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**UNICE POSITION ON THE WORKING PAPER (13.12.2001) PRESENTED BY
DG ENTERPRISE OF THE EUROPEAN COMMISSION ON THE REVIEW OF THE
NEW APPROACH FOR TECHNICAL HARMONISATION AND STANDARDISATION**

1. The New Approach is a success story

UNICE welcomes that the Commission is taking the initiative to review some aspects of the "New Approach" in the light of fifteen years of experience. The **New Approach**, combined with the Global Approach on conformity assessment, has proven to be a recipe for success. It has made the internal market possible. During the last fifteen years, the Commission and the Member States have gathered considerable practical experience and it seems appropriate to reflect on its strengths and weaknesses. After a phase where much effort was directed on the creation of the directives and the harmonised standards, the focus should now shift to the remaining problems of implementation. UNICE wishes to contribute to the discussion from a horizontal point of view.

The very essence of the New Approach is that it aims at creating a level playing-field throughout the EU without regulating the safety of products in detail. Therefore, a review of the New Approach should focus on reinforcing implementation without falling back into old habits of regulating everything in detail. In the light of the growing international dimension of product regulations, the open and flexible philosophy of the New Approach needs to be safeguarded. In UNICE's view, the New Approach provides an excellent basis for discussions on common regulatory objectives with main trading partners.

In the light of the positive experience, the EU should use the New Approach in other areas, such as the field of environmental product regulations, where necessary for the safeguarding of the internal market.

2. The modular approach should be optimised

The **modular approach** has proven to be a good instrument to minimise problems with divergent conformity assessment procedures in various directives. UNICE firmly believes that module A should be used more frequently in the various directives. An additional obligation to lodge a technical file with a notified body, as suggested by the Commission, is not necessary, as it does not improve the safety performance of the product.

The use of other modules is appropriate only in those cases where specific safety concerns make the involvement of a third party a precondition for the effective protection of health and safety.

Module H has proven to work sufficiently well in most circumstances. Any change would, in UNICE'S view, require that more experience is gathered with the new ISO 9000 standards. The Commission suggests extending the scope of this module in order to cope with the problem that it may be necessary to call upon more than one notified body in cases where more than one directive and multiple modules apply to a product. The choice of modules should however be made on the basis of an appropriate assessment of the potential risk of a product. Under the philosophy of the New Approach, the problem that notified bodies need to specialise on clearly defined modules has to be solved by the market.

The question whether it is appropriate to reduce the choice of modules can be answered on a case-by-case basis only.

The **relationship between standards and modules** is functioning well. Generally, the use of standards giving presumption of conformity is a big help to companies, especially SMEs. However, in some circumstances, problems may arise where a standard is changed in a way which is not safety-relevant. In these cases, the presumption of conformity is lost despite the fact that the essential requirements have not been changed. Nevertheless, this can lead to the need of applying another module. The Commission should reflect on the possibility that after a change in a harmonised standard which is not safety-relevant, the presumption of conformity could be given to the old and the new standard alike, if the essential requirements have not been modified.

3. Greater coherence in the notification and surveillance of notified bodies is desirable

The functioning of the system of notified bodies is essential to the effectiveness of the New Approach. Notified bodies have a double role to play: On one hand, they aid manufacturers in complying. On the other, they underpin market surveillance. This double role may create problems. UNICE wishes to stress that, notwithstanding the needs of market surveillance authorities, notified bodies should be seen as service providers to industry.

The **notifying authorities** should co-operate more effectively. Following the principles of the internal market, common criteria for notification and surveillance of notified bodies should be developed and applied in order to ensure uniform implementation of the directives .

In UNICE's view, **accreditation** is an effective instrument to ensure that notifies bodies function effectively and on a high level of competence. In this regard, the application of the relevant international standards and guidelines, above all those of the ISO/IEC – 17000 family, is essential, because these standards are the basis for acceptance of conformity assessment results all over the world under various multilateral recognition agreements. However, under special conditions, other instruments such as peer assessments, could be used to give adequate proofs of conformity. In any case, divergent national criteria for notification should be avoided.

UNICE proposes that the Commission should enter into a dialogue with the accreditation bodies on measures needed to ensure the effective implementation of the requirements and procedures for notified bodies. This should include the question of **sanctions**. A common legal text referring to accreditation as the basis for notification could therefore be useful.

4. The CE Marking needs to be clarified

The CE - marking has established itself as an administrative mark directed at market surveillance authorities. Its meaning should be clarified and misleading marks should be prohibited.

5. Market surveillance needs to be co-ordinated more effectively

UNICE is of the opinion that the **market surveillance activities** of the Member States have to be coordinated more efficiently. However, there is no need for additional legal instruments. The New Approach Directives offer a series of instruments which are not altogether being adequately applied. The safeguard procedure directed at national market surveillance measures is an instrument to control the legality of national market surveillance measures and should be used more effectively as an instrument to control the national application of the New Approach directives. The procedure foreseen in the Low Voltage Directive is a good example and could be used in the context of other directives, too. Apart from that, the new directive on General Safety of Products (2001/95/EC) creates a European framework for national market surveillance activities. Before taking any additional measures, the Commission should assess the effectiveness of the instruments foreseen in this directive.

6. The safeguard clause procedure is a last resort

The **safeguard clause procedure** directed at European harmonised standards should be the last resort to surmount differences in the interpretation of essential requirements. National authorities are an important player in the process of developing standards. They can bring into the process the experience of their market surveillance activities. Therefore, they should help to avoid problems with the content of individual standards by involving themselves as early as possible in the process of standardisation at national level. The Commission should give thought to a code of conduct on the use of this safeguard clause.

7. The consistency between the various New Approach directives could be better

A framework directive could be useful to improve the situation, e.g. in areas such as definitions, use of the CE - marking, market surveillance and use of modules. However, some differences between the individual directives are necessary to adapt them to specific sectoral needs. UNICE suggests that the Commission prepares an in-depth analysis of the legal and factual differences between the various