



Experience with the New Approach – Scope for progress

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The New Approach system, created 20 years ago, is based, as we know, on two main mechanisms:

- The directives set out the essential requirements applicable to the products in question and leave to standardisation the task of defining the technical solutions to meet those requirements;
- The standards are applied on a voluntary basis, but the use of Harmonised Standards confers a presumption of conformity on products that comply with those standards.

These principles are well known and have been implemented by means of a number of tools: CE Marking, market surveillance, certification and standardisation.

With this structure, experience shows that it has been possible to fluidify trade in a large number of products in the European Union, constituting one of the factors of competitiveness and economic growth in Europe.

Although the removal of trade barriers was the primary objective of the New Approach, two decades of implementation of the system have shown to what extent it has also been a decisive factor promoting allowance for occupational health and safety considerations in product design.

Concerning this aspect, the progress by comparison with the prior situation is undeniable. I think that two factors, among others, have strongly contributed to this:

- Firstly, by leaving aside the technical area, a real "bottleneck", to focus on the essential health and safety requirements (ESR's), the directives have been able to be worked out more quickly and are more durable over time. Now, it is a fact that since the creation of the New Approach, more than twenty directives have been worked out in accordance with the principles of this system, covering a very large number of products and equipment with CE marking. This therefore marks a big difference with the difficulty of adopting technical harmonisation directives at the Community level that was prevalent earlier.

- Secondly, one observes that the system established, by transferring the definition of products' technical specifications to documents other than the directives, has in a certain manner shifted the field of responsibilities by extending it to a large number of players. This structure has indisputably stimulated the European standardisation system and the production of European standards that must be transposed into the national collections of the EU countries, by creating a strong legal tie between the New Approach Directives and the standards through the presumption of conformity (granted to the application of Harmonised Standards).

Experience therefore shows that the establishment of the internal market could be compatible with the involvement of a large number of operators, in particular making allowance for workers' health and safety, consumer protection and environmental protection.

Accordingly, from the occupational health and safety viewpoint, the implementation of the New Approach has made it possible to allow for and deal with hazards as far upstream as possible, especially during the product design stage through taking part in standardisation work.

Moreover, it is thanks to the New Approach that networks of OH&S experts have been formed (or have developed), coming in particular from occupational risk insurance and prevention organisations, with a view to influencing the normative consensus.

The results are therefore extremely positive. So it is understandable that the New Legislative Framework (NLF) entails more of an adaptation of the New Approach, rather than bringing it into question and replacing it with another mechanism.

Given its extensive investment in the area of standardisation, the French OH&S Network recently considered the impact, for occupational risk prevention, of the involvement of the Network's members in standardisation and certification initiatives (two major tools for implementation of directives based on the New Approach concept).

A survey carried out by Eurogip at the end of 2006 on 1400 stakeholders from different horizons (public authorities, notified bodies, user firms, manufacturers, OH&S organisations) aimed to measure knowledge of the New Approach and its impact on the prevention of occupational risks through implementation of the Machinery Directive (98/37/EC) and the Personal Protective Equipment Directive (89/686/EEC).

Both the European Commission's consultation on the revision and extension of the New Approach and the Eurogip survey revealed a number of improvements that should be made to the system. What are the main things learned?

- There is clearly a problem of credibility of the CE Marking. Products in conformity with the ESR's of the applicable directives are distinguished (in their great majority) by the CE Marking introduced by the New Approach. However, this marking is not always perceived as such and its credibility is affected by this. Self-certification by the manufacturer (both judge and jury) for many products contributes to this persisting problem of confidence in the relevance of the CE Marking. This ambiguity regarding the significance of the marking is detrimental at a time when society's demand for safer products is increasing. In addition to the principles contained in the new regulations, special importance should probably be assigned to providing information for Community market operators by considering communication campaigns on the CE Marking and its real significance, so as to increase the visibility and transparency of the system.
- To strengthen confidence in the CE Marking, market surveillance should be stepped up. This point is also mentioned in the surveys conducted. Due to the principle of subsidiarity, market surveillance is referred to the Member States. Concerning this point, the changes contained in the NLF regarding the surveillance organisation and tools for PPE and machinery are especially welcome.

- Third-party operations should also be more harmonised so as to ensure fairer handling of certification applications. The NLF also proposes major changes along these lines.

A large number of observed dysfunctions and adjustments to be made have therefore already been taken into account in the new provisions.

However, field surveys and practices reveal other points to be improved, which are less directly affected by the reforms in progress.

This chiefly involves aspects relating to the normative system.

It is well known that this plays a key role in the New Approach system, but further progress could be made in several areas:

- For the New Approach mechanism to work effectively, the standards should constantly reflect the state of the art. The standards should therefore be updated regularly. However, during five-year surveys, one observes a trend to a decline in the stakeholders' participation, especially on traditional subjects such as machinery and PPE, for example. There is therefore still room for progress on this subject.
- Moreover, for the Harmonised Standards to correspond to the highest health and safety level reasonably expected of a product, there would be a real gain from capitalising more on operators' observations, establishing methods to provoke and maintain feedback from the field. What is needed is better collection and exploitation of experience feedback. For this purpose there exist networks such as the Euroshnet network, but also tools, such as, for example, sheets for noting occupational health and safety problems reported by the networks of OH&S experts (as exists in France) and recommendations established by the European coordination structures of notified bodies. Work should be carried out to pool knowledge.
- The content of the Harmonised Standards itself could be improved. From this viewpoint, the opportunity provided by the revision work currently underway in this area should be amply exploited. In particular, the current standards do not always cover (or cannot cover?) all the applicable essential requirements. Now, this fact creates legal uncertainties for the manufacturer in addition to his obligation, which still exists, to perform risk analysis. This situation could fragilise the system. Accordingly, the Harmonised Standards should become a reliable technical reference and provide support for the regulations in the fullest possible way.
- An improvement and simplification of the content of certain standards is also wanted. Here again, this implies efforts so that the Harmonised Standards may cover all the essential requirements applicable to the products in question, either directly or through reference to other standards.
- Finally, it is necessary to ensure improved representation of the product users in the standardisation bodies, to benefit from experience feedback. In theory, standards should be worked out by all the stakeholders and reflect the stakeholder consensus. In practice, there is a real imbalance of representation of the parties in the standardisation committees. Examples are, in particular, the virtual absence of the users, the small number of SMEs and, increasingly too, of OH&S experts, which is harmful to the cause of occupational health and safety. An equilibrium point must therefore be found so that there may be wide-ranging representation, although

without detracting from the responsiveness expected of standardisation work. Such broad participation is decisive, in particular for occupational risk prevention aspects and to defend established Community practice during standard revisions at the international level.

There you have a few areas for progress in addition to the current reforms, which could undoubtedly lead to further significant improvements in the system.

It is clear that the New Approach is based on complementarity of concepts, on mutual trust between Member States, industry and consumers.

It has admittedly revealed some weaknesses over time, whether for goods manufactured in the EU or imported from third countries, with, as a consequence, unequal equipment levels and involvement of the surveillance authorities in the various Member States.

Nevertheless, the system is evolving to correct these weaknesses, which is a sign of its vitality. In other regions of the world, moreover, it is seen as a factor of economic stability and good governance in which the public authorities and stakeholders are complementary. Efforts should therefore be continued to improve its functioning while retaining its principles. Thank you for your attention.