Letter from EUROPE

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This letter outlines recent developments of product testing and product certification. It follows the January 2010 letter on the new European system of conformity assessment and accreditation and illustrates the current situation of certification, marks, notified bodies and marking of products in Europe.

The role of Product Testing and Product Certification

The aim of product testing is to determine characteristics (attributes) of a given product and express them by qualitative and quantitative means. Product certification is defined as a third party attestation related to products (see *ISO/IEC Standard 17000*). Product testing and product certification are important elements in the interplay of conformity assessment and global trade. Metrology delivers the basis for the comparability of test results, e.g. by defining the units of measurement and the associated uncertainty of the measurement results.

European organisations engaged in product testing and certification are EUROLAB www.eurolab.org and CEOC International www.ceoc.org through their Joint Technical Committee for Product Testing and Certification (JTCPTC), co-chaired by Guy Jacques (EUROLAB) and Christian Priller (CEOC). Thanks is due to Anita Schmidt (BAM), the Secretary of JTCPTC, for kindly providing some information for this letter.

Product certification can be classified into:

- Product certification in the private area,
- Product certification in the regulated area on a legal basis.

In the private area, in principle any certification to any specification or criteria is possible; the market will decide on the relevance and success of a certification scheme. Therefore the quality of a certification scheme plays a major role. For certain security relevant products, testing and certification and the affixing of a "mark" may even be a pre-requisite for their placing on a market in a certain country.

International Standardisation for Conformity Assessment and Product Certification

On the international level, the major standardisation work for product certification is currently under revision. The standards issued in the period from 1982 to 2005 are compiled in Table 1 and the actual status can be described as follows:

- The International Standard *ISO/IEC WD 17067* "Fundamentals of product certification" will include revision of the ISO Guides 23, 27, 28, 53 and 67 and is currently in a working group draft stage (WD). The focus of the standard is on requirements for the quality and the development of certification schemes.
- The former European Standard *EN 45011* and the identical *ISO Guide 65* are revised to become *ISO/IEC 17065* "Requirements for certification bodies certifying products, processes and services." The aims of the revision are to explicitly include services and processes, alignment with *ISO/IEC 17021* as well as alignment with the functional approach (*ISO/IEC 17000*).

Table 1: Some International standards in the field of product certification

STANDARD	TITLE	STATUS
ISO/IEC 17000:2004	Conformity assessment -- Vocabulary and general principles	confirmed
ISO/IEC Guide 23:1982	Methods of indicating conformity with standards for third-party certification systems	all to be revised as ISO/IEC 17067 "Fundamentals of product certification"
ISO Guide 27:1983	Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity	
ISO/IEC Guide 28:2004	Conformity assessment -- Guidance on a third-party certification system for products	
ISO/IEC Guide 53:2005	Conformity assessment -- Guidance on the use of an organization's quality management system in product certification	
ISO/IEC Guide 67:2004	Conformity assessment -- Fundamentals of product certification	
ISO/IEC Guide 65:1996	General requirements for bodies operating product certification systems	under revision as ISO/IEC 17065
ISO/IEC 17030:2003	Conformity assessment -- General requirements for third-party marks of conformity	confirmed

Product Certification and the European System of Product Directives

In Europe, the safety requirements for certain safety relevant products are extensively regulated and have to be fulfilled before products are allowed to enter the market. The essentials of the so-called "New Approach" are compiled in the following box:

New Approach for the European Economic Community (Legislation 1985) intending to ensure the 4 basic freedoms for movements of goods, persons, services and capital:

New Approach for the European Economic Community (Legislation 1985) intending to ensure the 4 basic freedoms for movements of goods, persons, services and capital:

- Flexible regulatory framework providing access to the common market while protecting essential public requirements, e.g. safety, health, environment.
- "Essential requirements" defined in EU Directives: from machinery to toys.
- The EU-Directives have to be transposed into national laws of the EU member states (note: the European Union 2010 comprises 27 member states with 23 official languages for national laws and regulations.
- "Harmonised Standards" are referenced which are valid in the whole EU – conflicting national standards have to be withdrawn.
- CE marking: the manufacturer declares that the product is safe and in conformity with the relevant EU Directives.

The requirements are laid down in over 20 European Product Directives of the "New Approach." The Product Directives provide the legislative framework for the basic safety requirements for the products. For the technical details the "harmonised standards" are referenced. The products concerned have been estimated to equate some 1.500 billion turnover. The product directives (in alphabetic order) concern the following areas:

EUROPEAN PRODUCT DIRECTIVES	NUMBER
Appliances burning gaseous fuels	90/396/EEC
Cableway installations designed to carry persons	2000/9/EC
Construction products (under revision)	89/106/EEC
Electromagnetic compatibility	2004/108/EC
Equipment and protective systems in potentially explosive atmospheres (ATEX)	94/9/EC
Explosives for civil uses	93/15/EEC
Lifts	95/16/EC
Low voltage equipment	2006/95/EC
Machinery safety	2006/42/EC
Measuring instruments	2004/22/EEC
Medical devices: Active implantable	90/385/EEC

EUROPEAN PRODUCT DIRECTIVES	NUMBER
Medical devices: General	93/42/EEC
Medical devices: In vitro diagnostic	98/79/EC
New hot-water boilers fired with liquid or gaseous fluids	92/42/EEC
Non-automatic weighing instruments	90/384/EEC
Packaging and packaging waste	94/62/EC
Personal protective equipment	89/686/EEC
Pressure equipment (PED)	97/23/EC
Radio and telecommunications terminal equipment	99/5/EC
Recreational craft	94/25/EC
Simple pressure vessels	87/404/EEC
Toys safety (new: 2009/48/EC, entering into force 2011)	88/378/EEC
Transportable Pressure Equipment Directive	1993/36/EC

The measures that have to be taken to fulfil the requirements are defined in conformity assessment modules from A to H in the directives. Many – not all directives – require affixing of the CE marking. It is possible to include third-party testing and certification bodies – the so-called notified bodies in the product certification activities. For example module B (EC Type examination) requires involvement of a Notified body. The notified bodies have to be notified by a member state's government to the European Commission.

Conformity assessment procedures in EU Community legislation

CONFORMITY ASSESSMENT PROCEDURES IN EU COMMUNITY LEGISLATION			
MODULE A	**INTERNAL PRODUCTION CONTROL**	**MANUFACTURER** - declares conformity with essential requirements - keeps technical documentation at disposal of national authorities - affixes required marking	
MODULE B	**TYPE EXAMINATION**	**MANUFACTURER** - submits to notified body technical documentation, - supporting evidence for the adequacy of the technical design solution, - specimen(s) representative of the production envisaged, as required	**NOTIFIED BODY** - ascertains conformity with essential requirements, - examines technical documentation and supporting evidence to assess adequacy of the technical design, - carries out tests for specimen(s) if necessary, - issues EC type-examination certificate
MODULE C	**CONFORMITY TO TYPE**	**MANUFACTURER** - declares conformity with approved type, - affixes required marking.	
MODULE D	**PRODUCTION QUALITY ASSURANCE** (EN ISO 9001:2000)	**MANUFACTURER** - operates an approved quality system (QS) for production and testing, - declares conformity with approved type, - affixes the required marking.	**NOTIFIED BODY** - approves the QS - carries out surveillance of the QS
MODULE E	**PRODUCT QUALITY ASSURANCE** (EN ISO 9001:2000)	**MANUFACTURER** - operates an approved quality system for production and testing, - declares conformity with approved type - affixes the required marking.	**NOTIFIED BODY** - approves the QS - carries out surveillance of the QS
MODULE F	**PRODUCT VERIFICATION**	**MANUFACTURER** - declares conformity with approved type, - affixes the required marking.	**NOTIFIED BODY** - verifies conformity with essential requirements, - issues certificate of conformity.
MODULE G	**UNIT VERIFICATION**	**MANUFACTURER** - submits technical documentation and product, - declares conformity, - affixes the required marking.	**NOTIFIED BODY** - verifies conformity with essential requirements, - issues certificate of conformity.
MODULE H	**FULL QUALITY ASSURANCE (EN ISO 9001:2000)**	**MANUFACTURER** - operates an approved quality system (QS) for design, production and testing, - submits technical documentation to Notified Body, - carries out surveillance of QS, - declares conformity, - affixes required marking.	**NOTIFIED BODY** - carries out surveillance of the QS.

Customers and users of CE-marked product should note that the CE marking is not guaranteeing a certain "product quality" or a certain "product performance." By affixing the CE marking the manufacturer only declares that the products meet the requirements defined in the pertinent Module for the respective product in the EU directives.

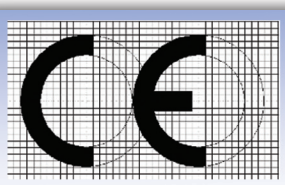
The CE marking system is completed by market surveillance. Due to improved market supervision, unsafe products can already be withdrawn from circulation at the borders of the European Union. RAPEX is the EU rapid alert system for all dangerous consumer products. The Commission publishes a weekly overview of the dangerous products reported by the national authorities (http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm).

The marking of products in product certification

A certification can be granted to a product for all kinds of specifications ranging from safety to sustainability, from specifications defined in standards to customer specific requirements. They can be internationally recognised or more regionally oriented. When marks or certification schemes for products become mandatory, they gain a major influence for trade.

There is a broad variety of marks and labels characterizing certification schemes and their results, for example the ISO 14000 environment management system certification, the FSC (Forest Stewardship Council), TransFair (Fair Trade), UL mark, National Organic Program and many more.

In the following some relevant markings in EU regulations are exemplified:



The CE marking certifies that a product has met EU consumer safety, health or environmental requirements

pi marking (TPED) Transportable Pressure Equipment Directive

The toy marking warns that a toy is not intended for use by children under 36 months of age

Expolsive atmosphere marking (ATEX)

The importance of marks can be illustrated for the product category of toys. Following severe product recalls of major toys manufacturers especially in 2007 – e.g. for lead in paints, chokeable parts, tiny magnets, - there were controversial discussions in Europe on how the safety of toys could be increased. In June 2009 a new directive on the safety of toys (2009/48/EC) was adopted and will be in force from 2011. Another important directive, the "Construction Products Directive" is under revision and will become the "Construction Products Regulation" in the near future.

FINALLY, SOME OTHER EUROPEAN LABELS OF GENERAL INTEREST MAY BE MENTIONED:	
The European Community Ecolabel scheme (Regulation 66/2010) is a voluntary system for environment-friendly products ("EU flower"). The label has so far been awarded to over 3,000 products such as detergents, paper and shoes. The criteria themselves are determined by subsequent decisions for each product group (laundry detergents, soaps and shampoos, tissue paper, camp site service, etc.).	
The Keymark is a uniform certification mark created by the European Standardisation organisations CEN and CENELEC. It is always combined with the member state's standardisation organisation's logo (e.g. DIN, the German Standardisation Institution). However, this logo has only gained relevance for some product groups – e.g. for solar energy products.	
According to Regulation (EC) No 834/2007 on organic production and labelling of organic products there must not be misleading labelling of organic products. From July 2010 the new Organic Logo of the EU (Regulation 271/2010) is the legal mark.	

Some final remarks

From the consumer's point of view, marks and labels are important aids to provide relevant information about a products, and are therefore of added value. The great number and diversity of certifications / labels clearly shows this.

On the one hand, the current diversity of existing labels is difficult to overlook – therefore unification of product safety labels that consumers can identify instantly might be helpful.

On the other hand, it would not serve the customers to restrict the application of (private) marks for the sake of one uniform mark, as this would restrict information for the consumer.

Conformity assessments must be based on testing (determining attributes of products) and on metrology (defining product-relevant units where possible). As such, the interplay of testing, metrology and global trade is and must remain an added value for the customer.

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