

Position Paper

Guidance on practical aspects of the implementation of Regulation (EU) No. 1025/2012 – Consultation of stakeholders

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Bitkom welcomes the initiative of the European Commission to consider a Guidance document on the Standardisation Regulation (EU) No 1025/2012.

Furthermore we support the position of the Federation of German Industries e.V. (BDI) (BDI document number: D 1073) and would like to list the most important points for Bitkom in the following, as well as additional topics which are particularly important from the point of view of the ICT industry.

- **Alignment of harmonised standards with international ISO/IEC/ITU standards:**
Bitkom and its members realize a growing desynchronization of the European standardisation from international. This becomes a significant issue for the success of the European industry, in particular SME's, serving global markets.
- **Professional interaction between HAS Consultants and experts from economy:**
A spirit of mutual respect – personal and professional – is desirable. No single expert shall claim a 'monopoly of truth' and conflicts shall be resolved in a professional and purposeful manner.
- **Clarification of the meaning "the state of the art":**
When the technical content of a standard has been approved during the international voting process the compliance of the technical requirement in the standard with the state of the art shall be presumed to be acknowledged.
- **Pre-assessment of international standards:** The involvement of the HAS consultants, Desk Officers, EU Commission's Legal service, and collegial checks is resulting in delays that makes the European Standardisation much slower than the international process, making parallel votes of European standards with international standards impossible (despite the principle of the Frankfurt agreement). An example for the ICT industry is the 3rd edition of the product safety standard IEC 62368-1 published on international level already in 2018. The described issues are delaying the European version (EN 62368-1) for several years, which makes the internationally recognized state of art safety standard basically unavailable for the industry preferred market access procedure, which is the application of listed harmonized standards to enjoy presumption of conformity.

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- **EC implementing decision in L Series of OJEU shall contain the complete list of harmonised standards:**

For transparency reasons there exists a strong request to continue with the good practise of a consolidated list providing an overview of all harmonised standards. For SMEs in the IT sector in particular, the current situation is unacceptable and leads to legal uncertainty.

- **Utilisation of the formal objection and a transition period of at least 18 months for harmonised standards being replaced.**

Besides the topics explicitly covered by the BDI paper, Bitkom, from the perspective of representing the ICT industry, would like to add the following:

We would like to propose the **inclusion of a conciliation process** for cases where there is **fundamental disagreement between the HAS consultants and Commission on one side and a SDO on the other side**. Examples could be when the consultants or the Commission challenge fundamental technical principles, or when man-made law basically ignores the law of physics. Dealing with such situations in a consistent and transparent way is from our perspective a key aspect of the overall process. The recent example with EN 62368-1 under RED and LVD showed that a formal process is either not existing or not visible to industry.

Bitkom represents more than 2,700 companies of the digital economy, including 1,900 direct members. Through IT- and communication services alone, our members generate a domestic annual turnover of 190 billion Euros, including 50 billion Euros in exports. The members of Bitkom employ more than 2 million people in Germany. Among these members are 1,000 small and medium-sized businesses, over 500 startups and almost all global players. They offer a wide range of software technologies, IT-services, and telecommunications or internet services, produce hardware and consumer electronics, operate in the digital media sector or are in other ways affiliated with the digital economy. 80 percent of the members' headquarters are located in Germany with an additional 8 percent both in the EU and the USA, as well as 4 percent in other regions of the world. Bitkom promotes the digital transformation of the German economy, as well as of German society at large, enabling citizens to benefit from digitalisation. A strong European digital policy and a fully integrated digital single market are at the heart of Bitkom's concerns, as well as establishing Germany as a key driver of digital change in Europe and globally.