

28-06-2007

Position Paper on the “Proposed Decision on a Common Framework for the Marketing of Products” (COM(2007) 53 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 the *Community technical legislation ensuring the free circulation of products* . However, laboratories, inspection and certification *bodies* 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 a better functioning of the marketing of products and also of conformity assessment activities.

This is a unique opportunity to bring significant improvement in the effective implementation of the Community legislation. Based on their experience CEOC International and Eurolab members would like to highlight some issues which are apparently not yet adequately covered by the existing proposal.

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- ✓ The basic purpose of the CE marking is clearly known : by affixing the CE-marking to a product, the manufacturer declares that the product is in conformity with the essential requirements in the applicable "new" approach directives. One of the difficulties undermining the credibility of the CE marking is that it is still often perceived as an indication of origin or as a proof that the product has been tested and approved by some kind of national supervising authority. We certainly suggest introducing at least a definition of the CE marking in order to avoid such type of misunderstanding.
- ✓ Among the numerous articles associated with notified bodies there is a very surprising article 25 related to "accredited in-house bodies" which will greatly contribute to create confusion when it will be applied. Article 25 refers to new specific modules where the manufacturer can choose between a notified body and an accredited in house body to perform conformity assessment of its product. For most of the economic actors these accredited in house bodies will have the taste of notified bodies, the smell of notified bodies but they are simply the manufacturers laboratories and/or inspectors. As stated before, a limited amount of people do understand the rules which are applicable when it goes about affixing the CE mark. We think it is dangerous to make the rules more complex. The situation should be kept as "simple" as it is now : depending of the risk the legislation foresees a manufacturer's declaration or the mandatory assessment by a notified body.
- ✓ It is often emphasised that administrative burdens on economic operators have to be proportionate to the goals to be reached. This must also be true for the notified bodies, specially when it goes about unnecessary and burdensome request for information by any interested party.

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Commission's Proposal of 14.2.2007	CEOC International and Eurolab proposed amendments
<p>Article 3, paragraph 1(c) – Conformity assessment procedures</p> <p>1. Where Community legislation requires conformity assessment to be performed in respect of a particular product, the procedures which are to be used shall be chosen from among the modules set out and specified in Annex I, in accordance with the following criteria:</p> <p>(a) whether the module concerned is appropriate for the type of product</p> <p>(b) the nature of the risks entailed by the product and the extent to which such risks can be managed by conformity assessment;</p> <p>(c) the need for the manufacturer to have a choice between quality assurance and product certification modules as set out in Annex;</p> <p>(d) the need to avoid imposing modules which would be too burdensome in relation to the risks covered by the legislation concerned.</p>	<p>Article 3, paragraph 1(c) – Conformity assessment procedures – add words in bold</p> <p>1. Where Community legislation requires conformity assessment to be performed in respect of a particular product, the procedures which are to be used shall be chosen from among the modules set out and specified in Annex I, in accordance with the following criteria:</p> <p>(a) whether the module concerned is appropriate for the type of product</p> <p>(b) the nature of the risks entailed by the product and the extent to which such risks can be managed by conformity assessment;</p> <p>(c) the need for the manufacturer to have a choice between quality assurance and product certification modules as set out in Annex. The choice shall however not be possible if the risks, as estimated by the legislator in sectoral legislation, are such that product certification is to be required;</p> <p>(d) the need to avoid imposing modules which would be too burdensome in relation to the risks covered by the legislation concerned.</p>
<p>Rationale: Sectoral legislation needs to be respected and in some cases the risks are too high to leave it open to free choice.</p>	

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Commission's Proposal of 14.2.2007	CEOC International and Eurolab proposed amendments
Article 6 Definitions	Article 6 – Definitions – NEW "Putting into service" means the first use, for its intended purpose, in the Community, of a product."
<p>Rationale:</p> <p>The concept of "putting into service" is widely used in existing directives and has been deleted in the proposal. It is supposed to be replaced by "making available to the market" but this new concept is not applicable to complex installations (assembly chain of a car factory...) . We suggest to use a definition based on the recently issued revision of the machinery directive (directive 2006/42/EC) .</p> <p>For industrial facilities/products, putting into service is the frontier between the activities of the manufacturer (and notified body) on one side and the activities of the user/employer (framework directive 89/391/EEC) as well as the authorities/organizations in charge of the surveillance of the work installations on the other side</p> <p>When it goes about a "combined product" as a part of an industrial plant the global compliance of the final product with all applicable directives only can be assessed when switching "on" the facility (putting into service) . This is the final stage of a succession of placing on the market of different components and sub-components (covered by different directives) by different operators in the supply chain. Great care should be taken in order to avoid the creation of a black hole where nobody will be responsible</p>	
Article 6 Definitions	Article 6 – Definitions – NEW CE marking : A marking that materializes the manufacturer's declaration that his product is in conformity with all applicable Community requirements.
<p>Rationale</p> <p>The proposed definition was present in a Commission preparatory document (SOGS 560, dated September 2006) and should not be deleted</p> <p>The Council Resolution of 10 November 2003 on the Communication of the European Commission "Enhancing the Implementation of the New Approach Directives" requests to "clarify the meaning of the CE marking and its relation to voluntary marks".</p> <p>Basis for the considerations concerning the relation between the CE marking and other markings (Article 16 (3)) is a clear definition of the CE marking. The proposed definition of the CE marking is based on recital (22).</p> <p>"Other markings" are normally voluntary "third-party marks of conformity". A definition is given in the International Standard ISO/IEC 17030, clause 3.1:</p> <p>"Third-party mark of conformity" means a protected mark issued by a body performing third-party conformity assessment, indicating that an object of conformity assessment (product,</p>	

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process, person, system or body) is in conformity with specified requirements.	
Commission's Proposal of 14.2.2007	CEOC International and Eurolab proposed amendments
<p>Article 16, paragraph 2.</p> <p>General principles of the CE marking</p> <p>The CE marking shall be the only marking which attests conformity of the product with the applicable requirements. Member States shall refrain from introducing into their national regulations or shall withdraw any reference to a conformity marking other than the CE marking in connection with conformity to the provisions contained in the legislation on CE marking.</p>	<p>Article 16, paragraph 2.</p> <p>General principles of the CE marking</p> <p>The CE marking shall be the only marking that materializes the manufacturer's declaration that his product is in conformity with all applicable Community requirements.</p> <p>Member States shall refrain from introducing into their national regulations or shall withdraw any reference to a conformity marking having the same meaning as the CE marking as defined in Article 6(12) other than the CE marking in connection with conformity to the provisions contained in the legislation on CE marking.</p>
<p>Rationale</p> <p>As it is written now, article 16 (2), first sentence, states that the CE marking attests the conformity of a product with the applicable requirements, which is incorrect. If so, market surveillance would be superfluous. The CE marking materialises the declaration of the manufacturer or his authorized representative that the product is in conformity with all the applicable requirements (see reason 22 and Article 16 (1)).</p> <p>If the CE marking shall be the only marking, other existing markings (see for example Directive 96/98/EC) have to be withdrawn and the possibility to introduce a consumer oriented European safety mark is ruled out.</p>	
<p>Article 16 3.</p> <p>General principles of the CE marking</p> <p>T The affixing on a products of markings, signs ad inscriptions which are likely to mislead third parties as to the meaning or form of the CE marking, or both, is prohibited. Any other marking may be affixed to the product provided that the visibility, legibility and meaning of the CE marking are not thereby impaired.</p>	<p>Article 16 3.</p> <p>General principles of the CE marking</p> <p>The affixing on a products of markings, signs ad inscriptions which are likely to mislead third parties <u>the market</u> as to the meaning or form of the CE marking, or both, is prohibited. Any other marking may be affixed to the product provided that the visibility, legibility and meaning of the CE marking are not thereby impaired.</p>

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<p>Rationale:</p> <p>The meaning of the CE marking referenced in Article 16 (3) is an important criterion for the differentiation between the CE marking and other markings. The meaning of the CE marking has to be clearly defined to avoid continuous misinterpretations or, even better, "meaning" can be deleted as differentiation criterion, especially because a different "form" is sufficient to differentiate between the CE marking and other markings and the historical reason to use "meaning and form", namely to avoid conflicts with the CE label of the motor vehicle company Mercedes, is not longer evident. The term "third-parties" is used for independent bodies (i.e. Article 22 (3)). We recommend therefore replacing "to mislead third parties" by "to mislead the market".</p>	
<p>Article 22, paragraph 4 Requirements for notified bodies</p> <p>4. The conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, nor the authorised representative of any of those parties.</p> <p>Nor shall they become directly involved in the design, manufacturer or construction, the marketing, installation, use or maintenance of those products, nor represent the parties engaged in those activities.</p> <p>They shall not provide consultancy related to the conformity assessment activities for which they are notified and relating to products intended to be placed on the Community market. They shall not preclude the possibility of exchanges of technical information between the manufacturer and the conformity assessment body and the use of assessed products that are necessary for the operations of the conformity assessment body.</p> <p>The conformity assessment body shall ensure that activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity and impartiality of its conformity assessment activities.</p>	<p>Article 22, paragraph 4 Requirements for notified bodies</p> <p>4. The conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, nor the authorised representative of any of those parties.</p> <p>Nor shall they become directly involved in the design, manufacturer or construction, the marketing, installation, use or maintenance of those products, nor represent the parties engaged in those activities.</p> <p>They shall not provide consultancy related to the conformity assessment activities for which they are notified and relating to products intended to be placed on the Community market. They shall not preclude the possibility of exchanges of technical information between the manufacturer and the conformity assessment body and the use of assessed products that are necessary for the operations of the conformity assessment body. However, they may own or use assessed products for normal private purposes.</p> <p>The conformity assessment body shall ensure that activities of its subsidiaries or subcontractors do not affect the</p>

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	confidentiality, objectivity and impartiality of its conformity assessment activities.
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<p>Rationale:</p> <p>The requirement that the top management and the personnel shall not purchase, own or use assessed products for private purposes (for example a medical implant or a sawing machine) is too restrictive.</p>	
<p>Article 25</p> <p>Accredited in-house bodies</p> <p>1. For the purpose of conformity assessment procedures set out in (Annex 1 – modules A1, A2, C1 or C2), an accredited in-house body, which forms a separate and identifiable part of an undertaking involved in the design, manufacture, supply, installation, use or maintenance of the products that it assesses and which has been established to supply conformity assessment services to the undertaking of which it forms a part, may be used.</p> <p>2. The in-house body shall meet the following criteria:</p> <p>(a) it shall be accredited in accordance with Regulation EC No (...);</p> <p>(b) the body and its personnel shall be organisationally identifiable and have reporting methods within the undertaking of which it forms a part, which ensure its impartiality and demonstrate it to the national accreditation body;</p> <p>(c) the body and its personnel must not be responsible for the design, manufacture, supply, installation, operation or maintenance of the products which they assess and must not engage in any activities that might conflict with their independence of judgement and integrity in relation to their assessment activities;</p> <p>(d) the body shall supply its services exclusively to the undertaking of which it forms a part.</p> <p>3. Accredited in-house bodies shall not be notified to the Member States or the</p>	<p>Article 25</p> <p>Accredited in-house bodies</p> <p>Delete</p>

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Commission, but information about their accreditation shall be provided to the notifying authority, on request.	
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<p>Rationale:</p> <p>Article 25 creates confusion with regard to other provisions of the decision. The risk of confusion is technically increased by the fact that these in-house bodies have to be accredited but that the proposal does not foresee that there should be a relation between the activities of these in-house bodies and their scope of accreditation. The independent conformity assessment bodies have shown deep concern about this approach. It seemed to have been cancelled but here it is again</p> <p>Modules A1/A2/C1/C2 are intended to amend the basic Modules A and C through the involvement of an independent (third party) conformity assessment body in the production process. The proposed use of an in-house body instead of an independent body contradicts this policy and gives no additional value to the basic modules A and C which may be supported by the testing results of an accredited (or not accredited) in-house (first party) testing laboratory. In-house bodies do not replace a notified body nor can they be considered as being equally independent as a notified body. Therefore the existing Modules Aa and C (supplementary requirements) should not be weakened by an in-house (first party) body which is not sufficiently independent from the manufacturer.</p> <p>On the other hand, the deletion of the existing Modules Aa and C (supplementary requirements) would not be dramatic for the New Approach Directives since its use has been very limited till now. Therefore the legislator should consider whether the introduction of the Modules A1/A2/C1/C2 is needed at all.</p>	
<p>Article 27, paragraph 5.</p> <p>Notification procedure</p> <p>5. The body concerned may perform the activities of a notified body only where no objections have been raised by the Commission and the other Member States within two months following that notification.</p> <p>Only such a body shall be considered as a notified body for the purpose of this ... (act).</p>	<p>Article 27, paragraph 5.</p> <p>Notification procedure</p> <p>5. The body concerned may perform the activities of a notified body only where no objections have been raised by the Commission for duly motivated reasons and the other Member States within two months following that notification.</p> <p>Only such a body shall be considered as a notified body for the purpose of this ... (act)</p>
<p>Rationale:</p> <p>This legal requirement gives the other Member States the possibility to prevent a conformity assessment body from performing activities as a notified body for an unforeseeable long period. Who shall be responsible in case the notified body goes bankrupt while the objections turn out to be invalid?</p>	

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<p>Article 32, paragraphs 1 and 2</p> <p>Information obligation for notified bodies</p> <p>1. Notified bodies shall inform the notifying authority of the following:</p> <ul style="list-style-type: none"> (a) any refusal, restriction, suspension or withdrawal of certificates; (b) any circumstances affecting the scope of and conditions for notification; (c) any request for information which they have received from market surveillance authorities; (d) on request, conformity assessment activities performed within the scope of their notification and, any other activity performed, including, cross-border activities and subcontracting. <p>2. Notified bodies shall provide the other bodies notified under this ... (act) carrying out similar conformity assessment activities and covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.</p>	<p>Article 32, paragraphs 1 and 2</p> <p>Information obligation for notified bodies</p> <p>1. Notified bodies shall inform the notifying authority of the following:</p> <ul style="list-style-type: none"> (a) any refusal, restriction, suspension or withdrawal of certificates on non-conformity reasons; (b) any circumstances affecting the scope of and conditions for notification; (c) any request for information which they have received from market surveillance authorities; (b) on request, conformity assessment activities performed within the scope of their notification and, any other activity performed, including, cross-border activities and subcontracting. <p>2. With the consent of their notifying authorities, notified bodies shall provide the other bodies notified under this ... (act) carrying out similar conformity assessment activities and covering the same products with relevant information on issues relating to negative results and, on request, positive conformity assessment results information on the validity of a given certificate.</p>
<p>Rationale:</p> <p>Transparency of the conformity assessment process is a fundamental requirement. But experience has shown that too much information can have detrimental effects because it is difficult for all the operators to handle an uncontrolled amount of raw data . The disclosure of information should basically be limited to information about non-conformities with respect to the requirements of the directives.</p> <p>The notified bodies have no legal link concerning e.g. responsibilities, liabilities or confidentiality to other notified bodies. Therefore information to these bodies is only possible under the responsibility of the national notifying authority.</p>	

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<p>Annex 1, Modules A1/A2/C1/C2, paragraph 4</p> <p>Notification procedure</p> <p>4. Product checks</p> <p>For each individual product manufactured, one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his behalf, in order to verify conformity with the corresponding requirements of the legislative instrument ¹⁸. At the choice of the manufacturer ¹⁹, the tests are carried out either by an accredited in-house body or under the responsibility of a notified body, chosen by the manufacturer.</p> <p>Where the tests are carried out by a notified body, the manufacturer shall, on the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.</p>	<p>Annex 1, Modules A1/A2/C1/C3 paragraph 4</p> <p>Notification procedure</p> <p>4. Product checks</p> <p>For each individual product manufactured, one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his behalf, in order to verify conformity with the corresponding requirements of the legislative instrument ¹⁸. At the choice of the manufacturer ¹⁹, the tests are carried out either by an accredited in-house body or The tests shall be carried out under the responsibility of a notified body, chosen by the manufacturer.</p> <p>Where the tests are carried out by a notified body, tThe manufacturer shall, on the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.</p>
<p>Rationale:</p> <p>Modules A1/A2/C1/C2 are intended to amend the basic Modules A and C by an involvement of an independent (third party) conformity assessment body in the production process. The proposed use of an in-house body instead of an independent body contradicts this policy and gives no additional value to the basic modules A and C which may be supported by the testing results of an accredited (or not accredited) in-house (first party) testing laboratory. Such bodies do not replace a notified body, nor can they be considered as being equally independent to a notified body. Therefore the existing Modules Aa and C (supplementary requirements) should not be weakened by an in-house (first party) body which is not sufficiently independent from the manufacturer.</p> <p>On the other hand, the deletion of the existing Modules Aa and C (supplementary requirements) would not be dramatic for the New Approach Directives. Therefore the legislator should consider whether the introduction of the Modules A1/A2/C1/C2 is needed at all.</p>	

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<p>Annex 1, Modules B (8), H1 (4,5)</p> <p>Each notified body shall inform its notifying authorities about the EC-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall periodically or upon request make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted .</p> <p>Each notified body shall inform the other notified bodies about the EC-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon reasoned request, about the certificates and/or additions thereto which it has issued.</p> <p>The Commission, the Member States and the other notified bodies may, on reasoned request, obtain a copy of the EC-type examination certificates and/or their additions. On reasoned request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall hold a copy of the EC-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer for a period up o the end of the validity of the certificate .</p>	<p>Annex 1, Modules B (8), H1 (4,5)</p> <p>Each notified body shall inform its notifying authorities about the EC-type examination certificates (<i>Module H1: EC-design examination certificates</i>) and/or any additions thereto which it has issued or withdrawn, and shall periodically or upon request make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted .</p> <p>Each notified body shall inform the other notified bodies about the EC-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, about the validity of a given certificate.</p> <p>The Commission, the Member States and the other notified bodies may, on reasoned request, obtain a copy of the EC-type examination certificates and/or their additions. On reasoned request, the Commission and the Member States may obtain with the consent of the responsible notifying authority, a copy of the EC-type examination certificate (Module H1 4.5: EC-design examination certificates), the technical documentation and he results of the examinations carried out by the notified body.</p> <p>The notified body shall hold a copy of the EC-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer for a period up o the end of the validity of the certificate .</p>
<p>Rationale</p> <p>The conditions for disclosure of information are specified in Article 32 and should not be repeated in different wording in Modules B, D, E and H. The notified bodies have no legal link concerning e.g. responsibilities, liabilities or confidentiality to other Member States and the Commission. Therefore information to these institutions is only possible under the responsibility of the national designation authority.</p>	

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