BUSINESSEUROPE

POSITION PAPER

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BUSINESSEUROPE'S VIEWS ON THE COMMISSION'S PROPOSAL FOR A DECISION ON A COMMON FRAMEWORK FOR THE MARKETING OF PRODUCTS (COM 2007/ 53)

EXECUTIVE SUMMARY

BUSINESSEUROPE welcomes the 'internal market package' the objective of which is to improve the free movement of goods and at the same time ensure safe products for the consumers and a level playing field for companies.

The *Decision on a Common Framework for the Marketing of Products* is based on the positive experience with the New Approach combined with the Global Approach on conformity assessment.

BUSINESSEUROPE supports the main principles of the proposal and suggests that the provisions are implemented in both existing and future product legislation, covering all aspects of products, including environmental. In particular we support common definitions and conformity assessment modules, a clearer indication of obligations of economic operators, a more equal level of competence of all notified bodies and more efficient market surveillance on behalf of Member States.

However we believe, in the spirit of better regulation, that some changes to the proposal are needed, as there are several elements of the proposal which imply more administration and thus more costly burdens for manufacturers which in our view are neither justified nor proportionate.

We also believe that there is a need for more equivalent, coherent and efficient market surveillance on the part of Member State authorities. As such we welcome that this proposal (together with the proposed regulation accreditation and market surveillance) includes provisions for a more consistent enforcement of Community legislation. We continue to believe that the rights of companies need to be better ensured.

In the case of safeguard procedures against a standard, we believe that the European Standardisation organisations should be informed and consulted if a case is brought against a standard in order to allow them to comment on the matter before any decision in the 98/34 Committee.

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GENERAL COMMENTS

BUSINESSEUROPE supports the New Approach combined with the Global Approach on conformity assessment, which has proven to be a recipe for success for ensuring the free movement of goods within the Internal Market[1]. Article 95 of the Treaty is, in our view, the most efficient way to ensure a common high level of safety, health and environmental demands together with a level playing field for industrial and consumer products.

By developing objective oriented legislation, setting essential requirements and leaving manufacturers to determine how best these can be achieved at the product level possibly through standards, European legislators have established a flexible regulatory framework.

This approach has resulted in both an improvement of the health and safety of users (consumers and workers) and at the same time contributed to the competitiveness of the European industry. It has enabled Europe's industry to establish a strong home base providing for growth and jobs whilst at the same time offering a good starting point for the global market.

Therefore, we support the basic principles of the proposal and we recommend that the provisions are implemented in both existing and future product legislation. This we believe can be carried through by a general provision with the aim of integrating the provisions of this framework into existing directives without opening up protracted and detailed discussions on all existing product legislation. The purpose of such a mechanism is to ensure that the benefits gained by the new framework comes into force as soon as possible and do not have to await a possible general revision of each single directive. It is more important as product legislation is almost already in place.

AN APPROACH FOR ALL PRODUCT LEGISLATION

Based on experience to date BUSINESSEUROPE believes that these principles can successfully be applied to areas other than just safety. We therefore support the proposal to apply the common framework to all aspects of product legislation which set for example environmental requirements. Manufacturers have to comply with many different regulations addressing the same products, often having to adopt different approaches which lead to unnecessary burdens and complications.

SOME CHANGES WILL IMPROVE THE APPROACH

Although the New Approach is considered a tool for better regulation, experience has also shown that some improvements are necessary in order to reap the full benefits of a well functioning Internal Market. A clearer indication of the obligations of economic operators, a more equal level of competence of all notified bodies and more efficient market surveillance on behalf of Member States are all required.

CLEAR DEFINITIONS - A HELP TO ENSURE COMPLIANCE

BUSINESSEUROPE believes that it is of vital importance that we have common definitions in the different product directives. The situation as it exists today in, for example, the electrical goods area is that we have numerous directives covering the same products but using different definitions which causes confusion as to the functions and obligations of the various actors.

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

EQUALLY HIGH LEVEL OF COMPETENCES OF ALL NOTIFIED BODIES

In some product areas Notified Bodies have an important role to play. When third-party conformity assessment is required before a product is launched on the market Notified Bodies have the power to decide whether the product is complying with the requirements or not. In addition they decide on the costs and the time involved with the certification.

For this reason alone it is of the utmost importance that Notified Bodies (of which there might be only one in a Member State for a certain product area) throughout the European Economic Area are able to assess conformity in a competent, impartial and consistent way and that a level playing field is created for their clients (i.e. the manufacturers).

Given that accreditation is to be regulated by the proposed regulation COM (2007) 37 it would be appropriate to introduce accreditation of Notified Bodies as an obligation as defined in Article 3.1. We therefore suggest an amendment to Article 19.2 of the Decision to require the assessment to be performed by a national accreditation body. That would ensure a common reference and high confidence in line with the scope of the regulation. The notifying authorities, on their part, should be required to accept the accreditations issued in order to ensure that any unnecessary and costly duplication of assessments and additional layers of bureaucracy are avoided.

BUSINESSEUROPE also suggests a reformulation of the provision of article 22.4 in which conformity assessment bodies are restricted from providing consultancy service related to the conformity assessment activities. We firmly believe that no conflict of interest should occur. However we are of the opinion that special consideration needs to be given to SMEs and their need to engage in technical dialogue with external specialists in order to continuously improve the manufacturing process, the product quality and the monitoring of potential risks. Such technical expertise is typically to be found with the notified bodies.

Therefore, the provision should not preclude assessment bodies from providing courses or to have an open dialogue with the companies provided that the persons directly involved in the assessment are not involved in the advisory services.

CONFORMITY ASSESSMENT PROCEDURES

Product conformity is companies' number one concern. Manufacturers want to stay in business on a long term basis and want to produce safe products. Whether notified bodies are involved or not product liability and the responsibility for product compliance lies with the manufacturer alone.

This is why BUSINESSEUROPE supports the use of *module A* (Internal Control) combined with the manufacturer's declaration as the preferred method for conformity assessment. It is we believe important therefore to retain the wording of Article 3.1.d) (which states that *legislators should avoid imposing modules which would be too burdensome in relation to the risks covered by the legislation concerned*). In this connection we would urge legislators to introduce wording into the common framework along the lines to suggest that *module* A should be the 'normal' or default procedure with deviations from it being properly justified.

OBLIGATIONS OF ECONOMIC OPERATORS

There are several elements in the proposal that imply more administration and thus more costly burdens to manufacturers which do not seem justified and proportionate. Article 7.4 (second paragraph) is an example. It states that "*Manufacturers shall… carry out sample testing of marketed products, investigating, and, if necessary, keeping a register of complaints, and keeping distributors informed of such monitoring*".

According to the principles of the New Approach, manufacturers have to prove conformity with the regulatory requirements *before* the product is placed on the market. The principles include a risk analysis and a conformity assessment procedure (i.e. the modules of Annex I) which might involve a notified body. This procedure is complemented by the authorities' market surveillance.

The process of ensuring product quality and further development and innovation will automatically imply a close contact with the market place (i.e. the distributors and the customers). However, to make it a legal requirement is not 'better regulation'. For instance, it adds extra administrative burdens and secondly it raises the unanswered question as to who will judge whether or not a 'register' is needed?

We would recommend the deletion of the second paragraph of Article 7.4 as a result.

Article 7.7 is also in our view increasing the burdens without providing any obvious added value to safety on the market. It outlines the reasonable obligation that a manufacturer shall take the necessary corrective measures to bring a product into conformity… if he believes that the product is not *in conformity* with Community legislation. It however also implies that the manufacturer should *immediately* inform national authorities of this…

This notification requirement in our view seems to have its origin in the General Product Safety Directive (GPSD 2001/95/EC) covering consumer products. There is a significant difference however in that in GPSD it is a question of only 'dangerous products' being notified and not *non-conformity* being notified which might be of a formal character, such as for example marking. We would suggest that a limit for businesses be introduced for the notification duty under Article 7.7 (with corresponding limits being introduced in Article 9.5 [importer] and 10.4 [distributor]) to dangerous products (as defined in the GPSD i.e. products which have unacceptable safety risks for the consumer/user).

IMPORTER'S NAME AND ADDRESS

Article 9.3 stipulates that importers shall indicate their name and the address on the product.

BUSINESSEUROPE suggests that it should be *enough to have the name and address on a document accompanying the product*. In practice, a foreign manufacturer will not always know who will import his product at the time of production, and there might be several different importers within the internal market. If the importer has to put his/her name/address directly on the product, he will have to open up all packaging, which might damage the product or the package and result in costly repackaging. Having different names on the product might in any case create confusion as to who has the full product liability, i.e. the manufacturer. We also believe that the 'address' should be interpreted as a single point of contact per company so as to avoid a multitude of different addresses for different manufacturing locations having to be provided.

MARKET CONTROL AND SAFEGUARD PROCEDURES

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 (together with the regulation COM 2007/37) includes provisions intended to ensure equivalent and consistent enforcement of Community harmonisation legislation (including cross-border cooperation) between Member States authorities.

However, BUSINESSEUROPE believes that the rights of companies need to be better ensured. Experience has shown that not all authorities draw the same justified conclusions. Therefore it should not be accepted that '*no reaction*' from the authorities of other Member States or the Commission should automatically lead to the conclusion that a measure is justified. *The Commission should be involved in all cases where a product is banned from the market*, including cases that fall under Article 38.2. This requirement to notify the Commission should also apply to cases where the judicial system (whether at the national or the European level) rules on measures. Such action is necessary in order to ensure both a 'European' view point and that the product (in the case where the measure is justified) is in fact taken off the market in all Member States.

We must admit to being puzzled by Article 37. As we understand it legislation should be such (and is under the GPSD) that there is no such thing as 'complying (with the legislation) products' that present an unacceptable risk. In cases such as this where products do not comply with the GPSD and/or product specific legislation, Article 37.1 of this proposal needs to be worded more precisely as there exist many products on the market that bear 'a' risk which is considered completely acceptable.

BUSINESSEUROPE recommends in the interest of clarity the replacing of 'a risk' by 'an unacceptable risk as defined in the GPSD'. It is also necessary in our view, in the context of Article 37 that a provision similar to that outlined in Article 36.2 requiring a withdrawal of such products that pose 'an unacceptable risk as defined in the GPSD' from all Member States be introduced. Only then will we have a European level playing field for business and consumers.

Concerning Article 38, BUSINESSEUROPE believes that a clear definition of the concept of 'formal non-compliance' is required. As we read it in (minor) cases of 'formal non-compliance' there should be a notion of proportionality as to measures taken by Member State authorities.

Finally, this proposed decision partly relates to the mechanism of the whole new approach, which is based on the link between legislation and standardisation. Compliance with standards gives the presumption of conformity. Substantial resources and effort are put into the development of correct and useful standards. It is a matter of grave concern to those who have developed the standards when cases arise where a Member State or the Commission considers a European standard as not being in line with the requirements of the applicable legislation.

Article 14 confirms the existing procedure for formal objection against harmonised standards, including the involvement of the 98/34 Committee for transparency and efficiency reasons. BUSINESSEUROPE proposes adding in Article 14.1 that the notifying entity should, at the same time, also inform the (national or European) standardisation body. In such a way, the drafters of that standard can provide additional information to the decision making process.

Other position papers which BUSINESSEUROPE (when known as UNICE) issued on the same or related topics and which may be of interest include:

- UNICE position on Mutual Recognition (November 2006)
- UNICE position on CE marking (May 2006)
- UNICE position paper on the review of the New Approach (October 2005)
- UNICE position paper on Market Surveillance (October 2005)