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Position Paper on the “Proposed Regulation setting out the Requirements for Accreditation and Market Surveillance relating to the Marketing of Products” (COM(2007) 37 final)

CEOC International, the International Confederation of Inspection and Certification Organisations, represents 29 members from 21 countries and through them represents some 60.000 employees.

EUROLAB is the European Federation of National Associations of Measurement, Testing and Analytical Laboratories. Members of EUROLAB comprise laboratory associations of 26 of the 30 EU, EFTA and applicant countries, representing a network of over 3000 public and private laboratories and conformity assessment bodies.

CEOC International and EUROLAB welcome the initiative taken by the European Commission to review the rules relating to accreditation and market surveillance. However, laboratories, inspection and certification organisations are concerned about a series of issues and would like to make some detailed comments and proposals on some aspects of the proposal.

In general CEOC International and Eurolab believe that the proposal clarifies the existing situation and aims to ensure that the role of accreditation is strengthened and that the evaluation of accreditation bodies is more efficient. However, as Conformity Assessment Bodies (CAB) are competing with non-European ones on markets, it should be ensured that there is a level-playing field or in other words that European CABs are not disadvantaged compared to non-European ones.

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CEOC International and Eurolab also believe that CAB and other relevant stakeholders should be allowed to carry out some of the tasks foreseen exclusively for EA.

Commission’s Proposal of 14.2.2007	CEOC International and Eurolab proposed amendments
<p>Article 1 paragraph 1. – Subject matter and scope</p> <p>1. This regulation lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing assessment of any substance, preparation or other product, whether or not such substance, preparation or product has undergone transformation, to be placed on the Community market.</p>	<p>Article 1 paragraph 1. – Subject matter and scope</p> <p>1. This regulation lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing assessment of any substance, preparation or other product, whether or not such substance, preparation or product has undergone transformation, to be placed on the Community market. This Regulation lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing conformity assessment for the Community market.</p>
<p>Rationale:</p> <p>Accreditation shall cover the compulsory and the voluntary field (Article 3 paragraph 1). The scope of accreditation should on this reason be in line with the scope of the European Standard EN ISO/IEC 17011: Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies (European version of the International Standard ISO/IEC 17011).</p>	
<p>Article 2, paragraph 10</p> <p>“accreditation” means a third-party attestation, related to a conformity assessment body, conveying formal demonstration of its competence to carry out specific conformity assessment tasks;</p>	<p>Article 2, paragraph 10</p> <p>“accreditation” means a third-party attestation, related to a conformity assessment body, conveying formal demonstration of its competence to carry out specific conformity assessment tasks;</p> <p>Conformity assessment bodies are organizations providing the following conformity assessment services: testing, inspection, management system certification, personnel certification, product certification and calibration.</p>
<p>Rationale:</p> <p>The scope of accreditation should be aligned with the scope of EN ISO/IEC 17011 (see also rationale on Article 1).</p>	

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<p>Article 6, paragraph 1 – Cross-frontier accreditation</p> <p>1. Where a conformity assessment body requests accreditation, it shall do so with the national accreditation body of the Member State in which it is established or with the national accreditation body to which that Member State has had recourse pursuant to Article 4(2).</p> <p>However, a conformity assessment body may request accreditation by a national accreditation body other than those referred to in the first subparagraph in any one of the following situations:</p> <ul style="list-style-type: none"> (a) where the Member State in which it is established has decided not to establish a national accreditation body and has not had recourse to a national accreditation body of another Member State pursuant to Article 4(2); (b) where the national accreditation bodies referred to in the first subparagraph do not perform accreditation in respect of the conformity assessment activities for which accreditation is sought; (c) where the national accreditation bodies referred to in the first subparagraph have not yet, or have not successfully, undergone the peer evaluation under Article 9 in respect of the conformity assessment activities for which accreditation is sought. 	<p>Article 6, paragraph 1 – Cross-frontier accreditation – add words in bold</p> <p>1. Where a conformity assessment body requests accreditation for a compulsory conformity assessment activity, it shall do so with the national accreditation body of the Member State in which it is established or with the national accreditation body to which that Member State has had recourse pursuant to Article 4(2)</p> <p>However, a conformity assessment body may request accreditation by a national accreditation body other than those referred to in the first subparagraph in any one of the following situations:</p> <ul style="list-style-type: none"> (a) where the Member State in which it is established has decided not to establish a national accreditation body and has not had recourse to a national accreditation body of another Member State pursuant to Article 4(2); (b) where the national accreditation bodies referred to in the first subparagraph do not perform accreditation in respect of the conformity assessment activities for which accreditation is sought; (c) where the national accreditation bodies referred to in the first subparagraph have not yet, or have not successfully, undergone the peer evaluation under Article 9 in respect of the conformity assessment activities for which accreditation is sought.
<p>Rationale: European conformity assessment bodies (CABs) have to compete with CABs from outside Europe. Cross frontier accreditation for CABs outside Europe is governed by the <i>IAF Guidance on Cross Frontier Accreditation, Issue 1, Version 3 (IAF GD 3:2003)</i>, and in a similar ILAC Guidance. The following is an extract from the IAF Guidance: <i>There are however situations where CRBs will seek more than one accreditation, or a "foreign" accreditation, and it is the CRB's right to do so.</i></p>	

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<p>The requirements for cross-frontier accreditation in the voluntary field should not be more restrictive than the IAF/ILAC policies to avoid discriminating (e.g. costly and bureaucratic subcontracting) the European CABs.</p>	
<p>Article 12 Requests to EA The Commission, following consultation of the Committee set up by Article 5 of Directive 98/34/EC, may request the EA to contribute to the development, maintenance and implementation of accreditation in the Community.</p> <p>The Commission may also, following the procedure laid down in the first paragraph, request the EA to develop sectoral accreditation schemes.</p> <p>Such schemes shall identify the sectoral technical specifications necessary to ensure the level of competence required by Community harmonisation legislation in fields with specific technology or health and safety related requirements.</p>	<p>Article 12 – add words in bold Requests to EA The Commission, following consultation of the Committee set up by Article 5 of Directive 98/34/EC, may request the EA to contribute to the development, maintenance and implementation of accreditation in the Community.</p> <p>The Commission may also, following the procedure laid down in the first paragraph, request the EA to develop in the compulsory area sectoral accreditation schemes and shall ensure an appropriate participation of the stakeholders concerned.</p> <p>Such schemes shall identify the sectoral technical specifications necessary to ensure the level of competence required by Community harmonisation legislation in fields with specific technology or health and safety related requirements.</p>
<p>Rationale Sectoral accreditation schemes as referred to in Article 12 have potentially significant impacts on the activities and costs of conformity assessment bodies, for example the implementation of intervals between surveillance visits, the number of on-site visits or the frequency of witnessing of personnel (i.e. inspectors).</p> <p>An appropriate representation of stakeholders in EA has to be ensured with respect to the development of sectoral accreditation schemes.</p>	
<p>Article 29 Bodies eligible for Community financing Community financing may be granted to EA for the implementation of the activities listed in Article 28.</p> <p>However, Community financing may also be granted to other bodies for the carrying out of the activities set out in Article 28 except those set out in paragraph 1 (a) and (b).</p>	<p>Article 29 delete words “(a) and” Bodies eligible for Community financing Community financing may be granted to EA for the implementation of the activities listed in Article 28.</p> <p>However, Community financing may also be granted to other bodies for the carrying out of the activities set out in Article 28 except those set out in paragraph (a) and (b).</p>

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<p>Rationale: The financing should also be granted to other bodies (e.g. co-operations of notified bodies) concerning activities listed in Article 28 (1) (a).</p>	
<p>Article 31 1(b) Financing arrangements</p> <p>1. Community financing shall be provided:</p> <p>(a) without a call for proposals, to EA to carry out those activities referred to in Article 28(1) (a) to (g) for which grants can be awarded in accordance with the Financial Regulation;</p> <p>(b) in the form of grants after a call for proposals of by public procurement procedures, to other bodies to carry out the work referred to in Article 28(1) (c) to (g).</p>	<p>Article 31, 1(b) – add the words “(1) and” Financing arrangements</p> <p>1. Community financing shall be provided:</p> <p>(a) without a call for proposals, to EA to carry out those activities referred to in Article 28(1) (a) to (g) for which grants can be awarded in accordance with the Financial Regulation;</p> <p>(b) in the form of grants after a call for proposals of by public procurement procedures, to other bodies to carry out the work referred to in Article 28(1) (a) and (c) to (g).</p>
<p>Rationale: The financing should also be granted to other bodies (e.g. co-operations of notified bodies) concerning activities listed in Article 28 (1) (a).</p>	

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