



*The Director General*

Mr Antonio Tajani  
Vice President of the  
European Commission  
Responsible for Industry and Entrepreneurship  
B – 1049 Brussels

Brussels, 30 June 2014

***Subject: Position of the European engineering industries as standardisation's main stakeholder on the implementation of the European standardisation package***

Dear Vice President,

We are writing to you because we are deeply concerned by the way the European Commission is implementing Regulation EU 1025/2012 and is already now considering its revision.

Industry is the main stakeholder in standardisation; it invests an estimated 1 billion euro per year in standards development and purchase of standards and thereby covers between 90 to 95% of the total cost of standardisation in Europe.

Our industry is a long lasting supporter of the European standardisation system, which in our view is a useful instrument to boost performance of European Industry while addressing the Commission's objectives in the framework of the 'New Approach' (2008 New Legislative Framework).

Our concerns arise from the fact that we do not believe that, the policy direction taken by the Commission is mainstreaming competitiveness into standardisation which is a crucial area for industry. This is a time when rapid technological change in our industry requires a flexible, responsive and market driven standardisation system. This is essential to the competitiveness of our industry in Europe and on global markets.

We therefore wish to highlight six areas of particular concern to us:

**1. Participation in the Committee on standards.** Industry being the prime stakeholder of standardisation finds it difficult to understand why it is not invited to participate as an observer within the Committee on Standards provided for under Regulation EU 1025/2012, where standardisation policy and priorities are discussed. This is both illogical and, in our view, an unbalanced approach, while other stakeholders, largely financed by public money, are invited to participate.

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*The European Engineering Industries Association*

**2. Standards are not a substitute for law.** We are increasingly sceptical of the European Commission's vision to use "*standard setting*" to develop a "*horizontal approach to industrial policy*"<sup>1</sup>. Whereas we fully support Commission mandates under product specific legislation (New Approach), we are not in favour of top-down initiated "*standards (...) to be adapted to help European policy address the 'big issues' such as climate change, sustainability, ageing, and innovation in general*"<sup>2</sup>.

We believe that recently adopted or foreseen standardisation mandates issued to CEN and CENELEC on such issues, which have an unspecified policy goal, are too general to mobilise the efforts of a voluntary acting standardisation community. Standardisers should not be policy makers – solutions to 'big societal issues' should be decided by legislators, not standardisers.

We moreover doubt whether such horizontal standards, which are of voluntary use, will offer practical value added to companies operating in Europe. Companies in our sectors, most of which are SMEs, are more likely to concentrate their limited resources on developing standards first and foremost to meet their particular market needs.

**3. Disproportionate focus on standards facilitating innovation:** Standards are – and should remain - a description of '*the state of the art*', that is a well-tested procedure. For our sectors, standardisation activities to harmonise market access conditions for products and services are by far the most important ones. Therefore, we are concerned that the European Commission seeks to align the framework conditions for European standardisation prominently on standardisation in support of innovation.

The main priority of the European Commission should be on the large majority of other standardisation objectives, which are important for industry's competitiveness.

Consequently, we call on the European Commission to provide a flexible framework for European standards organisations to support the whole range of standardisation objectives.

**4. On-going negotiations of the Framework Partnership Agreement (FPA):** we regret that the European Commission has set the pre-requisite for increased speed in the development time of standards to co-sign the Framework Partnership Agreement with European Standards Organisations. We do not understand the need for the European Commission to place what we see as disproportionate pressure on ESOs, without consideration for the progress made or the sector concerned. Such key performance indicators (KPI) should take into consideration that standardisation is based on the voluntary input of industry experts.

Assessing the performance of standardisation activities vary depending on the sort of standard and industry branch. Stakeholders and experts in CEN and CENELEC Technical Committees are best positioned to judge what prevails in terms of timing, consensus building and quality of the resulting standard, under the scrutiny of 'New Approach'/NLF consultants. Due to the difficulties in identifying generic KPIs such as speed of standardisation, we reiterate strongly our plea to include relevant KPIs in the specific contracts, rather than in the FPA.<sup>3</sup>

The currently unresolved disagreement between ESOs and the European Commission generates side effects that are detrimental to companies' competitiveness and confidence in the system: 'New Approach'/NLF consultants' work has been on hold since the 1<sup>st</sup> January 2014, a wide range of adopted standards are consequently blocked from citation in the Official Journal of the European Union (OJEU) and voluntary experts in technical committees – who are the backbone of the European standardisation system – are starting to lose confidence.

<sup>1</sup> [COM\(2010\) 2020 final](#) "Europe 2020: A strategy for smart, sustainable and inclusive growth" of 3.3.2010, page 16: "At EU level, the Commission will work: (...) to develop a horizontal approach to industrial policy combining different policy instruments (e.g. (...) standard setting; [COM\(2011\)311](#) - Commission communication on a strategic vision for European standards.

<sup>2</sup> [COM\(2010\) 614](#) "An Integrated Industrial Policy for the Globalisation Era Putting Competitiveness and Sustainability at Centre Stage" of October 2010, page 10.

<sup>3</sup> [Joint industry/CEN-CENELEC position](#) "Quality versus speed for European Standards" (21/02/\*2014)

Therefore we are calling on the European Commission for a rapid solution to overcome this unfortunate situation.

**5. European Commission delaying the publication of harmonised standards in the OJEU** (cf. [Vademecum](#) on monitoring of draft mandates page 10). After almost 30 years of successful co-operation, we are now increasingly seeing the Commission interfering in CEN and CENELEC's established practices in technical committees with regards to the drafting of the informative "Annex Z" to harmonised standards for an increasing number of 'New Approach'/NLF Directives. Such a request unnecessarily delays the drafting of standards and does not allow industry to benefit from a timely citation of adopted standards in the OJEU. It is all the more frustrating when technical committees are asked to perform modifications on standards that are already published.

In this context, we regret even more not being directly consulted on the ongoing revision of the *Vademecum* on European standardisation, which is likely to have practical consequences on the main stakeholder and user of standards. Nevertheless we will comment on the version made available via the "[notification system](#)" by 15 September 2014.

## 6. Too hasty review of the ESS

Stability is needed for the whole set-up of the European Standardisation System (ESS). Yet at the beginning 2014, the European Commission contracted a consulting company to conduct an "independent review" of the "European Standardisation system" (further to its last recommendation in [COM\(2011\)311](#)). We believe it is too early to draw conclusions on whether the so-called "*standardisation package*" *increases speed, innovation, and the "inclusiveness" of stakeholders in standardisation*". Much time has been spent on analysing the system in preceding years (for example in the EXPRESS group's work) – the result was what could be reasonably attained in the decision process. Now is the time to let it be properly implemented before new changes are introduced.

## Conclusion

We call on the European Commission to engage in a serious dialogue with European industry stakeholders and European standards organisations to examine what are the real needs of industry today.

It is important that the needs of business are given priority in the standardisation system. If not, there is an increasing risk that companies, especially in our manufacturing sectors, could move work to external fora and consortia to conduct their standardisation activities, free from the bureaucracy arising from the European regulatory system.

To conclude, we thank you in advance for taking these recommendations into consideration for implementing Regulation EU 1025/2012 and future standardisation policy.

We have substantiated our concerns and claims in the annex.

We would be pleased to discuss this with you and your teams in relevant services, in association with the European Standards Organisations.

Yours sincerely,

Adrian Harris (original signed)

Cc: Cabinet: Mr Canga-Fano, Mr Kuck, Mr Pannella  
DG ENTR: Mr Calleja Crespo, Mr Peltomäki, Mr Pettinelli, Mr Cozigou, Mr Bollens, Mr Garcia Porras, Mr Girao, Ms Weidel

## *Annex (letter of 30 June 2014)*

*to the position of the European engineering industries as standardisation's main stakeholder on the implementation of the European standardisation package*

### **1. Industry interests should be represented in the Committee on Standards**

Industry is the main stakeholder of European standardisation and represents the large majority of standards users, too. Orgalime together with partner European sector associations voice the concerns of millions of companies, most of which are SMEs. These companies contribute the most to the overall budget of the European standardisation system (90-95% of it is from private origin).

Contrary to the European Commission's approach as reflected in [COM\(2011\)311](#) (Commission communication on a strategic vision for European standards) we believe that it is up to companies to determine how standardisation can best support their needs and those of their customers. These needs depend on a great variety of parameters involving the type, size, and sector of the industry or businesses concerned, whether they are export-oriented or not, include significant manufacturing, logistics or services, incorporate new, fast-changing or evolving technologies and applications.

While national and European standards organisations organise the development of standards supporting the needs of standards' users, they have no mandate to devise jointly with national and European policy makers any industrial strategy orientations on their behalf. It is the mandate of national and European trade associations, to voice the expectations of companies, including the smaller ones, on the role of standards and standardisation in their sectors.

The financial support of organisations referred to in the Annex III of Regulation 1025/2012 cannot become a substitute for the application of the equity principle. The Regulation does not justify the European Commission discriminating against other relevant European standardisation stakeholder organisations, especially registered independent European trade associations and their membership. Such a bias is difficult to accept in the framework of transparent institutions operating in a better regulation framework.

Therefore, we call on the European Commission to ensure that European industry stakeholders can participate as an observer in the Regulatory Committee laid for in Article 22 of Regulation EU 1025/2012, for example according to a model similar to the EAAB. No one else could effectively and independently voice the views of industry today in this Committee, including Small Business Standards. Besides, it would acknowledge the societal dimension of industry stakeholders as being representative of all those that invest in research and innovation, create jobs and growth within the single market.

Such participation would greatly contribute to the Committee's understanding of industry and business needs by:

- improving the drafting of standardisation requests (mandates) to CEN, CENELEC and ETSI, so as to maximise the chances that their scope and relevance will meet market needs and business stakeholders' interests.
- monitoring the independent review of the European Standardisation System and helping to approximate policy needs with those of the market.
- revising the *Vademecum* on standards and contributing to solve misunderstandings and varying interpretations on the role of standards or the legal relevance of the presumption of conformity to European legislation, as has unfortunately been the case for the Medical Device Directives (involving DG SANCO) and the Gas Appliance Directive (involving DG ENTERPRISE and INDUSTRY).

**2. European standards should not be seen as an extension of European policies and legislation. They need to be relevant for companies to meet their market needs and facilitate their compliance with legal requirements.**

For more than a century, standards have been a successful tool because they result from bottom-up initiated standardisation projects (mostly from industry) and have been developed by voluntary experts. The outcome is market relevant standards that are attractive to industry because they are relevant for their market, and are subsequently applied on a voluntary basis. European standards fundamental underlying rationale has not changed.

As long as standards are initiated and designed by the main interested stakeholders to meet their market needs, they are more likely to be used and to deliver benefits for the economic sector concerned and for society at large.

On the contrary, if standards are conceived as macro-economic policy instruments that act as a top-down extension of the law with the same ambition to shape Europe's economic and innovation future, they are likely to fail.

Why? Because they risk being at odds with the expectations of those companies that are supposed to invest in developing, buying and using them: policy inspired standards, which would be engineered by researchers, academia, and consultancies are doomed to remain marginal. Policy making on big societal issues should not become the responsibility standardisers, but should remain within the remit of legislators.

Furthermore, it is our view that the European policy maker should not aim at standardising everything, especially in areas where the cross-border benefit is not relevant for economic operators, as is the case for many services.

This is also true in regards to the use of standards in R&D and innovation: existing standards are often useful to underpin the innovation process at the preliminary phase and through providing background information for validation and experimental research. However, innovation itself should only be standardised if the technology is mature enough to offer a market perspective to business and if standards are developed with a view to facilitating market uptake. The decision whether standards are an appropriate tool to support innovation should remain entirely up to industry and, in each particular case, up to the companies that have to decide to invest and take the risk of applying new technologies.

Therefore, we are concerned when we see Commission services shifting policy targets in standardisation requests to European Standards Organisations.

Recent examples are:

- [Mandate M/473](#) to include "Design for All" in relevant standardisation initiatives of 18 November 2013;
- The overall "Standards for innovation" macro-economic approach of the European Commission, which has been recently illustrated in a "Foresight study" mostly conducted by the JRC, researchers and academia.
- [Draft Mandate](#) in support of the implementation of the Communication [COM(2013) 216 final] relating to the EU Strategy on Adaptation to Climate Change of 25/10/2013.

We fear that such an approach may end up being counterproductive for the European economy and small manufacturers in particular.

Consequently, Orgalime and other European industry organisations have requested CEN and CENELEC to consider reviewing their adoption procedure of draft Commission standardisation requests, with a view to better identifying the potentially affected market sectors and investigating whether they consider it useful to start a new standardisation project that could meet both their market needs and policy needs.

### 3. Disproportionate focus on standards for innovation

Standardisation is downstream of the innovation process as a rule. It is used after the market introduction of innovations as a means for the description of the state of the art.

Even if the supportive role of standardisation in the innovation process is recognised, especially in convergent technologies and complex systems with a large number of interfaces, its potential to promote innovation must be realistically analysed and should not be overstated.

With new converging technologies and complex systems, it is important to be proactive at an early stage in the standardisation work. Therefore standards can be used to achieve economies of scale that are required as a prerequisite for successful market penetration. In addition, standards can be helpful as a basis for further developments, in defining a common terminology, as well as measuring and testing methods.

However besides science, the involvement of all industry key stakeholders is a prerequisite for the success of such standardisation activities.

Engineering practices also indicate numerous examples where the implementation of innovations in the market does not require any standardisation. In these company-or industry-specific cases, a top down "prescribed" standardisation programme would risk creating a straight-jacket for industry, restricting flexibility to innovate e.g. as it is the case for construction materials where standards are mandatory.

Furthermore, the idea that standards should also be implemented in rapidly changing markets can be counterproductive in terms of innovation, as has been perceived in areas such as additive manufacturing, smart grids, or energy storage.

Besides, the trend towards the growing participation of research and technology organisations (RTOs) in European standardisation committees is a consequence of the wording of topics in the Commission's 'Horizon 2020' framework programme. In our view, it is inappropriate to conceive an EU-funded Research and Innovation project to establish standards as if the technological paths could be one-way driven by a single consortium.

### 4. Let European standards organisations (ESOs) decide with their stakeholders on their own governance

Community financing should support certain elements of the development of harmonised standards in a timely, fair, proportionate and consistent manner through operational grants (for example for the work of the 'New Approach'/NLF consultants), without impairing the autonomy of the ESOs. Public funding should incentivise, not penalise the European standardisation system, e.g. by introducing yet more bureaucracy into the system.

In the context of the on-going negotiations on the Framework Partnership Agreement (FPA), we regret that the European Commission places disproportionate pressure on the European Standards Organisations' to respect a number of Key Performance Indicators (KPIs), such as reducing the development time of standards without consideration for the progress made or the sector concerned<sup>4</sup>.

We fully understand CEN and CENELEC's refusal to sign the FPA for 2014 as proposed by the European Commission under these conditions: such an approach takes no account of fundamental principles underlying standardisation work (voluntary participating experts, time for reaching consensus etc...). Furthermore for industry, speed should not be at the expense of quality.

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<sup>4</sup> Orgalime joint position paper with CEN and CENELEC on "Quality versus Speed for European Standards", 21 February 2014.

However, we are concerned that such an unresolved disagreement between CEN, CENELEC and the European Commission generates several side effects which have a detrimental impact on companies and their confidence in the future of the system:

- ‘New Approach’ consultants’ work has been on hold since the 1<sup>st</sup> January 2014, as their financing is covered by the FPA (as specified in article 10(5) of Regulation EU 1025/2012). This creates a huge backlog of non-assessed standards.
- Some Commission services are refusing to reference adopted harmonised standards in the OJEU, as long as the consultants do not assess them beforehand.
- Voluntary experts in technical committees, which are the backbone of the European standardisation system, are starting to lose confidence in the Commission’s ability to provide them with supportive framework conditions.

Therefore, we believe that regulators should not seek to question the governance structures of European Standards Organisations (ESOs), nor to impose adaptations that are not supported by their members, the national standards bodies (NSBs) and the variety of national stakeholders represented by them.

As private organisations, NSBs should remain free to decide for themselves the best ways to carry out their tasks, using a bottom-up approach based on the voluntary participation of experts. Any top-down attempt to transform ESOs and NSBs into service providers, working to answer EU policy needs, would undermine the basic standardisation principles which are essential to generate benefits out of any standardisation activity.

Finally, we would like to point out to the European policymaker the risk that companies, especially in our manufacturing sectors, could move work to external fora and consortia to conduct their standardisation activities, free from the bureaucracy arising from the European regulatory system.

## **5. The Commission should not block the publication of European standards in the OJEU because of disputes about the presentation in ‘Annex Z’**

A standard is a private and voluntary document that aims at reflecting the state of the art and the best means for market stakeholders to take it into consideration. It is not an extension of the law (except in rare and specific cases, when the law specifies that the use of a given standard is mandatory). Consequently, as soon as it is adopted by CEN, CENELEC or ETSI, it is available for use by all interested stakeholders, with or without referencing in the Official Journal of the EU.

The Council Resolution of 7 May 1985 introduced the mechanism of a "presumption of conformity" of a product with European harmonisation legislation, if the manufacturer applies the standards whose references are listed in the Official Journal of the EU. Later on, an additional informative “Annex Z” was introduced for standards users. With regard to the presumption of conformity, such ‘Annex Z’ links up as far as is feasible the standard’s specifications with the essential requirements of the Directive or Regulation.

It is our belief that this mechanism of presumption of conformity is successfully providing benefits to companies using a European harmonised standard. In addition it facilitates the work of market surveillance authorities, legal inspectors, who need to appreciate the safety of the product and its conformity with legal requirements. This benefit is considered as significant by manufacturers, particularly those applying ‘module A’ (internal production controls) to demonstrate their conformity with the relevant harmonisation legislation (for example directives on Low Voltage equipment, machinery, Electromagnetic Compatibility or radio equipment).

Over the past few years certain services of the European Commission have increasingly challenged the presentation in “Annex Z” in harmonised standards as is unfortunately the case, for example, for medical devices or gas appliances.

In our view, such attitudes are in most cases questionable and detrimental to the legitimate wish of European standardisation bodies, to have adopted standards cited as soon as possible in the OJEU, to support manufacturers' efforts to comply with European legislation.

Consequently, those services of the Commission do not act in a balanced way when they block the citation of a harmonised standard in the OJEU, if the technical specifications of the standard do not contradict the essential requirements of the law. This is verified by the application of the consensus building principle and by the adoption process of standards that are open for all interested stakeholders, including national authorities. Furthermore, a 'New Approach'/NLF consultant funded by the European Commission assesses all draft harmonised standards (*cf. [Vademecum on monitoring of draft mandates page 8](#)*).

Finally, we wish to stress that this approach to conformity assessment based on the use of harmonised standards which underpins all legislation under the New Legislative Framework (NLF) is beneficial to the competitiveness of European industry. Undermining this benefit will directly affect companies, but will also lead to undermining the NLF as a system and thereby the internal market.

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