

**European Commission Guidance
on practical aspects of the implementation of Regulation (EU) 1025/2012
(the Standardisation Regulation)**

ANEC response to stakeholder consultation

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?*

Yes, we agree the relevant aspects are covered. However, we propose additions in answer to the next questions.

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

Standardisation Requests – there is need for a clear and precise definition of the temporal validity of SReqs. We believe an SReq ought to be maintained, even if not accepted by the European Standardisation Organisations, or if no Harmonised Standards have been published, in order to be able to support market surveillance actions. It is strange that a Commission Implementing Act (secondary legislation) should expire if not accepted by another party.

We do not recall this point being addressed by the European Court of Justice but, noting a SReq contains detailed information on the legal requirements that need to be covered by standards, an SReq could be a useful tool in market surveillance to determine whether or not a product is compliant.

If there are legal reasons why an SReq/Implementing Act expires if not accepted, we would be pleased to hear them.

3. *Do you have any other comments?*

The procedure to amend SReqs - although it is important that the updating of an SReq is possible, it is equally important to ensure an open and transparent process for the amendment. The involvement of the Committee on Standards, aided by clear information on the scope of the modifications proposed and the possibility to object to such modifications, is a prerequisite.

Assessment of the standard, publication of its reference & Formal Objections – responsibility of the Commission and of the ESOs in the assessment of the standard: 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.

Formal Objections: we believe the 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, we suggest that deadlines for the procedure are set once a Formal Objection is introduced. Moreover, 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. Decisions could be taken according to the present rules.

In order to improve clarity, we suggest developing a detailed template for the lodging of the Formal Objection, with specific points to be addressed (such as the identified shortcomings of the standard, any related accidents/injuries, suggested changes). This would allow the problems to be presented in a clear and transparent manner, and aid the development of solutions. It would perhaps also allow for other issues to be identified at an earlier stage.

In order to improve the follow-up of a Formal Objection, we believe a deadline should be set for the revision of the related standard. This would be in line with the principle of the temporal validity of SReqs under which Harmonised Standards are developed. A special provision about revision further to a Formal Objection should be introduced in the template for SReqs.

It would be also helpful if the European Standardisation Organisations would address this point with their international counterparts, when the Harmonised Standard is also an International Standard.

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