BUSINESSEUROPE

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Comments relating to guidance on practical aspects of the implementation of Regulation 1025/12

CONTEXT AND KEY MESSAGE

In the Communication of 22 November 2018 on harmonised standards, the Commission has announced upcoming guidance on the implementation of Regulation 1025/12 relating to roles and responsibilities in the development process of harmonised standards. On 11 July 2019, the Commission has asked stakeholders for input on three specific questions related to this upcoming guidance.

BusinessEurope welcomes the opportunity to comment on future guidance. To ensure that the system for the development of harmonised standards continues to function and to support both free movement of goods in the Single Market and global competitiveness, we recommend the Commission to refrain from assuming additional responsibilities where those affect the roles of other key players in this system. We would like to emphasise that harmonised standards are essentially a compliance tool, and that as such cannot be considered as EU law themselves. Before further implementation of any changes to the system for the development of harmonised standards, we therefore recommend an independent assessment of the implications triggered by sector-specific case law.

REPLY TO THE COMMISSION'S QUESTIONS

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?**

The elements of the guidance proposed by the Commission relate to the standardisation request on the one hand, and to the assessment of the standards, publication of the reference in the OJEU and formal objections on the other.

While BusinessEurope finds that a clear outline of the responsibilities and tasks of the different actors in the process of drafting harmonised standards is necessary, as we have pointed out earlier in our view there should be no bureaucratic interference with planning and execution of standardisation work. The system should rather be based on mutual trust of actors in the "new approach" which has performed well for decades.

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There is no doubt that it is for the Commission to prepare and adopt standardisation requests. However, the standardisation request itself should have no pre-defined technical requirements and no temporary validity; where a list of standards is included in the mandate, this list should not be regarded as exhaustive. This is necessary to maintain sufficient flexibility and hence industry interest to participate in standardisation work, and to ensure that harmonised standards will maintain their market relevance in a European and global context.

Regarding the role of the HAS consultants, which aim to facilitate coordination with the Commission in the development process, there is room for improvement. These consultants should be involved early on in the work of the technical committees, and explicitly help to prevent deviations from underlying international standards (as opposed to an ex-post evaluation, which easily leads to back looping and hence to longer standard development times). Disagreements between HAS consultants and the technical committees should be resolved in a swift manner.

In relation to the publication of the reference to the harmonised standard in the OJEU, also here the role of the Commission to publish the reference is beyond dispute. The key element for industry is that this happens swiftly in order to avoid legal uncertainty.

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

The Commission explained in the Communication of 22 November 2018 on harmonised standards that most notably the *James Elliott* case[1] requires it to assume a more active role in the standardisation process than was previously the case. We challenge this notion which has become so central to the posture taken by the Commission, based on a highly relevant legal distinction between two situations.

First there is the general rule, i.e. cases where use of harmonised standards is a voluntary compliance tool. The presumption of conformity provided by use of the harmonised standard merely shifts the burden of proof regarding compliance with the underlying essential requirements in the legislation. Therefore, it cannot be considered to have a binding legal effect towards market surveillance authorities or the Commission. Market surveillance authorities can challenge both individual products regarding their conformity to the essential requirements, and the harmonised standards themselves.

Exceptionally however, harmonised standards become *de facto* or *de jure* mandatory. Regulation 305/2011 on construction products (to which proceedings in the *James Elliott* case relate) makes harmonised standards *de facto* mandatory for selling across the EU; Directive 2000/14/EC on outdoor noise directly refers to specific harmonised standards which are therefore mandatory *de jure.* While also in those cases the presumption of conformity shifts the burden of proof, in view of their mandatory nature it may be justified that the Commission would exercise a more substantive scrutiny.

In view of the significant effects of the case law on the practical realities of harmonised standardisation, we would also like to recall the EU's general principles of better

[1] Case C-613/14 of 27 October 2016.

regulation. Before further implementation of any changes to the system, we would recommend an independent assessment of the implications triggered by the case law, including an assessment of proportionality and impact on stakeholders, and an explanation of the legal rationale behind the changed practices.

3. Do you have any other comments?

All stakeholders in European standardisation have a key interest in a good process flow. BusinessEurope would like to reiterate that less flexible mandates and time-consuming control before publication of the reference in the OJEU make it less attractive for companies to engage in the drafting and using of harmonised standards. This will eventually pose a problem for the functioning of the system in its entirety and hurt competitiveness.

The implications of the implementation of Regulation 1025/12 therefore reach far beyond the impact on compliance costs. Harmonised standards are a tool for effective Single Market functioning, as they facilitate cross border trade by providing a presumption of conformity. At the same time, harmonised standards are also key in a global context. Since the EU has the ambition to be a world leader in standardisation, and thereby aims for European standards to become international standards, it is essential that these harmonised standards are in fact market relevant. A decrease of the market relevance of harmonised standards will translate in lower uptake of these standards both within and beyond the EU.

BusinessEurope would also like to point out that the very aim of the legislation, namely managing risks associated with products brought to the EU market in a responsible manner, will be counteracted by a poor functioning of harmonised standards that give presumption to conformity. A lack of available harmonised standards covering essential requirements set out in the legislation will give room to a great variety of interpretations of the legal provisions by economic actors, and rogue players will deliberately seek the minimal way to get away with them. Market authorities will not be able to mitigate the resulting risks as they already lack the resources for proper enforcement, and the capacity shortage will only increase. As a result, rogue players will have lower cost, hence become more competitive, and will flood the EU market with non-compliant products.

BusinessEurope intends to continue the dialogue with the Commission in order to ensure that harmonised standards are market-relevant and based on cutting-edge technology, rather than providing a mainly regulatory function.