



**EUROPEAN COMMISSION**  
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

**Regulatory policy**  
**Regulatory Approach for the free movement of goods**

**NOTE TO THE SENIOR OFFICIALS GROUP ON  
STANDARDISATION AND CONFORMITY ASSESSMENT POLICY**

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| <b>Title:</b>                                                                                                                                                                                                                                                                                                                                            | <b>CERTIF 2010–03</b><br><br><b>FOLLOW UP OF MANDATE M 417 FOR THE USE OF HARMONISED STANDARDS IN SUPPORT OF THE NEW LEGAL FRAMEWORK AND ECO-MANAGEMENT AND AUDIT SCHEME (EMAS) – UPDATE OF THE LIST OF STANDARDS</b>                                                                                                                                                                                                                                                             |                    |               |
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| <b>Doc. N.:</b>                                                                                                                                                                                                                                                                                                                                          | <b>SOGS N621 EN</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Issue Date:</b> | 2010-02-23    |
| <b>Version:</b>                                                                                                                                                                                                                                                                                                                                          | 1.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Meeting:</b>    | 2010-03-03/04 |
| <b>Status:</b>                                                                                                                                                                                                                                                                                                                                           | For information                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                    |               |
| <p style="text-align: center;"><b>Abstract:</b></p> <p><b>The present document includes the indicative list of standards, the Commission intends to ask CEN to consider in the scope of the update of the list of harmonised standards already published in the Official Journal of the European Union following the provisions of mandate M417.</b></p> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                    |               |
| <b>Keywords:</b>                                                                                                                                                                                                                                                                                                                                         | <b>Harmonised standards, New Approach New Legal Framework , certification, conformity assessment, testing, inspection, accreditation, Eco-Management and Audit Scheme (EMAS), ISO, CEN.</b>                                                                                                                                                                                                                                                                                       |                    |               |
| <b>References:</b>                                                                                                                                                                                                                                                                                                                                       | <b>Regulation (EC) No 765/2008 of the European Parliament and of the Council</b><br><br><b>Decision No 768/2008/EC of the European Parliament and of the Council</b><br><br><b>Official Journal of the European Union 2009 C/136/08 <a href="http://eur-lex.europa.eu/JOIndex.do?year=2009&amp;serie=C&amp;textfield2=136&amp;Submit=Search&amp;ihmlang=en">http://eur-lex.europa.eu/JOIndex.do?year=2009&amp;serie=C&amp;textfield2=136&amp;Submit=Search&amp;ihmlang=en</a></b> |                    |               |



**Follow up of mandate M 417 for the use of harmonised standards in support  
of the New Legal Framework and Eco-Management and Audit Scheme  
(EMAS) – Update of the list of standards**

As stated under §4.3 of the above mandate ESOs will update the list of standards in all EU official languages already provided to the Commission and published in the Official Journal of the European Union (see under <http://eur-lex.europa.eu/JOIndex.do?year=2009&serie=C&textfield2=136&Submit=Search&hmlang=en>) taking into account on-going developments.

In this respect, the Commission intends to ask ESOs to consider the following standards (already adopted or under drafting):

- EN ISO 13485 “Medical devices - Quality management systems - Requirements for regulatory purposes”.
- ISO 14004:2004 “Environmental management systems – General Guidelines on principles, systems and support techniques”.
- Future ISO 14005 “Environmental management systems – Guidelines for a staged implementation of an environmental management system, including the use of environmental performance evaluation”.
- ISO 14050:2002 “Environmental management – Vocabulary”.
- ISO 14064-1&2&3 “Greenhouse gases”.

Part 1 “Specification with guidance at the organisation level for quantification and reporting of greenhouse gas emissions and removals”.

Part 2 “Specification with guidance at the project level for quantification, monitoring and reporting of greenhouse gas reductions or removal enhancements”.

Part 3 “Specification with guidance for validation and verification of greenhouse gas assertions”.

- ISO 14065 “Requirements for greenhouse gas validation and verification bodies”.

- EN ISO 15189 “Medical laboratories -- Particular requirements for quality and competence”.
- EN ISO 15195 “Laboratory medicine -- Requirements for reference measurement laboratories”.
- ISO/IEC 17021-2 “Conformity assessment - Part 2: Requirements for third party auditing of management systems”.
- EN ISO/IEC 17043 “General requirements for proficiency test providers”.
- ISO /IEC 17065 “General requirements for bodies operating product certification systems”. In this respect ESOs will be asked to consider if ISO/IEC 17065 will replace EN 45011 “General requirements for bodies operating product certification systems”.
- ISO 22003 “Food safety management systems -- Requirements for bodies providing audit and certification of food safety management systems”
- EN ISO 22870 “Point-of-care testing (POCT) - Requirements for quality and competence”.
- EN 45503 “Attestation standard for the assessment of contract award procedures of entities operating in the water, energy, transport and telecommunications sectors”.
- A standard based on ISO Guide 34 “General requirements for the competence of reference material producers’