

The EC Regulation has been Passed

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On 23rd June 2008 the Council of the European Union passed the **EC Regulation No. 765/2008 of the European Parliament and of the Council Setting out the Requirements for Accreditation and Market Surveillance Relating to the Marketing of Products**.

The new Regulation belongs to the so-called "Goods package" and is the most important element in the revision of the New Approach. The basic aim of the package of laws is to strengthen the cross-frontier trade which has a direct impact on the competitiveness and the economic growth in Europe.

Although the Single European Market requires the same standards for product surveillance, in particular small and medium-sized enterprises (SMEs) encounter big difficulties when offering their products in other member states.

Another aim is to increase product safety as well as to tighten the liability of importers.

The Regulation forms the statutory framework for using accreditation as a harmonizing tool in the European Market. Thus, accreditation and market surveillance are regulated in Europe at the national level irrespective of the individual sectors.

The Regulation is mandatory for all member states and will become legally effective as of 1st January, 2010. It requires the responsible national authorities to exchange information. The Regulation is based upon the Peer Evaluation System established by the European cooperation for Accreditation (EA) for evaluating the national accreditation bodies in order to ensure the equivalence of the accredited bodies (Mutual Recognition Arrangement MLA). In a previous issue of DAR-aktuell we informed about the drafts of the Regulation which covers the following essential elements with regard to accreditation:

- **Scope:** covers all accreditations and confirmation of competence in the mandatory and voluntary areas.
- **Establishment** of a single accreditation body per member state that operates on a non-profit basis, shall not conduct any conformity assessment activities and is a member of the EA MLA recognized by the EU. A non-competition clause applies among the member accreditation bodies of the European Economic Area.
- **Responsibility** of the Member States for their accreditation bodies,
- **Commitment** of compliance with the defined rules (e. g. ISO/IEC 17000 standards series),
- **Cross-frontier** activities of the accredita-

tion bodies are possible only under certain conditions,

- **The national** accreditation bodies undergo a regular Peer Assessment as organized by EA,
 - The **European Commission** monitors the Peer Assessment System,
 - **Separation** of accreditation and regulatory approval.
- All member states, the accreditation bodies, and EA are now preparing for the new conditions. In Germany, the law on establishing the sole accreditation body is currently put up for discussion.

EA has set up several working groups and projects for smooth implementation of the requirements. European standards organizations are also working on standards to provide the basis for the implementation of the EU Regulation.

With regard to market surveillance, the Regulation contains the following essential elements:

- **Obligation** of the member states to establish an efficient system of required authority, resources and knowledge of the personnel,
- **National** coordination of the several authorities,
- **Obligation** of the member states to supply information to the other member states, to the European Commission and to the public about incidents on the market,
- **Cooperation** with the responsible EU agencies (e. g. at present pharmaceuticals, food).
- Another element of the so-called "Goods Package" is a **Regulation on Products of the non-harmonized area** which was also passed by the European Parliament in its first reading on 21st February, 2008; its implementation may be expected later.

This Regulation states that a product duly placed on the market in a member state shall be deemed to be approved in each other member state despite of different national regulations. In particular small and medium-sized enterprises (SMEs) shall benefit from this Regulation in future as it will simplify the import of products. Arrangements have been made that may be taken by the authorities in case a product does not meet the technical rules. To support the economy, in each member state so-called "**Product Contact Points**" will have to be established which aim to provide information about the respective technical regulations, safety standards and responsible authorities to the companies in an unbureaucratic way.

BAM S.2—N. Bendix

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EC Regulation and Consequences Arising for Germany

The development of evaluation of competence of conformity assessment bodies in Germany is characterized by a separation into the mandatory and the voluntary areas.

In the mandatory area, several accreditation bodies were established which are responsible for certain areas (e. g. telecommunications, safety, health, etc.) and — depending on the area — fall into the sovereignty of the Federal State or the State Ministries. In the private (voluntary) area (technically specialized) accreditation bodies have been established, and the existing accreditation bodies have been further developed. All private and a few governmental accreditation bodies co-operate under the umbrella of the German Accreditation Council (DAR).

The new EC Regulation along with the „Decision on a common framework for the marketing of products“ requires fundamental changes within this system (see page 1). A single national accreditation body has to be established. There are several options to do this.

The entrusted body

An entrusted body is supervised by the Government with regard to technical, legal and financial matters and acts as an authority with regard to its accreditation activities.

The central associations of the German industry assured to the German Federal Ministry of Economics and Technology (BMWi) to provide in due time a body that can be entrusted.

This body eligible to be entrusted with accreditation shall arise from an accreditation body developed from a merger of DACH, DAP, and TGA. All required competencies from the mandatory area will be integrated, whereby during a transitional period the staff members of the existing accreditation bodies — in case they will switch over to the new body — can operate in one decentral organization. The entrusted body can be established directly after this issue has been clarified politically through a German Law on Accreditation.

The Government agency (authority)

In case policy decides to establish a government authority to be the national accreditation body competence of the personnel will be assured by a transition of the personnel of the present-day accreditation bodies of the voluntary (private) area to that governmental authority.

The operative activity of the national accreditation body and the changes occurring for the direct and indirect users of the system

Accreditation bodies in Germany are already operating according to the rules of the relevant international standards. When

applying the Regulation there won't be many changes regarding operative actions for the clients of the accreditation bodies.

In addition, the rules of the Regulation governing transition — each accreditation granted before 1st January, 2010, will remain valid until re-accreditation — will ensure protection of status quo (see News from the DAR on page 3).

The German Law on Establishing a National Accreditation Body will provide for the national accreditation body to take over and continue with all current accreditations, whereas the already existing Accreditation Advisory Board (AKB) will represent the subordinate advisory level. This re-organization will simplify matters for the accreditation body's clients, as accreditation is granted and supervised only by one body. Solely conformity assessment bodies with outposts in the European Economic Area (EEA) would encounter an increased coordination work due to the prohibition to operate in the EEA; executive regulations will still have to be worked out.

Irrespective of the actual solution to the legal entity of the national accreditation body, models already exist on how the new accreditation body could become operative. Technical key aspects supervised at the locations of the existing accreditation bodies could be defined. The overall coordination as a head of the national accreditation body shall be taken over by the body with the highest contribution in the respective procedure.

The body shall as early as possible — surely before the end of 2010 — apply for conduct of the Peer Assessment by EA and attain it, if possible, as after 1st January, 2010, only bodies are allowed the accomplishment of accreditations or re-accreditations which have successfully passed the Peer Assessment.

For the mandatory area there is the possibility not to use accreditation as a tool for confirming competence to the notified bodies. In case Germany should pursue this path for certain areas and do not offer any accreditation in such particular areas, there is the problem that the German conformity assessment bodies may seek for accreditation abroad.

The German Law on Establishing a National Accreditation Body is currently being discussed within the ministries (inter-ministerial consultations) and will be submitted to the public for comments after successful voting. The sole national Accreditation body shall come into operation on 1st January, 2010.

For providing the body eligible to be entrusted with accreditation, the German Law on Establishing a National Accreditation Body and the conditions for entrusting this body need to be made reliably known

about 6 months in advance, since a merger of the accreditation bodies operating in the voluntary area will only take place if there is a certainty that the entrusted body will come into existence and the conditions for the legal bodies responsible for the entrusted body are acceptable. Passing the legal general conditions and actually establishing the entrusted body could happen in the second half of 2009.

With these conditions scheduled the latest date for providing general conditions for the entrusted body would be 1st January, 2009.

Article 27 of the Decision relating to accredited internal bodies could be of interest to the manufacturers. This Article clarifies that internal bodies (e.g. first party bodies) may be accredited and therewith the narrow definition of independence in the mandatory area would no longer be applied to this particular case.

Along with the recently proposed modules A1, A2, C1 and C2 [8] which shall be implemented in the new or revised Directives, the accreditation of company-internal conformity assessment bodies might possibly become interesting.

Résumé

The changes in the German accreditation system becoming necessary due to the EC Regulation on Accreditation mainly relate to the need to adapt the internal structure of the German accreditation system.

The users of the accreditation system will rather benefit from the new structure, since accreditation will be offered under one roof based on equal terms, and the validity of accreditation is ensured by legal regulation.

Risks exist concerning the timely implementation of the Regulation, though they are softened by the transition period for existing accreditations.

For economic purposes an entrusted body would clearly be preferred to a public authority/agency, as the entrusted body is able to react more flexible on alterations, changed conditions, new tasks, and necessary personnel changes.

All in all, with the implementation of the Regulation a more sound and transparent system of conformity assessment may be expected as well as a Europe-wide harmonized market access. This will enhance the cross-border trade and even improve the safety level of products.

(Excerpt taken from the article by Mr. Facklam "Revision of the New Approach / Accreditation scenery in Germany - Changes", June 2008; full version retrievable from http://www.tga-gmbh.de/share/files/NewApproachVDMA_13.06.2008.pdf)

News from the DAR

1. Implementation of the EC Regulation

On its 47th Meeting held in Mainz on 11th June, 2008, the DAR discussed a plan on the transition of the tasks of the DAR to the National Accreditation Body (NAB) after the official announcement of the Law on Establishing the National Accreditation Body had been given. It became apparent that all accreditation certificates issued before 1st January, 2010, will continue to be valid until 31st December, 2014, at the latest. The responsibilities, in particular for surveillance activities, will devolve upon the NAB by 1st January, 2010, at the latest.

2. Implementation of ISO/IEC 17021

The DAR document DAR-3-EM-03 *Instructions for Use of the Accreditation Certificate of the German Accreditation Council* was modified in order to harmonize the accreditation of certification bodies for various management systems. According to this docu-

ment, all accredited certification bodies for management systems should have been checked and the ISO/IEC 17021 should have been implemented by 15th September, 2008.

3. Revision of the DAR Rules

In preparation of the implementation of the EC Regulation, the DAR Rules have been revised. The documents may be downloaded from DAR's homepage.

The documents DAR-3-EM-06 (*Qualification Criteria for Assessors of the Accreditation Systems in Germany, Austria and Switzerland*), DAR-3-EM-07 (*Framework Program to Train Assessors in Accreditation Procedures*), DAR-3-EM-10 (*Regulation on Conducting Training Courses for Assessors in the DAR System*), DAR-3-EM-11 (*Mutual Recognition of Assessors in Training Courses*) and DAR-4-INF-04 (*Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes*) were endorsed with the modifications and revisions made.

The document DAR-3-EM-01 (*DAR Rec-*

ommendations for Cooperation between Accreditation Bodies from Mandatory and Voluntary Areas) has been withdrawn.

4. Confirmation of fulfilment of ISO/IEC 17025 by accredited certification bodies

According to the international resolution decision, certification bodies accredited under the umbrella of the DAR are in future bound by contract not to execute certifications according to standards that form the basis for the accreditation of conformity assessment bodies. The accreditation bodies operating within the DAR system will therefore influence their accredited certification bodies and will insist on a clear arrangement of confirmations issued in the context of subcontracting. These confirmations shall not be confused with an accreditation. In the event of a breach, legal proceedings may be instituted that may lead even to a withdrawal of the accreditation.

News from Standardization

1. Authorization of the standards of conformity assessment

In December 2007, the European Commission mandated CEN/CENELEC and ETSI to identify and assume harmonized standards for facilitating the new legal framework and sectoral certification systems. On 16th June, 2008, CEN/CENELEC TC1 dealt with the standards on conformity assessment provided in the proposal list compiled by the European Commission.

The aim is to support the new legal framework passed by the EU Council on 23rd June, 2008, by mandating the listed standards setting out the requirements for conformity assessment and accreditation and corresponding to the requirements of the EC Regulation.

Initially, in discussion with the representative of the EU Commission clarity was gained that this mandate would not cause any presumption of conformity for particular Directives/Regulations. It rather relates to the EC Regulation itself and to the requirements for conformity assessment bodies complying with the requirements

set out in the harmonized standards and therewith the requirements set out in the EC Regulation. Under this perspective, the proposal list was in discussion in CEN/CENELEC TC1 and a relevant proposal will now be submitted to the EU Commission via the Technical Board of CEN. Decision was reached that neither draft standards will be included in the mandate nor PAS (Public Available Specifications) nor guidance papers. The harmonized standards are expected soon to be published in the Official Journal of the EU Commission.

2. First Committee Draft on ISO/IEC 17043

Currently the ISO/IEC members participate in a survey on whether the existing draft may be distributed for comment as official Committee Draft on ISO/IEC 17043. Early in June, the German Institute for Standardization (DIN) dealt with the existing draft and will agree, considering a number of comments, that this draft may be distributed as official Committee Draft.

First Committee Draft on ISO/IEC 17065 – Revision of EN 45011

A rough draft is currently being discussed in the Working Group at ISO/CASCO. An official Committee Draft is expected to be published at the end of this year.

4. Revision of ISO 19011

In ISO TC 176 it was decided to commence the revision of ISO 19011 at international level. In May 2008 the Working Group held its first meeting and developed a rough outline of the working plan. In order to delimitate from ISO/IEC 17021-2 it was agreed that the latter should contain the requirements for certification bodies, auditors and the management of audits, while ISO 19011 will be maintained as a guidance setting out requirements for First, Second and Third Party Auditing. Both standards shall be applicable to all types of management systems; it is proposed to provide examples from various management systems in an Annex to ISO 19011.

BAM S.2—M. Wloka

European Developments - New Role of the European co-operation for Accreditation (EA)

The commencement of the "Regulation of the European Parliament and the Council Setting out the Requirements for Accreditation and Market Surveillance Relating to the Marketing of Products" has ushered in a new European accreditation era. Article 14 of the Regulation sets out that for realizing an infrastructure for European accreditation one body will be recognized by the EU Commission after consultation with the member states.

According to recital (23) of the Regulation, EA is intended to be the recognized European organization the main task of which shall be to "support a transparent and quality-oriented system for assessing the competence of conformity assessment bodies throughout Europe".

Thus EA is faced with great challenges, in particular regarding the strategic further development and adaption of the structures and systems on mutual recognition.

At the 21st EA General Assembly that took place in Tallinn, Estonia, from 28th to 29th May 2008, these new tasks were in discussion.

Within EA, preparations to solve the individual major tasks were already made by commencing the work of several project teams and subproject groups.

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Editorial deadline:
30th June 2008
ISSN-1436-2082

DIARY:

Next EA GAs:

- 18-19 November 2008, Estoril near Lisbon, Portugal
- 27-28 May 2009, Luxembourg
- 25-26 November 2009, Belgium
- May/June 2010, Bern/Switzerland
- Autumn 2010, to be decided
- May/June 2011, Berlin/Germany

Next EA MAC Meetings:

- 02-02 October 2008, Bucharest/Romania

Next ILAC/IAF GAs:

- 10-22 October 2008 Stockholm, Sweden

Miscellaneous:

- 12-15 November 2008 International Measurement Confederation - IMEKO TC 11 „Metrological Infrastructure; International Symposium „Metrology, Testing and Accreditation—breaking the trading barriers“, Cavtat, Dubrovnik, Croatia

EA Development Plan for 2007 to 2013

The further development of EA will strongly be focused on the new tasks. To this end, the entire organizational structure of EA is subject to verification, required resources are compared with the current status and potentials for improvement are developed. To begin with, the planning horizon for the changes is the year 2013, and the strategy is assisted by the following Teams:

- Project Team 1 "Review of the general structure of EA" (Convenor: H. Holmqvist)
- Project Team 2 "Strengthening the EA secretariat and related issues" (V. Andersen)
- Project Team 3 "Needs and ways of financing EA" (P. Stennett)

EA Development Project for Strengthening European Accreditation

To act in terms of the Regulation, EA is taking efforts within the frame of the project "ENHANCING EUROPEAN ACCREDITATION" for aiming at a harmonized understanding of accreditation in the scope of the New Approach Directives. This includes the consideration of the preconditions currently existing in Europe for notification, the establishment of new communication networks and working towards an assessment process at a possibly equal technical level for the bodies to be accredited. Furthermore, the mutual assessment of the EA members (Peer Assessment System) shall be expanded as a precondition for mutual recognition (MLA) in the fields of the EU Directives. Strategic considerations with respect to new tasks are made in various Project Groups:

- Sub-Project Group 1 (SP 1) "Harmonization of technical assessments" (M. Malmqvist)
- Sub-Project Group 2 (SP 2) "Information and knowledge database" (V. Andersen)
- Sub-Project Group 3 (SP 3) "Communications with National Regulators" (M. Hynd)
- Sub-Project Group 4 (SP 4) "Relations with the European Commission" (T. Hauge)
- Sub-Project Group 5 (SP 5) "Enhancing the Peer Evaluation Process" (G. Rødland)

BAM S.2—J. Thiele

Interview with Jaques McMillan, Head of Unit, DG Enterprise, European Commission, on the occasion of the EA General Assembly held in Tallinn, Estonia, on May 28th, 2008

The adoption of the new legislative package is a win-win achievement for all operators on the internal market and will facilitate the development of an open and fair European market.

1) How would you best qualify the adoption of the new legislative package in terms of benefits for the European society, the European business operators, the European conformity assessment bodies, and for EA and its member accreditation bodies?

- The adoption of the Regulation constitutes a major breakthrough because it gives a legal basis in two areas where it was missing. Market surveillance has been beyond the Commission's political reach for 25 years and, for accreditation, the package is providing the stabilizing and reinforcing instrument that we have been looking for about 25 years as well.
- It is a win-win achievement for everyone, interested parties, economic operators, conformity assessment community, public authorities, regulators and enforcement parties.
- It marks a new start for the internal market because it makes it possible to definitely abandon the distinction between the "Old" and "New" approach which means that modern instruments developed for the New Approach can now apply to all sectors irrespective of whether harmonised standards are used or not.

2) What are the Commission's expectations vis-à-vis EA ?

- EA should now feel and operate in a strong position to ensure equal, comparable quality of accreditation services throughout the Union and, above all, transparency in the accreditation processes.

Transparency is fundamental to the operation of the internal market because it is the one element that turns the world "trust" into a reality with respect to the Member States work; transparency is the key feature for the whole infrastructure to operate as expected.

All quality instruments put in place, including accreditation, have been designed with one objective: to create the level of trust indispensable for an open market and a fair trade, building up confidence in their ability to safeguard the needs of economy and society.

3) What are the next immediate actions to be undertaken - in the short term - to support implementation with regard to accreditation and EA?

- Our first task is to get an agreement on the guidelines for cooperation that will link EA not only to the Commission and EFTA but also to all EA major stakeholders including the national authorities. This entails the signing of a partnership agreement to translate the political guidelines in concrete terms for the implementation and reinforcement of the peer evaluation process, that must be seen as the major pillar of the whole European accreditation infrastructure. Also the agreement will help strengthen answerability of EA to public authorities both at European and national levels.
- One could see the road of accreditation in Europe over the last 25 to 30 years as a bit "bumpy". The fact is that we have developed a policy which we have put in place and operated well over the last 10 years or so. Now the Regulation is and should be a new start in that it forms the legal foundation for accreditation in Europe, protecting accreditation against the temptation to go commercial. It also gives accreditation bodies the means to be and act as the last level control in the whole quality chain that should ensure that products marketed in Europe are safe and health and safety requirements of European citizens are met in general.

We should all see the Regulation as a launching pad to EA which gives EA and its members in relation with major stakeholders and Public Administrations the best framework to deliver their services properly and efficiently. We should definitely avoid to see the Regulation as an obligation to put into place protective measures but use it as a dynamic instrument to put EA and European accreditation in a position of authority.

I would add that the legislative package will also give European accreditation the means to be a leader in the world in ensuring and demonstrating in reality the added value of accreditation.

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