

“Am I on the safe side if I comply with standards?”

What does “presumption of conformity” actually mean?

Section 4.3, “Presumption of conformity”, of the *Guide to the implementation of directives based on the New Approach and the Global Approach*¹ states the following:

“Conformity with a national standard that transposes a harmonised standard, whose reference has been published, confers a presumption of conformity with the essential requirements of the applicable New Approach directive that is covered by such a standard.”

Consequently:

1. As soon as the title of a standard has been published in the EU Official Journal, any application of that standard can be presumed to ensure conformity with the essential requirements.
 - This means that the market surveillance authorities, for instance, can only deem a product to be non-conforming if it can be proved that the manufacturer failed to comply with directive requirements.
 - Ultimately, then, presumption of conformity is no more than a *reversal of the burden of proof*. It is indeed possible to furnish such proof in specific cases as part of *safeguard action against the product*.
2. Moreover, the principle of presumption of conformity only applies to those directive requirements that are actually covered in harmonized standards whose titles have been published in the EU Official Journal.
 - Furthermore, the presumption can be partially or even completely lost if, for example, the standard is successfully contested by means of a *formal objection*.

Users of harmonized standards should therefore make sure they know precisely which directive requirements are covered in the standards and which are not. Users who rely purely on the normative part of harmonized standards, thinking they have thus complied with all of the directive requirements, do so at their peril. So it makes sense to check the exact scope of the presumption of conformity.

How do I know whether or to what extent compliance with a specific standard confers a presumption of conformity?

1. Nowadays, finding standards is no longer a problem:
 - http://ec.europa.eu/enterprise/sectors/mechanical/documents/standardization/machinery/index_en.htm. This site, in English, lists the standard titles related to the Machinery Directive most recently published in the EU Official Journal. The list can be downloaded in other languages in PDF format.

¹ This “Blue Guide”, as it is known, has to be revised due to the adoption of the New Legislative Framework. However, the only impact the revision will have in this context is that the requirement for publication at the national level is likely to be dropped.

- <http://www.newapproach.org>. This English site offers guidance for anyone dealing with harmonized standards. There are links to further information, provided by the European Commission, for all of the New Approach directives, plus links to related standardization activities. There is also a keyword search. If it proves impossible to find a specific standard in the Official Journal, the reason might be that the presumption of conformity has been revoked, especially if the standard is quite old. In the case of recently published standards, another reason might be that the European Commission has not yet published the titles though that does not mean that there is a problem with the content. In that case, however, compliance with the standards does not yet confer a presumption of conformity. Formally speaking, they can therefore only be applied if they have been checked thoroughly against the directive requirements, as is the case for other technical documents too.
 - <http://eur-lex.europa.eu/de/index.htm>. For users who would prefer not to use the English platform, there is an alternative in the form of "EUR-Lex", which is the web-based tool for searching the content of the EU Official Journal. EUR-Lex is available in all of the EU's official languages and offers an easy way of finding recent and past publications of the lists of harmonized standards. This can be useful, for instance, when a legal dispute arises and there is a need to carry out a search regarding products placed on the market in the past. The search function enables the user to determine which standards conferred a presumption of conformity at a given time.
2. *Annexes Z and scopes of standards – their role and the problems they cause...*
- Harmonized standards intended to flesh out internal market directives must include informative Annexes Z (or Annexes ZZ in the case of CENELEC standards). These annexes must specify clearly which essential requirements of the relevant directives are covered in the standard.
 - According to the European Commission, the Annexes Z for standards published by CEN should preferably take the form of detailed tables. The tables should show which sections of the standard cover which directive requirements. If it is not possible for a standard to cover all of the relevant requirements, be it due to a lack of knowledge or of consensus, the essential requirements covered and those not should be clearly indicated. This is usually complied with in practice.
 - Some standards whose titles have been published in the EU Official Journal note in their Annex Z that a certain amount of the essential requirements are not covered.
 - Compliance with such standards thus only confers a limited presumption of conformity. As a result, manufacturers also have to be able to prove how they meet the directive requirements that are not covered.
 - Standards relating to the Machinery Directive are also subject to CEN Guide 414:2004, "Safety of machinery – Rules for the drafting and presentation of safety standards". Sections 5.3 and 6.4.2.2 of the Guide require a clear indication of the hazards dealt with, which is very important for the user to know, to be given in addition in the scope. Unfortunately, it is rare for scope

definitions to also draw the attention of users of such standards to gaps in the coverage of the essential requirements. Instead, the scope usually rules out certain “applications” of a machine or individual “hazards”.

The fear is that many users of standards do not read the EU Official Journal, the Annexes Z or even the scope properly. As a result, they are not even aware of the easy-to-spot loopholes in the standards even though it is quite obvious that machinery that is manufactured in accordance with such standards only might be lacking in terms of safety.

“Presumption of conformity” does not mean exemption from liability²

- *Reversing the burden of proof* primarily has an effect in terms of administrative law. To put it more simply – the administrative law is intended to ensure fair competition by requiring all players to provide the same level of protection.
- Consequently, fault-based liability, due to negligence as defined in Germany’s Civil Code, and liability as defined in the German Product Liability Act, for which fault plays no role whatsoever, are two completely different matters. Compliance with standards does help to a large extent to prevent safety issues that could give rise to liability but the question is how large an extent?
- As explained above, there are various ways in which presumption of conformity can be explicitly limited, thereby giving a clear indication of what is and what is not covered by the standard.
- Furthermore, it is also possible that a standard might not cover certain hazards or requirements but that this is not clearly stated anywhere – not in the scope, nor the Annex Z, nor the EU Official Journal. There can be numerous reasons for this, e.g.:
 - a machine might have a specific feature, not covered in the standard;
 - the committee might not have covered a key aspect, or might not have covered it adequately, due to a lack of knowledge or consensus;
 - there might have been significant progress in the state of the art or the standard might be outdated.

Again, to put it in easy-to-understand terms – manufacturers who ignore standards are almost certainly guilty of negligence. But those who apply *standards only* are far from having displayed the due diligence that would ensure they could not be held liable.

Risk assessment a formal requirement

Annex I, General Principles, 1, of the Machinery Directive actually sets out a formal requirement for a risk assessment to be carried out to determine the safety and health requirements applicable to the machinery in question. Moreover, the “Guide to application of the Machinery Directive 2006/42/EC” reiterates the following points:

² KANBRIEF 1/2005: Prof. Dr. Justus Meyer: Product safety and product liability

- “The process of risk assessment is facilitated by the application of harmonised standards... However the application of harmonised standards does not dispense the machinery manufacturer from the obligation to carry out a risk assessment.”
- “A manufacturer who applies the specifications of a C-type standard must ensure that the harmonised standard is appropriate to the particular machinery concerned and covers all of the risks it presents. If the machinery concerned presents hazards that are not covered by the harmonised standard, a full risk assessment is required for those hazards and appropriate protective measures must be taken to deal with them.”
- “Furthermore, where harmonised standards specify several alternative solutions without defining criteria for choice between them, the choice of the appropriate solution for the machinery concerned must be based on a specific risk assessment. This is particularly important when applying B-type standards.”

Recommendations

1. Rather than relying purely on the normative content, users of standards should also always examine all of the available information concerning how exhaustive the standards are.
2. Even the fact that a standard’s reference has been published in the Official Journal does not guarantee that the standard covers all the necessary aspects.
3. Users of standards should also carry out a risk assessment, as defined in the Machinery Directive. This is important not only because such an assessment is required by law anyway but also in order to be completely on the safe side and to minimize the possibility of unpleasant surprises.

Corado Mattiuzzo
KAN Secretariat
Alte Heerstr. 111
53757 Sankt Augustin
Germany
Tel. +49 (0)2241 231-3466
mattiuzzo@kan.de
<http://www.kan.de>