EA Work Programme 2019

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CONTENTS

INTRODUCTION

The European co-operation for Accreditation (EA) is an association of the legally appointed National Accreditation Bodies (NAB) of the Member States of the European Union (EU) and the European Free Trade Association (EFTA), and of candidate countries. It further has members that are from potential candidate countries and countries identified by the EU in its European Neighbourhood Policy.

EA has its registered office in the municipality of Utrecht, The Netherlands, and is governed by the Law of the Netherlands.

The objectives of the association set out in its Articles of Association[1] are:

- To serve as a cooperative network of its Members for the furtherance of a coherent European accreditation system that operates in the general European interest;
- To harmonise and build consistency in accreditation as a public authority activity to support European trade and industry according to its needs and to the requirements laid down in applicable European legislation;
- To evaluate the compliance of National Accreditation Bodies with the requirements of applicable harmonised standards, European legislation, and other criteria as applicable and agreed by EA;
- To consolidate and strengthen the multilateral agreement based on the peer evaluation activities on mutual recognition of the accreditation activities operated by Members and to promote the international acceptance of this agreement;
- To promote the establishment of agreements on mutual recognition of accreditation activities at the international level;
- To promote confidence in the European infrastructure, competence and services in calibration, certification, inspection, testing and other activities covered by EA;
- To be a resource on technical matters and contribute to the development, maintenance and implementation of accreditation in the EU and EFTA countries, and internationally;
- To be the body recognized by the European Commission (EC) and EFTA as the European Accreditation Infrastructure.

Regulation (EC) No 765/2008[2] established the legal basis for accreditation in Europe. According Article 14 of this Regulation EA has been appointed as the body responsible for the European Accreditation Infrastructure.

[1] 20160116/HVZ dated 28 July 2016

[2] 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

On 1 April 2009, EA signed the General Guidelines for the Cooperation between EA, EC, EFTA, and Competent National Authorities. These Guidelines establish a common understanding of the importance of accreditation for the European economy and life of European citizens and of its supporting role for several European policies and legislation reflecting public interest, notably in the implementation of Community harmonisation legislation.

The Guidelines state that the EC, EFTA and the Competent National Authorities expect EA to undertake the following:

- Peer evaluation system

  - Operate a rigorous, transparent and uniform European peer evaluation system and continue to improve the system. Assurance should be provided that accreditation bodies that have successfully undergone the peer evaluation have the necessary technical expertise and capabilities to assess, attest and regularly monitor the technical competence of conformity assessment bodies, in particular, where members of the European accreditation infrastructure operate accreditation in support of the implementation of Community legislation.

  - Ensure that the peer evaluation between its members is operated in such a way that the results may be equivalent across the EU/EFTA and made public and can be justified on the basis of sound and transparent evaluation criteria and procedures, including appropriate appeals procedures. Peer evaluation should also serve as a benchmarking tool in order to stimulate further improvement.

- Training activities

  - Put in place an appropriate training system for evaluators to ensure reliable, equal and coherent assessments within the peer evaluation process.

- Cooperation with stakeholders

  - Ensure that its member bodies are fully accountable towards all interested parties, operate accreditation as a non-profit distributing activity, do not provide any activities that conformity assessment bodies perform, do not compete with other accreditation bodies.

  - Through its members, EA should also ensure that unnecessary burdens are not imposed on economic operators by conformity assessment bodies which they accredit. In addition, the conformity assessment bodies which they accredit should, in their activity, take into account, the diversity of companies, their size and the nature of their activities, without reducing the necessary level of protection or quality required. The necessary requirements relating to confidentiality should be also ensured.

- Cooperate with stakeholders and parties concerned and establish and maintain an appropriate mechanism for them to make their views known.

- Cooperation with the European Commission, EFTA and the Member States

  - Be responsive towards the European Commission and EFTA as well as the Member States' national authorities with regard to activities related to Community topics.

  - Cooperate with the European Commission, EFTA and the competent national authorities in the development and implementation of Community and EFTA programmes of technical assistance and cooperation with third countries.

- Market needs

  - To respond readily and appropriately to differing market needs in different sectors and the needs of national public authorities, in particular as far as the implementation and development of Community legislation is concerned. EA shall identify and raise awareness for missing tools for activities linked to the implementation of Community legislation and where possible, participate, on request, in their development.

- International cooperation

  - Provide encouragement to the progress of accreditation bodies in the countries that have applied for EU or EFTA membership, in view of their full participation in and achieving membership of EA. Grant full membership once the appropriate and approved conditions have been met. Endeavour to encourage the development of the quality infrastructures of those countries.

  - Actively participate in the activities of international organisations in the field of accreditation and report on these activities to the European Commission and EFTA.

- Promotion of accreditation

  - Undertake and support actions to improve the visibility of European accreditation and promote the European model of accreditation.

The formal relationship between EA and the European Commission is further elaborated in a Framework Partnership Agreement [3] (FPA) that was signed by EA and the European Commission on 24 June 2014 for a new 4-year period. A new FPA is under negotiation to cover the next 4 years period.

[3] Framework Agreement Number – 30-CE-0647816/00-85

The purpose of the FPA is to define the respective roles and responsibilities of the European Commission and EA in implementing their partnership. It further establishes the means for specific grant agreements that may be signed under the framework agreement that relate to grants for an action and operating grants.

In the context of the FPA, EA shall each year submit a work programme which shall be jointly agreed by the parties and shall serve as a basis for the award of grants during the year in question. The annual Work Programme shall be submitted by 30th September before the start of EA's corresponding financial year.

The European Commission published in December 2017 its report to the European Parliament, the Council and the European Economic and Social Committee on the implementation of Regulation (EC) No 765/2008. This report gives an overview of how the accreditation provisions of Regulation (EC) No 765/2008 and CE marking were implemented between 2013 and 2017.
The report confirmed that the European accreditation infrastructure created by the Regulation 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 conformity assessment bodies 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.
However, the European Commission noted in the report also that the European accreditation infrastructure faces the challenge of maintaining its solidity; i.e. keeping the whole accreditation system in line with the latest state of the art and ensuring that it is applied with the same stringency.
The European Commission emphasized in the report, that it would be essential that the EA continues to receive EU support to help it implement its tasks. Furthermore it would be important to maintain a high level of awareness and understanding of the accreditation system among its stakeholders in order to ensure its correct implementation especially in the new policy areas. The Commission will continue to promote the use of accreditation in accordance with Regulation 765/2008 in any new proposals requiring conformity assessment.

This document contains the EA Work Programme 2019 and is based on the key activities included in the EA Action Plan 2018 - 2021 that outlines the main areas EA will give priority to in developing and consolidating the European accreditation system, the EA Strategy 2025 that defines additional objectives for the period 2018 - 2025 as well as on the proposal to the Financial Contribution (Operating Grant) from the European Commission/EFTA for 2018 - 2022.
The Work Programme 2019 considers also the report from the European Commission to the European Parliament, the Council and the European Economic and Social Committee on the implementation of Regulation (EC) No 765/2008.

The 2019 EA Work Programme includes general cross references to the service contract for the "Support Service regarding the Accreditation Aspects of the Project on a European Voluntary Quality Assurance Scheme for Breast Cancer Services underpinned by Accreditation and high-quality Guidelines".

1. MAIN ACTIVITIES OF EA

Based on the established policy objectives for European accreditation and considering the formal role of EA as being the European Accreditation Infrastructure according to Article 14 in Regulation (EC) No 765/2008 and taking into account the expectations of the European Commission, EFTA and the Competent National Authorities, EA considers its activities within 8 main work streams. Item 9 contains activities, which are related to the Management of EA, including the EA Secretariat, who serves as the coordinating and administrative body to support EA and its Members.

1.1 Operation and management of the peer evaluation system, including its strengthening

Operating the peer evaluation system in accordance with the principles laid down in Article 10 of Regulation (EC) No 765/2008 is a major activity for EA. The procedures to be followed shall be rigorous and based on transparent evaluation criteria.

The purpose of performing peer evaluation of the national accreditation bodies is to evaluate whether the accreditation body meets the requirements laid down in:

- Regulation (EC) No 765/2008,
- The international standard ISO/IEC 17011 *Conformity Assessment – Requirements for accreditation bodies accrediting conformity assessment bodies*,
- Harmonised standards and/or normative documents relevant for the assessment of conformity assessment bodies, including any mandatory document issued by EA for the specific accreditation activity, and
- EU legislative documents such as regulations defining requirements for accreditation and conformity assessment bodies for specific areas (schemes).

The scope of an accreditation body is specified by the category of accreditation and the generic standard for which the accreditation body has signed the EA Multilateral Agreement (MLA) / Bilateral Agreement (BLA). In this respect 8 conformity assessment activities are currently differentiated:

- Testing laboratories (including medical laboratories);
- Calibration laboratories;
- Certification bodies for management systems;
- Certification bodies for products, processes and services;
- Certification bodies for persons;
- Inspection bodies;

- GHG Validation and Verification bodies;
- Proficiency Testing Providers (PTP);
- Reference Material Producers (RMP) – under development.

The peer evaluation system shall ensure that regulators, industry and other end users have confidence in reports and certificates issued by accredited conformity assessment bodies.

To ensure that peer evaluations are performed in a consistent and harmonised manner, team leaders and team members from the EA national accreditation bodies (who perform the peer evaluation activities in EA) receive appropriate training in peer evaluation.

When the EA MLA and peer evaluation system are extended to cover new fields, peer evaluators are introduced to the new field and any relevant procedure is revised to ensure that peer evaluation teams conduct peer evaluations in a harmonised manner.

The peer evaluation process covers the management system, procedures and processes of accreditation bodies. This evaluation comprises several activities including document review, witnesses and interviews.

The peer evaluation process consists of:
1. Application review based on the documents submitted by the applicant,
2. Pre-evaluation of the applicant,
3. Full evaluation of the applicant (visit to the applicant office and witnessing of accreditation assessments performed by the applicant),
4. Reporting to the EA MLA Council (EA MAC) by the peer evaluation team,
5. Decision by the EA MAC.

The peer evaluation team appointed prepares a report on the findings identified during the peer evaluation including comments and recommendation by the peer evaluation team to comments and proposed corrective actions proposed by the applicant and their evaluation by the EA team.

The report is then analysed by an EA MAC Task Force Group (TFG) - appointed by the EA MAC Management Group – and the TFG prepares a recommendation to the EA MAC on the peer evaluation report. The EA MAC takes the decision on granting signatory status to the applicant.

To ensure the ongoing fulfilment of the requirements for continuing as a signatory to the EA MLA, re-evaluation is performed by a peer evaluation team at maximum intervals of 4 years. Extraordinary evaluation may be performed in between as decided by the EA MAC.

The EA MLA Council

The EA MLA Council (EA MAC) is responsible for the management and operation of the EA peer evaluation system and meets normally twice a year.

The EA MAC consists of one representative of each MLA/BLA signatory, one observer from the EA Advisory Board representing the Members States and one observer from European Commission. Representatives of Full and Associate members being not a MLA/BLA signatory as well as NABs having signed a Contract of Cooperation with EA may attend the meetings as observers. The evaluated NAB is encouraged to invite a representative from the Member State to the EA MAC meeting where its evaluation report is tabled for discussion and decision.

The power to take decisions on EA MLA signatory status is delegated by the EA General Assembly to the EA MAC. The EA MAC recommends the operational procedures for the MLA system to the EA General Assembly which is responsible for endorsing the procedures to be applied. Supporting operational documents to the procedures are approved by the EA MAC.

The EA MAC Management Group
The EA MAC selects a management group composed of the Chair, the Vice-Chair and Secretary and representatives of the MLA membership (with a maximum of 8-10 persons). This group runs the daily business in close cooperation with the EA Secretariat and makes decisions on the evaluation team-composition using the approved team leader, deputy team leader and team member lists, in co-ordination with the persons involved. The management group follows up the working program for the EA MAC.

1.2 Interpretation and harmonization of accreditation criteria for national accreditation bodies and conformity assessment bodies

The technical work of EA is divided into 4 committees each responsible for a specific field. The current technical committees (TCs) are:
- Horizontal Harmonisation Committee (HHC)
- Laboratory Committee (LC)
- Certification Committee (CC)
- Inspection Committee (IC)

The Communication and Publications Committee (CPC) is involved in the development of any matter related to internal and external communications activities.

Committees may establish Working Groups and Task Forces to deal with technical issues or issues of specific concern in relation to applying the defined accreditation requirements.

The purpose of the technical work of EA is to assure that the accreditation activities covered or planned to be covered by the scope of the EA MLA meet the needs of the market place and to take action to extend the MLA scope as necessary.
Further, the purpose is to ensure that accreditation activities covered by the EA MLA are performed by the national accreditation bodies in a harmonized manner i.e. that the accreditation criteria are applied consistently by the national accreditation bodies and provide the equal level of confidence.

Whenever the EA MLA is extended to include new activities/schemes or there is a need to consider the actual application of the accreditation criteria the relevant EA committee will analyse if there is a need to develop any guidance document (informative or mandatory document) to ensure a harmonised application of the accreditation criteria throughout EA. These analyses are of major importance whenever new accreditation activities shall be included in the EA MLA following requests from regulators, scheme owners or other stakeholders and interested parties.

Recognized stakeholder organisations and other interested parties are directly involved in the technical work of EA. They are also invited to attend meetings of the EA technical committees.

1.3 Cooperation with the European Commission, EFTA and Competent National Authorities

The purpose of cooperation with the EU Commission (EC), EFTA and Competent National Authorities is to ensure that the strategic and policy developments in EA are in line with the policy of the European Union, EFTA and the Member States. The formal forum for meetings is the Expert Group on Internal Market for Products. Bilateral meetings between the parties may also be arranged for discussion of specific issues.

In addition to issues with regard to European accreditation policy and according to Article 13 of Regulation (EC) No 765/2008, the cooperation will also include development of new services and maintenance of existing services supporting the implementation of Community and national legislation. EA and the National Accreditation Bodies are prepared to contribute to the development of community legislation and to evaluate how technical requirements in proposed legislation can be assessed within the European accreditation system.

EA supports the implementation of accreditation and conformity assessment in trade agreements.
The EU and Canada signed on 30 October 2016 the Comprehensive Economic and Trade Agreement (CETA), which is designed to strengthen the economic relations and develop business between the partners.
CETA includes the protocol on the mutual acceptance of the results of conformity assessment. The protocol applies to 11 categories of goods. Within three years of the entry into force of CETA, the Parties may extend the scope of application by further 6 categories of goods.
EA and SCC (Standards Council of Canada) signed a Bilateral Cooperation Agreement pursuant to Article 12 clause 3 of the CETA Protocol on conformity assessment with the aim to implement the Protocol.

EA cooperates in joint initiatives with the Joint Research Centre, in particular the Institute for Health and Consumer Protection (IHCP) with respect to the European project for Breast Cancer Services.

The latter project has been initiated by the European Commission in order to develop a quality assurance scheme for Breast Cancer Services. The scheme will be based on a revision of the European Quality Assurance Guidelines for Breast Cancer Screening and Diagnosis and is to be underpinned by accreditation in accordance with the provisions of the Regulation (EC) No 765/2008. Based on a Service Contract with the European Commission the project started 2014 and will last until 2020.

1.4 Cooperation with the private sector in development, maintenance and implementation of accreditation and conformity assessment

Cooperation with stakeholders is important to ensure that the market place has confidence in accredited conformity assessment services. The main forum for involvement of stakeholders in accreditation issues is the EA Advisory Board (EAAB).

EA will ensure that stakeholders and other interested parties are effectively involved in any discussion of strategic and policy importance for the development of EA.

Cooperation with stakeholders also takes place at a bilateral level for discussion of general issues of importance for the accreditation system or specific technical issues related to accreditation within a certain sector.

1.5 Cooperation with stakeholders, third countries and other interested parties

Cooperation with stakeholders is important to ensure that the market place has confidence in accredited conformity assessment services. The main forum for involvement of stakeholders in accreditation issues is the EA Advisory Board (EAAB).

EA will ensure that stakeholders and other interested parties are effectively involved in any discussion of strategic and policy importance for the development of EA.

Cooperation with stakeholders also takes place at a bilateral level for discussion of general issues of importance for the accreditation system or specific technical issues related to accreditation within a certain sector.

EA has adopted a policy for its relationship with Accreditation Bodies of Countries not being Members of the EU or EFTA. EA has given priority to establish relations with accreditation bodies from countries being part of the EU Neighbourhood Policy and potential candidates for EU membership, through offering them Associate Membership.

EA may further decide to establish relations with accreditation bodies from other countries.

Where EA agrees to establish and reinforce relations with accreditation bodies from 3rd countries, they are invited to attend EA meetings as observers and by other means encouraged to contribute to the work of EA and apply the policy and approach to accreditation as adopted by EA.

Cooperation with accreditation bodies from third countries will only be established if it is in accordance with the EA policy stated in EA-1/13 *EA's relationship with accreditation bodies of countries not being members of the EU or EFTA*. Such cooperation will be through individual Cooperation Agreements which may be extended into signing Bilateral Agreements with the EA MLA.

1.6 EA at the international level - Cooperation with international organisations

Cooperation in the global accreditation system is through the International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF).

EA operates as a Recognized Region in both associations and manages its peer evaluation system to qualify EA members to be signatories to the global Mutual Recognition Agreements.

EA and its members are working actively in both associations with the purpose of ensuring that the European accreditation system is recognized at the global level and that the development of the international accreditation system as far as possible is in line with the accreditation policy adopted and implemented in Europe.

There are differences of accreditation systems in other regions and countries and hence in ILAC and IAF policies. In few countries accreditation is used as a profit activity and with competition between accreditation bodies instead of a public interest activity free from competition and not for profit. Only with those principles, set out in Regulation (EC) No 765/2008, accreditation can be the last level of control in the conformity assessment chain and provide confidence in certificates and reports.
Therefore, EA strives for:

- Disseminate the accreditation principles set out in Regulation No 765/2008, like not for profit and non-competition, on the global level and its implementation in ILAC and IAF policies.
- Enhance the cooperation with non-EA accreditation bodies as well as other regions.

1.7 Strengthening of the European Accreditation Infrastructure

One important element in the cooperation with stakeholders/partners, is the European Quality Infrastructure. An efficient Quality Infrastructure is contributing to governmental policy objectives in areas including industrial development, trade competitiveness in global markets, efficient use of natural and human resources, food safety, health, the environment and climate change. The European Quality Accreditation Infrastructure is comprised of Accreditation and Conformity Assessment, Standardization and Metrology.

Therefore, a close cooperation with the European Standardisation Organisations CEN/CENELEC and ETSI as well as with EURAMET, representing the European Metrology, is essential for the European market. Consequently, this cooperation shall be enhanced in the future based on the signed cooperation agreements.

1.8 Promotion (and the development) of accreditation and accreditation schemes as well as associated services

Accreditation is the appropriate tool to demonstrate competence of Conformity Assessment Bodies in the regulated and non-harmonised area.
The promotion and development of accreditation, in particular in new areas, is important for the European Accreditation Infrastructure. Thereby it is important that accreditation and conformity assessment is used in compliance with the principles set out in Regulation (EC) No 765/2008 and the harmonized standards for the accreditation of Conformity Assessment Bodies.

In order to promote accreditation and its appropriate application, EA shall provide the following:

- Information for use by EA members towards national regulators regarding new legislation and standardisation in accreditation.
- Information and guidance for regulators regarding the accreditation system, development of new accreditation areas, the use of accreditation and the advantages with accreditation.
- Actions to promote accredited conformity assessment and associated services in new and specific areas.
- Support to the European Commission and other European scheme owners (see also 1.3 and 1.4).
- Organisation, processes, principles and support for development of new areas and respond to the public policy demands.
- Support and coordination for close cooperation between NABs regarding existing and new areas, including training and sharing of recourses.

The communication activities are managed by the Secretariat, based on the communication strategy established by the Executive Committee and the General Assembly. The Communication and Publication Committee is the platform to exchange information regarding communication activities performed by National Accreditation Bodies.

1.9 Management of EA

The EA General Assembly is the highest decision-making body in EA. The General Assembly concentrates its work on policy and strategic issues and has transferred the responsibility for operational and administrative issues to the Executive Committee (EA EX) and the established Technical Committees. With regard to the management of the EA MLA, responsibility for administration and decision making is delegated to the EA Multilateral Agreement Council (EA MAC).
The Executive Committee is responsible for management of EA in accordance with decisions and instructions endorsed by the EA General Assembly and in close cooperation with the EA Secretariat.

Furthermore, and in accordance with the Articles of Association, the EA General Assembly is in charge of membership issues.
Applications for EA Full or Associate Membership will be reviewed first by the EA Secretariat. Based on the Secretariat report the Executive Committee will forward the application with its recommendation to the EA General Assembly for decision.

The EA Secretariat is in charge of the day to day activities of the organisation. Its main tasks comprise:

- Supporting the Executive and all of the other EA Committees, including the EAAB;
- Serving as secretariat for the EA General Assembly, the Executive Committee, the EAAB, the MLA Council, the CPC and the 4 Technical Committees;
- Dealing with requests for information and serving the network of members;
- Dealing with applications for membership;
- Conducting the association's day-to-day operations;
- Managing EA budget and dealing with legal issues;
- Managing contracts with EC/EFTA;
- Supporting and managing EA projects, including projects based on contracts with EC/EFTA;
- Managing training activities;
- Managing internal and external communications, including updating the EA website.

The EA Sec is also responsible for managing the peer evaluation process and EA evaluators.

2. WORK PROGRAMME 2019

The General Assembly has agreed an EA Action Plan for the period 2018 until the end of 2021, which outlines the main areas EA shall focus on until end 2021. Furthermore, the General Assembly has endorsed the EA Strategy 2025, which provides the objectives for the period 2018 - 2025.
The main areas defined in the EA Action Plan and the Objectives defined in the EA Strategy 2025, combined with the general activities of EA described above, form the underlying basis for the Work Programme 2019.

The work programme for 2019 is divided into 8 work streams and the Management of EA, including the EA Secretariat.

2.1 Operation and management of the peer evaluation system, including its strengthening

This relates to the main element i) in the EA Action Plan for the FPA 2018 - 2021:

- *Good governance to deliver consistent and sustainable results*
  - *Strengthening the EA Peer Evaluation system*

	Activity	Responsible
2.1.1	Administer and monitor peer evaluations planned in 2019 for the following National Accreditation Bodies (NABs): - Re-evaluations: SAS, Switzerland ALGERAC, Algeria MOLDAC, Republic of Moldova NAAU, Ukraine ESYD, Greece HAA, Republic of Croatia IPAC, Portugal FINAS, Finland OLAS, Luxemburg - Scope-extension: TURKAK, Turkey Plan and administer unscheduled additional/ad-hoc evaluations to include NABs requesting an extension to their current MLA scope, pre- or initial evaluations of members not already signatories to the MLA, and extraordinary evaluations that may be required to review follow-up of actions from previous evaluations or complaints (as requested by the EA Executive Committee).	MAC

2.1.2	Define actions, as needed, to ensure that EA implements the process for transition to ISO/IEC 17011:2017 in accordance with the provisions defined by EA, IAF and ILAC.	MAC
2.1.3	Launch the EA MLA for Reference Material Producers (ISO 17034) and continue the peer evaluation activities as needed.	MAC
2.1.4	Complete the ILAC/IAF re-evaluation of EA	MAC
2.1.5	Continue the re-engineering project of the EA peer evaluation system including starting its implementation (see EA Strategy 2025 Implementation plan 1.6).	MAC
2.1.6	Monitor transition and implementation of standards (so-called level 3 and 4 standards as well as defined level 5 standards, see EA-1/06 *EA Multilateral Agreement. Criteria for signing. Policy and procedures for development).*	MAC
2.1.7	Organize for (potential) peer evaluators newcomer training and refresher trainings for PTP and Persons.	MAC
2.1.8	Conclude the policy for peer evaluations in (third) countries with security problems and its implementation.	MAC/EX
2.1.9	Re-approval of peer evaluators	Sec
2.1.10	Prepare and publish the EA MLA annual report (for activities 2018)	Sec
2.1.11	Further development of the so-called sampling approach in the peer evaluation process.	MAC

2.2 Interpretation and harmonization of accreditation criteria for national accreditation bodies and conformity assessment bodies

This relates to the main element i) in the Action Plan for the FPA 2018 - 2021:

- *Good governance to deliver consistent and sustainable results*
  - *Ensuring harmonization and competence when accrediting Conformity Assessment Bodies, in particular in the regulated area*

	Activity	**Responsible**
2.2.1	Contribute to harmonize implementation of ISO/IEC 17011:2017 Conformity assessment —Requirements for accreditation bodies accrediting conformity assessment bodies and relevant ILAC/IAF and EA application documents as well as harmonized implementation of New Legislative Framework (NLF).	HHC

2.2.2	Manage discussions in the Committee about issues raised with the implementation of the new standard ISO/IEC 17011 - set up breakout sessions during HHC meetings and FAQ concerning the new standard as considered necessary.	HHC
2.2.3	Carry out revision of EA publications as necessary further to the publication of the new ISO/IEC 17011:2017.	HHC
2.2.4	Maintain and further improve the FAQ lists.	HHC, CC, LC
2.2.5	Interact with the other EA committees for handling and discussing horizontal matters.	TCs
2.2.6	Complete the revision of EA-2/17 *EA Document on Accreditation for Notification Purposes.*	HHC
2.2.7	Continuously apply the mechanism developed in 2018 to identify, analyse and manage situations where the same activity is accredited under different level 3 and 4 standards by different EA members, including the identification of the preferred standard for that activity.	HHC, TCs
2.2.8	Handling of sector schemes and implementation of EA-1/22 *Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members.*	HHC/TCs
2.2.9	Follow the implementation of ISO 45001 *Occupational health and safety management systems -- Requirements with guidance for use* with a view to ensure a smooth implementation under accreditation.	CC
2.2.10	Follow the development of ISO/IEC 17029 *Conformity Assessment -- General requirements for bodies performing validation and verification activities* and advise members and other EA committees as needed.	CC
2.2.11	Follow the implementation of EA-2/17 *EA Document on Accreditation for Notification Purposes* especially regarding modules where ISO/IEC 17065, ISO/IEC 17021-1 or ISO/IEC 17024 are preferred.	CC
2.2.12	Complete the guidance on the choice of ISO/IEC 17065, ISO/IEC 17021-1 and ISO/IEC 17020 in Conformity Assessment Schemes.	CC, IC, HHC
2.2.13	Revision of ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*. Complete the work resulting from the impact analysis of the transition to the new standard made in 2018 and complete revision of EA LC documents, as required.	LC

2.2.14	Revision of ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*. A new workshop will take place and the objective will be to share experience gained with implementing the new standard.	LC
2.2.15	Develop a common understanding and application of requirements for laboratory accreditation by preparing and updating EA documents as well as resolutions. Review will be conducted in the light of the relevant discussions at the ILAC level and the relevant documents, including ILAC P9 *ILAC Policy for Participation in Proficiency Testing Activities*, ILAC P10 *Policy on the Traceability of Measurement Results* and ILAC P14 *ILAC Policy for Uncertainty in Calibration*.	LC
2.2.16	Activate, develop and manage LC Technical Network forums on the new EA website.	LC
2.2.17	Common understanding and application of ISO/IEC 17020 *Conformity assessment -- Requirements for the operation of various types of bodies performing inspection* by treating current questions from members including follow up on the revision of ISO/IEC 17020: - to clarify unclear issues in the 2012 version of the standard (review discussion depending on the actual need). - to discuss current applications; - at stage of revision of the current version (if planned to revise soon). Establish and run review groups / review panels (RP) to facilitate the work and to treat technical issues in a more harmonized way. - Elaboration of submitted questions from members NABs and stakeholders. - Producing a first answer for presentation and discussion in the plenum of EA IC. - Finalizing the answer after final review.	IC
2.2.18	Technical network (TN) motor vehicle ("car") inspection, work in the field of periodical technical inspection (vehicle inspection) such as: a) Information sharing; b) Benchmarking, accreditation and harmonisation issues; c) Scope presentation d) Further discussion of EU directives and new proposals for inspection.	IC
2.2.19	Workshops for members on special issues of ISO/IEC 17020:2012 and document ILAC P15 *Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies*.	IC

2.2.20	Review of new and existing guidance documents. Comments and discussion of application issues concerning guidance documents for: a) ISO/IEC 17020:2012, b) Scope presentation, c) Testing activities under inspection and d) Non-destructive testing (NDT) issues.	IC
2.2.21	Completion of the Accreditation for Notification Package. Evaluation of those legislations, which were not covered at the first stage 2014/2015 and were aligned meanwhile according Decision (EC) No 768/2008.	EX/ES*
2.2.22	Support the MAC for the implementation of the EA MLA for Reference Material Producers (see item 2.1.3) and harmonization of accreditation practices – set up a workshop on accreditation against ISO 17034:2016 *General Requirements for the competence of reference material producers (RMP)* as was made in May 2017.	LC

* ES: Executive Secretary

2.3 Cooperation with the European Commission, EFTA and Competent National Authorities

This relates to the main element ii) in the EA Action Plan for the FPA 2018 - 2021:

- *Close cooperation with regulators and stakeholders to strengthen accreditation at the European and international level*
  - *Cooperation with regulators and stakeholders*

	Activity	**Responsible**
2.3.1	Maintain close liaisons with the European Commission (EC), in particular with the aim to follow EU legislation that include accreditation and conformity assessment issues.	ES, EX, HHC, CC, IC, LC
2.3.2	DG SANTE: Cooperation regarding Regulation (EC) No 396/2005 *on maximum residue levels of pesticides in or on food and feed of plant and animal origin*. Complete the drafting of the Guidance document on pesticides residues and publish it.	LC
2.3.3	DG GROW: Cooperation regarding the proposed Regulation on the approval and market surveillance of motor vehicles and their trailers, ad of systems, components and separate technical units intended for such vehicles.	ES/IC

2.3.4	Cooperation with the European Railway Agency	ES/TCs
2.3.5	DG ENV: Ship related issues: - Inspection of seaworthiness of ships, - Inspection of recycling of ship wrecks.	IC
2.3.6	Review periodically and maintain the HHC list of EC schemes not based on legislation.	HHC
2.3.7	EU Agency for Railways / DG MOVE: Cooperation with and support regarding - implementation of the assessment scheme for Notified Bodies and monitoring of Notified Bodies (Interoperability of the rail system), - Implementing Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment - Regulation (EU) 445/2011 on a system of certification of entities in charge of maintenance for freight wagons	ES, EX, CC, IC
2.3.8	DG CLIMA: Cooperation regarding EU-ETS and the implementation of Regulation (EU) No 600/2012 on the verification of greenhouse gas emission reports and tonne-kilometre reports and the accreditation of verifiers pursuant to Directive 2003/87/EC.	CC
2.3.9	DG CLIMA: Cooperation regarding the implementation of the Delegated Act on the verification activities and accreditation of verifiers pursuant to Regulation (EU) 2015/757 on the monitoring, reporting and verification of carbon dioxide emissions from maritime transport (MRV).	CC
2.3.10	DG GROW: Cooperation regarding the proposed Regulation on the approval and market surveillance of motor vehicles and their trailers, ad of systems, components and separate technical units intended for such vehicles.	ES, EX
2.3.11	DG JUST / Article 29 Working Party: Support regarding Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR). Implementation of the Guidelines for accreditation and certification.	ES, EX, CC
2.3.12	Comprehensive Economic and Trade Agreement between the EU and Canada (CETA) Implementation of the Protocol on the mutual acceptance of the results of conformity assessment.	ES, EX
2.3.13	Ongoing implementation of the Joint Research Centre – EA project on Breast Cancer Services.	PSG BCS*

2.3.14	Proposed Regulation on ENISA, the “EU Cybersecurity Agency” and on Information and Communication Technology cybersecurity certification (Cybersecurity Act): Support of ENISA regarding the preparation and implementation of the EU Cybersecurity Certification Framework.	ES, EX
2.3.15	Support of the European Commission regarding the proposed Regulation on the operation of small drones and the related introduction of conformity assessment, accreditation and CE marking.	ES, EX
2.3.16	DG MOVE: Supporting the preparation of a proposal for a Regulation on electronic freight transport information regarding conformity assessment bodies and accreditation.	ES, EX
2.3.17	DG EMPL: Supporting the pilot project on the integration of international, sectoral or private qualifications at European level (ESCO).	EX
2.3.18	DG ENV: Support of the EU Environmental Technology Verification (ETV) programme: - Participation at the EU ETV Steering Group meeting(s), - Further development of the EU ETV programme, - Implementation of the revised General Verification Protocol, including ISO 14034 Environmental management - Environmental technology verification (ETV).	ES/IC
2.3.19	Review and develop the existing procedures regarding responsibility and processes for support to European Commission and other stakeholders (see EA Strategy 2025 Implementation plan 2.4.1).	ES, EX
2.3.20	Identify key European scheme owners including directorate in European Commission, including contact person; prioritize after importance and timing (see EA Strategy 2025 Implementation plan 3.4.1).	ES, EX

* PSG BCS: Project Steering Group Breast Cancer Services

2.4 Cooperation with the private sector in development, maintenance and implementation of accreditation and conformity assessment

This relates to the main element ii) and iii) in the EA Action Plan for the FPA 2018 - 2021:

- *Close cooperation with regulators and stakeholders to strengthen accreditation at the European and international level*
  - *Cooperation with regulators and stakeholders*
- *Continue to develop accreditation to support innovation and growth in existing and new areas*

	Activity	Responsible
2.4.1	Cooperation with the European Group of Organisations for Fire Testing, Inspection and Certification (EGOLF) to support accreditation for new extended application standards (EXAP).	LC
2.4.2	Cooperation with the European Network of Forensic Science Institutes (ENFSI) regarding monitoring activities of ISO TC 272 (and CEN/TC 419) to ensure that the new ISO-standards for the forensic science process are technical level standards, not mirror standards to ISO/IEC 17025. Concerning the Council Conclusion 10128/16: to support the execution of the objectives listed in regards to accreditation. Activities started in 2018 to be continued.	LC
2.4.3	Cooperation with the European Directorate for the Quality of Medicines (EDQM): Follow up implementation of the Joint EA-EDQM Communication regarding Cooperation when carrying out (joint) audits/assessments in Official Medicines Control Laboratories – collect feedback and evaluate results.	LC
2.4.4	see 2.3.20	
2.4.5	Develop a process for the management of existing accreditation areas and schemes (see EA Strategy 2025 Implementation plan 3.6.1).	EX

2.5 Cooperation with stakeholders, third countries and other interested parties

This relates to the main element ii) and iii) in the EA Action Plan for the FPA 2018 - 2021:

- *Close cooperation with regulators and stakeholders to strengthen accreditation at the European and international level*
  - *Cooperation with regulators and stakeholders*
- *Continue to develop accreditation to support innovation and growth in existing and new areas*

	Activity	Responsible
2.5.1	Close cooperation with the EAAB.	ES, EX
2.5.2	Ongoing improvement of communication and cooperation with Recognised Stakeholders.	EX, CPC, HHC, CC, IC, LC, ES
2.5.3	Implementation of the Bilateral Cooperation Agreement with Standards Council of Canada (SCC) regarding CETA and the Protocol on the Mutual Acceptance of the Results of Conformity Assessment (see also 2.3.12).	EX
2.5.4	Implementation of EA-1/13 *EA's relationship with accreditation bodies of countries not being members of the EU or EFTA*.	EX, MAC
2.5.5	Implementation of the new stakeholder policy (see EA Strategy 2025 Implementation plan 2.1.1).	EX
2.5.6	Analyse the 'wishes" of stakeholders and specific partners and propose ways to fulfil (part of) them. Use the past analyse for traceability. (Stakeholder survey) Devise a method to use feedback from interested parties on the real-life value of accredited conformity assessment results (their perception or facts on the reliability). See EA Strategy 2025 Implementation plan 2.2.1	EX, MAC, ES
2.5.7	Congress of International Metrology Participation at the 19th Congress of International Metrology as partner organisation.	LC/Sec
2.5.8	See 2.3.19	

2.6 EA at the international level - Cooperation with international organisations

This relates to the main element ii) in the EA Action Plan for the FPA 2018 - 2021:

- *Close cooperation with regulators and stakeholders to strengthen accreditation at the European and international level*
  - *Enhance the role of EA at the international level*

	Activity	Responsible
2.6.1	Ensure appropriate contribution to the ILAC/IAF peer evaluation system, including evaluation resources.	MAC
2.6.2	Cooperation with ILAC/IAF and regional accreditation cooperation organisations in order to keep the international and regional groups informed about EA activities and to promote the European Accreditation Model.	Sec
2.6.3	Follow and implement ILAC/IAF (mandatory) documents and resolutions; assess their content against EU and EA policies, as specified in EA-1/14.	TCs/Sec
2.6.4	Active liaison with ILAC and IAF committees.	TCs, EX
2.6.5	Preparing a plan consisted of measures supporting the merger of ILAC/IAF (see EA Strategy 2025 Implementation plan 2.5.2).	EX
2.6.6	Develop a plan for cooperation with other regions (see EA Strategy 2025 Implementation plan 2.6.1).	EX

2.7 Strengthening of the European Accreditation Infrastructure

This relates to the main element ii) and iii) in the EA Plan for the FPA 2018 - 2021:

- *Close cooperation with regulators and stakeholders to strengthen accreditation at the European and international level*
  - *Strengthening of the European Quality Infrastructure*
- *Continue to develop accreditation to support innovation and growth in existing and new areas*

	Activity	Responsible
2.7.1	Cooperation with the European Association of National Metrology Institutes (EURAMET) - Maintain active liaison and annual meeting between EA and EURAMET.	LC
2.7.2	Close cooperation with European Standardization bodies CEN-CENELEC and ETSI based on the cooperation agreements.	ES, EX

2.7.3	Continue to develop and implement a corporate identity for EA to support and identify EA as a European Institution with the task to coordinate and enhance the European accreditation system.	CPC
2.7.4	Develop procedures for coordinating EA members work in European and international standardization (see EA Strategy 2025 Implementation plan 2.3.1).	ES, EX

2.8 Promotion (and the development) of accreditation and accreditation schemes as well as associated services

This relates to the main element iii) in the EA Action Plan for the FPA 2018 - 2021:

- *Continue to develop accreditation to support innovation and growth in existing and new areas*

	Activity	Responsible
2.8.1	Promote and support the one voice concept through developing and cascading EA communications.	CPC
2.8.2	Contribute to prepare communications to be used at European and national level for the promotion of accreditation and the EA MLA to increase the confidence, recognition and acceptance by Regulators and the marketplace of reports / certificates issued by Conformity Assessment Bodies accredited by National Accreditation Bodies.	CPC
2.8.3	Develop information for use by EA members towards national regulators regarding new legislation and standardisation in accreditation.	CPC
2.8.4	Align activities with the ILAC and IAF Communications committees to maximize the use of limited resources, and to coordinate activities (where appropriate) to deliver a stronger message.	CPC
2.8.5	Further development of the digital materials.	Sec
2.8.6	Continue to share and capture best practices so that it can be used by others in EA.	CPC
2.8.7	Support the development of an EA MLA mark including rules and procedures for use (see also 2.9.3).	CPC
2.8.8	Support the EA Secretariat in managing the EA website and further Social Media, up-date of EA documents and brochures, development and updating of EA promotional material.	CPC
2.8.9	Continue reinforcing use of Social Media.	Sec

2.8.10	Develop videos to be published on the EA YouTube chain and websites.	Sec
2.8.11	Establish an online FAQ system on the EA website, covering technical questions addressed by EA committees and other general questions received in the Secretariat with a view to provide information to and raise awareness in the general public and foster best practice at accreditation and conformity assessment level.	Sec
2.8.12	Carry out a study to develop further the EA website and Members' only website into a portal offering access and services to EA members and other stakeholders.	Sec
2.8.13	Prepare and publish the EA annual report 2018	Sec
2.8.14	Systematic review of EA documents (5 years interval)	Sec
2.8.15	Develop a structured approach to exchange experience in accreditation on top management level to include general/strategic management, development of policies, development of new areas and schemes as well as training of new assessors and ongoing training of assessors (see EA Strategy 2025 Implementation plan 1.5.2).	EX
2.8.16	Analyse current situation and propose new tools regarding cooperation and harmonization (see EA Strategy 2025 Implementation plan 1.5.3).	EX, HHC
2.8.17	Analyse and propose a project of digitalization, including e-training (see EA Strategy 2025 Implementation plan 1.5.4).	ES
2.8.18	Establish an EA-central resource as responsible for new developments, if needed (see EA Strategy 2025 Implementation plan 3.3.1).	ES, EX
2.8.19	Develop procedure how EA manage developments (see EA Strategy 2025 Implementation plan 3.3.2).	ES, EX

2.9 Management of EA

This relates to the main element i) in the EA Action Plan for the FPA 2018 - 2021:

- Good governance to deliver consistent and sustainable results
  - Strengthening the Management of EA

	Activity	**Responsible**
2.9.1	Implementation of the new Management structure.	EX

2.9.2	Further development of the EA Academy for training.	Sec
2.9.3	Preparing the rules and procedures for using an EA MLA mark (see EA Strategy 2025 Implementation plan 3.8.2).	HHC, EX
2.9.4	Carry out the relevant legal investigation for the registration and protection of the EA MLA mark and develop the necessary set of rules and documents for its use.	Sec
2.9.5	Implementation of the revised EA-1/17 Supplement 3 *EA Procedure for the investigation and resolution of Complaints and Appeals*.	Sec/EX
2.9.6	EA Management system: Implementation of a new documentation structure (quality manual).	Sec
2.9.7	Implementation of the new structure for decision making in EA (see EA Strategy 2025 Implementation plan 1.2.2).	EX
2.9.8	Implementation of the proposed system for enforcing EA decisions (see EA Strategy 2025 Implementation plan 1.3.2).	EX
2.9.9	Develop a resource plan to achieve the desired competences in the secretariat, including the impact on the EA budget (see EA Strategy 2025 Implementation plan 1.4.2).	ES
2.9.10	Develop a process for identifying NABs needs for closer cooperation and sharing of resources (see EA Strategy 2025 Implementation plan 3.7.1).	ES

Annex 1: General Assembly, Committees and Council meetings 2019

Committee	Number meetings	Comments
1. General Assembly	2	
2. Executive Committee	4	TFGs are established temporally for specific activities.
3. MAC Council - MAC Management Group	2 2	The MAC MG will hold additional 4 web meetings in between physical meetings.
4. Communication and Publication Committee - TFG website - TFG benchmarking	2	TFGs are communicating by email.
5. Horizontal Harmonisation Committee - Review Panel for FAQs	2	
6. Certification Committee - CC Management Group - WG Environment - WG Food - NWG EU ETS - Review Panel for FAQs	2 2 2 2 1	

7. Laboratory Committee
- LC Management Group
- WG Health Care
- Technical Networks for
  - Calibration;
  - Food and Feed;
  - Forensics;
  - Environment;
  - Mechanical, Electrical testing and Construction products;
  - Toys testing and Consumer goods;
  - ISO/IEC 17025.
	2
	2
	2
		The MG will hold 2 web meetings in between physical meetings.
		
		Technical Networks (TN) are communicating by email.

8. Inspection Committee - TN Vehicle (“Car”) inspection	2	Technical Network (TN) is communicating by email.

Annex 2 Budget estimate for the Work Programme 2019

Table 1: Eligible and Non-Eligible Expenditures

EA Budget 2019 Expenditures	2019 Costs in k€
ELIGIBLE	
Staff costs – EA Secretariat	715,5
Staff costs – EA Members	156,0
Total staff costs	871,5
Travel and subsistence – EA Secretariat	65,4
Travel and subsistence – EA members	102,0
Total travel and subsistence costs	167,4
Office rent and maintenance	149,0
Office consumables and supplies	4,0
Legal advice and consultants	24,0
Accounting and audit costs	31,0
Communications and publications	141,5
Miscellaneous (other costs)	21,7
TOTAL ELIGIBLE	**1.410,1**
NON-ELIGIBLE	
Staff costs – EA Secretariat	0,0
Staff costs – EA Members	0,0
Total staff costs	0,0
Travel and subsistence – EA Secretariat	0,0
Travel and subsistence – EA Members	0,0
Total travel and subsistence costs	0,0
Insurance	20,0
Miscellaneous	1,0
Transfer to reserves from membership fee to meet EA Reserves Policy	35,0
Transfer to reserves	10,6
TOTAL NON-ELIGIBLE	**66,6**
TOTAL EXPENDITURES	**1.476,7**

Table 2: Funding from the Operating Grant 2019

Funding from the Operating Grant	Amount in k€	Percentage of costs
Funding eligible costs		
Partner	669,9	47,5065
EC	722,9	51,2631
EFTA	17,3	1,2303
Funding eligible costs	**1.410,1**	**100**
Funding total costs		
Partner	736,5	49,8749
EC	722,9	48,9502
EFTA	17,3	1,1748
Funding total costs	**1.476,7**	**100**