

# APPROVED Minutes of the 35<sup>th</sup> Meeting of the EA Advisory Board

held on 21 October 2015 at the EFTA Secretariat, 12-16 Rue Joseph II, B-1000 Brussels

Participants:

EAAB Chair: Michael Nitsche (NA, Germany)
EAAB Vice-Chairs: Martin Stadler (BUSINESSEUROPE), Christian Priller (CEOC International).
CAB College: Pierre de Ruvo (EEPCA), Roger Brockway (IFIA), Manuela Held (IIOC).
Industry College: Andrew Evans (GANBICA), Lars Bo Hammer (BUSINESSEUROPE).
NA College: Maureen Maria Logghe (NA, Belgium), Ola Brohman (NA, Sweden), Devran Ayik (NA, Turkey).
EC: Nike Bönnen, Zacharias Bilalis.
EFTA: Elin Engelsen Geitle.
EA: Geir Samuelsen (EA Vice-Chair), Andreas Steinhorst (EA Executive Secretary), Frédérique Laudinet (EAAB Secretariat).

Apologies received from: Peter Blinksbjerg (EUROLAB) Alex Rasmussen (EUROVENT), Jörg Ed. Hartge (ORGALIME, BDI) Domagoj Validžić (NA, Croatia) Stephen Russell (ANEC) Pambos Kammas (CEN/CENELEC) Janko Drnovšek (EURAMET), Anneke Van Spronssen (WELMEC) Thomas Facklam (EA Chair)

The signed attendance list is available on the relevant EAAB intranet page.

#### 1. Opening of the meeting – Introduction of Members and guests Renewal of the EAAB membership: nomination results and election of Chair and Vice-Chairs Appointment of EAAB observers to MAC and HHC

The Chair opened the meeting, thanking EFTA for hosting it. He welcomed the delegates, especially the new ones who had been nominated further to the call launched for the renewal of the EAAB membership for the next 3-year term. He invited all participants to introduce themselves. A special welcome was also made to Zacharias Bilalis from the European Commission who will be replacing N. Bönnen.

The EAAB Colleges informed the Board of the appointments of C. Priller, M. Stadler and M. Nitsche as the Chairs of the CAB, Industry and NA Colleges, respectively.

As the only candidate, M. Nitsche was re-elected EAAB Chair.

M. Nitsche informed the Board of the willingness of M. Logghe to serve as the EA MAC observer for the EAAB. The industry and CAB colleges expressed their support for this proposal, and M. Logghe was appointed accordingly.

M. Stadler informed the Board of the willingness of A. Evans to serve as the EA HHC observer for the EAAB. The NA and CAB colleges expressed their support for this proposal, and A. Evans was appointed accordingly.

# Decision

For its next 3-year term starting at this meeting, the Board:

- acknowledged the appointment of Christian Priller, Martin Stadler and Michael Nitsche as the chairs of the CAB, Industry and NA Colleges, respectively;
- agreed upon the re-election of Michael Nitsche as the EAAB Chair, Christian Priller and Martin Stadler being then the two EAAB Vice-Chairs;
- agreed upon the appointment of Maureen Maria Logghe (NA College) and Andrew Evans (Industry College) as the EAAB observers in EA MAC and HHC meetings, respectively.

# 2. Approval of agenda; Approved Minutes of 34<sup>th</sup> Meeting of the EA Advisory Board; Action list (actions not covered elsewhere)

#### Approval of agenda

M. Stadler wondered whether the "*Project on EA Strategy 2025*" to be considered under Item 5.2 should not be more stressed under another, distinct item. G. Samuelsen and A. Steinhorst replied that the point was to be presented as information in order to get the EAAB's support. It was agreed that the "*Project on EA Strategy 2025*" should be considered as an information point, not subject to decision.

P. de Ruvo asked what the Board considered as "Key topics for discussion". In his view, such topics should be more focused on accreditation and conformity assessment topics. He also suggested including the EAAB Work Programme under this "Key topics" agenda item (see further decision under Item 7).

M. Stadler stressed that each discussion point should be based on a supporting document so as to allow the Board to contribute to the discussions in an active and efficient way. The CAB College shared this view, complaining that it was not always quite clear what the rationale for discussion was. P. de Ruvo put pressure that it should be the Chair's and the EAAB Secretariat's responsibility to ensure that enough relevant material are made available to the Board; each College should also have the possibility to send written comments in advance of the meetings. The Chair pointed out that, most often the timeframe could not make this possible.

The agenda was finally approved by the Board.

#### Approved Minutes

The Chair reminded that the minutes of the previous meeting had been approved further to the email call for comments, which had not resulted in substantial amendments.

M. Logghe thanked the EAAB Secretariat for having made the changes she had proposed regarding the person names (to be now indicated in full in the participant list at the top of the minutes) and abbreviations (the more recurrent of them to be now made explicit at the end of the minutes).

Although not a Board member at the 34<sup>th</sup> EAAB meeting, D. Ayik made further explanations on two agenda items. She briefly explained the history of Turkey - EU relations regarding the harmonisation of EU acquis by Turkey, appointment of Turkish notified bodies and TURKAK's full membership to EA - and therefore stated the importance of mentioning this special role of Turkey seperately in the relevant documents of EA such as the one under the agenda item 5.2 "Revision of EA-1/13: EA's Relationship with Accreditation Bodies of Countries Not Being Members of the EU or EFTA". Regarding the agenda item "5.5 Cooperation with Halal Accreditation Forum", she also

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gave information about how Turkey deals with halal certification and the role of "The Standards and Metrology Institute for Islamic Countries (SMIIC) on halal certification and accreditation.

M. Stadler proposed reducing the length of the minutes which should be kept less than 10 pages. There is no need for so many details. M. Logghe and D. Ayik disagreed, arguing that detailed minutes proved to be a very useful feedback for new EAAB members.

# Action List

All actions were considered to be either closed or included on the agenda for the meeting. No more comment was voiced.

#### Decision

The Board:

- asked that every agenda item meant for discussion is supported by relevant background documents, in order for EAAB Members to better prepare themselves and make active input into the discussions;
- took note that some EAAB Members, especially the new ones, appreciated having detailed minutes which they considered to be a precious feedback on the Board's meetings and, as a result, agreed that the minutes should remain with the same level of details as they were now.

# 3. Key topic for discussion

**3.1 Review of role of EAAB and interaction with EA** (updating draft of EAAB document *Role of the EAAB and Interaction with EA*)

The Chair reported that the Colleges had not managed to review the draft made by the EAAB Secretariat in light of the decisions made at the April meeting. He proposed reviewing it during the meeting.

P. de Ruvo asked about the background of the document.

M. Stadler answered that the document looked as if it were an addition to the EAAB Terms of Reference and Rules of Procedure. But it should be rather to be considered as a management review, which is deemed to complement neither the EAAB ToR nor the RoP. And the "management review" nature of the document should be made clearer through the language used.

P. de Ruvo insisted that the document lacked consistency.

M. Stadler supported the work done by the EAAB Secretariat, confirming that the agreements reached at the previous meeting had been correctly inserted into the document. Some language in the document should just be adapted so that the paper more clearly reflects its intended purpose as a management review. He added that there is no need for performing a review exercise more often; five years are a sufficient interval for conducting a management review.

It was suggested putting together the Colleges' expectations under the section "EAAB Terms of Reference and Rules of Procedure".

M. Stadler proposed some editorial improvements, such as changing the document's title into "*The EAAB: Management Review of role, operations and interaction with EA*". He also advocated rephrasing the conclusion of each section with expressions like "*At its meeting in April 2015, the Board confirmed that the existing rules and procedures are still adequate*", "*the Board expressed satisfaction on how it is managed*", etc. There is no need for much rewriting, but just clarifying the purpose. M. Held agreed that such language specific for management review was more appropriate for the document.

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On Page 4, M. Logghe asked to change "*how the NA College could represent more actively EA views and interests*" into "*how the NA College could give feedback more actively on* …". And R. Brockway proposed removing the yellow-highlighted last paragraph from the document.

P. de Ruvo and M. Stadler agreed not to spend too much time on the document. The different points should be streamlined more efficiently. A. Evans and L. B. Hammer also agreed to keep the rephrasing easy without a long process based on a TFG.

#### Decision

The Board:

- confirmed that the draft document should partly be rewritten to reflect better its purpose as a kind of management review;
- agreed that each College should send, by end of November 2015, written comments and proposals for improvement in a tracked-change version to the EAAB Secretariat, which should produce a consolidated final version for further discussion and adoption at the next EAAB meeting.

Action EAAB Colleges/Vice-Chairs, then EAAB Secretariat

#### 4. EAAB matters

One mistake was noticed on the agenda: Items 4.1 and 4.2 should be for information only, not for discussion.

#### 4.1 Reports from the EAAB HHC and MAC observers

Because no written report had been published before the meeting, the Chair asked the persons having attending the last MAC and HHC meetings to report orally.

# MAC meeting on 1-2 October 2015

N. Bönnen and A. Steinhorst reported that Daniela Ionescu from RENAR had been elected the new Vice-Chair of the EA MAC, whose chair would also change to be Paulo Tavares from IPAC as from the spring 2016 meeting.

Further issues discussed at the last MAC meeting autumn 2015 were – inter alia:

- Revision of EA-1/13 and developing a specific PE process for compliance with Regulation 765;
- Application to IAF MLA sub-scopes Result of EA survey and how to use them;
- Use of EA highlighted PT's as element for the PE's.

# • HHC meeting on 16-17 September 2015

A. Steinhorst highlighted the following points discussed by the HHC:

- whether accredited CABs shall use the EA logo on their reports and certificates;

- EA-1/22: EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members should be further revised for clarification purposes (see NWI proposal to be supported by the EAAB under Item 5.2);

- the new developments in the proficiency testing issue (see MAC above).

P. de Ruvo pointed out that whether to insert the accreditation logo on test reports was an old issue still discussed in ILAC and which had not been really solved so far. A. Steinhorst confirmed that the issue would be put forward to ISO CASCO WG 42.

The Board thanked N. Bönnen and A. Steinhorst for their oral reports on the last MAC and HHC meetings.

# 4.2 Application of ILAC P10:01/2013 *ILAC Policy on Traceability of Measurement Results* by EA Members: update from EA and EAAB position

The Chair recalled that the issue of ILAC P10 and the different routes for obtaining traceability had been discussed at length within the Board, including the adoption of an EAAB position.

A. Steinhorst indicated that there was nothing new or specific to be reported from the EA Laboratory Committee which remains the most relevant EA body on this issue.

No comment was voiced by the CAB College.

# 4.3 Transition process for ISO 9001:2015: update from EA

The Chair thanked EA for having kept the Board informed of EA's position as circulated to IAF by the Vice-Chair of the Certification Committee. A. Steinhorst reported that nothing more happened since then.

Everything has been solved as provided in the IAF-ISO Communiqué providing that, in line with IAD ID 9: 2015, the transitions of certified organisations to ISO 9001: 2015 and ISO 14001: 2015 must be complete by 15 September 2018.

# Conclusion

The Board:

- thanked EA for having kept EAAB Members informed of EA's position on the issue by circulating the EACC Vice-Chair's mails after the last EAAB meeting;
- took note of the Joint ISO/IAF Communiqué setting out that the transition of certified organisations to ISO 9001:2015 must be complete by 15 September 2018, and considers that the issue is now solved.

# 4.4 Guide to the expression of uncertainty in measurement – Comments on the CD of JCGM 100

Referring to Document EAAB(15)08, the Chair reported on the NA College's proposal for voting on the CD of JCGM 100, which NAs considered to be unacceptable and advocated rejecting it to its full extent.

P. de Ruvo agreed upon the NA College's position, asserting that too many guides were published every year on how to measure uncertainty and urging to adopt a more pragmatic approach.

The NA College Chair highlighted that some problems might arise if NABs used this guide. The CAB College did agree upon the NA College's recommendation to throw out the guide; there is no need for additional guidance document.

#### Conclusion

The Board took note of the CAB College's intention to follow the recommendation made in document EAAB(15)08 and to reject the proposed guide, considering that there was no need for an additional guidance document.

# 4.5 Uncertainty contribution of the Device Under Test to the total uncertainty budget in calibration process – Feedback from the EA LC September meeting

The Chair stated that Janko Drnovšek, the EURAMET representative who had raised the question at the previous meeting, could not attend the meeting to report on how the Laboratory Committee had answered the issue.

# 5. EA matters

# 5.1 Revision of ISO/IEC 17011 and ISO/IEC 17025

A. Steinhorst reported that the comments received on CD1 had been consolidated and were considered by the drafting group in ISO CASCO WG 42 in Geneva during these very days.

The most important issues are dealing with:

- the scope of the standard;
- the use of accreditation symbol by clients;
- the proficiency testing issue;
- impartiality of ABs and definition of related ABs;
- accreditation decisions with regard to surveillance activities;
- management system options A and B.

There was no comment from the Board, which thanked A. Steinhorst for his update.

# 5.2 New EA projects and work items

#### Project on EA Strategy 2025

G. Samuelsen recalled that EA was looking towards the future and thinking about new strategic objectives to be defined in a long-term vision throughout the period 2017-2025, 2017 being the end of the current strategic plan. In short, the EA Strategy 2025 will include not only the action steps, but also the resources needed to accomplish the objectives that will be defined along three tracks: with an EA members' perspective based on EA members' needs and required support; in relation to development of accreditation and conformity assessment as a service to regulators and the market place; and in light of EA's organisation, structure and services provided. G. Samuelsen invited the Board to read the full description of the project which had been made available for the meeting. He insisted that it was essential for EA to involve stakeholders in the process of defining these objectives. He added that the project was expected to last 16 months, until end of 2016. Further information will be given at the next meeting of the Board.

A. Steinhorst pointed out that a specific session on the EA Strategy 2025 project would be held during the EA General Assembly in November 2015 to consider specific questions asked to EA members. A questionnaire will also be sent to the EAAB to feed into the Board's discussions.

A. Evans pointed out that the stakeholders' expectations towards EA and accreditation, as contained in the relevant EAAB paper that was reviewed in April 2014, should be used as valuable input into the discussions on the project.

L. B. Hammer asked why the year 2025 had been selected. A. Steinhorst replied that 2020 was a too short term, all the more since the current strategic plan based on the FPA would end in 2017 and EA's visions should be reflected in EA's Strategy. Strategic objectives will have to be checked; some will remain opened in 2017. The EA Strategy 2025 should include all objectives to be larger and better structured.

M. Stadler wondered why a project team had been established as there was no such team for the previous EA Development Plan. G. Samuelsen answered that EA should now act as a more professional organisation.

P. de Ruvo was surprised about the many details indicated in the budget plan. A. Steinhorst specified that those were only estimations given for information, since the budget should be carefully prepared for submission to the EC. The most important for the Board should be the project's content.

Further to a remark by M. Nitsche, G. Samuelsen confirmed that the EA Strategy 2025 project should cover any relevant issues, including the international ones.

Furthermore, it is envisaged to have a specific session in regard to the EA Strategy 2025 at the next EAAB meeting spring 2016.

See decision below.

# • NWI on revision on EA-1/22: EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes (CAS) by EA Accreditation Body Members

G. Samuelsen explained that EA Members' feedback on the use of EA-1/22 evidenced a need for clarification of several concepts and procedural aspects of the document where different interpretations had arisen that might, if not quickly solved, result in a lack of harmonization in the application of the document towards the different scheme owners (SOs). He summed up the main points of the rationale for a further revision of EA-1/22:

- firstly, the HHC decided to include into the new revision that EA-1/22 had been specifically designed for CAS with an identifiable and accessible SO. In other situations (CAS fully based on standards, e.g.), some requirements in EA-1/22 may not apply. It is also proposed to specify that EA-1/22 is not applicable when the SO is the CAB asking for accreditation and the scheme is only applied by that CAB, as such a situation is covered by the relevant accreditation standard;

- another misunderstanding is to consider that EA-1/22 is a tool to decide whether a CAS is covered or not by the EA MLA, which is not the purpose of the document. It should then be made clear that EA NABs' acceptance of the CAS referred to in EA-1/22 is only to assure a harmonized response to the SO from all ABs accepting application for CABs using that CAS, with no impact on the EA MLA coverage;

- finally, EA-1/22 should be used whenever the EC asks EA to analyse a scheme owned by the EC.

See decision below.

# • NWI on revision of EA Articles of Association (AoA)

G. Samuelsen listed the 3 main reasons for revising the EA AoA:

- to provide all MLA/BLA signatories voting rights at the MAC;

- to allow EA Associate Members to vote at GA meetings;

- to introduce the option that EA may sign cooperation agreements with NABs from non-European countries and to establish closer cooperation with other regions.

G. Samuelsen added that if Associate Members' voting right was largely accepted by the MAC, it proved to be a more complex issue for the General Assembly.

See decision below.

# • NWI to develop guidance on the choice of ISO/IEC 17021 or 17065

M. Nitsche highlighted the importance of the issue and the need to solve the conflict between using a management system certification standard or a product certification standard. He pointed out that ISO/IEC 17065 was often preferred because products could be marked to be sold.

A. Steinhorst explained that the point was to identify which the best standard was for accreditation of a specific scheme or scope. There is a need for a common EA NAB approach on selecting the best fit standard for a given certification scheme. The document will also assist stakeholders, and specially scheme owners, to properly design their schemes according to the intended purposes. The guidance work will be likely an expansion of the existing text in EA-1/22, providing additional information to serve as a criterion to make the correct choice between the two most used standards for certification schemes.

C. Priller questioned the actual relevance of such guidance. For him, the purpose should not be to re-discuss what is already clear. P. de Ruvo agreed: he could not see how the appropriate standard can be deviated; two different standards mean two different processes and jobs.

While agreeing with the CAB College, the Industry College suggested waiting for a first draft to see whether the document would be really useful or not. For M. Stadler, if properly applied, both standards should lead to the same result.

M. Held found that it might be helpful to explain things in concrete terms. She noted that it would be a waste of time starting and then stopping drafting the document.

M. M. Logghe argued that, if some guidance was needed, certainly the standards themselves were not clear enough.

A. Steinhorst confirmed that the purpose of such guidance was to improve consistency of the use of both standards, which should be made clearer and easier.

See decision below.

# • NWI on revision on EA-7/04: Legal Compliance as part of Accredited ISO 14001: 2004 certification.

G. Samuelsen reported that the current purpose of EA-7/04 would remain the same, i.e. to ensure harmonised auditing of legal compliance aspects during an EMS certification process. But there is a need for updating the document according to the new version of ISO 14001:2015 which includes modified concepts and requirements related to legal compliance. Furthermore, ISO 17021-2 has been published with further requirements for auditor competence, which have not yet been taken into consideration in the current EA-7/04.

There was no comment. See decision below.

# Decision

The Board:

- thanked EA for the documents outlining the EA Strategy 2025 project, taking note of the plan to send a questionnaire to the EAAB to feed the discussions of the project team, and to organise a specific session with stakeholders in conjunction with the Board's next meeting;
   Action EA for next meeting
- endorsed the proposed new work item for revision of EA-1/22: EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members;
- endorsed the proposed new work item for revision of the EA Articles of Association;
- endorsed the proposed new work item for developing guidance on the choice of ISO/IEC 17021 or 17065. The Board, however, wondered about the relevance of the intended document and decided to wait for the first draft to judge further on the possible use of such guidance;

 endorsed the proposed new work item for revision of EA-7/04: Legal Compliance as part of Accredited ISO 14001: 2004 Certification.

#### 5.3 Update on the "Accreditation for Notification" (AfN) project; Application of ISO/ IEC 17065 for schemes

A. Steinhorst recalled that, since no EA position had been reached on the project's outcome at the EA General Assembly last May, the project team's conclusions had been distributed for comments within EA. It has turned out that the majority supports the project's results, while substantial comments have been made. The replies given to comments, which are being distributed this week to EA Members and recognized stakeholders, will be discussed at the November General Assembly in Budapest. In light of these comments, EA has also put forward a recommendation to the EC, advocating adding ISO/IEC 17065 as an option for modules D, D1, E, E1 and H1 in the *Blue Guide* table. The next and hopefully final step is to achieve an expert agreement at the EA GA in Budapest.

M. Nitsche wondered about whether EA should recommend only one standard for each directive. He called for EAAB members' opinions: should EA be more flexible?

For C. Priller, the AfN project's results should be followed for the job to be useful. He advocated not coming back to a situation where everything was allowed.

A. Steinhorst pointed out that the project's results were only recommendations achieved by EA since, at the end, the decisions would still lie on the national authorities' side. How to use the results is up to EA Members – and this is what will be discussed in Budapest.

M. Stadler confirmed that such an EA common position would have to be discussed with the NAs, recognized stakeholders and the EC.

#### Conclusion

The Board:

- thanked EA for updating EAAB Members on the project nearing completion, acknowledging the EA position to provide for the possibility to use ISO/IEC 17065 also in support of notified bodies that carry out conformity assessment tasks under the quality assurance modules (D, D1, E, E1 and H1), and to introduce this possibility in the *Blue Guide* table (annex 6);
- noted that it was up to EA Members to decide how to use the project's results, as would be considered further at the EA General Assembly in November 2015.

# 5.4 Voting rights of Associate Members in the EA MAC: progress report

The item was covered before under Item 5.2 - NWI on revision on EA Articles of Association (AoA).

# 5.5 Development in Hungary: close down of NAT end of 2015 and opening of a new NAB from 1 January 2016; impact for CABs until the new NAB becomes signatory to the EA MLA

A. Steinhorst reported that a Hungarian Act provided for the closure of NAT at the end of 2015 and the opening of a new NAB from 1 January 2016. The MAC noted that, in accordance with the EA *Articles of Association*, NAT's membership should consequently be terminated at the end of the year. NAT's re-evaluation due in November 2015 has been cancelled accordingly.

The pending issue lies in the repercussions on the certificates delivered by NAT, which are no more valid: they can still be used, but they are no longer covered by the EA MLA.

P. de Ruvo assumed that the new NAB would not start from nothing and would keep its staff.

M. Stadler asked about the consequences for the free circulation of products in the Internal Market, and about whether the EC should communicate on this. N. Bönnen confirmed that some specific communication should certainly be made by the EC.

However the question remains: which is responsible for the certificate validity?

For G. Samuelsen, if there is no NAB anymore, everything is changed. He reported that NATaccredited CABs had been informed of the situation.

P. de Ruvo was above all concerned about the *certificates* established by accredited CABs since they could not benefit from the EA MLA anymore.

M. Nitsche noted that the situation was similar to NABs failing their peer-evaluation, which were suspended for a period of time during which they could not issue certificates any more, at least for some scopes.

M. Held asked whether EA had distributed any information to NAT-accredited CABs so as to serve their clients' needs. G. Samuelsen answered that Hungarian CABs should have links with NAT only, not with EA.

A. Steinhorst specified that EA had been developing current contacts with the Hungarian government, but no clear information had been obtained yet.

R. Brockway asked why NAT-accredited CABs could not be easily and quickly recognized by other EA NABs. Could EA allow such flexibility and encourage EA Members to do that? IFIA's suggestion was supported by P. de Ruvo. G. Samuelsen replied that this would be the case in practice: if the CAB's processes prove good, the new evaluation will be performed swiftly. M. Stadler suggested that such an approach could be adopted by the relevant ministries. Likewise D. Ayik suggested that NAT could have a protocol with a few NABs so that accreditations could be transferred.

A. Steinhorst concluded that it was up to the Hungarian government to deal with the situation in the most appropriate manner. All suggestions are good, but remain purely theoretical and are not so easy to implement in practice.

# Conclusion

The Board:

- took note that, through a Hungarian act, NAT, the Hungarian NAB, would cease to exist at the end of the year and that, from 1 January 2016, reports and certificates issued by NAT would no longer be covered by the EA MLA;
- agreed to wait and see how the Hungarian situation would be evolving, notably with regard to recognition of NAT-accredited CABs and new accreditation of Hungarian CABs.

# 5.6 Impact of legislative requirements for ABs and CABs in relation to MLA obligations

The item was not tackled due to T. Facklam's absence.

# 5.7 ABs from countries of the EU Neighbourhood Policy (ENP): update

A. Steinhorst reminded that only ENP countries could be evaluated by EA provided that they were not directly evaluated by ILAC and IAF. Likewise, TUNAC and EGAC, for instance, have to decide upon they would like to be EA or ARAC members; they cannot be part of both at the same time (see revision of the EA *Articles of Association*). EA will introduce a process to ensure that - on request by the European Commission – those ABs may be evaluated for the purpose to

demonstrate compliance with Regulation 765/2008 and competence for the accreditation of CABs seeking notification.

# Conclusion

The Board noted that EA-1/13: *EA's Relationship with Accreditation Bodies of Countries Not Being Members of the EU or EFTA* was being revised in order to include a two-step process for countries in the EU's Neighbourhood Policy to sign "cooperation agreements" with EA provided that their accreditation system demonstrated that: 1) the requirements set out in Regulation (EC) 765/2008 were fully complied with; and 2) they were competent to accredit their CABs.

#### 5.8 CETA – Protocol about mutual acceptance of the results of conformity assessment

G. Samuelsen reported that a joint TFG was to draft a bilateral cooperation agreement (BCA) between the European and Canadian accreditation systems with a view to facilitating business between the EU and Canada. The elaboration of the BCA, to be coordinated by the EA Executive Secretary, is expected to be completed by mid-2016. The BCA will include reference and use of ILAC MRA / IAF MLA, exchange of information about mutual acceptance of conformity assessment results and application and interpretation of accreditation criteria, exchange of experts in on-site assessments or surveillance visits to CABs, regular meetings, and the establishment of a database containing the (regulated) accreditation requirements of the parties.

D. Ayik asked about the consequences for regulators in practice, as well as what would happen with the agreements signed by Turkey in relation to ILAC/IAF agreements. N. Bönnen answered that it was up to NAs to decide whether or not to accept conformity assessment results issued by third-country ABs that are signatories to the ILAC/IAF multilateral agreements. M. Stadler suggested that the Turkish regulators should bear in mind the consequences of non-acceptance for TURKAK and Turkish CABs.

#### Conclusion

The Board noted that EA was elaborating a bilateral cooperation agreement (BCA) between the European and Canadian accreditation systems, to be finalized by mid-2016 within the framework of the Comprehensive Economic and Trade Agreement (CETA) protocol negotiated between the EU and Canada.

# 5.9 Delegated Act under Regulation (EU) 2015/757 on the monitoring, reporting and verification of $CO_2$ emissions from maritime transport

A. Steinhorst reported that the Regulation had now been published and entered into force on 1 July 2015. The EC was preparing a Delegated Act to define the accreditation procedure by mid-2016. Verifiers will need to be accredited by end of August 2017 in order to perform verification of the monitoring plans to be submitted for each ship by ship-owners by 31 August 2017. Because ship-owners shall monitor emissions on each ship based on the assessed monitoring plan by 1 January 2018, accredited verifiers will have to assess the monitoring plans within a 4-month timeframe. It will be a challenge to have accredited verifiers for verifying about 11,000 ships, all the more since probably not all EU NABs will develop this field.

#### Conclusion

The Board thanked EA for reporting that EC DG CLIMA is preparing a Delegated Act to define, by mid-2016, the accreditation procedure for verifiers of  $CO_2$  emissions from maritime transport, who should be accredited by end of August 2017.

#### 5.10 Update on Breast Cancer Services (BCS) project

A. Steinhorst updated that the BCS project had been progressing quite well; it was now expected to terminate at the end of 2017. The accreditation procedure is being defined for CABs which certify breast cancer services that shall be certified. EA has been advocating that the scheme accreditation should be based on ISO/IEC 17065 together with an important diagnostic work based on ISO 15189. A. Steinhorst added that the project was not only supported by the EC, but also by clinicians and patients.

M. Stadler expressed concern about potential double certification of some medical devices that already fall within the scope of application of the Medical Device Directives. When A. Steinhorst argued that scopes were different, M. Stadler indicated that he reported a concern from industry about some overlapping and the risk of duplicate certification, and asked EA to be aware of such a risk and avoid or eliminate it as far as possible.

#### Conclusion

The Board:

- thanked EA for updating on the progress of the BCS project, whose expected duration had been extended until late 2017 due to the fact that the project was on hold during the last 10 months;
- noted that BCS would have to be certified by CABs, for which a specific accreditation procedure was being defined in cooperation with EA. Medical examinations will be covered under ISO 15189.

#### 6. Items for information

#### 6.1 Report on complaints and appeals

G. Samuelsen went through his report distributed among the meeting papers. The main pending complaint is the one lodged against DAkkS.

# 6.2 IAF/ILAC General Assemblies and related meetings (agendas and crucial issues, if any)

A. Steinhorst said that no specific issues had been tabled so far.

M. Stadler put emphasis on the growing importance given to regions, and the reinforced links between the international and regional levels. For him, it is of the utmost importance for EA.

# 6.3 Draft Agenda of the 36<sup>th</sup> EA General Assembly on 25-26 November 2015 in Budapest, Hungary

A. Steinhorst drew the attention on the break-out session dedicated to the EA Strategy 2025 project, as mentioned before.

There was no comment from the Board.

# 6.5 EA Activity Report

G. Samuelsen went through the report distributed for the meeting.

No comment was voiced by the Board.

#### Conclusion

The Board thanked EA for the written reports provided under this item.

#### 7. EAAB Work programme

The Chair went through the EAAB WP together with the Board's members to agree on the following:

#### Decision

The Board:

- agreed that, from now onwards, the EAAB Work Programme should be included under the "Key Topics for discussion" item; - TO BE REDISCUSSED BY CHAIRS THE NEXT MEETING
- agreed to include a new work item as a possible key topic regarding "Consistency and harmonisation among ABs"
   Action EAAB Secretariat for WP; CAB College for drafting a paper
- took note that P. de Ruvo (CAB College) will submit a paper deemed to improve the consistency of the Board's discussions by the first quarter of 2016 for circulation to all EAAB Members;

#### Action P. de Ruvo, EAAB Secretariat

 asked the EAAB Secretariat to reclassify the topic "Role of the EAAB; EAAB's expectations towards accreditation and EA" as "CLOSED", and to check whether the revised EAAB document EA Stakeholders' Expectations towards Accreditation and EA, as approved in April 2014, was available on the EA website.

Action EAAB Secretariat [Post-meeting note by EAAB Secretariat: the document as approved at the 32<sup>nd</sup> EAAB Meeting on 3 April 2014 <u>had been</u> published on the EA webpage: http://www.european-accreditation.org/structure#4 ]

#### 8. Any other business

No other issue was discussed.

#### 9. Selection of dates and places of next meetings

The Board postponed the date of the next meeting to Friday 29 April 2016 (meeting starting at <u>9.00 am</u> and closing at 3.30 pm), and agreed to meet on Wednesday 12 October 2016 at 10 am.

[Post-meeting note by EAAB Secretariat: the EFTA Secretariat has confirmed the availability of a meeting room on 29 April 2016.]

The EAAB Chair thanked EFTA for the meeting arrangements and the delegates for their valuable contributions. He closed the meeting.

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# List of the abbreviations taken for granted in these minutes

AB: accreditation body ARAC: Arab Accreditation Cooperation **CAB**: conformity assessment body **CAS**: conformity assessment scheme **CD**: committee draft **CCMC** : CEN-CENELEC Management Centre EA BLA: EA Bilateral Agreement (EA) CC: EA Certification Committee (EA) CPC: EA Communications and Publications Committee (EA) HHC: EA Horizontal Harmonisation Committee (EA) LC: EA Laboratory Committee (EA) MAC: EA Multilateral Agreement Council EA MLA: EA Multilateral Agreement EC: European Commission ECOS: Environmental Council of the States **ENP:** EU Neighbourhood Policy EU ETS: European Union Emissions Trading System **IAF:** International Accreditation Forum **ILAC:** International Laboratory Accreditation Cooperation **IMP** expert group: Internal Market of Products expert group **NAs:** national authorities NAB: national accreditation body NWI: new work item **RoP**: Rules of Procedure SS: sector scheme SO: scheme owner **TFG**: task force group ToR: Terms of Reference WG: working group **WP**: work programme