



Update on the European Commission's views on the broad context of harmonised standards

**CCMC's Workshop "Preparation of Harmonized
Standards"**

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Introduction – setting the scene

- *New Approach (NA) system was introduced in 1985 to harmonise EU Single Market for products*
- *It was based on 4 principles:*
 - 1) *legislative harmonisation limited to essential requirements*
 - 2) *Technical specifications for products meeting the essential requirements laid down in harmonised standards*
 - 3) *Products manufactured in compliance with harmonised standards benefit from presumption of conformity*
 - 4) *Use of harmonised standards remains voluntary*

The NLF

- *In 2008, the New Legislative Framework (NLF) was introduced to improve the NA system*
- *Regulation (EC) 765/2008 on accreditation and market surveillance*
- *Decision 768/2008/EC: reference provisions for all harmonised product legislation*
- *Regulation (EU) 1025/2012 (the Standardisation Regulation) replaced the relevant provisions of Directive 98/34/EC on 01.01.2013*

NLF has replaced NA

- *NLF and Standardisation Regulation have now replaced NA as basis for product legislation (while maintaining its four fundamental principles)*
- *Since 2016, EU product legislation has mostly been aligned with NLF*

Evolution of EU legislation and rules for harmonised standards

- *Since 2008, the standardisation system based on the NA has evolved and become more formally regulated*
- *The reason: to ensure legitimacy of private harmonised standards and of related legal effects*
- *New role of the Commission confirmed by EU Court of Justice in the James Elliott case*
- *Standardisation needs are determined in public consultations led by COM rather than in internal ESO consultations*

Harmonised standards - New Approach (NA) vs. NLF

- *NA did not set detailed requirements for citation in OJEU*
- *Under NA, the Commission had a “hands-off” practice for harmonised standards*
- *On 01.01.2013, the Standardisation Regulation became applicable and the situation changed: the Commission must ensure compliance of harmonised standards with essential requirements before citation in OJEU*
- *The Standardisation Regulation clearly defines the respective roles of all relevant actors*

Roles and responsibilities during the standardisation process

- *COM adopts a standardisation request after broad consultations and a vote in the Committee on Standards (Art. 10(1-2))*
- *ESOs can accept or reject the request; by accepting, ESO takes exclusive responsibility for developing the standards (Art. 10(3))*
- *Compliance of documents drafted by ESOs assessed by COM jointly with ESOs (Art. 10(5))*
- *COM decides to publish references of standards in OJ if they satisfy the essential requirements they intend to cover (Art. 10(6))*

Conditions for citation in OJEU as per Art. 10(6) of Reg. 1025/2012

- *There is no automatism; Commission is not bound by result of compliance assessment*
- *Commission must verify and assess various aspects (including legal requirements) before deciding to publish references*
- *Commission consults also the results of the assessments as per Art. 10(5)*

How NLF defines the legal effect following from citation in OJ

- *Legal effect of a harmonised standard (usually presumption of conformity) is limited to the legal requirements actually covered by it*
- *There is no legal effect for requirements that are not indicated in the relevant legislation, and standards must not be ambiguous on this*

Recent judgments of the EUCJ on harmonised standards and their implications

- *The James Elliott judgment of 27.10.2016 was a milestone ruling by the EUCJ*
- *First ruling by EUCJ on a harmonised standard*
- *The EUCJ ruled that it has jurisdiction to give a preliminary ruling on the interpretation of a harmonised standard cited in the OJEU*
- *Reason: harmonised standards, though voluntary, are “by their nature measures implementing or applying an act of EU law”*

The James Elliott judgment

- *Since the development of harmonised standards, which are considered a measure of EU law after citation in OJEU, is entrusted to private organisations (the ESOs), it follows that this assignment must be a “controlled delegation” in which the Commission plays a fundamental role*
- *This has consequences on the Commission’s internal processes and on the formal requirements for texts of relevant documents (Annex Z, normative references, etc.)*

The Global Garden case

- *The EUCJ clarified other aspects related to harmonised standards in its ruling on the Global Garden case of 21.01.2017*
- *Important to have legal certainty when publishing and repealing references in the OJ*
- *To set starting and ending dates for the legal effect is exclusive competence of Commission*
- *It is thus not possible to delegate this to the ESOs or have uncertainty to this regard (e.g. via undated normative references)*

Standardisation requests

- *Most old standardisation requests are problematic in the light of James Elliott ruling: fully executed, no expiration date, no or little value for assessment work, don't serve public interests, lack of transparency, limited control possible by COM, requirements from Articles 10(1-3) are bypassed*
- *New standardisation requests should clearly spell out policy objectives and public interests, identify all standards needed after transparent consultations, express the content requirements, set deadlines for adoption and expiration dates for all requests (no open-ended requests)*
- *Probable consequence: more mandates needed!*

Formalisation of Art. 10(6) decisions in the near future

- *From decision to publish references taken at the level of Commission's sectorial Units to a system of formal Commission Decisions*
- *Commission Implementing Decisions (in OJ L series), in a harmonised template, to identify compliant harmonised standards and to allow to set the legal effect and related dates in OJ C series (process under discussion)*
- *Non-compliant standards sent back to ESOs*

The new system of HAS consultants

- *In the past (NA), assessment of conformity was completely delegated to ESOs; COM's sectorial Units usually considered that they had no responsibility to review technical content of standards*
- *Commission paid full cost of New Approach Consultants (NAC), but they were fully managed by CEN/Cenelec*
- *NACs often went beyond assessment tasks, participating to the drafting work in the TCs*

Conformity assessment: NAC service after Reg. 1025/2012

- *Commission sectorial Units started to verify and assess conformity of standards themselves*
- *As NACs were still working under CEN/Cenelec's internal guides/rules which (in the Commission's view) did not reflect the changed legislation, cases of refusal by COM to publish references despite positive assessment of NACs became frequent*
- *Also, several NACs did not have a close collaboration with COM's sectorial Units*
- *The James Elliott ruling confirmed the need that COM takes over consultants' management*

Assessment of conformity: Commission to take leading role

- *Assessment of documents to be done on the basis of criteria set by COM, on the basis of initial standardisation requests and legislation*
- *COM needs technical assistance (HAS Consultants)*
- *COM and consultants must keep distance from drafting and from consensus building process of ESOs*
- *Results of assessments are not binding for COM*

The new role of HAS Consultants

- *The new system of Harmonised Standards (HAS) Consultants has replaced the NACs on 01.04.2018*
- *A contractor (Ernst & Young) has been selected via an open tender procedure for the administrative management of the pool of HAS Consultants*
- *HAS Consultants to work closely with, and on behalf of, COM's sectorial Units*
- *HAS Consultants can only receive tasks and requests from the Commission and its contractor*
- *Rules on conflicts of interests/incompatibility are much stricter than for NA Consultants*

Status of HAS Consultants project

- *So far, 45 HAS Consultants contracted (in the past triennium, there were 34 NA Consultants); however, no consultant yet for TDG (previous consultant did not apply; three candidates did not pass selection) and for Eco-design (new sector, not previously covered by NA Consultants)*
- *The new system is extended to ETSI*

Thank you for your attention!

Questions?

Federico Musso

European Commission

DG GROW/B.3 (the Standardisation Unit)

E-mail: Federico.MUSSO@ec.europa.eu