



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Single Market Policy, Regulation and Implementation

Single Market Policy, Mutual Recognition and Surveillance

Brussels, 10th January 2017

MINUTES (REV 1) OF THE MEETING OF THE EXPERT GROUP ON THE INTERNAL MARKET FOR PRODUCTS CONFORMITY ASSESSMENT AND ACCREDITATION BRUSSELS, FRIDAY 02ND DECEMBER 2016

1. Approval of the agenda

The agenda has been approved.

2. Nature of the meeting

The meeting was not public.

3. List of points¹ discussed

3.1 Opening of the meeting

No discussions under this item.

3.2 Accreditation – Report from EA

EA presented the progress report (Annex II). It stressed that it is not up to EA to define how authorities will deal with conformity assessment results being provided by an accredited Conformity Assessment Body (CAB) after the respective accreditation body has ceased to exist or is not a signatory to the EA Multilateral Agreement (EA MLA) anymore.

3.3 Notified Bodies – EA project on notification

EA presented the progress report (Annex III). It stressed that EA 2/17 "*Accreditation of CABs for notification purposes - AfN*" was developed to define an EA approach to the assessment of Notified Bodies. EA 2/17 defines the preferred harmonized standards and additional requirements per EU directive/regulation/ (Union Harmonization Legislation) detailed per modules if applicable, to be used as a basis for accreditation by the national accreditation bodies.

Replying to questions EA mentioned that it will reconsider Directives that will be updated/revised in the future.

¹ As laid down in the agenda

The group felt the need for a major involvement of Notifying Authorities in the implementation/application of EA 2/17 and for a clarification of the link EA 2/17 with the Blue Guide. In particular, certain delegations questioned what would be the consequences for an authority notifying a Conformity Assessment Body on the basis of a different harmonised standard than the one identified by EA 2/17. Furthermore the question was raised regarding the formalities that must be followed by the notifying authority towards its national accreditation body for the accreditation of an organization with an accreditation standard different from the one recommended by EA.

Some Member States stressed that EA 2/17 must be mandatory. Some others emphasised that EA 2/17 defines the "preferred" standards and thus gives the freedom to authorities to make use of other standards (than those laid down under EA 2/17). In this context the question was raised how EA identified the specific Directives/Regulations where accreditation standards may deviate from the "preferred" standards (column 'exceptions' to the table in document EA 2/17). In particular the example of two metrology legislative acts was given where the relevant ADCO adopted the accreditation standard EN 17020 for modules F and H1 while EA recommended the use of standard EN 17065.

European Commission expressed its support of EA 2/17 and stressed that there is no contradiction with the Blue Guide. It clarified that when the Blue Guide was drafted, EA 2/17 was not finalised. European Commission underlined that EA 2/17 is an EA document and thus it is up to EA to decide on its status.

The group agreed that European Commission will organise a workshop in 2017 on this topic.

3.4 EA Strategy 2025

EA strategy group presented the item (Annex IV). It underlined that the aim of the project "EA Strategy 2025" is to define the objectives that describe what EA expects to achieve throughout the period 2017 – 2025 and what is EA's vision.

3.5 Report from EAAB

EAAB presented the item (Annex V – common presentation with item §3.6).

EAAB (EA Accreditation Board) constitutes the primary organ within EA to ensure the effective and balanced involvement of all interested parties in European accreditation regarding policy and strategy issues. It serves as the main stakeholder forum for EA to deal with such issues, according to the requirements of Regulation (EC) 765/2008 and to the relevant provisions of the "General Guidelines" for Co-operation between EA and the EC, EFTA and the competent national authorities.

EAAB stressed the need of streamlining the information exchange among Notifying authorities.

3.6 Report from EA MAC

EAAB observer to the MAC presented the item (Annex V – common presentation with item §3.5).

EA MAC is responsible for the effective and impartial management and monitoring of the peer evaluation process among national Accreditation Bodies. As such it is the ultimate decision-making body on the Multilateral Agreement (MLA) and Bilateral Agreement (BLA) of EA.

The EAAB observer to the MAC highlighted the need to ensure the robustness of the peer evaluation process, since sometimes decisions on non-conformities were being postponed while keeping the signatory status.

3.7 Notified bodies – consultancy

Following comments from the last experts group meeting Commission services revised Document CERTIF 2015-02. The group suggested some further modifications, such as.

- Include reference to provisions of services by NBs on the Notifications procedure itself;
- Clarify the status of quality assurance services;
- Taking into account not only consultancy on a specific product but mainly on a specific sector;
- Clarify the question of quality assurance services.

European Commission invited experts that suggested or wish still to suggest further modifications to submit them in track changes to the following address: GROW-B1@ec.europa.eu.

3.8 Notification of Conformity Assessment Bodies following the entry into force of the Alignment Package and of aligned legislation in other areas

The European Commission presented the recent and future milestones concerning the notification in the relevant sectors, i.e.

- April 2016: alignment package.
- June-September 2016: Radio Equipment Directive, Pressure Equipment Directive, Marine Equipment Directive.
- Still to come: Personal Protective Equipment Directive, Gas Appliances Regulation, Cableways.

3.9 Developments in NANDO during 2016

The European Commission informed the group about the main latest developments in NANDO, i.e.

- ‘Expiry date’ in ‘Notification details’ no longer triggers reminder email, and no longer appears on NANDO web site. However that ‘date’ is still available for Notifying Authorities.
- A reminder email is triggered by the date set in the ‘Assessment details’ that indicates when the next monitoring review is due. This date remains internal in the database. There is a maximum period of 5 years on this date, to accord with the accreditation schedule.

The reminder email informs the Notifying authorities that an update to the notification is required to submit new supporting documentation (accreditation or other). The reminder email is sent 4 times – 6, 3, and 1 month ahead of the end date, and on the date itself.

- If a notification has not been updated by the date set in the ‘Assessment details’, a warning symbol (yellow triangle) appears next to the notification in NANDO with the tag stating that “The Commission has not received assurance of the continuing competence of this Notified Body concerning its tasks the specific Directive or Regulation”.

3.10 Accreditation in the data protection legislation

The European Commission presented the item. It stressed that the new General Data Protection Regulation (GDPR) applies as from 25 May 2018, contains a fundamental shift from *ex ante* to *ex post* verification of compliance and introduces certification as a new element in order to migrate to the new system based on the accountability of the controller. Furthermore it mentioned that GDPR enables the working group of the national Data Protection Authorities (DPAs) to establish criteria for certification under the auspices and supervision of the European Commission.

The experts felt that GDPR may undermine the trust to the European accreditation system, as it allows the "overwriting" of decisions taken by the Accreditation Bodies. Experts stressed also that accreditation by DPAs is not allowed; Regulation 765/2008 provides that accreditation is given only by Accreditation Bodies. In this context the question was raised if DPAs may proceed or act against accreditation decisions of the Accreditation Bodies.

Replying to the above European Commission mentioned that GDPR has been adopted by the Council and the European Parliament and open issues can be clarified in the (still to be drafted) delegated act foreseen in GDPR. Before deciding for a delegated act, Commission services intend to carry out a study. European Commission concluded that it will explore the possibility to invite national accreditation experts and EA to the meeting of the Commission expert group on GDPR.

3.11 EU-US TTIP (Transatlantic Trade and Investment Partnership)

The European Commission presented the item. Negotiations have been suspended following the US Presidential elections. The current US Administration considers that it has only authority to engage on purely technical work during the transition to the new Administration. Both sides' negotiating teams are now working on cleaning up and consolidating existing texts on the basis of the latest discussions in order to have a clear record of the state of play of the negotiations and of the respective proposals in all areas.

3.12 EU-Canada CETA (Comprehensive Economic and Trade Agreement) – Protocol on the Mutual Acceptance of Conformity Assessment Results

The European Commission informed the group that following signature of CETA on 30 October 2016, work is on-going in the Council and European Parliament on the package of legal texts on the provisional application of those parts of CETA in

respect of which there is consensus among Member States that they fall under the sole EU common commercial policy (i.e., almost all CETA areas except investment and the investor-state dispute settlement mechanism).

The European Parliament's must give its assent (i.e. "non-objection") in order for CETA to be provisionally applied. It is expected that provisional application will occur by mid-2017.

The existing bilateral Mutual Recognition Agreement will be replaced by the CETA Protocol on the Mutual Acceptance of Conformity Assessment Results as soon as CETA starts to apply provisionally.

3.13 Cooperation of EA with Standards Council of Canada

EA presented the item (Annex VI). Replying to questions, the European Commission and EA mentioned that CETA maintains the status quo in the telecoms sector under the existing MRA and thus takes full account of the specificities of the sector.

3.14 EU-Japan EPA (Economic Partnership Agreement)

The European Commission informed the group that negotiations are progressing at an intensified pace with a view to closing them by the end of year or early 2017. There is strong political will on both sides to achieve this result. The horizontal chapter on Technical Barriers to Trade (TBT) was provisionally closed at technical negotiators' level during the last round in Brussels at the end of September 2016.

3.15 Eastern Partnership

The European Commission presented the item (Annex VII).

Deep and Comprehensive Free Trade (DCFTA) Agreements were signed with Ukraine, Moldova, Georgia and already provisionally apply (from 1st January 2016 with Ukraine, from 1st July 2016 with Moldova and Georgia). They contain comprehensive provisions on regulatory approximation with the EU and in particular Ukraine and Moldova have expressed their keen interest in concluding an Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA) with the EU (i.e. an enhanced MRA based on equivalence of the respective quality infrastructure and sector-specific legislation).

Armenia could not sign the DCFTA following its decision to join the Eurasian Economic Union. Currently negotiations with Armenia on a much less ambitious Cooperation Agreement are under way. For the time being no negotiations take place with Belarus and Azerbaijan.

3.16 Southern Neighbourhood Policy

The European Commission informed the group that Association Agreements were signed with the majority of the EU Southern neighbourhood countries between 1998 and 2006. These agreements refer to the cooperation on different components of the quality infrastructure and foresee the possibility of concluding an ACAA agreement. Such an agreement was signed with Israel in the pharmaceuticals sector and entered into force in 2013. Currently, DCFTA negotiations are ongoing with Tunisia and Morocco.

3.17 Enlargement Countries including Turkey

The European Commission informed the group that the new methodology used for "Chapter 1- Free movement of goods" in the latest, recently published country progress reports on the Enlargement countries allows to indicate not only the progress made but also what level of preparation they reached when it comes to the final goal.

Bosnia-Herzegovina and Kosovo are potential candidates. Bosnia-Herzegovina formally requested the candidate status.

Albania, FYROM (Former Yugoslav Republic of Macedonia), Montenegro, Serbia and Turkey are candidate countries. Negotiations with Montenegro on Chapter 1 will be opened soon.

Both the EU and Turkey consider that the Customs Union with Turkey, dating from 1995, needs to be modernised. To that end, the Commission is currently finalising a proposal for the opening of negotiations on a new bilateral EU-Turkey agreement that will modernise and expand the scope of the current Customs Union.

3.18 Relationship EA-ABs (Accreditation Bodies) from countries covered by the EU Neighbourhood Policy

EA presented the item (Annex VIII). EA stressed that Accreditation Bodies joining the EA MLA through a BLA shall be peer evaluated only by EA.

3.19 AOB

Nihil

4. Conclusions / next steps

- The role of European Accreditation as a pillar of the Internal Market is confirmed.
- European Commission will organise a workshop in 2017 dedicated to the EA's project "Accreditation of CABs for notification purposes - AfN".
- Accreditation experts will work closely with their national DPAs for the implementation of accreditation provisions of GDPR.

5. Next meeting

Next meeting scheduled for Q4/2017.

6. List of participants

Participants (Annex I) are:

- Delegates from Member States national authorities responsible for Accreditation and Conformity Assessment policy;
- Representatives from the "European Cooperation for Accreditation" (EA). EA is the association of national accreditation bodies in Europe that are officially recognised by their national Governments. EA is recognised under Regulation 765/2008;
- Officials from the European Commission.

Annex I: List of participants

Annex II: EA report on Accreditation

Annex III:	EA report on notification project
Annex IV:	EA strategy report
Annex V:	Report from EAAB and EA MAC
Annex VI:	EA report on cooperation with Standards Council of Canada
Annex VII:	Report from Commission services on Eastern Partnership
AnnexVIII:	Report on relationship of EA with ABs from countries covered by the EU Neighbourhood Policy