

Draft Law on Establishing a National Accreditation Body—Readings in the German Federal Parliament and Federal Council of Germany

The draft Law on Establishing a National Accreditation Body (AkkStelleG) has been long-awaited and much has been speculated about its content. Now a draft is available to the public (<http://www.dar.bam.de/newse.html>).

Within which timeframe would the parliamentary procedure be arranged?

The draft on the AkkStelleG was approved by the German Federal Parliament on 18th June 2009.

The 2nd reading by the Federal Council of Germany will take place on 10th July 2009.

A decision on the Law is expected to be available by the end of August 2009 at the latest.

What will be regulated by the Law?

The AkkStelleG regulates the establishment of a single national accreditation body according to the EC Regulation No. 765/2008; we reported about this Regulation already in several issues of DAR-aktuell. Based on the Law, a national accreditation body shall have been established by 1st January 2010.

The draft Law assumes an entrustment of the body by the Government: Limited company under private law (66 % Federal Government/German Federal States and 33 % industry). Moreover, the Law regulates the supervision of the national accreditation body by the Government as well as the inclusion of the existing expert knowledge of the responsible authorities of the Federal and State Governments in assessments and decisions on accreditation.

An Accreditation Board will be established which on the one hand will give advice to the German Federal Ministry of Economics and Technology (BMWi) and on the other hand will ensure the inclusion of interested parties according to ISO/IEC 17011, Para. 4.3.2. Tasks of the Advisory Board will be, among others, the determination of the accreditation rules and the coordination of the German representation at EA. All stakeholders are invited to cooperate in this Board.

How will the new accreditation body be built up?

Once the Law has been endorsed, the actual work will start. Presently, not all details have been resolved.

A merger was proposed by the private accreditation bodies operating under the umbrella of the DAR. This merger could be the basis for establishing a single national accreditation body.

If all members of the Multilateral Arrangement on Mutual Recognition at EA - DACH, DAP, DKD, and TGA/DATech - merged into one body, the possibility would arise for transferring the existing international recognitions of accredited conformity assessment bodies to the new national accreditation body.

In order to transfer the EA Multilateral Arrangements, the approval of the EA General Assembly needs to be obtained.

The DAR also dealt with the draft Law on its last meeting held on 12th May 2009. A plan for transferring the tasks to the national accreditation body was approved and will be put into effect as soon as the new body will be able to operate.

Furthermore it was emphasized that all accreditations granted till today under the umbrella of the DAR shall be assumed by the new national accreditation body, so that regular surveillance visits of all accredited conformity assessment bodies would be ensured in future.

BAM S.2–M. Wloka

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News from the DAR

1. Interim arrangements

The 49th DAR meeting held on 12th May 2009 took place against the background of transferring the tasks to the new national accreditation body to be established. As the draft Law has not yet been approved by the German Federal Parliament, and the specific organization of the new national accreditation body still has to be arranged it was decided that the DAR will continue fulfilling its tasks until clear signals for a change of the tasks would be given by the BMWi.

Paragraph 13 of the draft Law was in the centre of the discussions. It states that once the Law becomes effective all accredited bodies would be transferred to the new body.

This means that all bodies accredited under the umbrella of the DAR need to be assumed by the new accreditation body. All steps necessary to realize this transfer were already taken by the DAR.

Once the Law is in effect it can be assumed that from 1st January 2010, accreditations and re-accreditations will no longer be issued along with the DAR certificate.

Irrespective of this, Article 39 of the EC Regulation No. 765/2008 applies whereby accreditation certificates issued before 1st January 2010 may be valid until

expiration of their term of validity, but not after 31st December 2014.

2. Amendments to the DAR rules

A decision was taken on further maintaining and updating the DAR Rules. In particular those rules which have recommendatory character to the DAR but have to be implemented as mandatory rules by the signatories to the MLAs of EA, ILAC, and IAF, will continue to be included in the Rules and Procedures and will be made available to the accreditation bodies or accredited bodies.

Therefore it was decided to translate IAF/ILAC A5:2009 (*IAF-ILAC Mutual Recognition Arrangements: Application of ISO/IEC 17011:2004*) into German language and to include the document in the DAR Handbook. This document interprets the application of ISO/IEC 17011; this standard is a mandatory document to be applied by the MLA signatories.

The revised interpretation paper on the application of ISO/IEC 17024, *General requirements for bodies operating certification of persons* (IAF GD 24:2009), is being updated as well, and the DAR Secretariat is preparing the translation into German (DAR-8-EM-01).

The German translations of the mandatory IAF documents IAF MD1 to IAF MD5 were endorsed and are available on the

DAR website. These documents represent interpretation papers on the accreditation of certification bodies for management systems. The above documents can be retrieved from the DAR website under the following link: <http://www.dar.bam.de/doc7.html>

As a result, DAR-7-EM-02 as interpretation paper on ISO/IEC Guide 66 has been withdrawn.

3. Technical issues on accreditation

The DAR Committee on Technical Issues (ATF) has discussed the currently valid rules on the accreditation of multiple sites. The results were presented to the DAR. The procedure to issue a certificate for more than one legal entity which is practised by a few DAR accreditation bodies has to be changed, as it is incompatible with the requirements set out in ISO/IEC 17011.

Further legal entities may be considered only with the status of a subcontractor acting for the conformity assessment body.

The DAR mandated the ATF to revise the DAR document DAR-3-EM-16 „Accreditation of conformity assessment bodies with several locations“ and to submit it to the DAR for endorsement.

BAM S.2–S. Stobbe

News from Standardization

1. Generating the new ISO/IEC 17065 to supersede EN 45011

The ISO CASCO WG 29 Drafting Group is intensively working on the revision of the standard on requirements for certification bodies for products.

At the end of June 2009, the entire Working Group WG 29 will discuss the first Working Draft (WD) for this new standard on product certification ISO/IEC 17065 (title following the previously valid ISO/IEC Guide 65, in Europe identical in wording with and known as EN 45011 and successfully applied in practice for many years).

Initially, the first working drafts prepared by the Working Group showed a distinctive analogy to the wording of ISO/IEC 17021:2006 (Conformity assessment—Requirements for bodies providing auditing and certification of management systems), probably due to identical authors in both Groups.

In summer 2009, the first Working Draft is expected to be issued and subsequently to be discussed in the respective committees of the German Institute for Standardization (DIN).

BAM S.1 – R. Schmidt

2. ISO/IEC 17020 in revision

From 4th to 6th May 2009, the first meeting took place of the recently established WG 31 on Revision of ISO/IEC 17020 (*General criteria for the operation of various types of bodies performing inspection*).

The survey on the necessity of a revision of this standard obtained the majority with one vote in favour of revising this standard. The German comment given by the German Institute for Standardization (DIN) argued for not yet revising this standard as it has been successfully applied in practice by the inspection bodies.

At the first meeting, a proposal was therefore declined to revise this standard basically and to change its wording similarly to ISO/IEC 17021.

Great importance was attached as well to the fact that ISO/IEC 17020 is a standard describing criteria for the inspection bodies themselves. It may be used by accreditation bodies. However, if they have special requirements these should then be

specified in respective papers to be developed by the accreditation bodies and need not necessarily to be included in the standard.

This means, the document IAF/ILAC A4 as interpretation paper on the application of ISO/IEC 17020 for accreditation bodies was considered for clarifying specific requirements, but only a few components were taken and not the entire document.

As an outcome of the first meeting, a rough draft was developed by the Working Group. The next steps will include a discussion of this draft by the Working Group and a next meeting to be held in September 2009 dedicated to the discussion of the first Working Draft.

It is also of great importance to the Working Group that in this standard the difference between inspection bodies and product certification bodies is made absolutely clear in order to establish a worldwide common understanding and to mark out the differences to the standard ISO/IEC 17065 mentioned above.

BAM S.2 – M. Wloka

16th Tutors' Exchange of Experience

On 12th March 2009, the 16th Tutors' Exchange of Experience took place at the Federal Institute for Materials Research and Testing (BAM), i.e. a meeting of the persons in charge of conducting training courses for assessors of accreditation bodies from the German-speaking area for the purpose of exchanging experience and recent knowledge in the field of accreditation and standardization.

One of the main topics were – according to current information – the consequences for the accreditation bodies in Germany in implementing the European Regulation 765/2008/EC, and the draft of the Law on Establishing a Single National Accreditation Body of which the wording was still unknown at that time.

The participants pointed out that the DAR needs to keep up the system until the new national accreditation body was ready to work and that the accredited bodies (as

to national and international recognition) shall not face any disadvantages in consequence of changes due to the implementation of the Law. Particularly participants representing the authorities indicated that the well-established and proven structures shall be maintained.

The participants were informed about news from international and European standardization.

Much attention was given to the exchange of experience on „Technical issues of accreditation in practice“. The following topics were covered:

- Application of ISO/IEC 17021 in notifications,
- Multisite certification in line with EN 45011 (EA-6/0x),

- Accreditation of reference materials producers - Position of EUROLAB-D,
- New international technical documents (including depth study of the document „EA-2/15 - EA Requirements for the Accreditation of Flexible Scopes“).

The German Calibration Service (DKD) informed that, in view of safeguarding a metrological national infrastructure, it was assigned - along with its previous accreditation tasks - to prepare recommendations for designations in line with the Directive on Measuring Instruments (MID).

Most probably, the 17th Tutors' Exchange of Experience will be held at BAM on **09th June 2010**, along with the **International Day of Accreditation**.

BAM S.2—N. Bendix

News from EA

1. Cooperation with the EU

On 1st April 2009, the „General Guidelines for cooperation between the European co-operation for Accreditation (EA) and the European Commission, the European Free Trade Association and the competent national authorities“ was signed by representatives of the EU Commission, EFTA, and EA.

Link to the English note:

http://ec.europa.eu/enterprise/newapproach/index_en.htm

This was a further step towards officially recognizing EA as the European accreditation infrastructure according to the EU Regulation No. 765/2008. The Guidelines state the basic general understanding and the objectives in respect of the development of accreditation in Europe.

The framework agreement on establishing EA's concrete financial support by the European Union, the so-called Framework Partnership Agreement (FPA), is presently in preparation and also under discussion in the European Commission. Tasks and duties of EA shall be specified in Annexes to the Framework Partnership Agreement.

2. EA General Assembly

On 27th and 28th May 2009, the 23rd EA General Assembly took place in Luxembourg. The General Assembly was largely dedicated to the implementation of the EU Regulation No. 765/2008 on Accreditation and Market Surveillance.

The Articles of Association and the Rules of Procedures of EA were not yet approved as originally planned, but are still under discussion in order to effectively adapt them to the new conditions.

Graham Talbot (UKAS) was elected

new Chair of EA and Daniel Pierre (Cofrac) new Vice Chair. Both of them will assume their mandates on 15th June 2009.

Thanks were given to the previous Chair, Lorenzo Thione from Italy for his work. New Chair of the EA M A C C o m m i t t e e (Committee for Multilateral Agreements/Arrangements) will be Thomas Facklam (T G A) f r o m Germany. He will assume his mandate on 1st October 2009.

EA is preparing for signing the so-called Framework Partnership Agreement (FPA) with the European Commission. The EA members are presently implementing the EU Regulation on accreditation. In Italy, for example SINCERT and SINAL merged to form the one body ACCREDIA, while SIT will be integrated in the Consortium COPA, so that there are still two accreditation bodies in Italy; both of their memberships in EA were confirmed. The integration of SIT in COPA is still an interim solution, and SIT's tasks shall be included in the new body ACCREDIA by the end of 2009.

Important results:

1. In consultation with the EA Advisory Board (EAAB) it is investigated, whether an extension of the EA MLA to the accreditation of providers of proficiency testing would be necessary.

2. The Terms of Reference for an EA Healthcare Working Group for Laboratory Medicine were confirmed. If laboratories for Point-Of-Care-Testing activities (POCT)



Grund, Luxembourg City

are accredited this shall be conducted by applying ISO 22870 in connection with ISO 15189 or ISO/IEC 17025. These accreditations are covered by the EA MLA for testing. For accreditation of medical reference laboratories, ISO/IEC 17025 along with ISO 15195 shall be applied. These accreditations are covered by the EA MLA for calibration.

3. The tasks and Terms of Reference of the „Horizontal Harmonisation Committee“ (HHC), which was established in November 2008 were approved by EA at its General Assembly. Thus, for the first time an attempt has been made in Europe to directly harmonize both the accreditation principles and the technical notification principles for the Directives and to harmonize them among the European countries.

BAM S.2—F. Behrens / U. Eggert

Imprint: Editor Dr. M. Wloka
BAM-S.2,
DAR German Accreditation
Council
c/o BAM
Unter den Eichen 87
12205 Berlin

Phone: ++49-30-8104 1942
Fax: ++49-30-8104 1947
E-Mail: office@deutscher-
akkreditierungsrat.org
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DIARY:

Next EA GAs:

- 25th - 26th November 2009, Brudes/Belgium
- May/June 2010, Bern/Switzerland
- Autumn 2010, venue to be announced
- May/June 2011, Berlin/Germany

Next EA MAC Meetings:

- 03rtd- 04th November, Oslo/Norway

Next ILAC/IAF GA:

- October 2009 Vancouver, Canada

Next ISO CASCO GA:

- 12th - 13th November 2009 Geneva/Switzerland

Miscellaneous:

- EURACHEM—14th International Congress of Metrology; Added value through better measurement; 22nd - 25th June 2009
- The Second International Proficiency Testing Conference, Sibiu, Romania, 16th - 18th September 2009
- CAFMET—Metrology Forum, Benin, 26th - 30th October 2009

Cross-Frontier Accreditation To Be Newly Regulated in Europe - Article 7 of EU Regulation No. 765/2008 in the focus of attention

New principles for confirming competence to European conformity assessment bodies will apply at the latest once the EU Regulation on Accreditation and Market Surveillance No. 765/2008 will come into effect on 1st January 2010. With this new European Regulation, accreditation is given a status of official activity. It shall be the highest instance and preferred means of conformity assessment bodies (CAB) for assessing conformity. This new status is accompanied by a strict restraint on competition for the national accreditation bodies in Europe, as specified in Article 6 of the Regulation. As laid down in Article 7 of the Regulation, from now on activities in the territory of another EU member state are allowed only in exceptions. This is reinforced by a commitment of the CAB to turn to the national accreditation body of the member state where the CAB has its location when seeking accreditation for the purpose of this Regulation.

Unfortunately, these strict Regulations often disregard that conformity assessment in Europe has long ago been established across the national boundaries. Nowadays, on the one hand, important sub-processes of a conformity assessment are brought together to single result across borders; on the other hand, in many cases, parts of conformity assessment activities are provided in the same way in foreign branches or branch offices, which, however, are managed, controlled, and determined by a central office or headquarters.

With these new provisions set out in the European Regulation, cross-frontier inspection and surveillance of those conformity assessments by one body will strongly be limited. This may result in various disadvantages for the European CABs compared to their non-European competitors. For example, there are fears that regulations of a multinational CAB will repeatedly become subject of assessment within the frame of a uniform management system and that this would cause additional costs.

For a notification based on accreditation it is indispensable that accreditation covers appropriately the entire notified member body with its cross-frontier activities thereby taking the requirements of the notified member state as a basis. Those areas that are exclusively regulated by national laws need to be handled similarly.

What are the solutions to compensate for these disadvantages? The provisions certainly require the national accreditation bodies to display a high degree of willingness to cooperate. Therefore, one of the great challenges of the near future is therefore to efficiently organize this cooperation within EA. In addition, the harmonized interpretation of the requirements for the conformity assessment bodies will be focused on.

Different interested parties in Europe are presently seeking for a practicable interpretation of Article 7 of the EU Regulation No. 765/2008. The aim of these efforts is to provide pragmatic solutions that will ensure cross-frontier inspection and surveillance of conformity assessment bodies without violating the principles of the non-competition clause of the EU Regulation.

The EU Commission has provided a first discussion basis by a SOGS paper that presents possible options how to find a remedy in view of multinational conformity assessment bodies. These approaches will certainly be further developed by the Commission. At the same time, EA is establishing its view on this topic by means of the recently founded „Horizontal Harmonisation Committee“ (EA HHC). During the discussions, special emphasis was laid on certification bodies. Moreover, EA is revising its fundamental principles on cross-frontier accreditation as set out in the EA document EA-2/13, and is adapting them to the provisions in the new EU Regulation.

BAM S.2 – G. Dudek

Harmonized standards published

On 16th June 2009, the EU Commission published in the Official Journal of the European Union, 2009/C 136/08, titles and references of harmonized standards in the framework of the implementation of the Regulation (EC) No. 765/2008 of the European Parliament and of the Council, Decision 768/2008/EC of the European Parliament and of the Council (Regulation and Decision on accreditation and market surveillance) and Regulation (EC) No. 761/2001 of the European Parliament and of the Council (EMAS Regulation).

The list of harmonized standards can be retrieved from the following link

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:136:0029:0030:EN:PDF>