

Brussels, 17 May 2010

Review of the European Standardisation System

In response to the public consultation on IPM:

http://ec.europa.eu/enterprise/policies/european-standards/public-consultation/index_en.htm

1. EXECUTIVE SUMMARY

Orgalime believes that the revision of the Community legal and financing framework of the European Standardisation System (ESS) can achieve positive results only if it does not change the ESS' voluntary, private and market-driven core features. Therefore the strengthening of the ESS' ability to meet the needs of innovative companies, including SMEs and society at large should remain the primary responsibility of its members, i.e. the national standards organisations (NSOs) which are closest to the grass roots stakeholders. The duties of authorities should therefore be to provide equitable conditions at national level to help promote, educate and foster the use of standards and voluntary participation in the ESS among all genuinely interested parties. In our view this is the best way to support the competitiveness of our industry.

Standards can be attractive and powerful tools to support internal market legislation, for which regulators alone can set the legally acceptable levels of health, societal and environmental protection.

2. GENERAL CONSIDERATIONS

The ESS is the best system to give support to EU legislation and policies. This is why Orgalime supports the ESS and its core features and benefits for eliminating barriers to trade within the internal market and for providing presumption of conformity to all EU laws, insofar as these are aligned with the New Legislative Framework (Regulation 765/2008/EC and Decision 768/2008/EC). For areas other than ICT, Orgalime is against any direct reference in legislation to documents developed by fora and consortia, which could only undermine the value of existing standards and hence the legitimacy of the ESS and respect for the EU regulatory framework per se. Normative documents from fora and consortia can support public policies provided that European standards organisations (ESOs) democratically process them into formal standards at the request of their stakeholders. For emerging technologies and services, the main drive for, and input in standardisation must come from the stakeholders affected, not from the regulator by means of standardisation mandates.

Standards are are voluntary tools and serve different goals than laws. Their relevance therefore depends on their capacity to serve the needs of their primary users, i.e. companies that will use them for designing products or supplying services. In the EU context, they are also useful tools in support of harmonised legislation for the protection of health and safety or in other policy areas, such as energy efficiency, the protection of consumers, workers or the environment.

Orgalime, the European Engineering Industries Association, speaks for 33 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 22 European countries. The industry employs some 10.6 million people in the EU and in 2009 accounted for some €1,427 billion of annual output. The industry not only represents some 28% of the output of manufactured products but also a third of the manufactured exports of the European Union.

www.orgalime.org

Whether society's expectations are met or whether "*innovation in strategic markets*" is satisfactory at EU level are however political and macro-economic questions that go beyond what standardisers and their stakeholders can be expected to integrate. Therefore standards may provide a response to "*new societal demands*" provided that they are considered by companies as useful to meet their primary needs and workable. They must also underpin their investment in the standardisation process. Otherwise the effect of standards on society will remain invisible.

Let standardisation decide on its own governance. Orgalime strongly believes that it is not up to regulators to seek to impose the governance structures and the operation of the ESS and to impose adaptations that would not be considered as acceptable and desirable by its members, the national standards organisations (NSOs). As private organisations, NSOs should remain free to decide for themselves the best ways to carry out their tasks. Standardisation should continue using a bottom-up approach based on the voluntary participation of experts. Any top-down approach that would transform European Standards Organisations (ESOs) into service providers, working on a pay-per-view basis to answer EU policy needs, would lead to a counterproductive regulatory standardisation system.

Awareness-raising and education are the priorities for SMEs. The most significant hurdle to accessing standards is not their price but ignorance about the economic gains that they could provide for a company, especially an SME. When applied correctly, the cost of implementing a standard is much more significant than the cost of its purchase. Therefore, Orgalime believes that ESOs should improve the quality and the adequacy of the information they provide to all potential users of standards (not only SMEs) in order to raise company awareness of the benefits of participating in the standardisation process. It is not the quantity of information that is essential but its quality.

Strengthening the ESS requires no widening of its scope, but more involvement. There is no need to integrate the WTO principles in EU Directive 98/34/EC. Instead of opening up the ESS to a greater number of organisations, Orgalime favours a procedure whereby there would be a greater flexibility in EC financial control for enabling the current ESOs to subcontract work to external fora and consortia that meet the WTO-TBT criteria because they are de facto included: all the NSOs have signed the WTO agreement. Moreover, authorities that reap benefits from standards in their supervision activities should show their commitment not only to participate but also to pay their fair share in the standardisation system, especially at national level. The financing of mirror committees by the Commission in all Member States is an interesting approach as it would help smaller countries or those with less industry to participate in standardisation.

In the national delegation principle we trust. Orgalime believes that the participation of SMEs, consumers and workers via trade associations and NGOs should be welcomed in all new standardisation work item projects where these groups have a genuine interest and therefore can provide a constructive contribution. This is best ensured at national level where participants can work in their own language and structures and at less expense than if they were to work directly at European level. The lack of resources of NGOs and SMEs would not be solved by setting artificial minimum levels of participation at European level.

In funding the ESS, the EU should support internal market needs first. The ESS is an essential tool to develop and underpin global markets for engineering products if it stays tuned to the ISO/IEC standards system, in order to guarantee true global harmonisation and coherence of standards. Hence, the EU could facilitate the opening of global markets by taking up the issue in international trade agreements. However, in our view, the EU should give priority to the provision of means to facilitate the use of European standards within the Internal Market.

How should EC/EFTA best fund the system? Community financing should encourage the preparation of harmonised standards in a fair, proportionate and consistent manner through operational grants and standardisation contracts, without impairing the autonomy of the ESOs. EU funding priorities should be focused on the drafting of explanatory summaries of standards in all EU languages and on promoting the inclusion of standardisation benefits and best practices at all levels of education.

3. ORGALIME DETAILED ANSWERS TO THE QUESTIONNAIRE

POLICY OBJECTIVE A:

Avoidance of the creation of new technical barriers to trade for products and services in the internal market

The emergence of national service standards and alternative standardisation documents (like Publically Available Specifications) developed by National Standards Organisations (NSOs) constitutes a risk of technical barriers to trade within the internal market. Since the 1980's, the Commission and the standardisation bodies (ESOs and NSOs) shall be informed – in the field of products – of the new subjects for which the NSOs have decided, by including them in their standards programme, to prepare or amend a standard. The same procedure could be envisaged for national programmes of service standards (including process standards) and alternative standardisation documents.

Question 1: Do you think that service standards (including process standards) and alternative standardisation documents should be included in the scope of Directive 98/34/EC or its successor?

Yes, Orgalime agrees that services are an important area for continued and expanded standardisation work, and in the interests of harmonisation **supports the inclusion of standardisation of services in the legal framework** by making the relevant changes in the definitions of Article 1 of Directive 98/34 (to include *services* in addition to *products*)

In the context of the revision of directive 98/34/EC we would like to underline that **the main input and promotion must come from the stakeholders affected, not from the regulator** by means of standardisation mandates. Indeed, Orgalime believes that the development of standards and their use in the provision of services as much as in product design should remain a business-driven process free from bureaucratic validation procedures. This is especially true for quality management, environmental management and other process standards such as accessibility following the design-for-all principle.

Question 2: Are you aware of specific cases where national service standards and alternative standardisation documents have caused technical barriers to trade?

No. As reported in [COM\(2009\)690 final](#) on the **Operation of Directive 98/34/EC from 2006-2008 of 21/12/2009**, the information procedure installed by the Directive operates successfully and still plays an important role in encouraging national standardisation bodies to bring their initiatives to European level, thereby proving to be an effective instrument for preventing barriers to trade.

Depending on the country, there is a significant number of standards that are developed in response to market needs in areas that are not regulated at European level.

POLICY OBJECTIVE B: Adaptation of the European standardisation system to the rapid evolution of technologies

The traditional standardisation process lasts an average of 1 to 3 years. This pace very often does not correspond to the speed with which new technologies are developed, and some sectors have been reluctant to ask the standards organisations to develop standards, even if such standards would have contributed to extend their market or rationalise their processes. Others, especially in the ICT sector, have developed interoperability specifications in fora and consortia, outside the ESOs as described in the Commission White Paper. However, neither the current legal framework of European standardisation (Decision 87/95/EEC), nor the rules on public procurement allow reference to such for a and consortia specifications in ICT regulations or public policies.

Question 3: For areas other than Information and Communication Technology (ICT), should it be possible to refer to documents developed by fora and consortia in legislation and public policies? If it should, how should it be implemented?

No. For areas other than ICT, **Orgalime is against any direct reference in legislation and public policies**, including rules of public procurement or for the allocation of public incentives and grants, **to documents developed by fora and consortia**, for the following reasons:

- 1) **Such references would undermine the legitimacy of the formal standardisation bodies**, which guarantee the principles of transparency, openness, impartiality, consensus, efficiency, relevance and consistency advocated by the European Commission and WTO. It is our view that the current European standardisation system efficiently ensures the necessary checks and balances for a standard to be acknowledged by the Commission as a European harmonised standard and therefore published in the OJEU; To give normative documents developed by non-formal fora or consortia a possible formal status without passing through the formal system might lead to a deterioration of the success of the ESS, i.e. stakeholders know where to be active if they want to influence the detailed requirements.
- 2) **Furthermore**, in the context of 'New Approach' legislation (*where harmonised standards give presumption of conformity to essential legal requirements*), reference to such documents **could open up undue influencing routes and undermine trust in and respect for the EU regulatory framework at large**. This would be particularly unfortunate, after the recent adoption by the Parliament and the Council of the New Legislative Framework (2008), which endorses the broadening of New Approach principles that harmonise the conditions for placing products on the Community market while protecting EU core interests in a wider range of policy areas, including the protection of SME interests;
- 3) Reference to publicly available specifications or industry technical/workshop agreements developed by fora and consortia in legislation and public policies **would hamper coherence with the existing standards portfolio issued by the European Standards Organisations**. Consequently the revision of Directive 98/34/EC should specify the WTO TBT criterion of "coherence" in this sense in order to avoid the risk of competing or conflicting requirements in standards.

Normative documents from fora and consortia can serve as a useful input for public policies. European standards organisations should be ready to process such normative documents into formal standards when asked to do so by stakeholders. This is more than a question of 'rubber stamping', as such a process includes verification of the standard for consistency including towards legislation, and achieving a broader consensus. European and national Standards Development Organisations (SDOs) should ensure proper coordination between themselves, taking into account also the ongoing work in consortia and fora and aligning with this where needed. All this should be organised with a view to minimising duplication of work and optimising the match of proven track record / expertise with the work at hand when it comes to who will develop a standard. Moreover, particularly in the ICT area, the fora and consortia are mostly driven by non-European bodies which compete with ISO and IEC. The documents of these bodies can be

proposed at ISO and IEC and adopted by them when they do not conflict with ISO/IEC standards and are consistent with the ISO/IEC corpus.

Question 4: How could ESOs and NSOs be encouraged to accelerate their standards development process? Should for example the Community financing for standardisation be subject to conditions in terms of speed of delivery whilst maintaining the openness of the process?

Improving the efficiency and reliability of the development and application of mandated standards is a major concern for business. This requires active involvement by all relevant stakeholders in a particular industry, which uses standards to design and manufacture products and supply services for the market place, not only at national or European levels, but increasingly at international level (see our answer to question 11).

Therefore ESOs and NSOs should be continuously encouraged to develop and improve their working methods, tools and processes in accordance with the needs expressed by stakeholders. NSOs should provide professional standardisation support to technical committees. The use of digital meetings, video conferences, project organisations etc. should be encouraged. Such efforts are paying off: for instance at both CEN/CENELEC and ISO/IEC level (through the parallel approval procedures), the time needed to make a European and an international standard has been significantly reduced to less than 3 years, including consensus-building at technical level, inquiry among relevant stakeholders through NSOs and the formal adoption of the standard.

In considering the time needed for developing a new standard, the voluntary character of the standardisation process is a main factor as well as the objective to have quality standards that will be used in 'real life'. Resources in terms of persons and time might be scarce. People involved in standardisation are often busy with many other tasks. It would be unfortunate to create a situation where the development of standards is carried out by 'professional standardisers' with no active link with 'real life' business. Furthermore, time to reach consensus is needed as well as time for public consultations to ensure transparency and applicability of the standard.

Delays in standards development must not be overestimated: they have already been significantly shortened and further improvement is possible thanks to stakeholders' steady willingness and broader use of ICT tools. We doubt that subjecting the financing of ESOs to administrative time conditions, such as answering an EC standardisation mandate within a 2-month time frame or delivering standards within 2 years, would accelerate the standards development process at EU level, if no concrete steps are taken to improve the current financing rules and relationship between the European Commission and the ESOs. As stressed in the study on the "*Evaluation of the Contribution of Community financing of standardisation to the fulfilment of policy objectives of the Commission*"¹, we are of the opinion that speed of delivery of standards supported by Community financing could be best improved by a "*significantly simpler and less bureaucratic set of arrangements for the financing of standardisation*" and that "*administrative requirements and financial controls are defined as clearly as possible*".

Thus, **Community financing should encourage the making of harmonised standards in a timely, fair, proportionate and consistent manner through operational grants and standardisation contracts, without impairing the autonomy of the ESOs.** Public funding should incentivise, not penalise the European standardisation system.

¹ Framework Contract on Evaluations ENTR / 04 / 093, Lot 1 - DG Enterprise and Industry - Final Report, submitted by GHK / Technopolis on 30th June 2009

POLICY OBJECTIVE C: Adaptation of the European standardisation system to new markets and societal challenges

European standardisation has been developed on the model of the international standards organisations, to contribute to rationalisation of production, growth of labour productivity, opening of markets and safety of products. Globalisation, new global challenges, “Better regulation” public policies, new societal demands as well as a growing share of services in the global economy and the boosting of innovation to resolve the current economic crisis request standardisation to adapt its traditional structures.

Standards remain voluntary instruments. Their effect depends on their credibility and of the level of consensus that they represent. The current diversification of the use of standards requires a broadening of the range of partners involved in the standardisation process, meaning enhanced openness, transparency and balanced representation.

Standards facilitate global trade and access to markets. Standards need to be accessible for all users, and the availability of translations of standards can help disseminate new technologies.

General considerations:

- Standards serve goals other than legislation: their relevance therefore depends on their capacity to serve the needs of the market first.
- The effect of standards on society depends first of all on the number of companies that will use them for designing products or supplying services, either in limited number or in niche markets (specific standards), or in larger numbers in consumer markets or for common technologies and processes (generic standards). The credibility and the level of consensus that standards represent is consequently related to their scope and the potential number of users.
- The current diversification of the use of standards does not require a systematic broadening of the range of partners involved in the standardisation process. It is obvious that the effects on society of standards depend on their being attractive to companies, which pay the bulk of their development costs. If standards are developed without taking into consideration industry’s needs, they will not be used in the design of products or the supply of services, and will eventually fail to benefit society or support innovation in strategic markets.

Question 6 (Q5 in French version): Should the WTO principles of transparency, openness, impartiality, consensus, efficiency, relevance and consistency² be integrated in the legal framework of European standardisation (especially in EU Directive 98/34/EC or in its successor)? How should this be implemented?

No. Orgalime believes that there is no need to integrate the WTO principles in EU Directive 98/34/EC or in its successor for the following reasons:

- 1) The ESOs and the national members of CEN and CENELEC already comply with the WTO/ TBT principles and beyond
- 2) Such an integration would open up the possibility to extend the list of recognised ESOs. While this may appear to some businesses as stimulating ESOs to respond in an efficient manner to business needs, it would generate several negative impacts:
 - the consistency of the overall standards portfolio may be jeopardised due to the limited number of available competent experts (duplication of standardisation work);
 - standardisation activities becoming scattered in this way would jeopardize company awareness of relevant standards for their business, efforts to achieve wider interoperability of products and systems, and the overall business goal of “one standard, one test, accepted everywhere”;

² As approved in the Decision of the Committee on principles for the development of international standards, guides and recommendations with relation to article 2, 5 and annex 3 of the WTO/TBT Agreement (G/TBT1/rev.8 23 may 2002)

- stakeholder participation would decrease because of the growing uncertainty as to whether investment in standardisation work will meet the expected outcome (as a consequence of competition between different recognised ESOs).
 - it may even widen the possibilities for private parties to manipulate standardisation outcome for their particular interests, as is already the case for some CEN Workshop Agreements, and thus could reduce the legitimacy of formal standards, which would once again be at odds with what is on the bill.
 - in particular, it could enable (foreign) consortia that meet the European recognition criteria to get their European standards acknowledged as internationally recognised standards against the WTO-TBT criteria, without the control of the currently legitimate European-only CEN and CENELEC standardisation bodies.
- 3) Moreover, it should be remembered that the European standardisation system does not work as a “closed shop”. In many cases processes are undertaken within the Vienna or Dresden agreements, in close cooperation with ISO or IEC; the international integration brings added value to the whole system, especially to standards users, and should be respected. Consequently Europe has implemented most international standards, far more than other countries or regions in the world, thus fulfilling the WTO TBT Agreement principles.

Instead of opening up the European standardisation system to a greater number of organisations, Orgalime favours a procedure whereby there would be a greater flexibility in EC financial control for enabling the current ESOs to subcontract work to external fora and consortia that meet the WTO-TBT criteria. The final adoption of a harmonised standard would remain the responsibility of the ESO governing bodies.

Question 7 (Q6 in French version): How could the participation of consumer organisations, environmental NGOs, trade unions and social partners, and SMEs be best promoted? What should be the role of public authorities (European Commission and Member States) in supporting such a participation in a transparent, open, impartial, consensual, efficient, relevant and consistent European standardisation system?

Due to the voluntary nature of standardisation, participation depends on its relevance to the needs of potential users of standards. Provided consumer organisations, environmental NGOs, trade unions, social partners and trade, crafts and SME associations are made aware of standards of interest to their members, access to the standardisation process should be open and in accordance with the WTO principles, as it is for companies that are directly involved in it and pay the bulk of its running costs.

Not all mainstream products, services or management standards need to integrate for example environmental or accessibility-for-all aspects; in other words everybody is not concerned by every standard. **The lack of experts and resources of NGOs and SMEs would not be solved by setting artificial minimum levels of participation for their claimed representatives at European level** as has been suggested during the discussions concerning the new visions; this would be counterproductive and conflict with the principle of openness of standardisation. Furthermore, it might lead to less involvement of business.

The participation of NGOs should be welcomed in all work where they have a genuine interest and therefore can contribute constructively. The existence of national mirror committees ensures that all stakeholders can actively participate in the work. The promotion of the participation of interested stakeholders in the process is the primary responsibility of NSOs, and is already practised in many EU Member States.

We believe that **authorities** reap benefits through using standards in their market surveillance and other supervision activities, that are not matched by their contributions. They **should show their commitment not only to participate but also to pay their fair share in the standardisation**

system by contributing to the funding of the national framework e.g. to help cover the basic running costs of the NSOs, thus ensuring that they fulfil the WTO principles.

The **financing of mirror committees in all Member States by the Commission is an interesting idea as it would help smaller countries or those with less industry concerned to participate** in standardisation. However such funding should be very well balanced according to needs and expertise. A level playing field must be maintained. It would not be desirable to encourage by Commission financing countries or stakeholders who are not affected by a particular standard to participate whatever the cost. This may have a negative impact on the efficiency of the standardisation process and the quality of standards.

Question 7b (Q7 in French version): How could the NSOs (National Standards Organisations) deepen their cooperation, and mutualise their activities? Could the following tasks be shared amongst several NSOs? 1.Management of the Secretariats of Technical Committees? 2.Notification of new national standardisation projects? 3.Promotion/sales of standards? 4.Others?

The European and international standardisation systems are based on the principle of membership of NSOs, the main reason for this being that proper and democratic inquiry must be guaranteed in order to give to products the necessary legal mandate and to provide confidence in the market. The expectations of societal stakeholders are best reflected at home in own language by local, national, trade sector, consumer or other interest-group associations, and are best channelled through NSOs into the European standardisation system. **Therefore it is not up to the legal framework to influence the cooperation amongst them or adapt the traditional structures of standardisation** to *“reflect new societal demands as well as a growing share of services in the global economy and the boosting of innovation to resolve the current economic crisis”*.

1. Co-operation should as much as possible continue to be done at International level (in accordance with the Vienna (ISO/CEN) and Dresden (IEC/CENELEC) agreements, and the procedures used in IEC for agreement of new work items should serve as good guidance. The management of Technical Committee Secretariats is already shared amongst NSOs, depending on the interest expressed by their respective membership (market relevance test) and their financial possibilities; in this way the mutualisation of resources is already implemented de facto. There is no action needed in the industrial field, where democracy and consensus-building are rooted in a competent dialogue which responds to the needs of interested stakeholders. Such an approach could be extended to other standardisation fields, provided that NSOs remain independent from certification interests.
2. The notification of new national standardisation projects for the electrical sector already operates in a satisfactory way via the existing Vilamoura procedure. The notification of new national standardisation projects for the mechanical sector already operates in a satisfactory way and therefore should be promoted. Such procedures ensure a convergence of national standards within the EU and minimise barriers to trade in the regulated area. Rendering the notification process more complex or extending it may in the long run be self defeating, since scarce resources of company experts, especially from SMEs would be allocated to this rather than to work on standards.
3. Promotion/sales of standards contributes to the financing of ESOs and NSOs according to their individual operation model. Nationally oriented NGOs and most SMEs need the national focal point. The strength of NSOs is their close relationship with national stakeholders. For this reason ORGALIME is not in favour of weakening the position of NSOs. NSOs could cooperate on issues which make them more efficient, e.g. if they speak the same language

they could make use of the same promotional material, such as study books, course material, etc.

4. Other? See our answer under question 7.1.

NSOs are free members of ESOs and should have the freedom to evaluate and decide by themselves, on a case-by-case basis, if they need further cooperation with other NSOs.

Question 8: Without prejudice to the national delegation principle, how could the European Standards Organisations (ESOs) manage directly, on a case by case basis, some standardisation activities, especially some Technical Committees?

The question seems to ignore the fact that Technical Committees (TC) are indeed managed by the ESOs directly through their technical boards. Perhaps the question refers to the role of the central structures of the ESOs vs. the role taken by their members? In our view, it is the responsibility of ESO members to decide which role they entrust to their central structures/offices, and which is best performed by other parts of the organisation, for instance the members.

There is no evidence that a centralised Brussels-based team of TC secretaries would do a better job than is today the case. On the contrary, we believe that the direct involvement of stakeholders, for the mechanical field, in the role of President of a TC, or, for the electrical field, in the role of President or Secretary of a TC, is a better guarantee that the TCs are managed with the appropriate topical expertise, which is more important for the quality and relevance of standards than a greater knowledge of the standardisation procedures.

Question 9: What support should the European Commission provide to facilitate the use of European standards as a means to open global markets? What would be the operational means that the Commission should use? (Support experts' participation in international standardisation activities, translation of European standards into extra-community languages?)

The facilitation of the use of European standards as a means to open global markets is already ensured by the Dresden and Vienna agreements, which enable a European input to standardisation work at ISO and IEC level. The use of International Standards as harmonised standards in the context of the New Approach is a better incentive to open European standards to the global market, as recently shown in discussions in international fora such as the UNECE WP6.

The best support that the European Commission could provide to ensure open global markets would be to take up the issue in international trade agreements. First and foremost, we need global *implementation* of international standards and acceptance by the authorities that compliance with international standards gives market access. As an alternative the Commission could negotiate market access on a bilateral basis where there is compliance with European standards.

The proposal to co-finance the participation of experts in international standardisation could help some stakeholders, especially in business areas with a large number of SMEs. However, this might entail a negative impact: it may breach the principle of national delegation which has proven to be the most effective way to enable a wide stakeholder participation, even for specific stakeholder groups, and which should be maintained. It could weaken the role of national committees that prepare input at international level.

Other support activities which might also be useful could be to facilitate the use of European standards within the Internal Market. Therefore, we recommend that the European Commission finances:

- **the drafting in all EU languages of explanatory summaries of standards already at their final drafting stage**, in order to increase interest among European SMEs. The funding should cover all European languages in order to bridge the linguistic gap at a time when the English language has become de facto the single working language of European standardisation working groups and technical committees.
- **the promotion of the inclusion of standardisation best practices and benefits at all levels of education**, especially higher education through the 'Erasmus'³ programme or through other educational initiatives such as 'Leonardo da Vinci' (vocational training)⁴ or life-long learning programmes⁵.

Question 10: Under which conditions do you think that the European Commission could launch, on a case by case basis, calls for tenders, open to the ESOs and to other organisations, to develop standards supporting EU policies and legislation?

Orgalime would not be in favour of establishing calls for tenders to develop standards supporting EU policies and legislation. The work of ESOs currently covers every area of potential standardisation, including services. The current procedure for mandates has proven its efficiency. There is no need to open up the European standardisation to other organisations.

Orgalime believes that calls for tenders to develop standards supporting EU policies and legislation would be a high risk exercise, leading to a deterioration of the strong points of the ESS. First, it might lead to a focus on price/time instead of quality. Then, it might create inconsistencies and lack of transparency. It would require experts to participate in many different fora, which would ultimately lead to a more complex system with higher costs, also due to the need for more cooperation between more parties. It would undermine the agreements between the recognised European and International standardisation bodies which currently maximise the global development of trade and avert new barriers to international trade.

By adding some other SDOs to the list of the 3 existing ESOs, recognised by Directive 98/34/EC, the risk also arises that non-European or non-full-public consensus SDOs will obtain legal status in European legislation. This cannot be in the interest either of industry or of the legislator. Furthermore, it would undermine the concepts of a single Europe, a single market for products and services, and an EU-level standardisation system based on the principles of the New Approach. It would contradict the objective of 'strengthening the European standardisation system'. It would encourage fragmentation and a lack of coherence, induce delays (e.g. who does what?) and impose extra costs. Moreover the open tender will lead to a bargain effect for some consultants ready to find ways for making business.

Besides, a document resulting from a tender published and paid for by the European Commission would be the propriety of the European Commission. Therefore, it cannot be considered as a standard according to the rules of European standards organisations!

³ http://eacea.ec.europa.eu/llp/erasmus/erasmus_multilateral_projects_en.php

⁴ http://eacea.ec.europa.eu/llp/leonardo/leonardo_da_vinci_multilateral_projects_en.php

⁵ http://eacea.ec.europa.eu/llp/index_en.php

Question 11: What is, in your view, the most efficient level of participation in the process of standards development: national, European, international?

The best way to attract stakeholders to provide the necessary technical input for drafting a standard and for choosing what is the most appropriate level (national, European or international) for a new work item project, is to consider the issues of market relevance, maturity of technologies, time-to-market and the avoidance of regional and differences.

All 3 levels of standardisation have their advantages:

- national standardisation is more relevant for specific and local needs, and for taking into account the need to be consistent for safety reasons with the installed basis (such as existing installations which are specifically excluded from the LVD for that reason);
- European standardisation provides support for EU legislation;
- international standardisation enables a common understanding at global level which could be implemented into regional and local standardisation, and thereby limit the large number of national deviations.

The overall business goal is “one standard, one test, accepted everywhere”. With this in mind, it is clear that the most efficient level for the development of standards is international, while of course the result must be applied at national level. National standards organisations are close to stakeholders who will determine in a democratic process the content of a standard and can bring the standard up to the international level and also ensure its diffusion at national level.

There are however a significant number of standards that are developed in areas that are not regulated at European level. In these cases standards development at national level is efficient.

Orgalime believes that national standardisation organisations should remain the basis of regional (European) and international standardisation for many reasons:

- Standards produced in this way gain the consensus of the widest group of stakeholders, provided that NSOs remain independent.
- International standards, like European standards, benefit from the legitimacy provided through national inquiries and acceptance.
- In a global economy the participation of multinational companies in NSOs can develop into a resource.

Question 12: In your opinion, where is the major added value in European standardisation with respect to national standardisation?

The major added value in European standardisation with respect to national standardisation is to help eliminate barriers to trade within the internal market. A European standard is uniformly implemented in 31 European countries (plus 15 affiliate countries) as a national standard, with the obligation to withdraw any conflicting standards. Products and services which are designed or supplied using these standards provide the assurance of state of the art and are presumed to be in conformity with European legislation. Thus European standards increase the common value of the European manufacturing and service industry **and facilitate the demonstration of conformity with the legislative framework.**

Orgalime supports the alignment of existing and future legislation, that would harmonise the conditions for placing manufactured products on the Community market with the New Approach model, as described in the New Legislative Framework (Regulation 765/2008/EC and Decision 768/2008/EC), where the use of standards provides the above-mentioned benefits.

POLICY OBJECTIVE D: Cost of standards

The costs of purchasing standards have been identified as an important barrier to their use, especially by SMEs. Purchasing a full collection of standards is sometimes necessary to answer a call for tender, access specific markets or take full advantage of the benefits of “New Approach” regulation. Some stakeholders consider that the price of standards – different in every National Standards Organisations – is too high with respect to their function of public interest.

Question 13: What are, in your view, the most serious barriers to the use of standards by enterprises: costs of standards (purchasing price)? Costs of operational implementation? Access to information? Knowledge of existing standards? ⁶

Although it is often maintained that the purchase price is the most significant barrier to using standards, Orgalime believes that there are many barriers to the use of standards by enterprises. In our view the purchase price is much less important than other factors. This is clearly shown in the conclusions of the CEN/CENELEC SME-Access study undertaken by the Erasmus University Rotterdam⁷.

Among others, the following causes result in costs for enterprises, listed by degree of importance.

1. Lack of awareness of the importance of standards for their own company in particular at a technical level

The most important barrier is the **ignorance of the economic gains** that the application of standards can provide for companies, especially SMEs. This starts with a lack of awareness of standards in general and of specific standards. Although the purchase price is clear, enterprises often do not know how to calculate the benefit of using standards because they are not aware of the added value of standards for their own company.

Orgalime would strongly advise **promoting education about the role of standards at all levels**, and every effort should be made to spread among all market operators guidelines and best practices about the role of standards in support of risk assessment and compliance with applicable EU legislation.

National and EU measures should strive for better education about standards, for example in technical schools to start with. This also means enhanced cooperation between NSOs and trade associations and ad hoc simple-to-grasp information to SMEs on the benefits provided by standards.

2. Lack of awareness of the importance of standards for their own company in particular at a management level

Apart from the application of standards, the economic benefit of participation of enterprises in relevant standardisation committees is often unknown to management.

Especially for SMEs, the growing lack of interest, involvement or even knowledge about standards and the standardisation process among CEOs and managers is a problem, for both companies and standardisation organisations. Companies therefore run the risk of higher costs for development and production and loss of markets, while SDOs suffer from declining participation in the technical work. However, standardisation is a long-term process; CEOs must be aware that any immediate return on investment is not to be anticipated.

Therefore, Orgalime believes that the lack of support from CEOs should be tackled in the following ways:

- ESOs and NSOs should continue planning and developing marketing packages aimed at explaining standards benefits to corporate management;

⁶ These barriers have been identified in the Study “Access to Standardisation” - EIM March 2009, contracted by the EC:

⁷ <http://www.cenelec.eu/NR/ronlyres/88D06BD5-CA51-479D-A416-AB1F3BE67E66/0/SMEAccessReport20090821.pdf>

- Further efforts should be made to demonstrate the **economic benefits both at company level and in general**, but the identification of success stories (“case studies”) may also be helpful. Further clarity on this issue might be provided by the development of a tool to determine the benefit for companies of investing in standardisation;
- ESOs and NSOs must be able to show to their stakeholders that they are efficient and modern organisations, working with restructuring and cost reductions in the same ways as their stakeholders (“industry”) do;
- ESOs and NSOs should improve the management (organisation, priorities) of the large number of documents provided to experts; abstracts should be provided in order to allow experts and managers to identify quickly the relevance of documents and topics to their business.

3. Understanding and implementing standards

Many enterprises, especially SMEs, have difficulty understanding the wording of the standards, due to the need to be correct from the legislative and technical points of view. Often, especially for SMEs, English is a foreign language and constitutes a barrier. Implementing standards in the enterprise requires much proficiency in the company in order to bring into practice exactly what is meant by the authors of the standard. For standards users, the most serious barrier is the adaptation to new technologies, tools, which may be reflected in standards, particularly due to the fact that European regulation, mainly for health, safety and environmental reasons, introduces new requirements which have to be dealt with by standardisation. **When the standard requirements are applied correctly, the implementing cost is much more significant in comparison with the mere cost of purchase.**

4. Cost of purchasing standards

Common aspects which play a role in subjects to be standardised are mostly dealt with in a separate standard. This is an efficient way to standardise aspects, rather than to mention them in all standards where they play a role. Other standards using these aspects mostly make reference to these aspect standards. The consequence is that the price of a full set of standards for the conformity of one product can be rather high due to the large number of standards which are referred to (e.g. the well-known example of standard(s) for garage doors).

Consequently, we call on NSOs to consider significant price reductions on their catalogues of standards, in particular when provided in coherent sets by product categories or market segments. NSOs are also kindly invited to reconsider their pricing policy for direct users of standards, especially those that are members of trade associations or other stakeholder associations.

Orgalime believes that measures, as mentioned above, would contribute to overcome the barriers and facilitate the implementation of standards, especially for SMEs.



Question 14: What could the standards organisations do, in addition to their current practice, to facilitate the access to standards, especially by SMEs?

Orgalime believes that the quality and the adequacy of the information provided to all potential users of standards (not only SMEs) are of paramount importance for raising company awareness of the fitness-for-purpose of available standards.

ESOs and NSOs should find ways, possibly with the financial support of authorities, to reduce the mass of information which is currently generated by the distribution of files of uncommented documents: this is an obstacle to full and efficient stakeholder participation in the standardisation process.

The ESOs and NSOs should develop methods to communicate simply and clearly the state of progress of each standardisation project and deliver executive summaries together with the documents highlighting the achievements and the critical points. In other words, a professional project and document management system, as is often used in industry, should be implemented by the ESOs and NSOs.

This is a prerequisite to convince company managers that standardisation is for their very benefit. If financial support is provided by national and European authorities to facilitate access to standards, especially by SMEs, it should be provided to the operators of professional networks and sector-specific information channels such as those operated at national level by trade federations and other stakeholder associations, which are mandated to defend their stakeholders' interests.

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