BUSINESSEUROPE

POSITION PAPER

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BUSINESSEUROPE VIEWS ON THE COMMISSION'S PROPOSAL FOR A REGULATION SETTING OUT THE REQUIREMENTS FOR ACCREDITATION AND MARKET SURVEILLANCE RELATING TO THE MARKETING OF PRODUCTS

EXECUTIVE SUMMARY

BUSINESSEUROPE supports the Commission's proposal for a regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products. To facilitate the free movement of goods and services in the Internal Market, it is absolutely essential that there is mutual trust between Member States, their bodies and institutions.

While we support the objectives and main principles of the proposal we do have a number of suggestions with a view to ensuring a more coherent and better functioning in practice:

- Accreditation must be considered the highest level of approval in the system and as a result should not be subject to competition.
- With a view to enhancing the functioning of the principle of mutual recognition, the provisions on accreditation should apply to bodies carrying out conformity assessment in both the regulated and non-regulated areas.
- The requirements of the regulation must apply to all accreditation bodies and their services within the European Economic Area irrespective of the kind of conformity assessment activities provided by their customers.
- It is necessary to establish a clear legal basis for a co-operative European accreditation system.
- Member states must take responsibility for and support the proper functioning of the European accreditation system.
- A cross-frontier company must be able to request accreditation of its "internal" conformity assessment bodies, test and calibration laboratories from either the local or the parent organisation's national accreditation body.
- Accreditation bodies must be required to demonstrate that the confidence placed in them is justified through their successful participation in peer evaluation.
- With regards to market surveillance we think that the exclusion outlined in Article 13.2 (GPSD) could result in confusion rather than increased cohesion in the market surveillance activities and should therefore be deleted.
- The requirements in the regulation should be kept to what is necessary without adding to the administrative burdens of companies or lead to excessive regulation.
- The legal text needs to clearly state that measures taken in response to a demonstrated lack of conformity must be proportionate.

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A POSITIVE STEP TOWARDS COMMON PRACTICE

BUSINESSEUROPE welcomes the proposal for a regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products. The purpose of this proposal is to strengthen the overall accreditation and market surveillance framework ensuring that products respect high levels of protection, of health and of safety while establishing at the same time a level playing field for economic operators.

To facilitate the free movement of goods and services it is essential that there is mutual trust between Member State, their bodies and institutions having a key role in the functioning of the framework as well as an equivalent level of competence and performance.

BUSINESSEUROPE therefore believes that the decision to proceed with a 'regulation' is the right way to proceed in order to ensure common rules and a common structure across the Internal Market[1].

While we support the objectives and main principles of the proposal, we do have a number of concerns and suggestions with a view to ensuring a more coherent and better functioning in practice.

ACCREDITATION

The purpose of accreditation is to provide an authoritative statement of the competence of a body that carries out conformity assessment activities or testing of a product's performance.

BUSINESSEUROPE believes it to be of utmost importance that accreditation be considered the highest level of approval in the system and as a result should not be subject to competition. Competition in this instance would introduce an even higher layer of control of competence.

We therefore support the requirement that Member States should maintain not more than one national accreditation body. The competence, objectivity and impartiality of the activities of this national accreditation body should we believe be subject to peer review, such as is proposed in the draft regulation.

Recital 9 states that binding rules will contribute to enhancing the principle of mutual recognition of certificates and test reports. Therefore the provisions on accreditation in the regulation should apply to bodies carrying out conformity assessments in both the regulated and non-regulated areas. BUSINESSEUROPE stresses the importance of this and supports the statement.

In addition to these general comments on accreditation we believe that some change to and clarification of the proposal is still required.

SUBJECT MATTER AND SCOPE

We suggest that the subject matter and scope of the proposed regulation (*Article 1.1*) be re-formulated in line with the aforementioned comments and with reference to r*ecital 9* and *Article 3.1* i.e. the regulation (and thus the legal text) should cover all the activities undertaken by accreditation bodies. By this we mean they should also apply to the non-regulated area which includes test and calibration, second party or in-house laboratories. The accreditation of such laboratories should be encouraged with a view to facilitating cross-border trade (including third countries).

[1] The Internal Market consists of the 27 EU Member States plus the three EFTA European Economic Area countries Norway, Iceland and Liechtenstein.

We therefore suggest that the definition of accreditation should be changed to include "*bodies performing calibration as well as testing, certification, inspection and other conformity assessment activities*". *Articles 1.1* and *3.1* would need to be changed accordingly to reflect this.

Furthermore, we would suggest the inclusion of the following sentence "*irrespective of whether accreditation is provided to support conformity assessment required by legislation or not*" in *Article 1.1* (at the end of the first paragraph) and in *Article 3.1*.

We would also suggest that with a view to a clear and common understanding of accreditation used within the European accreditation system and the requirements that accreditation bodies have to fulfil, there should be no exemptions. It should be stated clearly under *Article 1.1* that "*the requirements of this regulation apply to all accreditation bodies and their accreditation services within the European Economic Area irrespective of the kind of conformity assessment activities (be it for products or services) provided by their customers*".

A NON-PROFIT UNDERTAKING

Article 4.6 states that national accreditation shall operate on a non-profit basis. We support this as a principle, however, the proposed formulation may cause problems for both public and private accreditation bodies, as it is normal that they have to accumulate a capital base to secure a sound financial basis for their operation. This requirement is also stated in ISO/IEC 17011 "*the accreditation body shall have the financial resources, demonstrated by records and/or documents, required for the operation of its activities*".

If accreditation bodies are not allowed to accumulate an appropriate capital base, we run the risk that they may come into conflict with the requirements of the standard and cannot run a consistent service. This is especially true for private bodies who may not be in a position to cover possible losses through the public budget.

BUSINESSEUROPE suggests a reinserting of a previous version of this part of the text (*Article 4.4* in document EN 560) which stated that "*national accreditation bodies shall operate accreditation as a non-profit distributing activity, i.e. the accreditation body may not deliver surplus to its owners, whether public or private*".

EUROPEAN ACCREDITATION SYSTEM

Article 4.8 states that the national accreditation body should seek membership of European Cooperation for Accreditation (EA).

BUSINESSEUROPE is of the opinion that it is necessary to establish a clear legal basis for a co-operative European accreditation system, of which all national accreditation bodies are members. Confidence in the certificates and other conformity assessment results issued in the internal market can only be strengthened by means of a properly functioning accreditation system which aims at ensuring equivalence, transparency, consistency and efficiency of accreditation performed across the Europe Economic Area.

With a view to the role played by accreditation today in support of the implementation of Community legislation, it is for Member States to take responsibility for and to support the proper functioning of the European accreditation system. With reference to the documented positive experience of the peer evaluation system operated by EA and its support of the regulatory field, BUSINESSEUROPE supports the proposal that EA's role should be consolidated in order that EA be formally entrusted with the operation of the European accreditation network.

We therefore suggests reformulating of *Article 4.8* to read "*National accreditation bodies shall organise themselves in, and be members of, a co-operative European accreditation network with the aim of ensuring equivalence, transparency, consistency and efficiency of accreditation operated throughout the internal market. Member States shall support the proper functioning and coherence of the European accreditation network. The European accreditation network shall be operated by the European co-operation for Accreditation (EA)*".

In order to stress the importance of respecting the mutual recognition principle, BUSINESSEUROPE suggests that it be stated that this proposed body should also be a signatory to the relevant part(s) of the multilateral agreement (MLA) operated by EA. This may be implicit through the obligation for participation in a peer evaluation system (*Article 9*) however we think it should be stated explicitly in order to avoid misunderstanding and duplication in the system.

CROSS-FRONTIER ACCREDITATION

As already stated BUSINESSEUROPE believes that accreditation bodies should not be subject to competition. As such we support the principles outlined in *Article 6* of the proposed regulation. However we do believe that an exhaustive list of exceptional cases where cross-frontier accreditation should be allowed as suggested in *Article 6.1 a), b)* and *c)* to be too limited.

In cases where conformity assessment bodies, test and calibration laboratories etc. form part of a larger, cross-frontier organisation they should be allowed to be accredited either in the Member State they are based in or in the Member State their parent organisation is established in. We would suggest that the following exemption be added as a new *Article 6.1 d)* "*where the body to be accredited forms a part of a subsidiary of an organisation established in another Member State, it may request accreditation from either the local or the parent organisation's national accreditation body* (i.e. the national accreditation body of the Member State on the territory of which the parent organisation is established)".

PEER EVALUATION

Article 9.1 states that national accreditation bodies shall operate a peer evaluation system and participate in it. Membership of EA does not imply an obligation for national accreditation bodies to participate in this peer evaluation system. This system is a key instrument in achieving equivalence and transparency of accreditation practice. BUSINESSEUROPE believes that if peer evaluation is to facilitate and improve the proper functioning of the internal market by increasing the level of confidence, then it needs to be organised *'within the European accreditation network*' and operated according to the harmonised rules as applied within EA.

We would also suggest with a view to strengthening respect for the mutual recognition principle that the consequences of successful participation in the peer evaluation should be clearly spelt out in the text of this regulation. We believe that this can best be done as a qualification to the present *Article 9.4* stating that "*national accreditation bodies that have successfully undergone the peer evaluation shall recognise the equal reliability of each other's accreditations and of the conformity assessment results issued by conformity assessment bodies accredited by them.*"

Article 9 itself states that the "*results of the peer evaluation*" shall be communicated to all Member States and the Commission. In our view this seems to introduce a further new procedure when one considers the procedures currently used by EA's MLA Committee. Given existing procedures work well we would suggest keeping them. This requires that *Article 9.5* should refer only to the final results i.e. whether or not the signatory status of the EA MLA is upheld. Besides, the results of the peer evaluation are of direct interest not only to the Member

States and the Commission but also to the customers and other stakeholders of accreditation. We therefore suggest that *Article 9.5* should be amended accordingly to require that *"the final results of the peer evaluation shall be made public and communicated to all Member States and the Commission."*

PRESUMPTION OF CONFORMITY

Article 10 states that national accreditation bodies that comply with the criteria laid down in the relevant harmonised standard, the reference of which has been published in the Official Journal of the European Union, shall be presumed to fulfil the requirements set out in *Article 7*. BUSINESSEUROPE suggests that this article should also indicate that "*compliance with the standard is to be demonstrated through the peer evaluation process described in Article 9*".

If the use of accreditation is intended to efficiently support the proper functioning of the internal market by increasing the levels of confidence, then the accreditation bodies themselves need to be required to actively demonstrate that the confidence placed in them is justified on the grounds of their *successful* participation in the peer evaluation.

INVOLVEMENT OF STAKEHOLDERS

To balance the status of accreditation non-competitiveness we believe that all stakeholder interests (e.g. including customers and users of the system) should be represented on the Governing Board of the accreditation body. This we believe needs to be stated in the text of the regulation (perhaps under the general principles in *Article 4*).

MARKET SURVEILLANCE

In its October 2005 position paper BUSINESSEUROPE called for more equivalent, coherent and efficient market surveillance by Member State authorities. As such we welcome the fact that this proposal includes provisions intended to ensure equivalent and consistent enforcement of Community harmonisation legislation (including cross-border cooperation) between Member States authorities.

Given that the need for more equivalent, coherent and efficient market surveillance appears irrespective of the stipulations outlined in Directive 2001/95/EC (the General Product Safety Directive – GPSD) BUSINESSEUROPE is very concerned by the exclusion outlined in *Article 13.2* of the proposed regulation. This we believe will result in confusion rather then increased cohesion, the more so given the very wide scope of the GPSD.

We would suggest a re-alignment of existing provisions (of directives already in force) with this proposed regulation which would result in a clearer text as well as contributing to the better functioning of market surveillance.

We are also of the opinion that the principle of better regulation should be respected which means that this regulation should be kept to what is necessary without adding to the administrative burdens of companies or lead to excessive regulation.

BUSINESSEUROPE agrees that there should be a system of rapid exchange of information between Member States and the Commission (*recital 25*) and that the existing RAPEX system (provided for in *Article 12* of the GPSD) could be used to assist market surveillance. However with regards to this system we have previously expressed concerns on its functioning. We think that there needs to be better guidelines in place to ensure a more homogeneous use of the system by Member States authorities.

We find *Article 24* to be of particular importance and welcome the check by the customs authorities of required documentation and marking (outlined in *Article 24.2 b)*). We also support increased requirements for cooperation between national Member States authorities and the customs authorities.

FURTHER SPECIFICATIONS NEEDED

In order to ensure coherent implementation of the requirements already in place we are of the opinion that the practical approach needs to be outlined in more detail in this proposal.

We do note that the Commission is mandated to draw up guidelines (*Article 34*) which we believe will prove useful. However and given that guidelines are not legally binding the legal text needs to clearly state that measures taken in response to a demonstrated lack of conformity must be proportionate. We would suggest the following changes:

- *Article 17.2* – "The market surveillance authorities shall take appropriate *and proportionate* measures in order to… about any product they have identified as presenting an *unacceptable* risk";

- *Article 19.1* (third line) – "…shall ensure that any measure taken… to withdraw it from the market or recall it, *is proportionate and* states the exact grounds…"