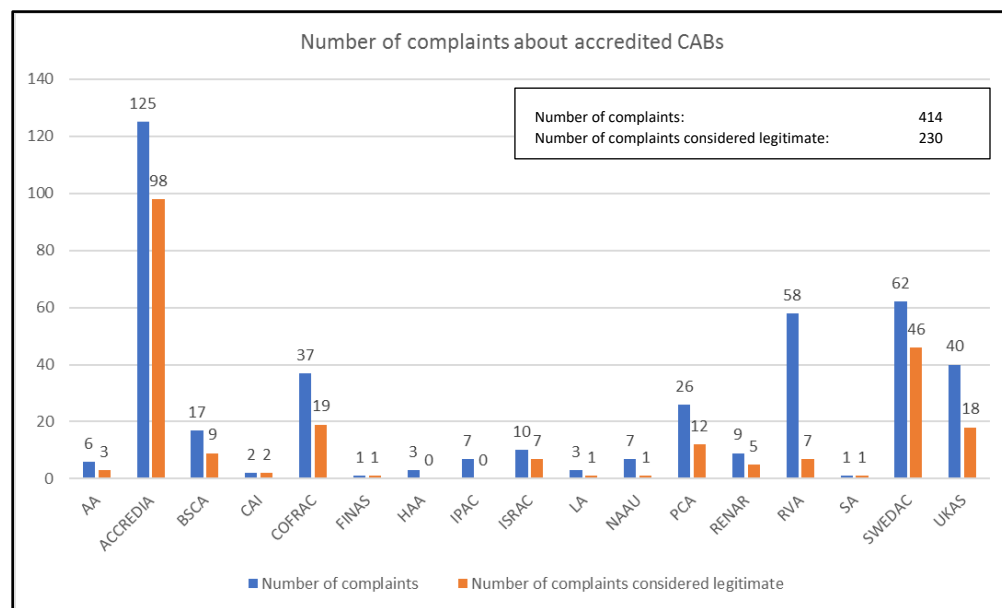
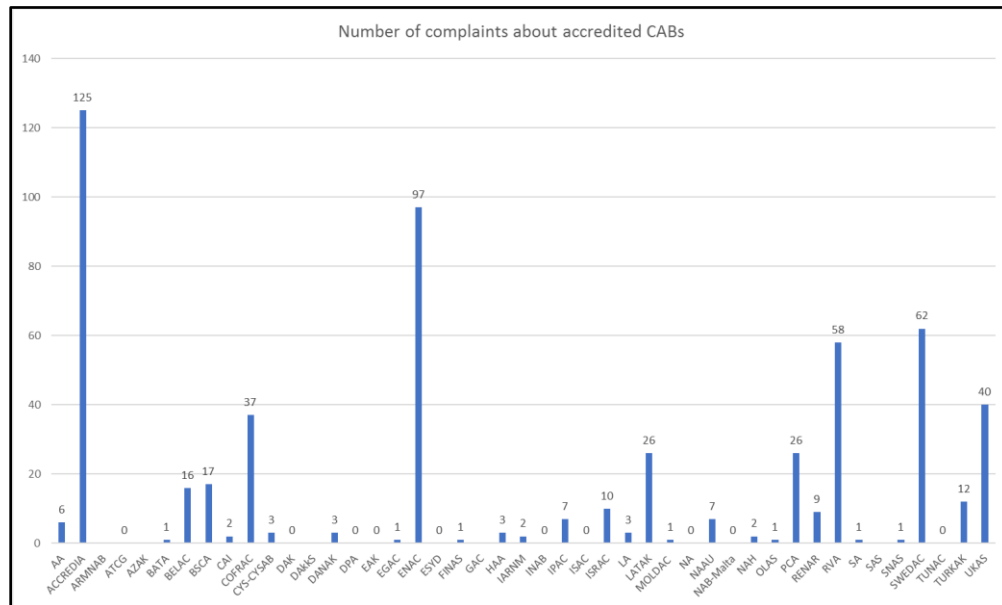
That means that some complaints are related to the NABs and their activities/services, and others to the accredited conformity assessment bodies.

317 complaints have been received regarding the accreditation activity/service of the NABs. That are around 30 % of all complaints received.



18 NABs have additionally provided the number of complaints, which have been graded as legitimate. From these NABs, 111 complaints (out of 252) have been considered as legitimate.

26 NABs reported that they have received 580 complaints about accredited CABs in 2018. 17 NABs have provided additionally the number complaints about accredited CABs, which have been graded as legitimate. From these NABs, 230 complaints (out of 414) have been considered as legitimate.

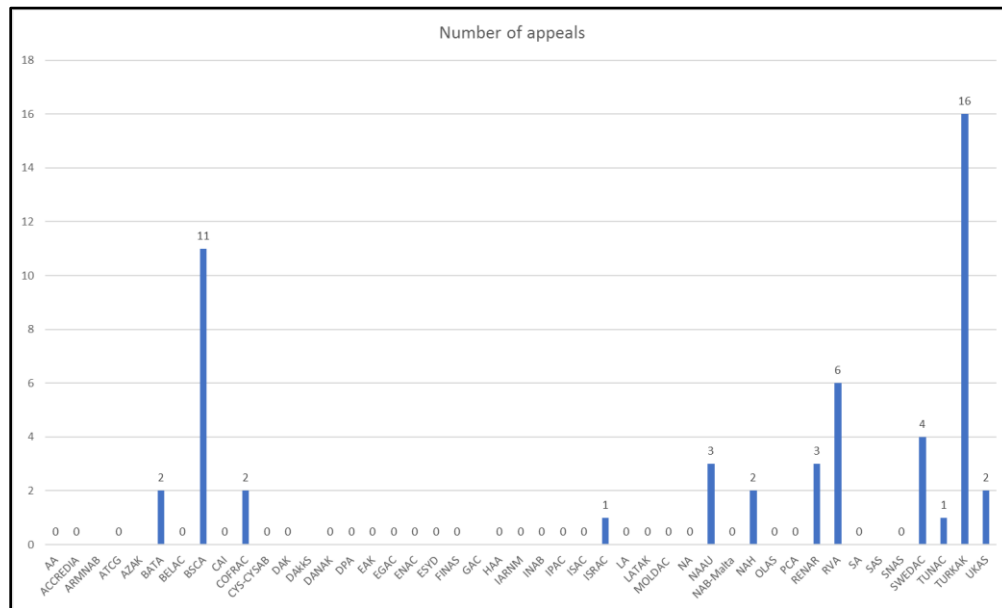


4.7.2 Appeals

53 appeals have been received in total by 40 NABs. 5 NABs were not able to provide the information about appeals.

The number of appeals per NAB must per compared - like the number of complaints - in relation to the number of accreditations that has been issued by the NABs.

It is obvious, that those NABs which have issued many accreditations may receive more appeals than those NABs with a low number of accreditations.

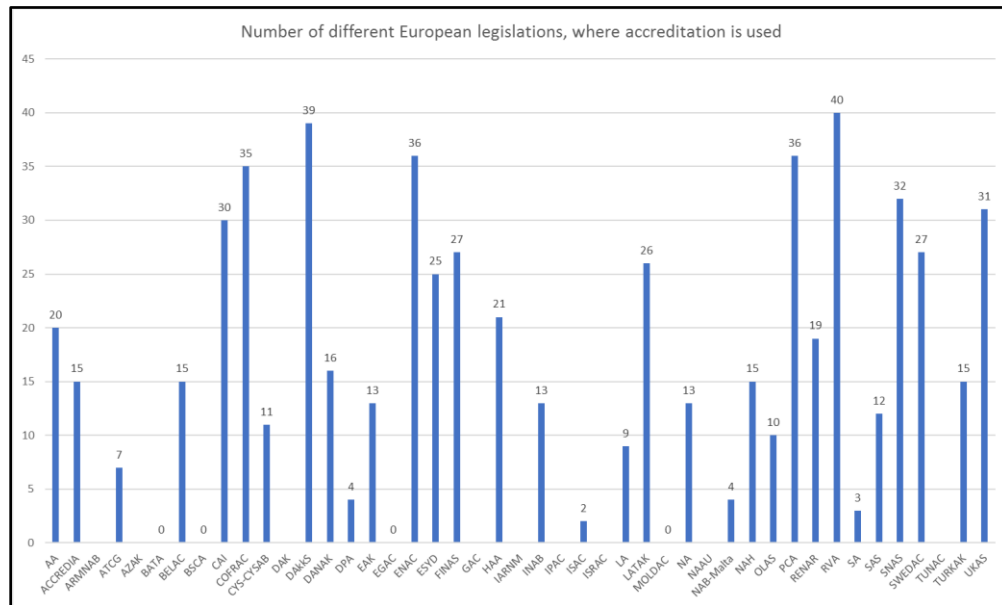


7 appeals have been considered by two NABs as legitimate.

Apart from the appeals process established by the NABs according ISO/IEC 17011:2017 (see above), the Member States shall establish procedures for the resolution of appeals, including (where appropriate) legal remedies against accreditation decisions or the absence thereof. These legal procedures have not been part of this survey.

4.8 Acceptance of accreditation

The acceptance of accreditation is closely linked to accreditation in the regulated sector. But the acceptance of accreditation can vary from country to country. In some countries (Member States) accreditation is used mainly as the means to demonstrate the competence of CABs. In other countries (Member States) the competence of CABs is mainly assessed by the national authorities, but with the consequence that they have to demonstrate regarding European legislations that their assessments are equal robust and reliable than the assessments (and accreditations) performed by the NABs (see above item 4.2).



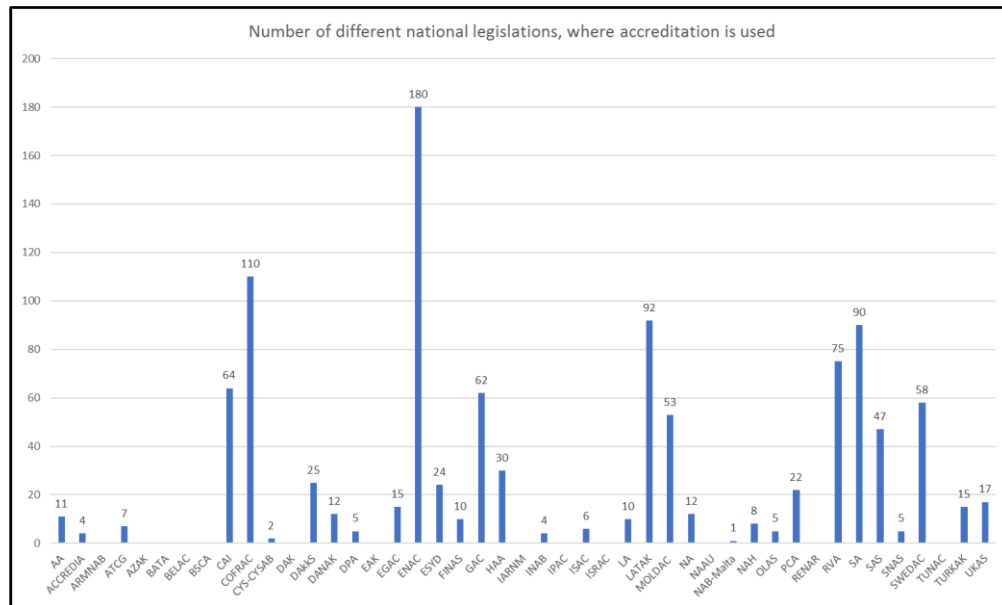
The numbers of European legislations, where NABs deliver accreditation of CABs, demonstrate that the European regulator relies on accreditation and takes recourse to accreditation as the preferred means to demonstrate the competence of CABs.

Accreditation is not only used by the European regulator, but also by national regulators when CABs shall demonstrate their competence.

The 8 sectors where accreditation is most commonly used by the European and national regulators are:

- Food/Feed
- Environment
- Construction
- Product safety
- Healthcare
- Safety at Workplace
- Legal metrology
- Vehicles

More details about accreditations according to European and national legislations see above 3.2 and 3.5.1.



The 8 sectors where accreditation is not considered by national authorities as the appropriate means to demonstrate the competence of CABs are:

- Healthcare
- Medical laboratories
- Regulation on medical devices and in vitro diagnostica
- Vehicles
- Food/Feed
- Environment
- Railway
- Electrical installations

The comparison of sectors where accreditation is most commonly and not used at all demonstrates that in one country the national authority takes recourse to accreditation and in the same sector another national authority does not take recourse to accreditation. Examples for those sectors are Healthcare, Food/Feed and Environment.

4.9 Challenges for National Accreditation Bodies

Accreditation is applied in so many different regulated and non-regulated sectors. New examples for accreditation are the General Data Protection Regulation (GDPR) and the Regulation on unmanned aircrafts (drones).

For all sectors (see also 3.2 - 3.5) the NABs shall establish the competence to accredit CABs, unless a NAB decides not to offer a specific scope for accreditation (see 3.5.3).

According to ISO/IEC 17011:2017 clause 4.6.4 the NAB shall establish, document, implement and maintain a process for developing and extending its accreditation activities/schemes. The following shall be considered:

- a) feasibility of launching or extending an accreditation scheme;
- b) analysis of its present competence and resources;
- c) accessing and employing expertise;
- d) the need for application or guidance documents;
- e) training of accreditation body personnel;
- f) implementation or transition arrangements;
- g) views of interested parties.

The biggest challenges for the NABs regarding the accreditation of CABs for existing and new activities/schemes are:

- Availability of qualified assessors/ experts,
- Recruitment of qualified (internal) personnel,
- Digital transformation of the accreditation process,
- Financial constraints,
- Foreign accreditation bodies.

Apart from these general challenges, some NABs have identified also the following challenges:

- Become EA MLA signatory for certain scopes,
- Establishing the resources and competence for the accreditation of CABs for Biobanks, RMP, PTP, GDPR and the Cybersecurity Act,
- Brexit.

5. Summary

It is important that regulators, industry and consumers can have trust in conformity assessment results. Testing, examination, verification, inspection, calibration and certification are used for better control and regulation by the European and national authorities.

Accurate calibration, measurement and testing, performed in accordance with best practice, help limit errors and product failure, improve control of production costs and contribute to an innovative environment.

Increasingly consumers rely on independent evidence, rather than simply believing in suppliers' advertisements. Consumers' confidence on the market is enhanced when they know that the products and services they choose are regularly evaluated and checked by an independent and competent third party. Choosing a product based on its certification mark, consumers can be sure of the quality of what they are buying.

Accreditation has been strengthened following the implementation of the Regulation (EC) No 765/2008 to provide the legal framework for the provision of accreditation services across Europe and to cover the operation of accreditation in support of voluntary conformity assessment as well as conformity assessment required by European and national legislations.

This report demonstrates the successful implementation of Regulation (EC) No 765/2008 and that accreditation is the best means to ensure this trust in conformity assessment results.

Accreditation supports the implementation of European and national legislations. In all EA countries the national authorities take recourse to accreditation, that provides a “stamp of approval” to confirm compliance with standards and widely accepted (legal) requirements. But in some EA countries the use of accreditation by the national authorities is very limited and restricted to a few numbers of (national) legislations only. Therefore, those countries shall be encouraged to make more use of accreditation, because it is not only the preferred means by the European regulator, but it is also the most transparent and robust means for demonstrating competence of conformity assessment bodies.

Accreditation and conformity assessment are applied almost in all sectors. That demonstrates the acceptance of accreditation by authorities, industries and consumers, but it is also a challenge for national accreditation bodies, because the national accreditation bodies have to establish for every sector the competence according Regulation (EC) No 765/2008 and ISO/IEC 17011.

More than 35000 accreditations have been granted by national accreditation bodies, which are appointed by their governments as the sole accreditation body in its country and which are acting as public authorities.

Accreditation is not based only on Regulation (EC) No 765/2008, but also on the international standard ISO/IEC 17011. Following Regulation (EC) No 765/2008 and ISO/IEC 17011 the national accreditation bodies have implemented a reliable accreditation process in order to ensure trust in accredited conformity assessment bodies. That include the regular surveillance of conformity assessment bodies and the processes for complaints and appeals which demonstrate the robustness of the accreditation process.

The EA peer evaluation system ensures that national accreditation bodies comply with the requirements set out in Regulation (EC) No 765/2008, ISO/IEC 17011 and additional requirements from regulators or the market. Accordingly, only certificates and reports issued by conformity assessment bodies accredited by an EA MLA signatory (successfully EA peer evaluated national accreditation bodies) shall be accepted.