

Considerations in the EU Commission to Improve the Single European Market

CONTENTS

Considerations in the EU Commission to Improve the Single European Market	1
Current Developments in the German Accreditation Council	2
KAN Study on Accreditation	2
Reform of the Accreditation System	2
ISO/IEC Guide 68:2002 Adopted - "Arrangements for the Recognition and Acceptance of Results in Conformity Assessment"	3
Survey of Standards and Projects in the Field of Conformity Assessment	4

The Direction General Enterprise made an online survey last year.

The results covering improvements of the strategy of the Single European Market and the implementation of the Directives of the New Approach [KOM(2003) 238, KOM(2003) 240] were introduced in the relevant communications of the COM to the Council.

Manufacturers, conformity assessment bodies, accreditation bodies, authorities from almost all EC countries took part in the survey.

It was the purpose of this initiative to include those which are most directly involved in the present system and to ask them about their opinion of the weaknesses and strengths of the system.

The KOM 238 covers a strategic concept on the optimal use of the advantages of the Single European Market after an extension of the EU and describes the prior-ranking tasks from 2003 to 2006. The Commission focuses on new incentives to remove the remaining weaknesses and to enable the full development of the Single European Market in view of competitiveness, growth and employment.

The KOM 240 focuses on strengthening the system of free movement of goods also with regard to an extended European Union. Basis for this is the New Approach which has been amended by the Global Approach.

These documents represent a technique of law drafting which is used in the field of free movement of goods and is generally recognized as highly efficient and successful.

The Communications include recommendations, e.g.:

- to improve the procedure of notification,
- with regard to the introduction of an internet-assisted notification system,
- on the role of accreditation (see 2.2.4, p. 10),
- uniting mandatory and voluntary areas,
- on a strengthening of the cooperation between the notifying authorities,
- on conformity assessment procedures by means of the modules H, E and D,
- on market surveillance.

which help to make the functioning of the Single European Market more efficient and thus to strengthen the competitiveness of the European industry by cost-effective measures proposed by numerous interest groups.

Both Communications represent a new challenge to all parties involved in the Single European Market, i.e. to its governing, administrative and surveillance structures as well as to manufacturers, merchants and indirectly to consumers.

BAM S.42 - N. Bendix

- COM(2003) 238 Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the committee of the Regions, Internal Strategy - http://europa.eu.int/eur-lex/de/com/cnc/2003/com2003_0238de01.pdf
- COM(2003) 240 Communication from the Commission and European Parliament; Enhancing the Implementation of the New Approach Directive http://europa.eu.int/eur-lex/de/com/pdf/2003/com2003_0240de01.pdf

Current Developments in the German Accreditation Council (DAR)

For many years the DAR has been having discussions for changing its internal method of operation and its representation abroad. Due to legal examinations of the present approaches an actual need for action recently arose. In particular its coordinating role for the voluntary area assigned to the TGA since the foundation of the DAR which the TGA carries out in addition to its accreditation activities has permanently been under discussion. Currently the TGA is parting with its coordinating function in the voluntary area. In discussions with the parties concerned it is being

looked for a satisfactory follow-up regulation to be brought into agreement with the authorities. These discussions are also about the issue to handle present applications for admission into the DAR in the voluntary area according to legal requirements.

The German Federal Ministry for Economy and Labour is presently working with all parties concerned to establish a reliable temporary regulation and furthermore to reach a re-organisation of the overall system of conformity assessment in Germany the aim of which is to be accepted by

almost all parties concerned. It is the aim - and not least in the interest of the German industry - to consequently improve the cooperation between the mandatory and the voluntary areas and to ensure a consistent representation abroad especially at international level.

The activities of the accreditation bodies in the DAR and the validity of the accreditation certificates issued is not restricted by these activities. After having re-organised the system sustainably an adequate temporary regulation for the accredited bodies can be expected.

BAM S.42 - M. Wloka

KAN Study on Accreditation

At its 37th Meeting the DAR reported about first results of a study made by the KAN (Commission for Occupational Health and Safety and Standardization). The KAN commissioned a study *Accreditation of Testing and Certification Bodies*. In this study the legal relevance and the new concept of the laws and standards as well as the authorisation of these standards should be checked. It should be ascertained whether the presumption of the conformity of the EN 45000 standards series can be sustained any longer from the legal point of view. Weaknesses should be identified and proposals for consistent rules and regulations for conformity assessment of bodies should be made.

As a result it appeared that

1. the presumption of the conformity of the standards series can no longer be sustained from the legal point of view.

2. the authorisation of the standards shall be repeated.

3. the designation and reporting procedures for the bodies in Europe are to be harmonised.

4. the surveillance of the designated bodies is to be improved.

5. general common requirements for bodies are to be formulated with harmonised elements.

The KAN Study is available on the Internet at www.kan.de and was published both in German and English languages as KAN Report 30.

The KAN Study provides the following recommendations:

1. The BMWA (German Federal Ministry of Economics and Labour) shall bring the results in the national and European committees/boards.

2. The EU shall re-establish the presumption of conformity by harmonising the requirements for the bodies and by a legally binding act.

3. The DAR and the KOGB (Coordination Body Mandatory Area) shall use the study for further developing the German accreditation, recognition and designation system.

4. The DIN (German Institute for Standardisation) shall discuss in its committee NQSZ-3 to what extent the results of the study can be brought in the European and international standardisation.

The results are currently used for the discussions in the DAR for further developing the German accreditation system. In the DIN a Working Group "Mandatory Area" has been established in which additionally to the NQSZ-3 the issue was discussed how to formulate the text modules in the standards 17000er series so as to apply them by the mandatory area and how the standards series on conformity assessment can be affected internationally.

BAM S.42 - M. Wloka

Reform of the Accreditation System

KANMAIL Interview with Norbert Barz, Head of the Division for "Technical work equipment, testing and certification, electrical installations", [BMWBA], Member of KAN

The German federal government is currently considering reforming the German accreditation system. What are the reasons behind these plans?

It is the authorities' task to permanently ensure that those testing and certification bodies which are commissioned to carry out conformity assessments on the basis of laws and other legal provisions have sufficient

competence to do so. Usually, the authorities conduct an accreditation procedure to establish whether or not that competence exists. In addition, the accrediting bodies have to monitor the work of the testing and certification bodies.

However, conformity assessments are also conducted outside the scope of legal provisions - mostly due to specific market requirements.

But a large number of conformity assessments in this sphere are also concerned with certain aspects of public welfare such as safety, environmental protection and consumer protection. In the private sector, not governed by the legislation, it is completely up to the contracting parties to decide how to assess the testing and certification bodies' competence and what such assessment should cover.

At present, Germany does not have one all-embracing accreditation act. Instead, the issue is covered by provisions in various specific laws, e.g. the Equipment Safety Act, the Electromagnetic Compatibility Act, the Medical Devices Act and the Telecommunications Act. Whereas it is usually the federal government which draws up the legislation, in most cases it is the federal states which are responsible for enforcing it. In practice, this means that the 16 different federal states are responsible for accreditation of statutory testing and certification bodies within their own boundaries. There are only a few sectors (Equipment Safety Act, Medical Devices Act) where the federal states have appointed joint bodies to conduct accreditation on the basis of inter-state treaties.

There are also numerous accreditation bodies in the private sector, many of which presently collaborate within the framework of the Trägergemeinschaft für Akkreditierung (TGA).

What would be the aim of a reform?

A key problem is the multipartite structure of the German accreditation system.

Consequently, centralisation, particularly with regard to the federal states' responsibilities, is one of the reform's main aims. Close cooperation between the remaining accreditation bodies ("accreditation from one source") could guarantee a high degree of efficiency. The statutory and private spheres should be put on an equal footing to enable them to recognise each other's results. This would resolve the authorities' resource problem without there being any loss of competence. At the same time, industry would benefit a great deal from close cooperation because it would prevent work being carried out twice. The general level of acceptance amongst the parties involved in Germany and other states could also be significantly improved in this way.

What might be the cornerstones of a legislative solution and what would be the advantages?

To begin with, the accreditation bodies would have to fulfil defined minimum criteria. In particular, peer assessments (by other accreditation bodies) are to be used to guarantee a permanent, common standard of quality.

The federal and federal-state authorities responsible would then designate the bodies which fulfilled the initial requirements and advise the Federal Ministry of Economics and Labour accordingly. The bodies should be designated in such a way that there is only one responsible accreditation body for each field. This will rule out competition between private accreditation bodies or between private bodies and public-sector bodies.

The bodies will centrally co-ordinated so as to guarantee close cooperation. A legally safeguarded symbol is intended to serve as an incentive, especially for private accreditation bodies, to participate in the accreditation system.

A legislative framework of this kind would provide the German accreditation system with a reliable, future-oriented basis. By means of close cooperation based on common rules, multiple accreditation could be avoided and costs slashed.

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ISO/IEC Guide 68: 2002 Adopted- "Arrangements for the Recognition and Acceptance of Results of Conformity Assessment"

The ISO/IEC Guide 68:2002 "Arrangements for the recognition and acceptance of conformity assessment results" was published by ISO at the end of 2002.

It will be included in the German standards as DIN 55391 "Arrangements for the recognition and acceptance of results of conformity assessment".

The Guide contains general rules for the development and maintenance of arrangements for the recognition and acceptance of results of conformity assessment.

Recognition and acceptance of bodies carrying out an equivalent conformity assessment.

An Annex to the Guide provides examples of recognition arrangements between accreditation bodies which are already implemented, such as the IAF MLA, the APLAC MRA and between certification bodies the IEC CB Scheme, IQNet and IECEx-Scheme.

The Guide points out to a conceptual difference between "Mutual Recognition Agreements (MRA)

often used between governmental bodies and with legal binding and "Mutual Recognition Arrangements (MLA) concluded on a voluntary basis between private accreditation and certification bodies or organisations.

It should be the aim of all these arrangements and agreements to reduce multiple assessments and therewith to save costs and efforts appropriately.

BAM S.42 - J.- Thiele

Survey of standards and projects in the field of conformity assessment

European Standard	ISO/IEC-Guides/Standards presently in force	ISO/IEC-Guides/Standards planned to be implemented
BEGRIFFE		
DIN EN 45020:1998 Standardization and related activities - General vocabulary	ISO/IEC Guide 2:1996 Standardization and related activities - General vocabulary	The section <i>conformity assessment</i> will be revised as ISO/IEC 17000 "Conformity assessment - General vocabulary" Scheduling: DIS for voting until October 2003
LABORATORIES		
DIN EN ISO/IEC 17025:2000 General requirements for the competence of testing and calibration laboratories	ISO/IEC 17025:2000 General requirements for the competence of calibration and testing laboratories	Revision in terms of alignment with ISO 9001:2000 Scheduling: until 2004
ACCREDITATION		
DIN EN 45003:1995 Calibration and testing laboratory accreditation systems - General requirements for operation and recognition	ISO/IEC Guide 58:1993 Calibration and testing laboratory accreditation systems - General requirements for operation and recognition	Both standards shall be cancelled and replaced by FDIS 17011 <i>General requirements accrediting conformity assessment bodies</i> Scheduling: Final Draft until the end of 2003
DIN EN 45010:1998 General requirements for assessment and accreditation of certification/registration bodies	ISO/IEC Guide 61:1996 General requirements for assessment and accreditation of certification and registration bodies ISO/IEC TR 17010:Nov. 98 General requirements for bodies providing accreditation of inspection bodies	
INSPECTION		
DIN EN 45004:1995 General criteria for the operation of various types of bodies performing inspection	ISO/IEC 17020:1998 General criteria for the operation of various types of bodies performing inspection (identical in wording with EN 45004:1995)	
CERTIFICATION OF PERSONNEL		
DIN EN 45013:1989 General criteria for certification bodies operating certification of personnel At present, revision as ISO/IEC 17024		ISO/IEC 17024 General criteria for certification bodies operating certification of persons Scheduling: Published in July 2003
CERTIFICATION OF PRODUCTS		
DIN EN 45011:1998 General requirements for bodies operating product certification systems	ISO/IEC Guide 65:1996 General requirements for bodies operating product certification systems	
CERTIFICATION OF MANAGEMENT SYSTEMS AND ENVIRONMENTAL MANAGEMENT SYSTEMS		
DIN EN 45012:1998 General requirements for bodies operating assessment and certification/registration of quality systems	ISO/IEC Guide 62:1996 General requirements for bodies operating assessment and certification/registration of quality systems ISO/IEC Guide 66:1998 General requirements for bodies operating assessment/registration of environmental management systems (EMS)	Future ISO/IEC 17021 General requirements for bodies operating assessment and certification/registration of quality of environmental management systems Scheduling: Currently CD2
SUPPLIERS OF CONFORMITY ASSESSMENTS		
DIN EN 45014:1998 General criteria for supplier's declaration of conformity	ISO/IEC Guide 22:1996 General criteria for suppliers' declaration of conformity	ISO/IEC 17050-1:2003 Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements Scheduling: Draft published in July 2003 ISO/IEC 17050-2:2003 Conformity assessment - Supplier's declaration of conformity - Part 2: Supporting documentation Scheduling: Draft published in August 2003
MUTUAL RECOGNITION		
	ISO/IEC Guide 68:2002 Arrangements for the recognition and acceptance of conformity assessment results	