



ORGALIME position paper

commenting on the Commission draft working document (November 2003) on

The role of European standardisation in the framework of European legislation and policies

30 January 2004

ORGALIME is the liaison group representing the interests of the European mechanical, electrical, electronic and metalworking industries at the level of the EU. ORGALIME's members include, at the present time, 34 national trade federations representing some 130,000 companies in 23 European countries. These industries, which include mainly small and medium sized companies, employ some 7.2 million people and account for around 1,200 billion Euro in the GNP and one third of the industrial exports of the EU.

ORGALIME believes that European standardisation together with the New Approach is an excellent regulatory tool, which has efficiently supported the development of the European single market. By developing objective oriented legislation, which sets essential requirements to be fulfilled, but leaves it to experts to determine how these can be achieved at the level of products through standards, the Community has provided a flexible regulatory framework. The system has provided a boost to the competitiveness of the European engineering industry and has enabled our industry, by establishing a strong home base on the internal market, to strengthen its capacity to operate on world markets. It is therefore, in our opinion, one of the cornerstones of reaching the Lisbon objectives.

It is acknowledged that the changing conditions for the European standardisation indeed call for a review of its objectives, scope and needs. We therefore welcome the Commission's initiative to issue a working document and an invitation for comments. We provide hereafter ORGALIME's views on most of the chapters of the working document.

The comments we provide follow the structure of the document and the headings of the respective chapters.

1. Introduction

1.1 Executive summary

We appreciate the interest expressed by the Commission in the elaboration of these recommendations, which concentrate on the solution of problems encountered by European standardization, while also recognizing the considerable positive contributions made. Some of the proposals, in particular those relating to actions to be undertaken by the authorities at the national and the European levels to support standardization and its use in the public policies, are also welcomed.

However, we have some general comments and concerns:

- The standardisation process is a voluntary consensus-driven activity carried out by and for the interested parties, who invest time and resources on the process.
- When they support legislation, standards should take into account legislative aspects to increase their relevance (health, safety, environment, compatibility, etc). As a consequence, some new stakeholders are becoming involved, and their views taken into account.
- Most markets are now global. Many European standards are implementations of international standards, which have been drafted with the participation of European experts. Any divergence between a European standard and an international standard may lead either to barriers to trade or to difficulties for European industry at the level of exports.

Orgalime supports the main recommendations of the summary with the exception of the fourth one, which recommends a review and amendment of the current legislative framework. The need for such a review should be evaluated very carefully before embarking on it.

Orgalime considers the New Approach with its reference to European standards as the first and most practical option for legislation regulating our sector. But this should not be taken as an invitation or encouragement for new legislation. The main objective must still be to restrict regulation and legislation to the extent necessary, no more.

Indeed, a Commission communication promoting “more extensive use of European standardisation” should also include a very strong commitment from the Commission to keep the standardisation process voluntary and the ESOs independent. It should not be forgotten that standards serve to relieve the legislator of burdens. The two advantages for the legislator are:

- Less work with the intricate details of the legislation
- Support for the objective to deregulate and issue less legislation.

European standardisation is not only a tool used in the framework of legislation under the New Approach context, but is also a tool to improve interoperability between products. We wonder if the constraints given to the procedure for writing standards dealing with safety, health and environment should not be different from those dealing with pure interoperability. The first category is characterized by a slow procedure with full consensus (all stakeholders), the second needs a quicker procedure with restricted consensus (stakeholders involved in the interoperability only).

1.3 The broader political context

The preparation of standards allows for better acceptance of regulations, because these are discussed not only with the Member States but also with the stakeholders. This leads to the acceptance of a common European view by many and the achievement of the single market. It also facilitates the task of the Commission, which does not have access to technical expertise for all industrial products.

As representatives of industry we understand that we have the responsibility to manufacture products complying with a certain number of requirements in the area of health, safety, environment and compatibility. While our industry takes its responsibilities seriously, we are not the only stakeholders who should address “*the needs of both society and enterprises*”. This is a task and a responsibility to be shared among all stakeholders. Abolishing the so-called command and control legislation must not lead to commanding and controlling the ESOs and their work. The cooperation between administration and standardisation must be built on mutual trust.

It is therefore difficult to subscribe to the conclusion that the “Union’s policies can bring standardisation closer to market needs” cannot be followed. This is a task of the standardisation bodies and it has to be assumed that any “Union policy” will only result in new legislation thus inevitably reducing flexibility.

2. “Standards receptive legislation and policies since 2001”

2.1 New legislation and new legislative initiatives

In view of our previous support to regulation of products under the New Approach (see Appendix for references), ORGALIME of course favours the use of standards to support legislation. This should not however be taken as an invitation to create or a request for new legislation. The objective of any better regulation programme must be to simplify and reduce legislation.

Even though industry believes that it may be feasible to spend more resources in standardisation in order to “*expand it into new areas such as services, ICT, transport, consumer and environment protection*”, it is inevitable that industry will have to decide in which areas of standardisation to concentrate its limited resources. Any attempt to use legislation as an indirect “incentive” to create more involvement in one or other part of standardisation has to be rejected and considered as a return to the Old Approach.

2.2 Policy areas supported by standards other than related to legislation

2.2.1 Improving the internal market for goods and services

It is agreed that European standardisation in support of the internal market in the area of goods in general has been successful and now has reached a mature stage.

The intention of the last sentence of the second paragraph (“Interested parties are invited ...”) is not clear. Of course it is the task of the interested parties to maintain the achievements of European standardisation. The need for new initiatives from the Commission in this process has to be examined very carefully. The text, as it reads, may be interpreted as a suggestion that the Commission is looking for possibilities to get more involved.

Concerning the planned regulations for services and the safety of services, again a thorough examination of the needs is necessary. If regulation for services is necessary then the New Approach and the development of standards would seem to be the appropriate method

2.2.2 Environment

Concerning IPP ORGALIME believes that standards may be used in support of legislation. The need for and the scope of any new legislation in that area, however, must be carefully analysed (see Appendix for references).

We support the use of New Approach in the environmental field, based on the principle of Life Cycle Thinking. Within this area experts from industry and having knowledge of environmental aspects will certainly make valuable contributions.

ORGALIME’s position on the Greening of Standards issue has been communicated in its reply to the Commission’s questionnaire already. The international standardisation bodies have drawn up guidelines on how to integrate environmental aspects into the standards. Further initiatives by the legislator or by the Commission are not considered necessary.

2.2.3 e-Europe initiative

We support the statement that the activities in this area are “primarily the responsibility of the private sector”. The offer to facilitate the coordination of the different economic players is welcomed, but one must question whether there is a need to coordinate the standardisation initiatives in this field. Of course, coordination is to be encouraged, but the way it is written in the document it suggests that the Commission would like to take the lead in this process instead of just participating.

2.2.4 Innovation

We support the statement that standards play an important role for innovation.

One of the key requirements for successful innovation is that it is conducted in a flexible and unregulated environment. Voluntary standards may be one of the tools in this environment. Standards must be developed with minimum time delay and the development and use of manufacturers’ or fora standards should be encouraged.

3. The new challenges for European standardisation

3.1 Enlargement

ORGALIME also believes that it is important that all national standards bodies from the new member states are integrated in the European standards system according to the same criteria as the current members in order to ensure the proper functioning of the system. Support from the Commission will definitely help this process.

3.2 The strategic importance of European standardisation for enterprises and the need to increase efficiency

ORGALIME supports both statements of the Commission: more awareness by industry's top management about the benefits of standards and standardisation and more efficiency in the standardisation process is needed. The question is how the Commission can assist in these areas. Specific suggestions are not made in the document.

ORGALIME would welcome supportive actions from the Commission to help raising awareness of business leaders about the benefits of participation in standardisation for their enterprises, e.g. in information campaigns, public relations, or other "marketing" measures. In this context "business leaders" are not only the top managers of manufacturers, but of all stakeholders, including governments and authorities, see our comments under 3.4.3. The awareness of top managers should be a follow-up of what they have learned during their earlier training. The Commission could encourage the teaching of future managers and engineers on standardisation items. Some incentives from the Commission could be given for actions through ESOs and through NSBs.

ORGALIME would however not be in favour of additional legislative measures in this field.

The example of the Construction Products Directive (CPD) shows the difficulties, which arise when standards are rendered mandatory. In ORGALIME's opinion, the CPD is not a true New Approach Directive and lacks a suitable formulation of the essential requirements. This has led to the poor results in terms of the number of standards issued.

The Commission's offer "to support ESOs in their drive to increase the efficiency of the standardisation process" is noted with interest even though there is no indication as to what concrete measures are intended. In our opinion, though, the efficiency of the process is mainly a concern of the stakeholders.

3.3 New standardisation products ("New deliverables") and their role in European policies

3.3.1. The diversification of standardisation products

ORGALIME does not support the conclusion that an increasing development of new technical specifications by consortia is a major challenge to standardisation. These new deliverables were invented because there was a need for them. They should not be considered as a major challenge to standardisation, but rather as a contribution to provide the flexibility and variety needed in a complex world.

The increasing number of new technical specifications developed by consortia operating outside of the standardisation framework is mainly due to the slow pace of conventional standardisation, which has to follow the principles of openness, consensus and transparency.

Some of these new deliverables give an opportunity to speed up the standardisation process. Many of them become standards after having followed the appropriate procedure, standards with the benefit of real tests on the market.

The conclusion that the use of new deliverables in support of legislation is possible has to be requires very careful consideration. The new deliverables are based on limited consensus, whereas legislation must be based on a democratic, consensus-oriented process.

3.3.2. Lessons learnt & conclusion

ORGALIME believes it is important to distinguish between the new deliverables and the conventional standards. The new deliverables are pre-normative documents developed promptly by industry to fulfil its needs.

The last sentence of 3.3.1 must not be misconstrued. The involvement of all stakeholders does not apply to the development of the deliverables. In that case we would be back to the development of conventional standards!

3.4 The increased participation of societal stakeholders and SMEs in standardisation

3.4.1 Participation at ESO level

The participation of all stakeholders and interested parties in the standardisation process is an indispensable precondition, as stated correctly. Therefore, in our view, the establishment of European stakeholder associations is a natural process. But it must be pointed out clearly that the task of these associations is to promote the participation of their members on a national level.

The membership conditions of CEN and Cenelec include requirements on openness, transparency and the capacity to build national consensus. The participation of all stakeholders is thus an intrinsic requirement.

3.4.2 Participation at NSB level

See comment to 3.4.1.

3.4.3 Participation of authorities

Standards are indeed important tools for the authorities to carry out their responsibilities. It has therefore been ORGALIME's proposal for many years that – authorities, in particular market surveillance authorities, should participate in the standardisation process. Due to the financial restrictions they seem to refrain more and more from this task.

The use and benefits of standards by the authorities are actually threefold:

- as an instrument in the market surveillance
- as a reference in legislation thus avoiding the problems of detailed regulations
- participation and leadership in standardisation as a tool for industrial policy

The financial participation by some national authorities does not seem to be in proportion to the benefits they derive. The reason is that the financing system is not transparent. National governments are the biggest user of standards at the national level by their reference to standards in legislation, but their financial support and input into standardisation are not always in line. When national governments claim that standardisation is a task for the (other) stakeholders, they do not take their responsibility as stakeholders in the process. Support from the Commission to increase transparency in this area and to get more involvement of the national authorities would therefore be welcome.

We do not agree with the Commission's conclusion that participation of the stakeholders at national level is not guaranteed in a robust fashion. This conclusion seems to have the purpose to introduce specific measures on community level, which must be questioned strongly.

3.5 Existing legal framework regarding standardisation – new challenges

At this stage it is difficult to determine whether the existing legal framework has the alleged shortcomings or not. This would require a comprehensive legal analysis, which cannot be made in the short time period available.

There are two reasons why a revision proposal for Directive 98/34 has to be scrutinized.

The main purpose of 98/34 is to notify the Commission and member states of national specifications, the objective being to prevent barriers to trade. The directive is not a standardisation law.

The revision aims at regulating also the new deliverables. This would seem inappropriate because:

- The new deliverables are completely voluntary instruments and legislation may contradict this character
- They are flexible instruments. Legislation may restrict their degrees of freedom
- They are rather new instruments; more experience should be gained before even considering to include them in a legislative framework

We would like to refrain from further comments except that a revision of the 98/34 directive has to be planned very carefully and should not be made without the proper involvement of all stakeholders. It would seem, e.g., that there is no difficulty to introduce the concepts adopted by the TBT agreement: transparency, openness, impartiality, consensus, effectiveness and coherence. Except for that, the recommendation of industry is to restrict any revision to only those elements of the directive, which clearly have to be adapted to new circumstances. Any further regulations or provisions introduced during a revision process cannot be accepted.

3.6 Financing

3.6.1 The Commission's financial contribution to the system

The “five pillars” are accepted, especially as long as the pillar of standardisation contracts remains voluntary. It has to be left to the discretion of the ESOs whether to accept a contract or not. However, for the viability of the ESOs it is essential that they can rely on stable conditions of EU/EFTA funding.

3.6.2 The viability of the system

If in the Commission's opinion a legal basis is needed for providing the financial support then it should be developed.

But we cannot follow the Commission's statement that the central secretariats of the ESOs need additional financing sources. The secretariats are financed by the member organisations, a system which has worked satisfactorily for many years. There is no reason to assume that this situation will change.

ORGALIME cannot accept the recommendation to increase the financial income of the central secretariats by selling standards. This is the original task of the NSBs and there is no need to change this system. Many of the NSBs receive a major part of their income from the selling of standards. Taking away these revenues will weaken the complete system. This, we presume, is of course not the aim of the Commission. Furthermore, it is in contradiction to the agreed opinion that standardisation should be based on the principle of national delegation.

Our concern with the proposal to ask stakeholders to participate in the financing of the ESOs is that these stakeholders may withdraw their contributions to the financing of the NS's. Large stakeholders may also gain more influence on the European level to the detriment of the smaller ones.

3.7 The European principles of good governance in international standardising bodies

ORGALIME fully supports the Commission's proposal to promote the European principles of good governance and accountability.

3.8 The global dimension of standardisation

ORGALIME certainly appreciates that the Commission wants to promote international standards and their uniform transposition in the EU. But we have to regard the statement that “the Community needs strong and uniform standards bodies at European level” with caution. This must not be understood as an expression by the Commission to encourage the modification of international

standards/standardisation so that they fit to European legislation. Non-European countries would frown on such actions.

Neither should the Commission impose too many specific requirements on the ESOs. The international community, for instance, tends to frown on these specific requirements. The Global Relevance approach will lead non-European countries to request European countries to introduce their specific requirements in an EDR clause (essential differences in requirements), applicable only to European countries. In this way, European products complying with European standards and EDR of international standards will become less competitive on the global market.

In ORGALIME's opinion, it should be the objective of the Commission to promote the legislative approach of the EU throughout the world and the use international standards worldwide. This is the direction, in which the political power of institutions like the Commission should aim.

4. Conclusions and summary of the actions proposed

Many of the above considerations are based on the difficulties of finding a balance between two basically contradictory objectives: the shortening of time for production of documents on one hand and on the other hand the desire to ensure a solid base for the documents in terms of openness and transparency. The search for consensus between the stakeholders is a process, which takes time and which requires strict rules, even in a world with electronic communications.

The recommendations on how to improve efficiency or increase the participation of stakeholders may be interpreted as proposals for further action. The question then arises how the Commission will implement such measures, bearing in mind that its main policy instrument is legislation. There is a risk is that many of the measures suggested by the Commission will lead to more centralisation of the European standardisation system and in consequence a weakening of the NSBs.

In our opinion, the Commission's objective should be to take up the political task of promoting the use of international standards. This, however, should not be done by promotion of the European standardisation system in the "bilateral and multilateral contacts with non-member countries." The other way round would be the more constructive way: to advertise the principles of the European legislative system throughout the world in order to increase worldwide acceptance of international standards.

We also fear that the standardisation community when seeking to fulfil the new requirements will do so without the possibility for industry to optimise and to introduce added value in the process or in the products.

We would therefore welcome the Commission's response in the following areas:

- limit administrative burdens (for example an unnecessary or too detailed Annex Z, excessive scrutiny of standards by consultants or standing committees),
- suggest ways of measuring the impact and benefits of participating in standardisation activities by the stakeholders
- suggest ways of making the use of standards by governments transparent
- avoid transforming the New Approach into the old approach by introducing specific technical requirements in directives or in mandates.
- avoid as far as possible specific European requirements in European standards if we want them to stay or become truly globally relevant.

Appendix

ORGALIME involvement on Issues related to European Standardisation in the framework of European legislation and policies

Active links to the ORGALIME Web site

ORGALIME positions on European standardisation

- [19/09/2003 - Integration of Environmental Aspects into Standardisation 2003](#)
- [11/09/2002 - Integration of Environmental Aspects into Standardisation 2002](#)
- [28/05/2001 - Proposed elements for European guidelines on International Standardisation](#)
- [24/01/2001 - International Standardisation](#)
- [28/09/1993 - European Standardisation and the new approach to technical harmonisation and standards](#)

ORGALIME positions on the New Approach

- [30/03/2002 - Answer to the EC Questionnaire on the Future of the New Approach](#)
- [29/03/2002 - The Future of the New Approach](#)
- [08/02/1999 - Guide to the implementation of directives based on the new approach and global approach](#)
- [28/10/1998 - Peer Assessment as a Tool for Mutual Recognition of Certification Bodies](#)
- [29/10/1996 - Operation of the new approach directives in the internal market](#)
- [28/09/1993 - European Standardisation and the new approach to technical harmonisation and standards](#)