



European legislation and globalisation

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Introduction

Let me begin by thanking EUROSHNET for inviting me here to today as a speaker at the second conference on standardization, testing and certification in occupational health and safety.

The timing of this conference is very well chosen, in that this year we are celebrating the 20th anniversary of the New Approach, and the Commission has just organised a conference on international co-operation in standardisation as part of the World Standards Day.

The Council Resolution of 7 May 1985 founding the "New Approach" paved the way towards a radical change in our approach to the harmonisation of technical rules. By helping to achieve the objectives of the completion of the internal market and the free circulation of industrial goods, the New Approach made it possible for a legislative environment to emerge that was flexible, fostered business efficiency and at the same time guaranteed a high level of safety.

Today we are faced with new challenges: the recently renewed Lisbon Strategy, focussing on the objectives of growth and employment, invites us to think of ways of improving our regulatory approach. How can the model of the New Approach and the reference to voluntary standards help us to achieve these objectives? What role do we see for international standards in our legislative environment?

Before attempting to give something of an answer to these questions, I would like to start by looking back and reviewing the benefits of the New Approach, and its necessary adjustment to the changes that have occurred since it was introduced.

1. The contributions and development of the New Approach

Today we are in a position to refer back to considerable experience in the field of shared responsibility. Twenty years ago, the Member States, following a Commission proposal, reached agreement on the implementation of a new legislative technique replacing detailed regulations: the New Approach established a framework guaranteeing a high level of health, safety and environmental protection. Players in the economy would be henceforth free to develop within private European standardization bodies technical rules for voluntary application, whose observance would be one way of demonstrating compliance with the essential requirements. By involving private operators in the standardization process we hope to facilitate the observance of the essential requirements through the implementation of consensus-based technical solutions.

The New Approach introduced a clear separation of responsibilities between on the one hand public authorities and inspection bodies, and on the other, producers and standards setters. At the time it was a practical solution to the challenge of free circulation.

We soon realised that this new legislative method, by providing flexible framework, fostered innovation. Clearly, "New Approach" type legislation, by setting results-oriented targets, does not necessarily require adjustment with every technological innovation. It is up to the standardisation process, and therefore the interested parties, to make these adjustments through the revision of harmonised standards. The small number of safeguard clauses and formal objections entered by Member States against the content of harmonised standards – some fifty in all over twenty years – is evidence that the framework chosen was the right one and that it is able to protect the interests of the interested parties, and ultimately, to improve the quality of life. The system works, its problem resolution mechanisms ensure it works efficiently.

We can therefore assert today that this process has unquestionably been a success. The evidence is unmistakable if you look at the situation in the twenty or so sectors where the New Approach has been used, from telecommunications to toys to pressure vessels, and of course in machinery safety and personal protective equipment.

By placing responsibility for the harmonisation of technical standards in the hands of the interested parties, we have been able to greatly accelerate the progress of the Internal Market. This movement has generated strong demand for voluntary standards, including in sectors on the sidelines of the New Approach. By and large, standards bodies have been able to rise to this challenge. The New Approach has stimulated the role of industry as an active partner in defining the rules of the road.

The recommendations of the UN Economic Commission for Europe, that take their lead from the New Approach, come as an endorsement of our concept and provide an opportunity to extend our model to the rest of the world. Europe is ready and willing to share its experience with its partners in order to promote regulations that foster at the same time free circulation of goods, health, safety, environmental protection and international trade.

However, the success of the New Approach must not be allowed to hide the need for further developments especially in the areas of market surveillance and designation of notified bodies. The revision begun in 2004 should enable us to further strengthen the credibility and application of our regulations in the whole of the Union.

2. Lisbon strategy and simplification

On a broader level, the Lisbon Strategy quite rightly calls for efforts to improve our regulatory environment as a whole. By taking a closer look at the impact of our legislation, we could make it more effective, and tailor the regulatory tools to the targets chosen.

The recent Commission communication on improving regulations for growth and employment confirms that *the EU and the Member States must develop their regulatory approach in order to ensure the defence of public interests in a way that fosters the growth of economic activity and does not hinder it*. In this respect, and so as to observe the principle of proportionality between actions and objectives, the Commission is intending *to promote the use of European standards as technical support to European legislation or as an alternative to legislation*.

We see here that the use of standards in the field of European regulation and policies is an as yet unfinished process. Over and above the New Approach, it will be up to the interested parties to innovate and suggest new applications for standardisation. Environmental protection and information technology are of course key sectors, where standards must still be able to develop their full potential and continue to promote rationalisation, interoperability and optimum use of resources. Occupational health and safety is doubtless also one of the areas where standards should help us to improve worker protection without imposing disproportionate burdens on businesses.

3. The challenge of globalisation for standardization

The Lisbon strategy stresses the need to guarantee open markets. National technical specifications, whether in the form of regulations or standards, are still too often barriers to trade, despite the progress made through WTO.

Standards can turn out to be a powerful instrument for market access. The transposition of European standards to the international level can help our businesses penetrate Asian and American markets more easily. Conversely, Europeans must monitor developments in standards outside Europe so as to be able to anticipate and, if necessary, take action to prevent the emergence of standards that would adversely affect trade. Standards also offer a significant channel for the dissemination of innovation.

It is with these objectives in mind that the Commission will support all initiatives aiming at harmonisation at the global level. By way of example, we are a stakeholder in the European standardization's plans to appoint an Attaché in charge of standards in Beijing as of 2006.

Harmonisation via standardization of specifications or practices at the international level provides businesses with the advantages of a stable and transparent environment. The co-operation agreements signed by the European standardization bodies with their international counterparts have already proven their effectiveness, since in some industrial fields more than half the European standards are identical to the international ones.

Having observed over the last twenty years the complete transfer of standardization programmes from the national to the European level, we are now witnessing – and taking part in – the internationalisation of standardization, as a natural accompaniment to the processes of globalisation. This growing importance of the international level means that not only standards setters, but all the interested parties, are faced with serious challenges. In the interests of all concerned, the Commission will pay particular attention to the following aspects:

- International harmonisation must be done with consideration of European interests and our regulatory requirements. In particular, there can be no question of allowing the principle of “high level of safety” to be downgraded by technical standards that grant presumption of conformity with regulatory requirements. European standardization bodies have a vital co-ordination role to play in preparing European positions here, whilst they in no way challenge direct national participation in international bodies.
- All interested parties must have the opportunity to be involved in the drafting of international standards as easily and effectively as they do at European level. The Commission, for example, fosters inputs by consumer associations, workers and

environmental protection organisations into standardization. The emergence of networks such as EUROSHNET between OSH and inspection bodies is an appropriate form of response that seeks to exert greater influence over the standardization process. The role of national standardization bodies and Member States in mobilising the interested parties remains nonetheless fundamental.

- Global harmonisation must not be used as a means of pressuring for changes to European regulations.

Against this background, the recent discussions by standardization bodies of the concept of "Global Relevance" may enable us to work towards even wider dissemination and application of standards. With proper consideration for regional practices, climate conditions or local needs, "globally relevant" standards recognize the existence of basic differences that are currently impossible to overcome. They help to reinforce transparency and thus make it easier for our companies to access markets. This however does not mean that "Global Relevance" should lead to a new "share-out of the world" among the companies and countries that apply different standards. This approach has to be seen as a first step towards full harmonisation, which alone guarantees process optimisation and full interoperability.

The "Global Relevance" of international standards must not generate any legal insecurity as regards the technical solutions to be applied under the presumption of conformity with regulatory requirements. Without wishing to interfere in the standardization process, the Commission nevertheless expects European bodies to propose a simple approach, able to removing any ambiguity which might appear in standards mandated and drafted, on a delegated basis*, at the international level.

Conclusion

In conclusion I would like to assure you that we are quite certain that standards have the potential to make an essential contribution to the success of the Lisbon Strategy and improved regulation. Market globalisation calls for a strengthening of international standards – a process that standardization bodies are already well aware of. In my view this will not lead to any devaluation of European standardization, and I am sure that European standardization bodies will find a suitable role for it in a constantly changing international environment.

Thank you for your attention.