

EA report, October 2009

The last months have been an outstanding period of the life of EA, marked by many important achievements, such as the signature of the Cooperation Guidelines between the EA, the European Commission, EFTA and the competent National Authorities, the starting of the preparatory work for the stipulation of the Framework Partnership Agreement with the European Commission, the substantial progress in the implementation of the EA Development Plan, including finalizing the revision of the Articles of Association and Rules of Procedure and planning of the future of the EA Secretariat.

POLICY AND STRATEGIC ISSUES

1. The new role of EA as official European Accreditation Infrastructure

Following the adoption of the new European legislative package in particular of Regulation (EC) 765/2008 – the recognition of EA as the official European accreditation infrastructure has made a major step forward with the signature of the “*General Guidelines for the cooperation between the European co-operation for accreditation and the European Commission, the European Free Trade Association and the competent National Authorities*” (Certif doc 2009-01) that took place in Brussels on April 1st 2009 on the occasion of the meeting of the Senior Official Group for Standardization and Conformity Assessment (SOGS).

The Guidelines have been signed by the Director General of DG Enterprise Mr. Heinz Zourek, the Deputy Secretary General of EFTA Mrs Bergdis Ellertsdottir, the Chairman of EA and nearly all representatives of National Authorities attending the SOGS meeting.

The Guidelines set up the policy common objectives of the cooperation, the related principles and the expectations and commitments of the Parties to pursuing the common aims.

As such, the Guidelines represent a major step forward in the development of European accreditation at the service of the European economy and society.

The recognition of EA will be completed by the forthcoming stipulation of a Framework Partnership Agreement with the European Community (represented by the Commission) that will set up the conditions for EA to receive, starting from 2010, financial contributions from the Commission in the form of an operating grant consisting of a contribution to the operating budget of EA, covering a given percentage of the eligible costs related, in turn, to a work programme to be submitted by EA and approved by the Commission.

Discussions are in progress with the Commission to finalise the terms of the Agreement and its annexes and the requested “quotation” for 2010 (work programme and full budget of eligible costs). A draft package of documents supporting the quotation was discussed by the Executive Committee end of September and will be discussed soon with the EA members. The full package should be ready as soon as possible, before it is submitted to the Commission on October 30 2009 which is the deadline for preparation of the Commission budget for 2010.

The General Assembly mandated the Executive Committee to finalize the above work and empowered the Committee to authorize the EA Chair to sign the Framework Partnership Agreement and the specific agreement for 2010.

Still in preparation for its new role, important policy issues concerning full alignment to the requirements of Regulation 765/2008 are being dealt with at the EA Committees and MLA Council (MAC) levels. This has an impact on both EA and its members and work is being developed in this regard.

As for EA, the revision of the Articles of Association and Rules of Procedure should enable to adapt the new criteria for membership and other aspects, but it is also important to ensure the effectiveness and harmonization of the approaches adopted by the members to achieve compliance with the applicable requirements. These concern, in particular, Article 4 “General principles” and Article 7 “Cross-border accreditation” of the Regulation. Work has started to elaborate on such aspects and especially on the implementation of Article 7.1, in cooperation with the Commission.

2. The EA Development Plan

The **EA Development Plan** for the period 2007-2010 (development phase) and 2011-2013 (consolidation phase) continues to progress.

The Plan includes:

- policy developments;
- structural and organizational developments and financial developments;
- technical developments;
- development of relations with European and international stakeholders;
- development of relations with accreditation bodies of “third countries”.

2.1. Policy developments

Top policy developments of the Plan will be completed in a few weeks with the signature of the Framework Partnership Agreement.

Moreover several policy initiatives have been conducted to strengthen the relations with the services of the European Commission to foster, as far as possible, the use of accreditation in the EU sectoral regulatory policies. In this regard, it’s worth mentioning in particular:

- The cooperation with DG Environment to promote the use of EA MLA accreditation within the EU Emission Trading Scheme (ETS) and within the new Regulation on “Voluntary participation by organizations in a Community eco-management and audit scheme” (EMAS III);
- The cooperation with DG Health and Consumer Protection (SANCO) and DG Enterprise, to develop and pilot – in partnership with ECN “European cancer Network” the European branch of IARC “International Association for Research on Cancer” – an accreditation/certification scheme of breast cancer prevention and diagnosis services in Europe. The project is strongly promoted by the European Parliament and supported by DG SANCO.
- The cooperation with DG AGRI to foster the application of accreditation in the fields of “Organic Production” (EC Regulation 834/2007), “Geographic Indication and Designation of Origin” (EC Regulation 510/2006) and “Traditional Specialities Guaranteed” (EC Regulation 509/2006). The possibility and opportunity of developing EA sector schemes for the accreditation of Control Bodies operating in such fields were further analyzed and confirmed.
- The cooperation with DG Energy and Transport in the frame of the implementation of Regulations (EC) 715/2007 and (EC) 692/2008 regarding “Type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles and access to vehicle repair and maintenance information”. Such Regulations introduce the concept of “independent operators”, namely undertakings (other than the authorized dealers and repairers) working in the field of repair and maintenance of motor vehicles, and specify that, to be allowed to access vehicle information concerning security measures and protection of the emission calibration system (encrypted by the vehicle’s manufacturer) operators need to be qualified through what is called an “accreditation” process.

Discussions take place with the competent European Body (Forum on Access to Vehicle Information) with a view to set up an accreditation scheme across the EU to enable repairers to obtain secure information from the automobile manufacturers.

- The cooperation with the Joint Research Centre (JRC) of the Commission. Discussions have continued and agreement has been reached on how to revise the existing Collaboration Arrangement to enhance the cooperation between EA and JRC in line with the objectives of the Cooperation Guidelines.

EA has also been contacted by the European Railway Agency (ERA) and the European Clinical Research Infrastructures Networks (ECRIN). Further discussions will develop in the near future through the Horizontal Harmonisation Committee.

In general, relations between EA and the Commission's services are developing pretty well. EA is invited regularly to attend the SOGS meetings every time accreditation is tabled on the agenda. EA is also now a member of the Accreditation Steering Group recently established within the Commission to act as the EC main forum gathering representatives of all Directorates to discuss issues related to use of accreditation in the EC regulatory policies.

2.2 Structural and organizational developments and financial developments

The new Horizontal Harmonization Committee (HHC) has been established and is now fully operational. The MAC management system and ToR of the MAC are being aligned to reflect the transfer of specific responsibilities to the HHC.

The ToR of the Communications and Publications Committee have also been amended and its role enhanced.

The reinforcement of the Executive Committee, by the insertion of four additional members, has been achieved as a result of the elections held in May 2009 in Luxembourg, as detailed below:

According to EA Resolution 2009 (23)12, the General Assembly elects the following officers to the EA Executive Committee for a two-year mandate starting on 1 January 2010:

EA Chair Graham Talbot (UKAS)
EA Vice-Chair Daniel Pierre (COFRAC)
Multilateral Agreement Council Chair Thomas Facklam (TGA)
Horizontal Harmonisation Committee Chair Merih Malmqvist (SWEDAC)
Inspection Committee Chair Norbert Müller (BMWfJ)
Certification Committee Chair Leopoldo Cortez (IPAC)
Communications & Publications Committee Chair Vagn Andersen (DANAK)
Laboratory Committee Chair Christina Waddington (FINAS)

Four additional members of the Executive Committee including:

Biserka Bajzek-Brezak (HAA)
Hanspeter Ischi (SAS)
Róza Ring (NAT)
Jan Van der Poel (RvA)

The process of revision of the Articles of Association and of the Rules of Procedure is nearing completion. An ultimate legal check is being carried out to confirm compliance with the Dutch law. Then the very final texts will be submitted to the members for voting.

Reinforcement of the human resources of the central Secretariat in Paris is also in progress. The team have been brought to three full time persons in 2009. To further complete the process, the General Assembly decided that EA should become an employer in France, hiring the present staff by transfer of the working contracts from COFRAC to EA, and achieving better control of its operation regarding also the administration and audit of accounts and other aspects.

2.3. Technical developments

Technical developments are part of the continuous EA improvement process and those specifically related to the assumption of the new role have been dealt with within the ad-hoc Project on “**Enhancing European Accreditation**” which started in 2006.

Sub-project 1 “Harmonisation of assessment practices in view of notification”, finalised the horizontal guidance document that has been approved and published as EA-2/17 “EA Guidance on the Horizontal Requirements for the Accreditation of CABS for Notification Purposes”. Conditions for its implementation have been clarified and reinforced by a resolution of the General Assembly in May 2009.

Sub-project 2 “Information and knowledge database” completed the task of setting up networks of contact points for Directives that will enable the EA members to access and exchange relevant information. Appointment of conveners for the networks has been finalized and tasks and reporting procedures have been worked out through the HHC. A kick-off meeting of the nets conveners took place on 4 September 2009. The objective was to clarify the role of the conveners and the work program of the nets and elaborate on the tools needed in future to support the activities. The Secretariat, together with the CPC, is making research and testing IT facilities to enable web-based interaction and efficient, controlled sharing of knowledge.

As for the work of Sub-project 3, after the publication of the first issue of the Best Practice Guide for “Communications with the National Regulators” to be used by national accreditation bodies, a benchmarking exercise was launched to evaluate actions undertaken and progress made in this field and will be repeated in 2010.

Sub-project 4 “Relationships with the European Commission” has been working to develop appropriate mechanisms for effective communication between EA and the various services of the Commission. Such channels have now been successfully established and the activity of the group has been concluded.

Sub-project 5 “Enhancing the peer evaluation process” started a pilot phase to test in practice the principles of a new risk-based approach. The group also started to identify specific criteria for the assessment of the competence of ABs to evaluate and accredit CABS operating in the mandatory area and to elaborate on mechanisms to ensure appropriate involvement of the national Regulators and of the EC in the peer evaluation process, as foreseen by the new legislation.

The WG is also elaborating on training and qualification of peer evaluators and reporting procedures and will be invited to make a detailed presentation to the EA Advisory Board at its coming meeting on 29 October 2009.

As the results of the sub-project groups are naturally and progressively being transferred to the normal structure and operations of the EA Committees, the General Assembly will be invited to consider to close the SP groups at the November meeting.

2.4. Development of relations with European and international stakeholders

Development of relations with stakeholders is a major part of the EA Development Plan. Serving stakeholders expectations is a distinct obligation for EA stemming out from the new EC Regulation and, as such, is ranking high in EA’s priorities.

EA is being approached by a growing number of stakeholder organisations, including industrial and service sectors that wish to establish reliable and recognised conformity assessment schemes benefiting from the EA MLA coverage, associations of conformity assessment bodies, metrological organizations and others. Several cooperation agreements have been already concluded with many stakeholders as shown on the EA website. An MoU with WELMEC was signed during the General Assembly meeting in May 2009.

The first draft of the EA policy document for relations with stakeholders (EA-2/16), which introduces the category of EA Stakeholder Member and defines rules for stakeholder participation to EA activities, has not been adopted by the EA members. The policy is being revisited within the Executive Committee. One of the main objectives is to set out the criteria and conditions to allow stakeholders willing to be institutionally involved in the work of EA, to be able to do so. The EA Advisory Board will be submitted a revised proposal for discussion in October.

More generally, the role of the EAAB has been strengthened. The Terms of Reference and Rules of Procedure of the EAAB have been revised accordingly and mechanisms for improving interaction between EA and the EAAB have been established including through an upgraded administrative support from the EA Secretariat to the EAAB.

At the international level, the EA Chair and Vice Chair, together with the other liaison persons, continued to ensure close contacts with ILAC, IAF and the other regional accreditation co-operations. An MoU between EA and APLAC has been signed in January 2009 and similar initiatives are being considered towards other regional bodies.

EA continued to pro-actively contribute to the work in progress regarding the development of the international accreditation system, within the JCCC TF established by the Joint ILAC/IAF GA in Stockholm.

Effective liaisons are also being maintained with ISO/CASCO, through EA's participation (on behalf of ILAC and IAF) to the newly established ISO/CASCO Groups STAR "Strategic Alliance and Regulatory Group" and ISO/CASCO Group TIG "Technical Interface Group".

2.5 Development of relations with accreditation bodies of "third countries"

A policy has been developed to provide for a better framework for cooperation with accreditation bodies of countries not being members of the EU and EFTA but falling within the European Neighbourhood Policy (ENP), and particularly belonging to the Euro-Mediterranean area. This policy has been just recently approved and published as document EA-1/13. A detailed review of the existing contracts of cooperation and bilateral agreements was carried out by the Executive Committee at the end of September. The Executive also discussed a proposal for a mechanism to provide recognition to non EU/EFTA accreditation bodies to demonstrate they comply with the additional requirements of Regulation 765/2008 over and above the requirements of the ILAC and IAF arrangements. The proposal will be submitted to the EAAB and General Assembly before further development.

OPERATIONAL ISSUES

1. EA Membership

At its last meeting in May 2009, the General Assembly agreed to the transfer of the EA membership jointly from SINCERT and SINAL to the legal entity named **ACCREDIA**. The General Assembly also agreed to the transfer of the EA membership from SIT (INRIM) to the legal entity named COPA. Transfer of MLA signatory status of both new members will have to be confirmed by decision of the MLA Council (MAC).

DGA, the new German accreditation body resulting from the merge of DACH, DAP and TGA has been accepted as EA full member. MLA signatory status of the three former ABs has been transferred to DGA by unanimous decision of the MAC.

To date, the EA family counts 34 full AB members and 18 signatories of a contract of cooperation, including the two last contracts signed with the ABs of Montenegro and Kazakhstan. Nine of such contracts have developed into Bilateral Agreements. The contract of cooperation with A2LA and the related BLA terminated on June 30th due to difficulties for the signatory to fulfil the requirements established by EA for its members pursuant to Regulation 765/2008.

Among the EA 34 full members, there are 32 bodies signatories to the EA MLA out of which 18 have signed for all accreditation activities presently covered by the MLA.

2. Technical, cultural and promotional activities

As for the **MLA Council** (MAC), work is in progress to revise the EA cross-frontier document (EA- 2/13) to align it with the new legislation and include guidance on how to deal with transfer of accreditation during the transition period.

The EA-2/11 “Policy for sector schemes” is being supplemented by a better definition of process and criteria for the technical assessment of the scheme, in cooperation with the HHC.

The MLA scopes concerning accreditation of certification of management systems (QMS, EMS, others) have been unified under a single scope related to ISO/IEC 17021.

The **Horizontal Harmonization Committee** has just started its work, beginning to elaborate on the issues related to the implementation of Article 7.1 of Regulation 765/2008 (*cross frontier accreditation*) with a view to feed in the discussions within the Commission.

Furthermore, the HHC is reviewing EA-3/09 “Surveillance and Reassessment of Accredited Organisations” and developing a procedure for the expansion of the EA MLA.

An increasing number of sector schemes are approaching EA for recognition under the EA MLA. The HHC will play a key role in the relevant processes that are being established. The HHC will rely on and interact with the technical committees for the technical evaluation of the conformity assessment schemes. The appropriate procedure and processes are being finalised with the MAC.

The HHC established a TFG on ISO/IEC 17011 whose role is to come up with harmonised positions on how to implement the standard requirements. The TFG was first asked to address a question about the Impartiality criteria, upon request of the MAC. A proposal has been consolidated and will be forwarded to the MAC for their consideration in November.

The **Communications and Publications Committee** (CPC) has been focussing on a number of priorities:

- new pages have been created to promote the EA MLA and additional information will be soon published to raise public awareness about EA’s new role as foreseen by Regulation 765/2008;
- the “Members only” homepage continues to improve. An “RSS” system is being considered that would issue a warning to subscribers when a new page or new information is published.

- The Intranet now offers the possibility to users to put brief written comments online on a given topic or document;
- A briefing for Governments and Regulators has been designed for use by the ABs.
- EA-1/08 is the current list of MLA and BLA signatories. As suggested by the MAC, the CPC is elaborating on a more sophisticated brochure outlining the main features and benefits of the peer evaluation system.

The **Laboratory Committee** (LC) went through a good deal of work in 2009 covering in particular the cooperation with WADA, ENFSI and EPPO (for the latter a joint communiqué has been published on March 2009), the planning of ILCs in testing and calibration, the “accreditation” of calculation methods and the development of a library of examples of flexible scopes.

The LC started also to look at developing new working practices.

The Management Group for instance started to hold web-based meetings in between LC meetings to sustain progress of the work and improve coordination. Participants’ feedback is excellent.

In addition, technical networks have been set up as a new mechanism for ABs to share opinions and discuss issues of common interest without the need for “physical” meetings. Such nets are operational in the fields of Food & Feed, Forensic, Environment, Calibration and Mechanical/ Electrical issues.

The Net Environment is developing Good Practices for flexible scope in environment. The Net Calibration will start revision of EA-4/02 Expression of Uncertainty of Measurements in Calibration. The Food Net carried out two surveys on residue analyses and revision of EA-4/10 Accreditation for Microbiological testing. The Net on Mechanical and Fire testing is deeply involved in cooperation with EGOLF. In the field of Forensics, the Net is cooperating closely with ENFSI and the ILAC corresponding WG.

At the September meeting, the LC reviewed and endorsed a proposal for TOR of the nets; they will be submitted to the GA for approval in November as well as nominations for the MG members of the MG who are, in addition to the Chair and Vice Chair, the convenors of the nets and WGs ILC in testing, ILC in calibration and Health Care.

The Convenors of the two WGs ILCs in testing and calibration reported progress in the development of their activity plan. In both WGs, it was identified a need for ABs to continue to reinforce their commitment and involvement in the activity of their accredited labs.

Reflections will progress with the Communications & Publications Committee on how to better value and promote results of ILC and PTs in EA.

The Committee decided to publish a “Stack emission package”, consisting of a summary prepared by RVA on the main requirements of CEN 15765, and the resolution of the GA in May 2009 on accreditation in the field; and resolved that activity against “EN 14181 Stationary source emission. Quality assurance of automated measuring systems” should preferably be accredited as a testing activity according to ISO/IEC 17025.

Finally, The LC endorsed an EA announcement supporting the ILAC BMC/CMC communiqué and agreed that the target for completion of the transition should be end of 2010. The announcement will be published on the EA website for information of accredited laboratories.

The **Certification Committee** (CC) has been working on several issues including: the production of EA-3/11 “Food Safety Management Systems – Scope of accreditation” and the endorsement of a sectoral certification scheme, CERTALARM in the field of fire and security industry.

The CC came up with draft TOR for a new WG on Environment covering all the environmental issues. The General Assembly will be invited to appoint the nominated convenor and endorse the proposed TOR.

A new convenor will also have to be appointed for the CC WG Food as Ignacio Pina indicated he would step down after many years of deep involvement in the WG.

The CC "Reference List between the 39 codes of IAF GD:2005 Annex 1 and NACE codes Revision 2" has been published as an advisory document and a guidance on the accreditation of certification according to ISO/IEC Guide 65 for producers with multiple production locations is under development.

At its September meeting, the CC decided to start revision of EA-6/03 Guidance on Recognition of Verifiers under EU/ETS directive and to start the drafting of a guidance on scopes for accreditation of organic production certification.

The meeting was Norbert Müller's last meeting as Chair of the CC and the Committee paid him a warm tribute for a very busy and successful mandate. Leopoldo Cortez, from IPAC Portugal, who was involved in the Committee as a Vice Chair will take over from Norbert in 2010. We wish Leopoldo an exciting time in the CC!

As for the work of the **Inspection Committee (IC)**, after publication of EA-5/03 "EA/ENFSI Guidance on the implementation of ISO/IEC 17020 in the field of crime scene investigation" end 2008, the Committee finalised an "Independence package" and the list of questions and answers dealt with over the past 5 years, marking the successful chairmanship of Merih Malmqvist's since 2005. Merih indeed chaired her last IC meeting in September and Norbert Müller, BMWFJ Austria will take over in 2010.

No doubt that the IC will remind Merih's time in the Committee for long, for her enthusiasm and talent to get things done!

EA MEETINGS 2009 - 2010

2009

29 October 2009	EA Advisory Board, Brussels
24 November 2009	Executive Committee, Bruges (Belgium)
25-26 November 2009	General Assembly, Bruges

2010

26-28 January 2010	Executive Committee, Paris
4 February 2010	Laboratory Committee MG web meeting
22- 26 February 2010	Certification, Inspection Committees dates and location to be defined)
9 March 2010	Laboratory Committee MG, Amsterdam
10-11 March 2010	Laboratory Committee, Amsterdam
22-23 March 2010	Horizontal Harmonisation Committee (location to be defined)
14 April 2010	Executive Committee, Brussels
15 April 2010	EA Advisory Board, Brussels
20-21 April 2010	Communications & Publications Committee, Sofia
19 May 2010	Executive Committee, Zürich
20-21 May 2010	General Assembly, Zürich

More information available on www.european-accreditation.org