Subject: Guidance on practical aspects of the implementation of Regulation (EU) No. 1025/2012 – Results of the consultation of stakeholders

Introduction:

Regulation (EU) No 1025/2012 (“the Standardisation Regulation”)¹ has, since its entry into force, provided the main legal framework for the European standardisation system, including the division of responsibilities and obligations of the key actors involved. However, further clarification of certain provisions of the Standardisation Regulation appears necessary, notably in light of the recent case law² of the Court of Justice of the European Union (“the Court”).

Therefore, on 22 November 2018, the Commission published a Communication on “Harmonised standards: Enhancing transparency and legal certainty for a fully functioning Single Market”³ defining specific actions to be undertaken by the Commission to further support the implementation of the Standardisation Regulation.

One of the actions announced in this Communication is the elaboration of “a guidance document on practical aspects of implementing the Standardisation Regulation, paying particular attention to the division of roles and responsibilities in the development process of harmonised standards as well as to efficiency and speed.”

The Communication announced that this guidance document (“the Guidance”) would be elaborated “in consultation with stakeholders”.

To commence these consultations, on 11 July 2019 the Commission distributed to the key stakeholders a note requesting feedback on the points to be addressed in the Guidance. The


² Case C-613/14, James Elliott Construction Limited v Irish Asphalt Limited, Judgment of 27 October 2016; Case T-474/15, Global Garden Products Italy SpA (GGP Italy) v European Commission, Judgement of 26 January 2017; Case C-630/16, Anstar Oy vs Turvallisuus- ja kemikaalivirasto (Tukes), Judgment of 14 December 2017.

³ COM (2018)764 final
note was also published in the publicly accessible notification system according to Article 12 of the Standardisation Regulation:


The deadline for comments was set for **27 September 2019**.

Within the framework of this consultation, the Commission asked the following specific questions:

**Questions with regard to the Guidance:**

1. Do the foreseen elements of the Guidance cover the relevant aspects of the process of harmonised standards development, which require clarification in order to improve its transparency and increase its predictability and efficiency?

2. Are there any particular aspects from the recent relevant case law that you would like to see addressed in particular in this Guidance?

3. Do you have any other comments?

This document summarises the responses of interested citizens and stakeholders submitted to the Commission within the framework of the above consultations.

**Overview of respondents:**

Within the framework of the above consultations, in total 42 responses were submitted. The responses include in particular contributions from:

- the European standardisation organisations (CEN, Cenelec, ETSI);
- the European stakeholder organisations representing consumers, environmental interests, SMEs and societal interests (ANEC, ECOS, SBS, ETUC);
- EFTA;
- several Member States;
- several National Standardisation Bodies;
- numerous European associations representing industrial stakeholders from various sectors;
- several entreprises including SMEs.

A complete list of all contributors can be found in Annex 1.
Summary of contributions

The most common views of stakeholders can be briefly summarised as follows:

I. Assessment of the current situation

The consultation revealed a number of concerns with the current situation in the field of harmonised standards, in particular amongst industry representatives, but also among the European standardisation organisations, national standardisation bodies and Member States.

One of main concerns has been the rate of citation by the Commission of harmonised standards in the OJEU, but concerns are also expressed with regard to the new format of standardisation requests and publication decisions, as well as the new system of HAS consultants. The recent measures introduced by the Commission are often perceived as excessive and seen as an incorrect interpretation of the rulings of the Court of Justice.

II. Relationship to the existing guidance documents

Most of the stakeholders therefore recognise that the process of development of harmonised standards would benefit from a number of clarifications, in particular with regard to the division of roles and responsibilities among the individual actors. The initiative of the Commission to provide the necessary clarifications and by that to increase the transparency, predictability and clarity of the process are thus welcomed.

The elaboration of the Guidance is mostly seen as an opportunity to preserve the strengths and benefits of the NLF and to re-establish trust amongst the various stakeholders involved in European standardisation. It should generate a transparent, efficient and predictable process that ensures legal clarity and certainty for the Commission, but also for European and National Standardisation Bodies, as well as for standardisation experts and users of standards.

Nevertheless, several contributions point out that the Guidance aims to address numerous issues which are already covered in the existing guidance documents (in particular in the Vademecum on European standardisation) and invite the Commission to reconsider development of an additional new piece of guidance. A revision of the existing guidance documents appears to be the preferred way to provide the necessary clarifications while guaranteeing consistency of all guidance documents.

III. Process for the development of the Guidance

No matter in which document the clarifications would be provided, the stakeholders request that the document should be developed in a collaborative process between the Commission and the relevant actors.

Therefore, the stakeholders welcome the consultation at the beginning of the process of the elaboration of the Guidance.

At the same time, numerous stakeholders express the understanding that the consultation process and close cooperation with the Commission will continue and that they will have an
opportunity to contribute to the further development of the Guidance in subsequent exchanges.

Some stakeholders recommend that the task to draft the Guidance should be entrusted to a dedicated working group or task force which would comprise the relevant stakeholders, e.g. within the framework of the Committee on Standards. The process used in the past for the development of Vademecum on European standardisation or for the elaboration of guidelines for several sectorial legal acts (e.g. Machinery Directive, EMC Directive and Low Voltage Directive) are cited as examples of best practice.

Some contributions express the opinion that the elaboration of the Guidance should be preceded by some kind of an independent assessment of the current situation with regard to harmonised standards, and in particular the recent approach pursued by the Commission and the concrete measures introduced by the Commission. In concrete terms, an independent assessment ‘of the legal basis, proportionality and impact on stakeholders of the formal legal steps that the Commission has set out prior to the citation of European harmonised standards in the Official Journal of the EU’, as well as ‘of the implications triggered by sector-specific case law’ is requested.

**IV. Scope of the Guidance**

The scope of the Guidance as proposed by the Commission is overall considered sufficient. It should make it possible to work on the overall process of developing harmonised standards and to shed operational light on the principles laid down in Regulation (EU) No 1025/2012 and the existing guidance documents, in particular the Vademecum on European standardisation.

Nevertheless, proposals were made to extend the scope of the Guidance in order to cover also the following issues:

- Article 5 of the Standardisation Regulation regarding facilitation of stakeholder participation in standardisation, in particular at the international level;
- Article 8 of the Standardisation Regulation regarding the Annual Union Work Programme for European standardisation and its links to the process of the development of standardisation requests.

Several contributions stressed the need to recognize specific issues relevant for certain sectors and to provide the necessary clarifications on such issues. In particular, the specifics of harmonised standards in the construction sector were highlighted. With regard to that, recommendations were made to adress these specific issues within the framework of the Guidance, eventually to consider a separate guidance document for the construction sector.

A proposal was also made to develop a separate guidance document on formal objections, or at least to dedicate a separate section of the Guidance to formal objections.
V. Standardisation requests

It is generally recognized that it is for the Commission to initiate, prepare and adopt standardisation requests.

However, a strong call was made that the market relevance of all standardisation requests should be systematically examined by the Commission. Standardisation projects that are driven by political decisions only (topdown approach) entail the risk of not being relevant to the market. The Commission is invited to consult not only the European Standardisation Organisations, but also the industry sectors concerned at an early stage of the preparation of a standardisation request. The Standards Market Relevance Roundtable “SMARRT”, created as a result of the Joint Initiative on Standardisation (JIS), is a suitable platform for such consultations.

Many stakeholders are concerned about the new format of standardisation requests, in particular about the expiry date and the very precise identification of harmonised standards to be developed/revised. These elements are seen in particular by industry as unnecessarily restricting flexibility during the execution of the standardisation request and reducing the interest of industry to participate in standardisation work.

a. Expiry date:

There is a consensus that a clear and precise definition of the temporal validity of standardisation requests is necessary. However, a fixed expiry date as laid down in the new format of standardisation requests (the date for the delivery of the last harmonised standard + x years) creates uncertainty about the status of the harmonised standards developed on the basis of the respective standardisation request. In particular, it is unclear what the consequences are for the presumption of conformity if a standardisation request expires while the respective harmonised standards have not yet been published. This needs to be clarified moving forward.

Proposals were made that the lifetime of a standardisation request should be linked to that of the corresponding sectorial legal act to allow the constant maintenance of the portfolio of existing harmonised standards (adaptations to the state of the art).

An opinion was expressed that a standardisation request should not expire even if not accepted by the European Standardisation Organisations, in order to be able to support market surveillance actions.

However, other stakeholders welcomed the introduction of an expiry date.

b. Detailed scope:

Some contributions recognize that it is in the best interest of all stakeholders involved in the standardisation process to ensure that the substance and scope of the standardisation request are sufficiently defined. However, it is important to make sure that the standardisation request does not stipulate any technical requirements that are for the stakeholders to specify during the actual standardisation process.
The majority of stakeholders however find the Commission’s identification of harmonised standards to be developed/revised as stipulated in the new format of standardisation requests too prestrictive. In their opinion, standardisation requests should leave a sufficient level of flexibility to smoothly incorporate and disseminate through harmonised standards technical/societal evolving needs.

In this connection, the stakeholders believe that it should be largely up to the European standardisation organisations to develop the work programme for the execution of the standardisation requests. The standardisation request should not define the work programme in too much detail as otherwise changes/amendments to the work programme might require changes/amendments of the standardisation request.

c. Amendments to standardisation requests:

It is recognised that amendments to standardisation requests might be needed in the course of their execution. The procedures for such amendments should however be as streamlined as possible so as not to risk delaying the preparation of the required harmonised standards. The procedures should provide for necessary flexibility and should not overload the system. With respect to that, the procedure according to Article 10 of the Standardisation Regulation including the opinion of the Committee on Standards should be avoided in order to reduce administrative burdens and increase efficiency.

In the field of construction products, the need for a clear process (with responsibilities and deadlines) for Commission’s response to amended answers to the standardisation requests provided by the Technical Committees was highlighted.

d. Transparency of preparation of standardisation requests:

Several suggestions were made to improve the transparency of the process of preparation of standardisation requests. These suggestions include the introduction of a tool that would provide overview of comments received by the Commission on each draft standardisation request. Ideally, such a tool would be publicly accessible throughout the whole period of preparation of the draft standardisation request.

Some stakeholders also wish to obtain a more detailed insight into the division of roles and responsibilities within the Commission in the process of drafting standardisation requests, in particular which Commission service can intervene at which stage or phase of the overall process.

The importance of a proper consultation with the ESOs and Member States during the drafting phase of the standardisation request was highlighted. This consultation is essential to ensure that the final Standardisation request is responding to market needs and that the relevant resources (expertise, funding, etc.) and timeframe are taken into account.

e. Other issues related to standardisation requests:

The necessity to ask the European standardisation organisations in the standardisation request to indicate a correspondence between each technical specification in harmonised standards with the corresponding essential requirements in the Union law was put into question. It was recommended that the Commission should consider requiring an annex Z in requested standards for new or revised standards only after consideration of the opinion of the ESOs /
technical committee(s) concerned (including its level of detail), in view of the joint assessment foreseen in Article 10(5) of Regulation (EU) No. 1025/2012). For existing standards without Annex Z, introducing such an Annex Z should not be the only reason to call for the revision of the standards, especially if these are considered as state-of-the-art by the end-users and are satisfactory in use.

Further, a recommendation was made that the Commission refrains from imposing dated normative references systematically in future standardisation requests. The need for dated normative references in standards should be considered on a case-by-case basis. While these could bring more clarity as to what are the relevant technical specifications that a manufacturer should comply with to claim the presumption of conformity, this is especially true where the legal text of the enabling act does not refer to a specific standard - for instance for a measurement purpose. In addition, the Commission was called to undertake a thorough cost-benefit analysis of its plan to require systematically dated normative references in standards, as their cost for companies would disproportionately discourage economic operators from using harmonised standards.

VI. Assessment and publication of harmonised standards

The stakeholders perceive that there is a significant room for improvement in the current system of assessment and referencing of harmonised standards in the OJEU. In particular, the recent measures introduced by the Commission (in particular additional reviews of draft harmonised standards by HAS consultants, time-consuming verification of harmonised standards by the Commission, publication of harmonised standards in the L-series of the OJEU instead of the C-series) are considered too burdensome.

The importance of a better communication and alignment between the Commission and the ESOs during the whole process of assessment and publication of harmonised standards was highlighted as key for improvement. It is crucial that both parties identify jointly, in close liaison and consultation with industry and HAS consultants, possible issues as soon as possible during the development of new harmonised standards/revision of existing harmonised standards.

The importance of fast (with deadlines) and clear processes for the assessment and publication was highlighted. The speedy processing is essential so that the European standardisation system is able to keep pace with the technological development and that standards continue to be a relevant, useful and attractive tool for European businesses.

a. Assessment of drafts of harmonised standards:

The stakeholders are convinced that a common understanding between the Commission and the ESOs of how making an assessment together as requested in Art. 10(5) of the Standardisation Regulation is essential in the development process of the harmonised standards. The assessment should be carried out in dialogue between the Commission/HAS-Consultants and the responsible ESO(s). A crucial element to implement Art. 10(5) of the Standardisation Regulation is to agree on:

- A timeframe for the assessment reports;
Early and close cooperation between ESO’s technical bodies and HAS Consultants in order to facilitate the link between ESOs (standardisation) and the European Commission (legislation).

It is necessary to build a stable, reliable and inclusive procedure for assessing drafts of harmonised standards. Currently, there appears to be a great need for clarification with regard to the distribution of roles and responsibilities of the individual actors. The assessment should follow clear rules with clearly defined responsibilities, steps and timelines. It should be outcome-oriented, focused on achieving the most useful Annexes Z for the users of standards. Redundant checks by the HAS consultants and unnecessary level of detail required should be avoided.

A recommendation was made that the particular case of harmonised standards relating to several harmonisation laws should be addressed in the Guidance as assessments of different relevant HAS Consultants could lead to diverging outcomes on the same essential requirement.

It was proposed that a distinction should be made between harmonised standards that are indirectly referred to in EU legislation as a voluntary tool for manufacturers to facilitate their demonstration of conformity with EU law on one hand and harmonised standards that are directly referred to in EU legislation (such as Directive 2014/94/EU on the deployment of alternative fuels infrastructure) on the other hand. The former should be subject to a lighter assessment, the latter may deserve a more in-depth scrutiny by the Commission.

Further, it was pointed out that a defined process is necessary for the assessment of those standards submitted under Directives/regulations not covered by the HAS Consultants system (e.g. eco-design, GPSD).

On a different aspect, it was recommended that the way the contributions of societal stakeholders were taken into account should be also part of the assessment. This reflects the inclusiveness of the system developing harmonised standards.

Last but not least, it was recommended that the Guidance should clarify the meaning of the “state of the art”.

b. HAS consultants:

It is considered crucial that the role and the scope of the tasks of HAS consultants is described in detail in the Guidance. The Guidance should stipulate clear rules to ensure the independence and impartiality of the HAS consultants throughout the assessment process.

There was a consensus that HAS consultants need to be involved in standards development as early as possible in order to mitigate to the maximum possible the risk of a negative evaluation at the end of the cycle. In this connection, a proposal was made that the past process of the New Approach Consultants should be analysed in order to identify possible further ‘best practices’ that could facilitate early involvement of the HAS Consultants in the assessment process. A timely availability of HAS Consultants assessments was also considered key. With respect to that, it was proposed that the Guidance should specify a time-frame for the assessment reports.
The consistency of the HAS Consultant assessments and coordination of their work was considered important. It was suggested that controls are required to ensure consistency of assessments and a uniform common understanding both between various HAS Consultants, and between the HAS Consultants and the Commission, and to articulate such positions clearly to all stakeholders. The roles, methodologies, procedures and access instructions for these controls should be explained in the Guidance.

It was proposed that the final HAS consultant’s assessment should not take place prior to the Formal Vote on a draft harmonised standard which is developed in parallel with technical bodies of ISO or IEC (as is now the case contrary to homegrown European standards) but during the Formal Vote (FDIS).

A strong call was made for swift and efficient mechanisms to resolve disagreements between HAS consultants and the Commission on one hand and the technical committees on the other hand. This is of particular importance at the final stage before the Formal Vote. These mechanisms could take the form of dedicated resolution meetings or appeals.

Additionally, a clear and transparent process for the recognition of the responses made by the TCs in case of non/partly compliant HAS assessment is considered necessary. This is an essential measure to increase the currently insufficient number of positively assessed harmonised standards before their referencing in the OJEU.

Further, it was proposed that the Guidance should address a deeper involvement of the HAS Consultants and the EC in the drafting of harmonised standards by attending drafting meetings, also on the international level. It would allow a better understanding of the concerns of all involved parties as well as to recover the main goal of standardisation: reaching a consensus between all stakeholders.

The importance of a good level of expertise of the HAS Consultants and a professional interaction between HAS Consultants and experts from economy was highlighted. The HAS Consultants should understand not only legal requirements but also the European standardisation process and its specific terminology. The stakeholders would appreciate more transparency from the Commission administration and its contractor managing HAS consultants to disclose information on the capacity and expertise of the HAS consultants in the respective fields of standardisation.

It was pointed out that HAS Consultants should be obliged to help prevent deviations from underlying international standards wherever possible and to duly justify them if required. A pre-assessment of international standards by HAS Consultant would reveal potential issues early in the process.

The Commission was invited to continue working with CEN-Cenelec on the implementation and putting in practice the key performance indicators (KPIs) recently developed by CEN-Cenelec. In this connection, it was also recommended that a feedback mechanism on the functioning and performance of the HAS Consultants system is created.

A proposal was made that qualified "European Industrial Associations for..." of EU Member States should be specifically included in the list of "Harmonised Standards Consultants".
Last but not least, it was recommended that the Guidance should give guidelines for the contract between the Commission and Ernst and Young.

VII. Process of publication of references to harmonised standards in the OJEU

a. Submission of harmonised standards to the Commission:

The consultation highlighted that the ESOs have already in place a mechanism (including an IT platform) to ensure a timely submission of all relevant documents to the EC to facilitate a smooth process. Interoperability, compatibility and user-friendliness of the IT systems of ESOs and the European Commission (including the EC HAS database) is essential to ensure transparency and efficiency. The ESOs are ready to jointly address with the EC any further improvement that may be needed for the submission of documents.

It was noted that the key performance indicators (KPIs) recently developed by CEN-Cenelec address this issue. The KPI 1 monitors that the draft harmonised standards to be submitted contain the necessary elements required by the standardisation request (completeness).

b. Publication in the OJEU:

With regard to publication of references to harmonised standards in the OJEU, the Guidance should provide a description of practices ensuring a good coordination between the management of the standardisation catalogues of the European standardisation organisations, and the lists of references published by the Commission in the OJEU. The process described in the 2017 Action Plan (Structural solutions to decrease the stock of non-cited harmonised standards) was proposed as best practice.

The responsibility of the Commission to publish the references to harmonised standards was acknowledged. However, the Guidance should ensure transparency regarding the EC’s internal decision-making process (including timeframes and criteria) leading to the decision to cite or reject a candidate harmonised standard, in particular in case of rejection despite a positive assessment from the HAS Consultant. The KPI 4 recently proposed by CEN-Cenelec relating to the time required by the EC to cite candidate harmonised standards is fundamental in this transparency exercise and must be in line with the timing agreed in the ‘Action Plan for the backlog’ to pursue the objective of timely citation of standards. It was also pointed out that the publication should not depend on the opinion of an individual EC Desk Officer. Ideally, the final verification of harmonised standards should take place in dialogue between the Commission/HAS-Consultants and the responsible ESO.

The importance of timely and regular publications was highlighted, in order to avoid legal uncertainty. The timely publications should be at the center of attention in order to enable economic operators to fully benefit from the presumption of conformity, keep them motivated and engaged in European technical harmonization, and support their competitiveness in the global market. The Guidance should thus reflect the need to keep alignment as far as possible of the list of harmonised standards in the OJEU with the publication of the ESOs. This is of particular importance for European transpositions of international standards. Currently, depending on the sector, the delay of publication of European standards compared to international standards reaches a long period of time, leading to obsolete products which are still covered by the presumption of conformity based on a harmonised standard already
withdrawn by the ESOs. A recommendation was made that the Guidance should commit the Commission to an explicit timeline for final verification of harmonised standards prior to their citation in the OJEU. In addition, the Commission should dedicate sufficient resources to the final verification and publication.

Requests were made to continue with the good practise of consolidated lists providing an overview of all harmonised standards in the respective sector. This is of particular importance for SMEs. The absence of consolidated lists decreases legal clarity and certainty.

Requests were also made to consistently provide for a transition period of at least 12-18 months for harmonised standards being replaced.

It was also considered important that the Guidance establishes clear guidelines for cases where a harmonised standard has been revised but the new version of this standard cannot be cited in the OJEU (either because the EC has rejected it or because the ESOs have not offered for citation after a negative assessment). This type of scenario often creates confusion among standards users, as the version cited in the OJEU is also indicated as withdrawn by ESOs. The EC should ensure that lists of harmonised standards contain no withdrawn document or, at the very least, provide standards users with a clear explanation regarding which document they should refer to.

It was also noted that in the past, certain standards (that were not withdrawn by the ESOs) simply disappeared from the OJEU listing which lead to uncertainty and confusion for manufacturers (e.g. hEN 55020 cited under the EMCD was unlisted without notice in 2016). This kind of situations should be prevented.

Last but not least, it was pointed out that the new format of EC implementing decisions for the publication of harmonised standards in the OJEU does not provide the necessary clarity and legal certainty for potential users of harmonised standards. In particular, the identification of the correct relation between Annex I and Annex III of the implementing decision is a challenge and can create misinterpretations.

**VIII. Formal objections**

The intention of the Commission to provide clarification with regard to Art. 11 of the Standardisation Regulation and the impact of formal objections on the citation process was welcomed.

However, in this connection, it was pointed out that the Guidance must also address the substance of the formal objection procedure. In addition, it was suggested that the Guidance must touch upon the link to the current procedure for the development of specifications and standards that should be designed in a way that gives a greater role to the national administrations. With regard to this, it should be considered whether the Guidance deserves a special document dedicated to the formal objection procedure.

The Guidance should also address the important issues related to the procedure and potential consequences thereof for the withdrawal of the presumption of conformity with regard to the impact on economic operators and market surveillance authorities as well as with regard to risks associated with market fragmentation.
It was perceived that the current process for resolving a formal objection takes too long. Moreover, the process appears to be a source of misunderstanding among different stakeholders (including the Member States and ESOs). In order to shorten the timeframe, it was suggested that deadlines for the procedure are set once a formal objection is introduced. In addition, the relevant sectoral committee should be consulted immediately by correspondence, if no meeting is imminent. The same process should be extended to the Committee on Standards.

In order to improve clarity, a suggestion was made to develop a detailed template for formal objections, with specific content to be addressed (such as the identified shortcomings of the standard, any related accidents/injuries, suggested changes).

It was recommended that in case a formal objection is (partially) accepted, a deadline should be set for the revision of the related standard. Ideally, the European Standardisation Organisations would address this point with their international counterparts, when the harmonised standard is also an international standard.

In this connection, in case a formal objection is (partially) accepted, it was also proposed to consider a transition period allowing manufacturers to update the design of their products, the technical documentation and the EU declaration of conformity. In consequence, the list of harmonised standards in the OJEU should synchronize the “date of cessation of presumption of conformity from the OJEU” with the “date of withdrawal of conflicting standard” provided by the ESOs. Nevertheless, when the removal from the OJEU is published, the effective date of the removal from the OJEU should not be earlier than 18 months from the publication date in the OJEU (18 months was seen as a reasonable transition period for requirements that doesn’t endanger the user of the equipment). Particular attention needs to be considered for Directives which doesn’t allow the use of Module A when no harmonised standard is listed in the OJEU. In case of module A is not possible anymore and a manufacturer is obliged to go to Module B+C (EU TEC) or H (full quality assurance), sufficient transition time needs to be foreseen to offer legal certainty to the manufacturer. In addition, the process of removing Harmonised Standards from the OJEU (stakeholders, reason, and procedure) needs to be transparent for the industry in order to prepare for such situation. This shall allow manufacturer updating the design of their product, the technical documentation and their EU declaration of conformity.

It was noted that in the past, Member States have challenged harmonised standards before their citation in the OJEU, informally, without following the formal objection procedure. This resulted sometimes in a delayed citation by the Commission of concerned harmonised standards for several years. For those cases, it is necessary that the Commission sets a clear time limit for the Member State to withdraw their informal claim against the standard or to turn it into a formal objection.

**IX. Other issues**

Some proposals were made to review the Standardisation Regulation and to streamline the rules regarding the publication of references to harmonised standards in the OJEU. This was seen as the only possible way forward that could ensure a proper functioning of the European standardisation system with regard to harmonised standards for the future.
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