ORGALIME

Position Paper

Brussels, 12 September 2014

Orgalime comments on the European Commission's Draft Vademecum on European standardisation

Orgalime welcomes the European Commission's intention to 'revise and rationalise' the process of elaborating mandates/requests for standardisation *such as "to include a consultation phase with relevant stakeholders and a thorough analysis that justifies the need for new standard-setting activity".*

The 2008 New Legislative Framework that regulates most engineering products works well. We see no need to make changes to the European standardisation system, which complements it satisfactorily, especially in regard to the development time of standards, the supporting activities of European Standards Organisations (ESOs), and the involvement of "New Approach" consultants.

We are deeply concerned about ideas to make greater use of documents that lack consensus, such as those drafted by research institutes or test/certification bodies. Only a coherent standardisation system in Europe and internationally (related to ISO and IEC standards), rooted in consensus, transparency and openness, will be able to support European industry's competitiveness.

The Vademecum on European standardisation is an important guidance document which should describe, in a form acknowledgeable to all interested parties (including industry and other standardisation stakeholders), the role of standards in support of the application of Union legislation and how Commission services may interact with ESOs to develop standards, when needed.

Therefore, the difference in the role of standardisation compared to legislation should be made clear from the outset: harmonised standards are in no way to be considered as an extension of the law. We regret that this lengthy revised version of the Vademecum lacks transparency on describing a process that should apply to mandated standardisation only and on distinguishing it from other standardisation activities carried out by CEN, CENELEC and ETSI to meet the expectations of their own members and larger constituencies.

While some of the suggestions/clarifications seem appropriate, the revised Vademecum reflects a number of regrettable misconceptions, which may lead to wrong assumptions among Commission services of what the European Standardisation Organisations and their stakeholders could deliver.

The document specifies a variety of new requirements for ESOs that do not take into account the positive experiences collected over the last two decades of successful cooperation between the European Commission and ESOs to prepare candidate harmonised standards in support of compliance with Union harmonisation legislation. In particular in Part III, this document partly neglects existing framework conditions on both sides (legislation, standardisation) and jeopardises existing achievements that support the smooth operation of the EU Single Market. This seems to us to run counter to the objective of ensuring the mainstreaming of competitiveness into all policies.

Therefore, we are pleased to provide our comments and suggestions for improving this important document for the smooth operation of European standardisation.

Orgalime, the European Engineering Industries Association, speaks for 40 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 23 European countries. The industry employs some 10.3 million people in the EU and in 2013 accounted for some €1,800 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.

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1. GENERAL COMMENTS

1.1 Role of standards

The document includes a number of worrying misconceptions about the role of standards "*in support of Union legislation*". Therefore, we would like to reiterate the following principles:

1. The voluntary character of standards is stressed in the Vademecum. This means that they support legislation only insofar as they are actually purchased and used by interested economic operators.
2. Standards are not laws (whether mandated or not). Standards' development should remain free from interference by public authorities, including on the validation of technical specifications such as testing methods (contrary to what is stated under Part II, section 3.9).
3. Meaning of presumption of conformity: Because standards are not an extension of Union legislation, presumption of conformity should remain "*prima facie evidence*" (initial proof) that products designed according to European harmonised standards are meeting Union legislation. For the past 40 years – since the Low Voltage Directive (1973) – presumption of conformity has facilitated manufacturers' demonstration of conformity. It was never meant as an obligation for manufacturers to use standards, nor to bind authorities to "*automatically accept [it]*" (Part II, section 3.7.1), nor to discharge these authorities from carrying out a risk or compliance assessment on suspicious products.
4. Legal relevance of harmonised standards: It is because the bona fide and knowledgeable manufacturing industry values the facilitation of the presumption of conformity, that it continues investing in developing and applying harmonised standards, while rogue operators ignore both rules and harmonised standards. However, all stakeholders are equal before the law and market surveillance authorities have a duty to verify product conformity directly against the essential/legal requirements and not against the standard alone, if a manufacturer chooses not to make use of the advantage provided by the harmonised standard for the purposes of undertaking conformity assessment.
5. Legal and economic relevance of European standards: although they are developed without a prior request from EU, they do not have a negative role, contrary to what is stated in Part I. On the contrary, they contribute to improve free movement within the Single Market. Whether mandated or not, their role is to facilitate the economic operator's task to demonstrate compliance with both market/technical requirements AND Union legislation. Whether they are of European or international origin (ISO/IEC), the referencing of these non-mandated standards in the OJEU should remain possible after a detailed assessment, as is currently the case under Union legislation providing for framework mandates or the GPSD.

1.2 Role of standardisation actors

1. "Standardisation needs" should be assessed by both public and private parties: Consequently, there is no such thing as (mandated) standards supporting legislation on the one hand, and standards supporting market needs on the other hand. The whole point of standards is to provide a way for manufacturers and service providers to meet both public policy needs and private market interests.
2. Public authorities are invited to participate in standardisation work, as mentioned in Regulation EU 1025/2012. However the Vademecum should insist on the reasons why -, that is to ensure that public interests such as health & safety and environmental protection are taken into consideration during the standardisation process. Likewise, their participation at an early stage in the elaboration of standards contributes to a well-balanced consensus

with all other stakeholders. It also avoids misguided interference at the end of the standardisation process, including the misuse of formal objections.

3. Role of standardisation actors: in various places the document, in our view does not provide a correct interpretation of Article 10(5) of Regulation (EU) No 1025/2012 regarding the assessment of the compliance of candidate harmonised standards. According to this Article the Commission should make such an assessment **together** with the ESOs. Two independent and uncoordinated assessments would result in time delays and different interpretations, which in turn would hamper the effectiveness of the whole system. In this respect, we wonder why the document makes no mention of the current practice of using "New Approach" consultants to assist with the assessment process of new standards.
4. Role of stakeholders: industry should be acknowledged as the main – and most important – group of standardisation stakeholders. There is no way to prepare European standards without the involvement of its mainly private experts. ESOs and their members are not "executing" the technical work for the development of standards but are coordinating the work that is mostly performed by company experts. It is therefore more than legitimate to consider these stakeholders as a legitimate group of "actors" in the European Standardisation System (ESS) (this is missing in Part I section 3.1 in the table on page 9).

Therefore we call on the European Commission to reformulate the draft revised Vademecum with a view to clarifying that the European standard-setting system is not part of EU law-making and that Regulation EU 1025/2012 is not a reason to impose unnecessary bureaucratic requirements on standardisers (such as Annex Z) who, for the most part, are not civil servants but voluntary experts on the payroll of private companies, most of which are SMEs. This clearly runs counter to the much-vaunted support of the Commission for simplifying the application of regulation and helping SMEs.

1.3 Consultation of industry (and other) stakeholders

As mentioned before, the success of standard-setting lies in ensuring that the candidate standard or deliverable meets both public AND private interests. Therefore:

- We acknowledge the usefulness of the annual Union Work Programme (UWP) in providing an overview of planned requests from the Commission services. However, it is not appropriate as the only public consultation on specific requests. Stakeholders cannot judge the usefulness of such planned requests on the mere basis of the UWP, which remains vague on policy objectives and content.
- We regret that the revised Vademecum does not mention Article 12 of Regulation EU 1025/2012 which provides that the Commission should develop *a notification system for all interested parties*. It is therefore misleading and counter-productive to stress the difference between "mandatory consultations" (of for example stakeholders mentioned in Regulation EU 1025/2012) and "*other relevant European level stakeholder organisations which are representing typical users of requested deliverables*" (under Part II, section 4.5).
- The revised Vademecum should explain that such a consultation of all interested parties is key for ensuring the market relevance of European harmonised standards. The market relevance of candidate standards cannot be appropriately assessed by Member States, either in the relevant regulatory committees of Union harmonisation legislation or in the Committee on Standards. Therefore an appropriate consultation:
    - should involve ALL relevant stakeholders, including industry organisations and not only "*ESOs and sectorial experts of the Member States*", or those "*receiving Union funding*" (as mentioned in the Vademecum, table 3 under Part II section 4.5. Cf. also Part I section 4.2 paragraph 2).
    - is not only necessary on the annual Union Work Programme (UWP) but also on all draft standardisation requests (mandates) from the many Commission services; These should be more consistently posted in the "notification system" provided for under Article 12 (see Vademecum Part II, point 3.3.2)

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- should occur early enough so that industry stakeholder comments can result in more than just minor details being changed, as stated in the paper.

2. COMMENTS ON PART I: ROLE OF THE COMMISSION'S STANDARDISATION REQUESTS TO THE EUROPEAN STANDARDISATION ORGANISATIONS

Standards vs. technical specifications

On Page 6, No. 2.1: The Draft states "*however the legislator may on case by case also use technical specifications developed elsewhere*". We strongly support the New Legislative Framework (NLF) concept supported by mandated harmonised standards in Europe. Therefore, we are concerned about the possibility to use technical specifications – such as international fora agreements – which often do not result from a consensus and would jeopardise the coherence of the European standardisation system.

Union Work Programme (UWP)

According to Regulation (1025/2012), the Commission must indicate policy objectives and societal interests in the request for a standard. According to article 8.2 such specific goals and policies should already be formulated in the UWP. This should be better described in the Vademecum and fulfilled in practice, as it will facilitate responses to the consultation.

Content of mandates

Orgalime welcomes the statements (on pages 8 and 10) that standardisation requests should be 'precise' – and that the Commission cannot 'delegate political power' to private organisations (ESOs). This corresponds to the position expressed in Part II, section 3.6 that '*an insufficiently precise mandate will lead to differences in interpretation and to a possibility that the ESOs will deliver work that is not well targeted to the public needs'.* This is exactly why Orgalime in its position papers calls for not mandating overall general challenges/concerns, such as climate change and innovation, without precise political objectives. Standardisers should not be requested to act as policy makers. Moreover, policy makers should not act as technical experts, but leave the room for finding the right solutions to standardisers.

Market relevance

On Page 9, No.3.1: We are concerned about the following statement: "*One of the specific actors in this market is the public authorities, which may consider a need for technical specifications in order to support implementation of legislation or its policies*." In practice, policy needs cannot be decoupled from market needs that are determined by economic operators and other stakeholders (industry, service providers, NGOs, etc.).

Harmonised standards without a prior request are positive

Regulation EU 1025/2012 defines a harmonised standard as one developed on the basis of a request from the Commission and published in the OJEU. However, the revised Vademecum derives two erroneous conclusions from this:

1. On page 14, the text states that a standard *not* based on a mandate cannot be published in the OJEU, and thus cannot be accepted for giving presumption of conformity. We disagree with this statement which is counterproductive for the following reasons:
    - It challenges the well-established practice of framework mandates and the numerous standards that have been developed without a specific request from the Commission. Therefore we call on the Vademecum to clarify that existing standards developed within a framework mandate could continue to give presumption of conformity, even if there was no specific prior request from the Commission.
    - Practice shows that after a detailed assessment, such non-requested existing standards (international and/or European) could be used to give presumption of

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conformity. This was for example the case when the General Product Safety Directive was revised and the use of standards was introduced.

2. On page 20, section 4.6, the text further concludes that if European standards are developed outside relevant mandated work programmes (outside mandates) and are dealing with regulated subjects, they may have a negative impact on the functioning of the Single Market and on the transparency of European standardisation.

   However, basing a standard on a mandate (or not) has no impact on the transparency of the European standardisation system. The system is developed to ensure coherence of the total package of standards, so that there are no conflicts between new and existing standards. Therefore, the paragraph under section 4.6 dealing with 'regulated subjects' should be deleted as it is based on wrong assumptions.

Unnecessary call to update all existing standards

Page 24, last paragraph, tackles the adaptation of standards based on 'old' mandates. The text says that such "*standardisation work must respect the legal requirements given in the Regulation* EU 1025/2012 – *and thus the common requirements given in part III of this Vademecum".* These latter requirements need to be elaborated upon in a separate informative annex, including a table clarifying the correspondence between the technical specifications of the standard and the legal requirements aimed to be covered. Such an update of all existing standards would request to restart work on these standards, without a clear added value.

Therefore, we call on the European Commission to first carry out an impact assessment before calling for such an enormous administrative task to be completed and not set this as a general rule inside a guidance document. See further comments under Part III.

3. COMMENTS ON PART II: Preparation and adoption of the Commission's standardisation requests to the European standardisation organisations

Orgalime welcomes the Commission's intention to ensure that all mandates work for both the Commission and ESOs and contain realistic deadlines. However, we cannot assume that Commission requests are 'unconditionally' acceptable to ESOs.

The acknowledgement of realistic deadlines and transparency of the process is welcome, provided that the Commission ensures that all relevant stakeholders – non-SME and SME stakeholders – are thoroughly and effectively consulted on draft standardisation requests regardless of whether they decide to take part in the technical work or not.

The content of chapter 3.3.1. "*Commission Implementing Decision*" (page 6) stipulates that such a decision could "*give legally binding requirements as to the content to be met by the requested deliverables in line with Article 10(1) of the Regulation*".

As standardisation is, as well recognised by the Commission, a voluntary process driven by stakeholder experts, ESOs have no power or authority to influence the content of the outcome. Therefore, ESOs cannot be "*bound*" as legally responsible by such a decision, but can only facilitate and ensure (within the framework of the standardisation mandate) a fair, transparent and democratic process. This is in line with the statement in Part 1, 4.3 (page 17): "*the Regulation does not specify any legally binding sanctions which could be used against the ESO's by not fulfilling i: "the requirements for the content" or ii: deadlines for publication of requested deliverables*".

As in most cases standards are of voluntary use, economic operators cannot be held liable if they do not apply the standards that would incorporate the legal requirements transposed from Union legislation or, sometimes, in a Commission Implementing Decision. The compliance of their products is to be assessed directly against these requirements.

Chapter 3.4 page 7: We agree that the Regulation alone cannot be regarded as sufficient justification, but always requires a sector-specific justification for a mandate. However, we disagree that "*a mandate can be adopted on the basis of: (…) when non-legislative documents foresee that European standardisation could promote defined policy objectives*".

This consideration shifts the responsibility of defining checks and balances for society from the legislator on to the standardiser. Again, the voluntary nature of standardisation calls for preliminary steps: we believe that the Commission cannot request the production of "other" types of standards without clearly identifying the need for them from an in-depth dialogue with concerned stakeholders. Autocratic top-down mandates forcing ESOs to fulfil policy objectives run the risk of discouraging voluntary participation of experts and could lead to poor quality and even useless standards.

4. COMMENTS ON PART III: Requirements and principles for the European standardisation organisations for execution of standardisation requests

This part of the Vademecum contains certain statements and intentions which can be supported, such as:

- no requirements regarding a manufacturer´s management system(s) in product standards (page 8; 6th indent), or
- ensuring that technical specifications do not unfairly discriminate against certain products, services or economic operators (page 9).

However, Part III of the Vademecum deals with issues in a way that could challenge existing well-functioning procedures and rules.

1. In particular, the 2nd paragraph of clause 2.4 and clause 2.6 give the impression that "programming mandates", which have been used successfully up to now for nearly all New Approach Directives, will no longer be possible. If the Commission issues individual mandates for each particular work item, this would lead to an administrative overkill for both the European Commission and ESOs.

2. The procedure for the reporting process described in clause 2.5 could develop into a lot of red tape without added value, such as the requirement to "*list all stakeholder groups, enterprises, organisations, institutes, public authorities" etc.* In addition, public reporting could create conflicts with regard to the protection of personal data.
   Moreover, we are of the opinion that it is not up to ESOs but to the Commission to report on any actions under its direct responsibility (such as in relation to Formal Objections or standards refused by the Commission for referencing in the OJEU; see 2.5 indent 5 on pages 6 and 7).

3. Clause 2.7.2: ESOs already have in place different tools to enable technical bodies to develop harmonised standards. For instance, CEN Guide 414 has been providing necessary guidance to standard writers for nearly 2 decades for standardisation in support of the Machinery Directive 2006/42/EC.

4. Clause 2.7.4 and Annex I of this document specify the requirements for a clear indication of the relationship between the technical specifications of the standard and the corresponding legal requirements to be covered by the candidate harmonised standard.

   Orgalime warns that the task of presenting standards specifications in correspondence with legal requirements (Essential Requirements) in the various pieces of Union legislation could be very complex. It is almost impossible for the Machinery Directive 2006/42/EC which has a 30-page Annex I with a variety of essential requirements, many of which could not be referred to unambiguously in the technical specifications of standards.

   Additionally, one must consider that for all risk-based legislation a differentiation between the legal approach (specification of essential requirements) on the one hand and the standardisation approach (identification of significant hazards) on the other exists. Because of this, it will not always be possible to have a one-to-one relationship between clauses of candidate harmonised standards and the corresponding essential requirements in the Union legislation.

   In the machinery sector, CEN Guide 414:2014 (http://boss.cen.eu/ref/CEN_414.pdf) tried to minimise this problem in providing a new informative Annex D "Examples of significant hazards, hazardous situations, hazardous events and their relation to the Essential Requirements of the Machinery Directive 2006/42/EC". Therefore, we are convinced that a one-size-fits-all approach regarding the presentation of the informative annex Z is not possible.

   We strongly advise the European Commission to take stock of the already established and widely proven solutions in the various specific sectors of CEN and CENELEC, instead of proposing a rigid common framework as specified in Annex I of the Vademecum.

   Orgalime, as the main stakeholder of the machinery sector, would be ready to contribute to the development of suitable and practicable solutions.

5. Clause 2.7.4, penultimate paragraph (top of page 11): As the informative annex Z is an integral part of the standard, the normal ESO rules for amending or revising ENs apply. Therefore an immediate removal (without delay) of the informative annex containing references to the legal text would not be possible. Alternatively it would be much more practicable to use the Commission webpage (http://www.newapproach.org/Directives/DirectiveList.asp) to provide the corresponding information without delay.

6. Clause 2.9.4: Indicating the essential technical changes between the old and a revised standard is already covered by a corresponding CEN/BT resolution and, for the machinery sector, also required by CEN Guide 414.

7. Annex 1, clause 1, 1st paragraph: According to Article 10(5) of Regulation EU 1025/2012, the Commission should make an assessment together with the ESOs. Two independent and uncoordinated assessments would be time consuming and could result in differing interpretations which will hamper the performance of the whole system.

8. Annex 1, clause 1, 3rd paragraph: How legal requirements are covered is included in the main part of the candidate harmonised standard and not in the informative annex.

9. Annex 1, clause 2.3, Example: Reference to the standardisation request (mandate) and further information about the mandate are not of interest to potential standard users (the Construction Products Regulation is probably the only exception).

10. Annex 2: ESOs have already developed many different sector guidelines that facilitate compliance of harmonised standards with the relevant mandates (New Approach Legislation).

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This is the case in the machinery sector where CEN Guide 414:2014 fulfils this task. Therefore, it is used by “New Approach” consultants in their assessment work in accordance with Article 10(5) of Regulation 1025/2012.

11. Annex II, clause 2.5, point 8: ESOs are required to monitor ‘coherent application of the requirements given in mandates’. Further explanation on what is meant here is needed.
ESOs can only monitor the result of the development process, and not a coherent application in practice.

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