UNICE
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**POSITION PAPER**

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# UNICE VIEWS ON THE REVIEW OF THE NEW APPROACH (APPROPRIATE INITIATIVES IN THE FIELDS OF CONFORMITY ASSESSMENT AND MARKET SURVEILLANCE)

## SUMMARY


UNICE supports the New Approach and the global Approach and believes that the principles can successfully be applied to areas other than just safety.

It is of great importance that all Member States "speak the same language" in order to ensure uniform implementation and efficient market surveillance. This requires clear definitions and close cooperation across borders and between different national authorities and more harmonised European market surveillance.

Notified Bodies have an important role to play in correct implementation. Therefore, there should be common rules for assessing and controlling these bodies. An efficient network for ensuring a common approach to conformity assessment should be established in this regard.

Module A for conformity assessment is the preferred option by industry, and procedures should be kept at a cost-efficient level (which would be manageable for SMEs as well).

To ensure efficient market surveillance proof of conformity should be provided by the individual introducing the product into the EU/EEA in cases where a product's safety is questioned.

CE-marking should be strengthened for example, through information campaigns.


## GENERAL COMMENTS ON THE PROPOSAL

UNICE would like to thank the Commission for giving the opportunity to comment on the ongoing process of revising the New Approach (Commission letter to UNICE, 25th April 2005). UNICE has already made a number of statements in related fields and will continue to participate in the dialogue concentrating on the issues which we in industry and business give the highest priority to: conformity assessment, market surveillance, CE-marking and definitions. To this end UNICE would like to outline its position in relation to the general document, *CERTIF 2004-1* (provided by the Commission with its 25th April letter).

## TECHNICAL REGULATIONS FOR THE SAFETY AND FREE MARKETING OF INDUSTRIAL PRODUCTS

UNICE 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. 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. UNICE therefore urges the European Commission, the European Parliament


AV. DE CORTENBERGH 168
B-1000 BRUSSELS
VAT BE 863 418 279

TEL +32(0)2 237 65 11
FAX +32(0)2 231 14 45
E-MAIL: MAIN@UNICE.BE
WWW.UNICE.ORG

and Member States Governments not to deviate from the general principles of the New Approach when addressing regulatory issues dealing with products.

Today, environmental issues have become a priority issue for product legislation. It is unfortunate that environmental aspects tend to be regarded as a separate issue rather than an integral part of product regulation. This not only leads to confusion, higher expenses and uncertainty in the market, it also increases bureaucracy when different enforcement systems for safety and environment are applied. This can be avoided without compromising environmental needs by using the New Approach and Article 95 for all aspects including environmental. UNICE therefore urges the Commission to ensure that article 95 is used for all future product regulation. Experience from the recently debated EUP-directive has shown that there is an urgent need for information and even education of e.g. many Members of the European Parliament in order to have a better understanding of the principles of the New Approach. We believe that the Commission could have an important role of ensuring such better knowledge by decision makers, both at European as well as at national level.

**CLEAR DEFINITIONS - A HELP TO ENSURE COMPLIANCE**

An indicative list of definitions is given in the CERTIF 2004-1 document. UNICE will not in this paper comment on all the definitions, we would, however, stress the importance of having common definitions in the different product directives, especially considering that the same product may be subject to many different directives. Today, different product directives, e.g. for the electrical goods, use different definitions. This may cause confusion as to the functions and obligations of the various actors.

**LEGAL BASE FOR ACCREDITATION**

Accreditation is the best and most reliable way to demonstrate competence and impartiality when performing conformity assessment both in the harmonised and non-harmonised area. For European industry it is therefore natural to support an even closer connection of accreditation to European legislation. UNICE has no reason to comment upon how the different accreditation organisations are set up in the Member States, but has concerns when it comes to certain principles involved.

Accreditation should not be subject to normal competition because it risks increasing bureaucracy which in turn can be detrimental to quality. Several national accreditation bodies with the same competence competing with each other only serves to increases bureaucracy because it requires another, higher authoritative, level of technical competence. A single national body or a single system of sectorial bodies with their own competences in certain fields would be the best way to ensure a functioning system for monitoring, interpreting, practising and developing accreditation.

Given that UNICE favours a national accreditation body or system that will be superior in its role, we urge that such a body operate on a non-profit basis independent of commercial motivations apart from what is needed to undertake its business.

Regardless of whether the Member States have privatised their national accreditation bodies or not, accreditation bodies should be recognised as equal in respect of their performed activities and decisions. Finally UNICE, as the body that represents EU business, which we consider an important stakeholder in accreditation issues is in

favour of a more formalised and closer relationship with EA (European co-operation for Accreditation) to make the system more transparent and credible.

**NOTIFIED BODIES**

In some product areas Notified Bodies have an important role to play. When a certificate is needed before a product can be launched on the market, they have the full decision power to decide whether the product is complying with the requirements, as well as to decide on the costs and the time involved with the certification. This is why it is of the utmost importance that notified bodies (of which there might be only one in a country for a certain product 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). Furthermore, it should be demonstrated that they have enough resources to assess products within a reasonable timeline, and they should have an obligation to serve all companies needing their assistance. Especially, SMEs often experience that they are put behind in the queue which is a serious barrier.

A well-functioning network of notified bodies can only be maintained if the assessment criteria and competences of such notified bodies are similar if not the same. Common rules and criteria for assessing notified bodies combined with efficient follow-up on their qualifications are a precondition to create a level playing field for companies. Furthermore, it must be a condition that the notified bodies participate actively in a European network in order to align procedures and interpretation of the various requirements. As it is illustrated in the examples given in the UNICE Internal Market publication "It's the Internal Market, stupid!", different interpretations is often creating extra challenges for companies. UNICE is in favour of harmonised European criteria for the designation and operation of notified conformity assessment bodies. The use of accreditation for assessment would be a good tool in this respect.

**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 lies with the manufacturer. This is why UNICE supports module A - Internal Control - combined with the manufacturer's declaration as the preferred method for conformity assessment.

Aside from what has already been expressed in our letter (dated 24th March 2005) on the modules and the preferred use of module A, UNICE has serious concerns regarding the proposed requirements for technical documentation to be available in the language of the country of destination of the product, as suggested by the Commission, as well as the obligation to inform market surveillance authorities about the exact location of the technical documentation. The latter would require a form of pre-registration which is even opposite to the idea of the New Approach. It must be stressed that in many cases the technical files are very comprehensive. Thus the translation of the documents into all spoken European languages (depending of the country of destination) would place an enormous administrative burden on business without any real call or need for it. The costs incurred especially for small and medium sized enterprises would be prohibitive. Translating technical files, or part of, can only be justified if an authority requests it when performing market surveillance.

Furthermore, it should be noted that the product directives don't require the technical documentation to be available when the product is placed on the market, but for it to be assembled within a reasonable time period. It is not in the spirit of better regulation and simplification to introduce new administrative burdens on companies. The same goes for the proposal of demanding importers or manufacturers' representatives to inform the national authorities of the Member State in which the product is first introduced. This procedure can be compared to a pre-market registration system which is not accepted according to the principles of the New Approach. It may also be questioned whether this requirement is in accordance with WTO rules, if it is only required in the case of products originating from a third country. Furthermore, for practical as well as financial reasons UNICE does not find it appropriate to require that all third country manufacturers have to appoint a representative within the Community. For imported products, the person responsible for the first entry into the EU/EEA must take responsibility to prove conformity with EU rules. This should be stated clearly in the specific product directives or in a horizontal directive.

For improving market surveillance in the case of imported goods (for which there is indeed a big need) we believe that it's appropriate to establish close cooperation between "normal" market surveillance authorities and the customs authorities to check whether the products conform with the essential requirements.

Innovative thinking on the part of all interested stakeholders is required to address new issues that are arising regarding conformity assessment. The rise of the internet for instance as a tool used by private users to purchase goods outside the EU/EEA requires some consideration given the conformity assessment and market surveillance implications that it entails i.e. who is responsible for technical documentation, what is the role of market surveillance authorities in this context etc. In the increasingly global world issues such as these need to be considered.

**CONFORMITY MARKING REQUIREMENTS**

There exists today confusion regarding what CE-marking stands for and should stand for. Even if CE-marking was conceived as marking addressed to the authorities when it is on the product consumers ideally, would also know what it stands for. First of all, CE-marking tells the consumer that the product in question is subject to European safety product regulation. CE-marking is the only mark that tells both authorities and consumers that the manufacturer has done all that can be done to ensure that the product meets all the requirement of the applicable directives. This must be communicated to market players and especially to the consumers. In parallel, the market surveillance needs to be strengthened in order to maintain confidence in the system.

The fact that a high number of private, national marks were used to demonstrate conformity with both national and European rules (e.g. within the electrical area) long before the CE-marking was introduced, means that the CE-marking is "up against" all these marks in the conscience of consumers. Companies often claim that national marks create *de facto* barriers to the free movement of goods.

For safety reasons there is no need for additional conformity assessment by third parties – CE-marking should be seen as the passport for industrial products to the

European market. As they are organised at present, 3rd party conformity assessment services fragment the Internal Market, as they are mainly addressed to their own national market. This has been highlighted in our survey "It's the Internal Market, stupid!", where the companies complained about barriers due to multiple testing requirements within the EEA.

There is a need to understand why the market in conformity assessment services remains organised like this, what organisational structures and market demands are decisive for the use of national marks, and look into ways of encouraging the services to see the whole of the European Economic Area as their potential market.

Furthermore, better information on the meaning of the CE-marking should be provided to the market players.

**MARKET SURVEILLANCE**

The New Approach is based on confidence between the various actors. It is therefore important that each actor fulfils his tasks. To ensure safe products on the market is a shared responsibility. Legislators are to make high quality and easy to understand legislation. Manufacturers are to produce safe products and to demonstrate their conformity with the essential requirements. Notified Bodies (when required) are to assess conformity in a competent and consistent way, and Member States are to ensure proper market surveillance. Furthermore, consumers have the responsibility to use products according to their intended use and the instructions of the manufacturer.

As of to day, market surveillance is not carried out in a coherent and equivalent level throughout the internal market. Therefore, it is of high importance that effort be invested in this area. We suggest that the Commission establishes a project with relevant parties to analysis the situation in order to find viable solutions.

UNICE supports most of the suggestions regarding market surveillance outlined in the document (CERTIF 2004-1). UNICE believes that harmonised European rules are the best (if not the only) way to strengthen market surveillance in Europe. We believe it should be combined with annual reporting and scoreboards detached from or included in the Internal Market strategy. Legal and financial means must be provided both at the community and national level to keep market surveillance in the different Member States on a uniform level and to establish best practices. Furthermore we would suggest that there should be administrative co-operation groups under each directive to deal with market surveillance issues.

Different reporting and unclear rules for dealing with unsafe products is time consuming and creates added costs both for industry and authorities. Streamlining and/or a possible merger of the different notification systems (such as LVD, RAPEX, safeguard clause, vigilance, ICSMS etc.) could contribute to a more efficient exchange of information amongst authorities and make the process more effective. Furthermore, there is a need for detailed guidelines as to when and how to notify unsafe products in order not to create unnecessary fears among consumers when a product is announced on a website as being unsafe. There is also a need for aligning the measures taken by the authorities and to ensure that the principle of proportionality is observed in all cases.

It would also be appropriate in view of efficient market surveillance, if authorities take a more active part in the standardisation process in order to ensure a common understanding and interpretation of the requirements, both across border and between manufacturers and authorities.

A high level of information to the market place and to the economic operators on regulation and safety issues should also be given priority[1].

**METROLOGY AND CALIBRATION**

UNICE welcomes that the Commission addresses the issue of metrology and calibration in its paper. In fact, it's of no use to have product regulation with specific requirements on values and uncertainties, such as e.g. for the contents of ingredients or substances, if there is no common measurement system, and if measurements are not traceable.

However, metrology is an often neglected framework condition. Experience from the previous research framework programme showed that when funding is not allocated specifically to metrology projects, then it becomes very difficult to compete with other research issues. Nevertheless, metrology is also a precondition for research as well as for proper conformity assessment.

To ensure a proper European infrastructure on metrology should therefore be of high priority, and requirements for metrology institutes to ensure traceability of their measurements should be part of the "package". Furthermore, it must be part of the Commission mandates to standardisation bodies to establish common standards for measurements whenever product regulation sets specific requirements.

[1] For further comments by UNICE on Market Surveillance please refer to our position paper on the Draft Community Framework for Market Surveillance (Certif 2005-7) issued in October 2005.