



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Regulatory policy
Regulatory Approach for the free circulation of goods

Brussels, 4th December 2007
M/417 EN

STANDARDISATION MANDATE ADDRESSED TO CEN, CENELEC AND ETSI FOR THE USE OF HARMONISED STANDARDS IN SUPPORT OF THE NEW LEGAL FRAMEWORK AND SECTORAL CERTIFICATION SCHEMES

1. SCOPE

This mandate concerns the adoption at European level of international standards in support of the New Legal Framework (revision of the New Approach) as well as sectoral certification schemes. The mandate covers existing and future standards.

2. JUSTIFICATION

2.1 Political context

2.1.1) In the context of the revision of the New Approach, in February 2007, the Commission adopted a package of measures consisting of a proposal for a Regulation and Decision relating to a New Legislative Framework for the marketing of products (hereafter NLF). When this NLF has been adopted by the Council and the Parliament (end 2008), European standards covering accreditation, conformity assessment, quality assurance etc. will be needed to facilitate implementation of the legislation.

Furthermore, existing Directives adopted following the New Approach (Council Resolution of 07.05.1985) and the Global Approach (Council Resolution of 21.12.1989, Council Decision 93/465/EEC) also make use of such standards.

2.1.2) In addition, various sectors (e.g. environment) use their own certification and quality assurance schemes, which are very similar to those foreseen under the NLF. These other schemes also use European standards for the technical expression of their requirements and in order to propose stakeholders reliable methods to prove their compliance to these requirements.

A typical example is EMAS - the Eco-Management and Audit Scheme – which is an EU run voluntary instrument which acknowledges organisations that run an environment

management system in order to improve their environmental performance on a continuous basis.

2.2 Rationale

Presently the situation concerning the standards used under the NLF and in different sectors is not as clear as it should be, because:

In cases where such standards exist today (usually as adoptions of International standards), they are not yet harmonised;

In some other cases the existing international standard has not yet been adopted at European level;

In order to formalise the use of the relevant European standards, facilitate the implementation of the NLF and sectoral certification and quality assurance schemes as well as for the sake of clarity, the Commission intends to harmonise all these International standards at European level by means of this mandate and then to reference them in the Official Journal.

Further information referred to above can be seen on the following websites:

For NLF:

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

For environmental management:

http://ec.europa.eu/environment/emas/index_en.htm

3. DESCRIPTION OF THE MANDATE

In this context the Commission tasks ESOs with the following:

a) Identify all international standards and/or standardisation documents (e.g. guides) from ISO, IEC, ITU that are relevant to the NLF and/or to the sectoral policies mentioned under §2.

Annex I defines the indicative set of international standards and standardisation documents the Commission considers necessary in support of the NLF and sectoral certification schemes;

b) If they meet European requirements, adopt the relevant International standards at European level or endorse standardisation documents that are not adoptable. At the same time existing conflicting European standards (if any) must be repealed;

c) ESOs should issue a report covering the areas a) and b). The report may serve as a basis for further mandates. The report may serve also to reinforce the EU's contribution to the dialogue with third countries.

4. EXECUTION OF THE MANDATE

4.1 The Commission hereby asks CEN, CENELEC and ETSI to carry out the work described above.

4.2 CEN, CENELEC and ETSI will provide, within 3 months of the acceptance of the mandate, a list in the same format as Annex I with:

- all international standards / standardisation documents they have identified (taking into consideration the indicative set laid down in Annex I – see also 3.a of the mandate);
- the respective ENs / other types of documents they have been already adopted / endorsed; independently of the fact if the adoption / endorsement has taken place before or after the acceptance of the mandate;
- the respective conflicting European standards (if any) that have been repealed;
- a justification for the standards / standardisation documents that have not been adopted / endorsed.

4.3 CEN, CENELEC and ETSI will update the list mentioned under §4.2 every year for three years after the acceptance of the mandate.

4.4 While executing the mandate, CEN, CENELEC and ETSI must also take into account on-going developments in the NLF and sectoral policies mentioned under §2. They must co-ordinate their activities in order to avoid any duplication of work.

4.5 The standstill period referred to in Article 7 of Directive 98/34/EC¹ of 22 June 1998 will commence on acceptance of this standardisation mandate by CEN, CENELEC and ETSI.

5. BODIES TO BE ASSOCIATED

The execution of the mandate should be undertaken in co-operation with the widest possible range of interested groups: International standards bodies (ISO, IEC, ITU) including the competent bodies (European co-operation for Accreditation, Groups of Notified Bodies, manufacturers, etc). Representatives also from regulatory authorities, users NORMAPME², ANEC³, ETUI-REHS⁴ and ECOS⁵ should also be invited to take part.

Annex I: Indicative set of international standards

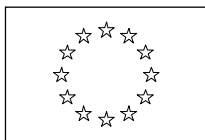
¹ OJ L 204 of 21.07.98, p. 37, as amended by Directive 98/48/EC, OJ L 217 of 5.08.98, p.18.

² European Office of Crafts, Trades and Small and Medium- Sized Enterprises for Standardisation

³ European Association for the Co-ordination of Consumer Representation in Standardization

⁴ European Trade Union Institute – Research, Education, Health and Safety

⁵ European Environmental Citizens Organisations for Standardisation



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ANNEX I TO MANDATE M/417

INDICATIVE SET OF INTERNATIONAL STANDARDS TO BE HARMONISED

1. Standards for accreditation bodies / Standards for accreditation and assessment

International standard	Adopted standard in use at European level	European Standard(s) that have been replaced by the international standard	European Standard in use
ISO/IEC 17011:2004 “Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies” that replaced ISO/IEC Guide 58:1993, ISO/IEC Guide 61:1996 and ISO/IEC/TR 17010:1998	EN ISO/IEC 17011:2004 Relevant also for the environmental area.	EN 45003:1995 “Calibration and testing laboratory accreditation systems – General requirements for operation and recognition” – adopted under mandate. EN 45010:1998 “General requirements for assessment and accreditation of certification/registration bodies” was based on ISO/IEC Guide 61:1996 – adopted under mandate. EN 45002:1989 “General criteria for the assessment of testing laboratories” - adopted	

		under mandate. This standard has already been withdrawn and its requirements were transferred to EN 45003.	
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2. Standards for conformity assessment bodies- operational standards

International standard	Adopted standard in use at European level	European Standard(s) that have been replaced by the international standard	European Standard in use
ISO/IEC 17020:1998 “General criteria for the operation of various types of bodies performing inspection ” (wording identical to EN 45004).	EN ISO/IEC 17020:2004	EN 45004:1995 “General criteria for the operation of various types of bodies performing inspection ”.	
ISO/IEC 17021:2006 “Conformity assessment Requirements for bodies providing audit and certification of management systems ” that replaced ISO/IEC Guide 62:1996 and ISO/IEC Guide 66:1999.	EN ISO/IEC 17021:2006 Relevant also for the environmental area.	EN 45012:1998 “General requirements for bodies operating assessment and certification/registration of quality systems ” – adopted under mandate – was based on ISO/IEC Guide 62:1996.	
Future ISO/IEC 17021-2 “Conformity assessment - Part 2: Requirements for third party auditing of management systems”.			

ISO/IEC 17024:2003 “Conformity assessment - General requirements for bodies operating certification of persons ”.	EN ISO/IEC 17024:2003	EN 45013:1989 “General criteria for certification bodies operating certification of personnel ” - adopted under mandate.	
ISO/IEC 17025:2005 “General requirements for the competence of testing and calibration laboratories ”.	EN ISO/IEC 17025:2005	EN 45001:1998 “General criteria for the operation of testing ” – adopted under mandate.	
Future ISO /IEC 17065- currently ISO/IEC Guide 65:1996 under revision - “General requirements for bodies operating product certification systems”. Review to be finished by 2009.			EN 45011: 1998 “General requirements for bodies operating product certification systems” - adopted under mandate (European equivalent of ISO/IEC Guide 65:1996).

3. Standards for quality assurance

International standard	Adopted standard in use at European level	European Standard(s) that have been replaced by the international standard	European Standard in use
ISO 9000:2005 “Quality management systems – Fundamentals and Vocabulary”.	EN ISO 9000:2005		

ISO 9001:2000 “Quality management systems – Requirements”.	EN ISO 9001:2000		
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4. General standards

International standard	Adopted standard in use at European level	European Standard(s) that have been replaced by the international standard	European Standard in use
ISO/IEC 17000:2004 “Conformity assessment Vocabulary and general principles”.	EN ISO/IEC 17000:2004	EN 45020:1998 Standardization and related activities – General vocabulary , Clauses 12-17 “terminology related to conformity assessment”.	
ISO/IEC 17040:2005 “Conformity assessment – General requirements for peer assessment of conformity assessment bodies and accreditation bodies”.	EN ISO/IEC 17040:2005		
ISO/IEC 17050-1:2004 (part 1) “Conformity assessment - Suppliers declaration of conformity – Part 1: General Requirements”.	EN ISO/IEC 17050-1:2004	EN 45014:1998 “General criteria for supplier’s declaration of conformity ” - adopted under mandate – was based on ISO/IEC Guide 22:1996.	
ISO/IEC 17050-2:2004 (part 2) “Conformity assessment -	EN ISO/IEC 17050-2		

Suppliers declaration of conformity – Part 2: Supporting documentation”.	:2004		
			EN 45020:2006 “Standardization and related activities -General Vocabulary” that replaced EN 45020:1998 apart from Clauses 12-17 “terminology related to conformity assessment” - see also 1 st row of this table.
Future standard(s) based on ISO/PAS 17001:2005 “Conformity assessment – Impartiality – Principles and requirements”.			
Future standard(s) based on ISO/PAS 17002:2004 “Conformity assessment - Confidentiality - Principles and requirements”.			
Future standard(s) based on ISO/PAS 17003:2004 “Conformity assessment –			

Complaints and appeals - Principles and requirements”.			
Future standard(s) based on ISO/PAS 17004:2005. “Conformity assessment – Disclosure of information – Principles and requirements”.			
Future ISO/IEC 17007, currently ISO/IEC Guide 7:1994 under revision “Guidelines for drafting of standards for use for conformity assessment”.			
Future ISO/IEC 17043, currently ISO/IEC Guide 43-1&2:1997 “Proficiency testing by inter-laboratory comparisons”. Part 1 “Developments and operation of proficiency testing schemes”. Part 2 “Selection and use of proficiency testing schemes by laboratory accreditation bodies”.			
ISO/IEC Guide 53:2005 “Conformity assessment –			

Guidance on the use of an organization's quality management system in product certification”.			
ISO/IEC Guide 60:2004 “Conformity assessment - Code of good practice”.			

5. *Environment standards*

International standard	Adopted standard in use at European level	European Standard(s) that have been replaced by the international standard	European Standard in use
ISO 14001:2004 “Environmental management systems – requirements with guidance for use”.	EN ISO 14001:2004		
ISO 14004:2004 “Environmental management systems – General guidelines on principles, systems and support techniques”.			
Future ISO 14005 “Environmental management systems – Guidelines for a staged			

<p>implementation of an environmental management system, including the use of environmental performance evaluation”.</p>			
<p>ISO 14050:2002 “Environmental management – Vocabulary”.</p>			
<p>ISO 14064-1&2&3 “Greenhouse gases”.</p> <p>Part 1 “Specification with guidance at the organisation level for quantification and reporting of greenhouse gas emissions and removals”.</p> <p>Part 2 “Specification with guidance at the project level for quantification, monitoring and reporting of greenhouse gas reductions or removal enhancements”.</p> <p>Part 3 “Specification with guidance for validation and verification of greenhouse gas assertions”.</p>	<p><i>PrEN ISO 14064-1&2&3??</i></p>		

ISO 19011:2002 “Guidelines for quality and/or environmental management systems auditing”.	EN ISO 19011:2002		
<i>EA specifications to be input to ISO/CEN??</i>			