

Myths and realities of the presumption of conformity

Scope and relevance of the presumption of product conformity with Union harmonisation legislation in 10 questions and answers

by Philippe Portalier, version 1c of 15/5/2017

Disclaimer

This paper is proposed by the author as a background for discussion among stakeholders in the working group of Action 8 “*Provide high- quality standards delivered and referenced in a timely manner*” under the Joint Initiative on Standardisation initiated by the European Commission*.

It cannot be regarded as a position paper of Orgalime.

Executive summary

The presumption of conformity is a concept that is widely used in the context of the European “New Approach” better regulation technique, which has efficiently served the needs of manufacturers for more than 3 decades for their lawful placing of products on the EU Single Market. It has recently gained attention further to the adoption of Regulation 1025/2012 on European Standardisation. This Regulation codifies the main avenue for manufacturers to benefit from this presumption, that is by complying in the design of their products with so-called “harmonised standards”, the titles of which have been cited in the Official Journal of the EU.

Yet, few understand what legal effect the presumption of conformity grants to standards users (typically industrial manufacturers, service providers and their B2B customers), once it has been initiated by the European Commission under the scrutiny of the national market surveillance authorities and the European Parliament. Furthermore, the ECJ ruling in the James Elliott Case has fuelled more misconceptions around its implementation.

This article attempts to clarify the meaning of the concept and its relevance in the framework of Union harmonisation legislation. It seeks to demonstrate that it is a legal benefit which stems from the citation of harmonised standards in the Official Journal of the EU, but which has no value (legal effect) if manufacturers do not activate it upon their free choice, by designing a product in compliance with applicable harmonised standard(s). Regulation 1025/2012 has not changed the relevance of the presumption of conformity, which is to facilitate the legal acceptance of harmonised products for their placing on the market of the 28 EU Member States.

Consequently, when the European Commission turns the legal relevance of a potential benefit for private operators into a “legal liability” for itself, it is a far-fetched interpretation which carries the risk of jeopardizing a key facilitation feature of the “New Approach” to technical harmonisation. It could even make the European standardisation system as set in Regulation 1025/2012 increasingly irrelevant to economic operators. The confidence of all the actors: national authorities, economic operators and their customers in product conformity lies elsewhere; to start with, in an improved market surveillance.

* Joint Initiative on Standardisation: responding to a changing marketplace: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8852

Introduction

Like on any market, trust among providers and customers is a key element to ensuring fairness, prosperity and growth on that market/ territory. Each Member State of the EU has put in place the stability and predictability of a set of preconditions for such a trust and a means to demonstrate the trustworthiness of economic operators. The European Union has over time set up a framework for harmonising the nationally scattered conditions in over 20 product sectors¹.

As put forward by the European Commission on its web site, *“in the majority of sectors (e.g. electronic and electric equipment, machinery, lifts, medical devices), EU legislation is limited to essential health, safety, and environmental protection requirements.”*²

The purpose of European harmonisation legislation such as the Machinery Directive, is *“to ensure the free movement of machinery in the internal market and to satisfy the imperative and essential health and safety requirements relating to machinery by replacing national certification and conformity certification systems by a harmonised system”*.³

The concept of the presumption of conformity is intimately linked with this system, which was put in place in a Council Resolution of 7 May 1985 as the “New Approach” to technical harmonisation⁴. Its key feature is that to demonstrate their conformity with the product Directives’ essential requirements, manufacturers may voluntarily comply with so called harmonised standards or other technical specifications. Nothing indicates in the preamble of the Regulation 1025/2012 that the Council Resolution on the New Approach has been repealed. It merely cast into law the respective duties of the various stakeholders to operate in the broader context of the New Approach.

1) What is product conformity in the framework of the ‘New Approach’?

The New Approach has been fundamental in combining two essential elements of trust in products placed on the market:

- a) **Market or technical fitness for use (or for purpose):** describes the **confidence of market operators** in core aspects of the products placed on the market in relation to their own business needs, such as safety, quality, reliability, interoperability, etc... of these products, based on the ‘state of the art’ and the latest available engineering practices. For more than a century (in the electro-technical field) and several decades in all other “traditional engineering sectors”, these aspects have often been the result of a consensus elaborated among economic operators that is cast into technical standards. This is acknowledged by the ECJ in the James Elliott Case⁵.
- b) **Product conformity/ safety:** describes the **confidence of the Member States authorities** that products coming from other EU member States are subject to the same requirements as those that apply to home-grown products, based on the claim that the products are in conformity with applicable requirements and will not harm users. Hence conformity and means to presume it result from the applicable conformity assessment procedures which involve various compliance assessment tools such as the use of harmonised standards or certificates from independent, accredited notified bodies.

¹ New Legislative Framework (NLF) https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

² EC DG GROWTH on Free movement in harmonised and non-harmonised sectors: https://ec.europa.eu/growth/single-market/goods/free-movement-sectors_en

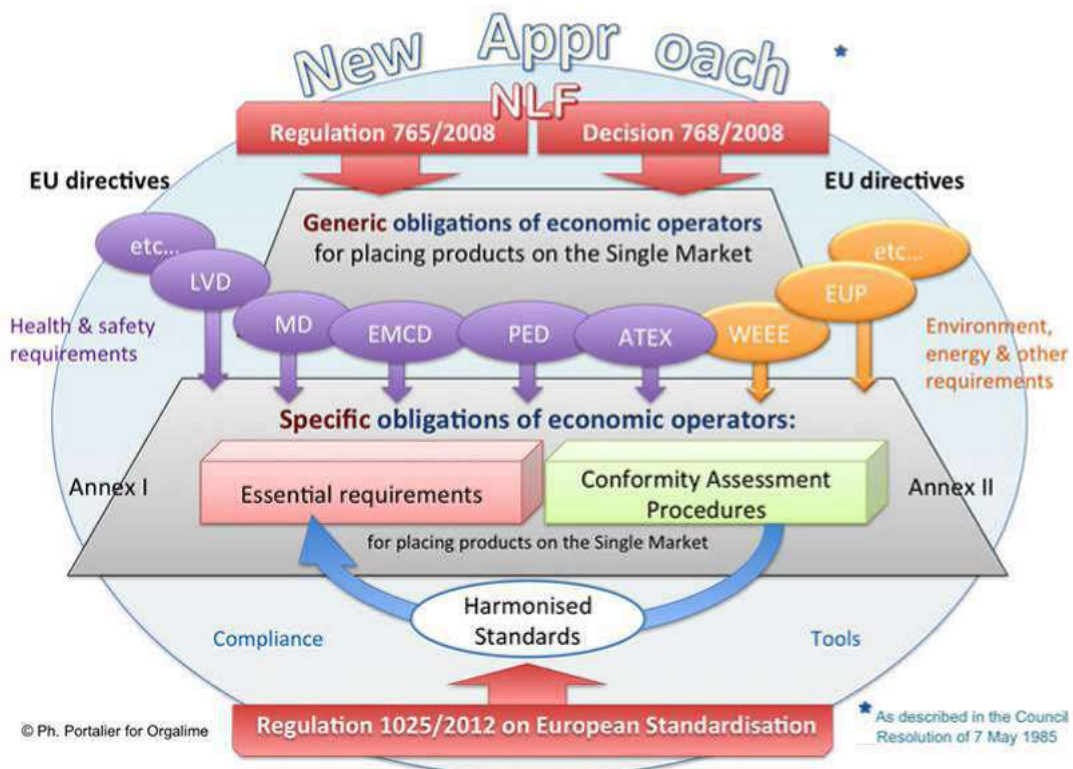
³ Case C 470/03 A.G.M.-COS.MET Srl v. Suomen valtio (Finland), paragraph 52: <http://curia.europa.eu/juris/showPdf.jsf?text=&docid=63389&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=637359>

⁴ New Approach as set out in the Council resolution of 7 May 1985 (OJEU 1985 C 136, p. 1): [http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31985Y0604\(01\)&from=EN](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31985Y0604(01)&from=EN)

⁵ See J. Elliott Construction Case C-613-14 of 27 October 2016 last sentence of the paragraph 3: *“a product is presumed fit for use if it conforms to a harmonised standard (...)”*.

The success of the New Approach stems from the flexible means that have been put in place to combine technological progress, evolving business models and a reassuring “high level” of safety for the marketing of products across all EU Member States. These are described in the three legislative pillars of the New Approach that are:

1. Regulation (EC) 765/2008 “setting out the requirements for accreditation and market surveillance relating to the marketing of products”⁶ and Decision 768/2008/EC setting “a common framework for the marketing of products”⁷, also known as “the New Legislative Framework” which together codify the “New Approach” to technical harmonisation;
2. EU harmonisation legislation under the New Approach / New Legislative Framework, these are over 20 Directives and Regulations setting out essential legislative requirements for specific product sectors, the related conformity assessment procedures and the role of harmonised standards to facilitate the manufacturer’s duty to demonstrate their conformity with the law.
3. Regulation 1025/2012 on “European standardisation” which establishes the legal basis for the European Commission to mandate the European Standardisation Organisations to develop harmonised standards that could be used to facilitate the demonstration of conformity with European harmonisation legislation⁸.



[Figure 1: the New Approach ‘System’ and its Legal Basis]

Conformity assessment procedures are part of the EU product specific directives.

- The presumption of conformity has a different signification depending on the applicable conformity assessment procedure or “module”.
- Under module A – Internal production control and self declaration of conformity – the presumption of conformity provides greater legal significance than under other more stringent conformity assessment procedures imposed on the manufacturer, such as for gas appliance products (see Blue Guide page C 272/48, paragraph 2).

⁶ Regulation (EC) 765/2008:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:en:PDF>

⁷ Decision 768/2008/EC: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0082:0128:en:PDF>

⁸ Regulation (EU) No 1025/2012 on European Standardisation:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:PDF>

2) What does ‘product conformity’ mean under Union harmonisation legislation?

Product conformity means the conformity of the product with the applicable EU requirements which are set out in the general part of the law (a European directive or a regulation) and often in a specific Annex describing the risks that are aimed to be mitigated by compliance with the legal requirements.

It is the result of a procedure of conformity assessment carried out under the responsibility of the manufacturer, as a result of a choice among several optional or mandatory conformity assessment modules during the design and production phases (see Blue Guide table on page C 272/74). This procedure may involve a third party conformity assessment body, independent from the manufacturer to scrutinise the product and or various phases of the manufacturer’s design and production process (cf. above Figure 1: the New Approach).

3) What does ‘presumption of conformity’ mean?

The Blue Guide does not specify what the “*legal effect that stems from the publication of the reference [of a harmonised standard] in the OJEU*” (page C 272/48, last paragraph) is.

The presumption of conformity is the legal consequence that derives from a known fact – the claim that the product conforms with the harmonised standards cited in the OJEU – to establish the unknown fact that the product conforms with the essential requirements of the EU law.⁹

“Basically, if all interested parties throughout Europe agree that a given technical solution reflects the state of the art for a given essential requirement, authorities accept this judgement insofar as it merely creates a presumption of conformity that can be challenged through the procedures foreseen by the Directives.”¹⁰

It is different than the presumption of conformity for national accreditation bodies (cf Blue Guide C 272/93).

In the context of the New Legislative Framework, the presumption of conformity:

- does not refer to the presumption of fitness for purpose (technical relevance of the standard)
- nor does it refer to the fitness for use by the market across the EU (market relevance and removal of conflicting national standards, if any), but it refers only to the fitness for acceptance by the authorities of all 28 Member States of the EU for free circulation on their territory of a product for which the Declaration of Conformity claims compliance with the harmonised standards (cf. Figure 2: the three dimensions of a standard under the New Approach).

⁹ Source (in French): *Ministère de l'Équipement, du Logement, des Transports et du Tourisme Direction de la Recherche et des Affaires Scientifiques et Techniques - Rapport d'Etude : Insertion du réseau scientifique et technique du Ministère de l'Équipement, du Logement, des Transports et du Tourisme dans la normalisation nationale et internationale, 26 novembre 1999 – Footnote n°31* : – Translated from French : “*In civil law, a presumption is the consequence that the law or the judge derives from a known fact for an unknown fact, the existence of which is rendered probable by the former. This process entails an exemption for the one who claims the benefit of the presumption of conformity from proving the unknown fact, which is difficult or impossible to establish directly, subject to him submitting the easier proof of the known fact (hence a displacement of the object of the evidence). However, such a benefit of the presumption of conformity could be challenged by an opponent, where the presumption is rebuttable (i.e. could be countered by evidence), to provide the evidence of the non-existence of the unknown fact (hence a reversal of the burden of proof). As regards European law, the unknown fact is that the product complies with the essential requirements of a directive and the known fact is that the product conforms with the harmonised standards cited in the OJEU*”.

<http://temis.documentation.developpement-durable.gouv.fr/docs/Temis/0080/Temis-0080306/21093.pdf>

¹⁰ EC Working Document SOGS N302 EN - The role of the authorities in standardization under the New Approach (1999-11-15), page 10.

4) Is the publication of the title of a harmonised standard in the Official Journal of the EU necessary to trigger the presumption of conformity?

No, the citation in the OJEU of a harmonised standard is only one of two options that enable the presumption of conformity:

1. The compliance of the product with harmonised standard(s) cited in the OJEU

The ECJ confirmed that the benefit of the presumption of conformity is opened by the citation of a harmonised standard in the OJEU (cf. James Elliott Case paragraph 38).¹¹ However, it is a product's compliance with the technical requirements defined by that standard which "allows the presumption that that product satisfies the essential requirements contained in [the EU harmonisation legislation]" (cf. James Elliott Case paragraph 41), in line with Council Resolution of 7 May 1985 on a new approach to technical harmonisation.¹²

2. The certification of the product by an independent third party

Where a product has been certified as compliant and bears the CE marking of conformity provided by that harmonisation legislation, it is presumed in conformity with it, as clearly spelled out in the Council Resolution of 1985¹³. This has been recently recognised by the ECJ in its ruling in Case C 470/03 A.G.M.-COS.MET Srl v. Suomen valtio (Finland)¹⁴. The certificate of conformity constitutes prima facie evidence of such product conformity, with the possible limitations stated in this certificate.

The Case study of harmonised gas appliances standards

Today, there are disagreements in the application of the European directive on gas appliances between the European Commission services and CEN experts (industry) on the formal presentation of the so-called informative "Annex ZZ" – that describes the correspondence between the standard's technical specifications and the essential requirements of EU legislation. As a consequence, not a single harmonised standard under this directive has been cited in the

¹¹ See J. Elliott Construction Case C-613-14 of 27 October 2016 paragraph 38: "such publication [of that standard's references in the 'C' series of the Official Journal of the European Union] has the effect of conferring on products which are covered by that directive (...) the benefit of a presumption of conformity with the basic requirements of that directive": <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:62014CJ0613&rid=9>

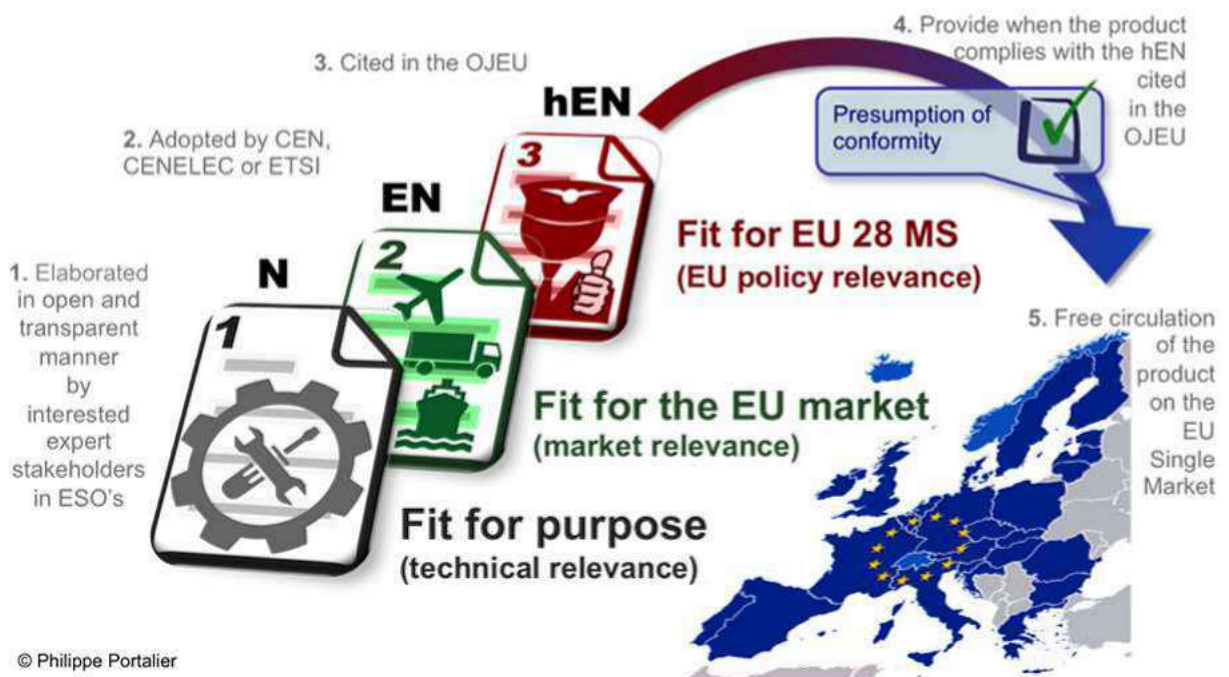
¹² Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards, Official Journal C 136, 04/06/1985 section V. Means of proof of conformity and effects §3.2: "The presumption of conformity is constituted by the fact that the conformity of a product to harmonised or national standards is declared by one of the means of attestation set out in point VIII" (...) "(a) certificates and marks of conformity issued by a third party; (b) results of tests carried out by a third party; (c) declaration of conformity issued by the manufacturer or his agent based in the Community. This may be coupled with the requirement for a surveillance system; (d) other means of attestation which could possibly be determined in the Directive.": [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:31985Y0604\(01\)](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:31985Y0604(01))

¹³ Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards, Official Journal C 136, 04/06/1985, Section V.3 in combination with Section VIII.1.a & b: "Member States shall accept that the products for which the manufacturer has not applied any standard (...) are considered to be in conformity (...) when their conformity is demonstrated by (...) (a) certificates and marks of conformity issued by a third party [or] (b) results of tests carried out by a third party;"

¹⁴ Case C 470/03 A.G.M.-COS.MET Srl v. Suomen valtio (Finland), Paragraph 53: "(...) the Directive harmonises exhaustively at Community level not only the rules relating to the essential safety requirements for machinery and certification of conformity with those requirements but also the rules concerning the action that may be taken by the Member States with regard to machinery that is presumed to comply with those requirements." Paragraph 54: "All national measures within the scope of those articles of the Directive must therefore be assessed in the light of the provisions of the Directive". Paragraph 61: "In the present case, the vehicle lifts were presumed to be compliant, in accordance with Article 5(1) of the Directive, since they had been certified as compliant and bore the CE marking of conformity provided for in Article 10 of the Directive." <http://curia.europa.eu/juris/showPdf.jsf?text=&docid=63389&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=637359>

OJEU since 2010! Nevertheless, manufacturers of gas appliances are using these harmonised standards (mandated by the EC) to design their product: Indeed, they made a significant investment in contributing to their development and, as a result, these standards describe the best available technologies that are requested by their customers: these standards are relevant both technically and to the market, EU-wide (see figure 2: the three dimensions of a standard under the New Approach). Furthermore, manufacturers of gas appliances do not complain (too much). Why? Simply because the conformity assessment procedures under the Gas Appliance Directive require manufacturers to obtain a certificate (of compliance) from a third party conformity assessment body. Hence, it is no longer the conformity of the product with the non-cited standards that grants them presumption of conformity, but the third-party conformity assessment with the law and its resulting certificate.

The Three Dimensions of a Standard under the New Approach



[Figure 2: the three dimensions of a standard under the New Approach]

5) Is the presumption of conformity necessary for a company to place its products on the EU Single Market?

No, the law requires all products that are placed on the European Single Market to be compliant with applicable EU legislation, but there are often several other lawful means to do it.

Conformity with applicable EU law (once transposed into national law) is a "must" which all manufacturers are obliged to prove through the constitution of a technical file that may incorporate various elements of proof, such as drawings, certificates, etc... *"By affixing the CE marking to a product the manufacturer declares that the product is in conformity with all applicable requirements and that he takes full responsibility therefor"* (Decision 768/2008 (Recital 31)).

So the presumption of conformity is a 'benefit' but not an obligation for economic operators. It is formulated as such in the ECJ ruling in the James Elliott Case (paragraph 38)¹⁵. It is important to note here that the references of harmonised standards are published as Commission communications in the C series of the OJEU, for information to whom it may concern (as acknowledged by the Blue Guide p. C 272/47 of 26.7.2016, third paragraph).

Besides the legal benefits of increased legal certainty and the possible reversal of the burden of proof for the purpose of demonstration of compliance (see hereinafter), the presumption of conformity may provide several other benefits to the economic operator.

The manufacturer may use harmonised standards even if these have not been cited in the OJEU, without the benefit of the presumption of conformity (Blue guide C 272/44).

6) Is compliance with harmonised standards cited in the OJEU necessary to benefit from the presumption of conformity?

No, the New Approach regulatory technique does not oblige manufacturers to use harmonised standards to demonstrate their conformity with the law. Typically, for machinery, the manufacturer should:

1. Study the essential health and safety requirements (EHSRs) of the applicable EU directives and determine which requirements apply to his machine;
2. Determine if his product complies with the applicable EHSRs;
3. Study the lists of European harmonised standards that are cited in the OJEU under the name of the applicable European EU Directives, and make an inventory of the applicable standards. If there are no product specific standards, the manufacturer may consider standards that apply to certain aspects of the product (for example EN 349-1 on safety of machinery – minimum gaps to avoid crushing of parts of the human body), or generic standards (for example EN-ISO 12100 on safety of machinery).

The use of harmonised standards is one way to facilitate the manufacturer's demonstration of conformity, it is not the only one, depending on the available conformity assessment procedures under the applicable legislation.

The flexibility offered by the New Approach enables the manufacturer of an innovative product to demonstrate conformity with the essential legal requirements with alternative means than with the use of the harmonised standard. Indeed his assessment of the technical specifications of the standard may lead him to the conclusion that the standard is not fit to address the technical aspects of his product's novelties, or does not provide the elements of demonstration to prove that these technical aspects comply with the law.

It is often stated that harmonised standards under the Construction Products Regulation – formerly a Directive – are de facto mandatory. This is essentially a perception which is triggered by the high costs of the alternative route for demonstrating conformity with the Regulation, which is product certification. This was acknowledged by the ECJ in the Global Garden case: *"Admittedly, the Commission's interpretation does not create a legal vacuum, since the manufacturers and their representatives have means other than resorting to harmonised standards whose references have been published in order to conform with the essential health and safety requirements set out in the relevant directive with respect to the machinery that they wish to market. However, it must be noted that those other means are more onerous."*¹⁶

¹⁵ ECJ Ruling in Case C-613/14 §38: "(...) such publication has the effect of conferring on products which are covered by that directive, and which satisfy the technical requirements defined in the harmonised standards relating to those products, the benefit of a presumption of conformity with the basic requirements of that directive (...) allowing the CE marking to be affixed to them."

¹⁶ ECJ Ruling of 26/01/2017 in the Case T 474/15 Global Garden against the European Commission, paragraph 67 <http://curia.europa.eu/juris/document/document.jsf?text=&docid=187179&pageIndex=0&doclang=EN>

7) Does the presumption of conformity provide increased legal certainty to manufacturers?

Yes, the presumption of conformity contributes to the legal certainty that manufacturers need in the conduct of their business: to start with, it confirms the proper conduct of the manufacturer and means that products in conformity with harmonised standards benefit from a favourable opinion from the market surveillance authorities or the occupational health inspectors¹⁷.

In the recent *Global Garden* Case T 474/15, the European Court of Justice even lectured the Commission for having deprived economic operators of the potential benefit of using harmonised standards and subsequently of “*the application of the principle of legal certainty*”.¹⁸

“*The decision of the competent authority to take corrective action must always be based on an established non-compliance with the essential requirements*” (Blue Guide C 272/110). Indeed, other initiatives of the authority which would challenge the manufacturer’s legal certainty of a product presumed compliant are sanctioned by the ECJ¹⁹.

However, the presumption of conformity does not exonerate the manufacturer from its civil liability – under the Product liability Directive (cf. Blue Guide p. C 272/13), with or without presumed or proven conformity of his product with the law. In the application guidelines of the Directive on Personal Protective Equipment (PPE), it is even stated that “*the fact that the transposed European harmonised standard is regarded as supporting the presumption of conformity does not relieve the manufacturer of his responsibility to design and manufacture PPE which meets the current state of the art (...)*”.²⁰

8) Does the presumption of conformity reverse the burden of proof of non-compliance to the benefit of manufacturers?

Yes, to some extent. The presumption of conformity means that a manufacturer can assume he has met the requirements of the corresponding directive provided he has complied with the specifications in the standard(s) that cover all the essential requirements of all applicable directives... in any case, the manufacturer has the obligation under the NLF to conduct a risk assessment with the very purpose of verifying that such an assumption could be sustained in case it is challenged. This would have to be documented in the product’s technical file.

So, does the presumption of conformity provide the manufacturer with a reversal of the burden of proof in case he is challenged by a market surveillance authority?

¹⁷ Cf. Franck Gambelli, *Aspects juridiques de la Normalisation et de la Règlements technique européenne*, Eyrolles 1994).

¹⁸ The ECJ has annulled a Commission Implementing Decision (EU) 2015/902 of 10 June 2015 on a measure taken by Latvia in accordance with Directive 2006/42/EC to prohibit the placing on the market of a lawnmower manufactured by an Italian manufacturer. Namely, the Court ruled that the Commission decision had an adverse effect as it resulted “*in a type of machinery which has been covered for several years by a published harmonised standard being ‘without a harmonised standard’ during (...) approximately 15 months before obtaining a new published harmonised standard*”. Consequently, according to the Court, “*the Commission position, (...) results in very significantly reducing the number of harmonised standards which can be used during the early part of the application of that [new EU legislation] and therefore adversely affects the effectiveness of the system*” (Paragraph 67 of ECJ Ruling of 26/01/2017 in the Case T 474/15 that upholds the claim of *Global Garden Products Italy SpA (GGP Italy)* against the European Commission):
<http://curia.europa.eu/juris/document/document.jsf?text=&docid=187179&pageIndex=0&doclang=EN>

¹⁹ In Case C 470/03 *A.G.M.-COS.MET Srl v. Suomen valtio (Finland)*, the Court states that “*the statements of an official to be attributed to the State (...) describing machinery certified as conforming to Directive 98/37/EC (...) as contrary to the relevant harmonised standard and dangerous thus constitute a breach of Article 4(1) of that directive.*”

²⁰ Guide to application of the PPE Directive 89/686/EEC, Version of 19 October 2015, page 29:
<http://ec.europa.eu/DocsRoom/documents/13241/attachments/1/translations/>

Some authors believe that this would be preposterous for those standards that are incorporated into public order (criminal) legislation, while even the civil legislation on product liability for defective products has simplified the onus of proof without reversing it.²¹

However, literature from both public and private origin seems to confirm such a reversal of the burden of proof, which would oblige the enforcement authority to prove the misconduct of the manufacturer.²²

The Council Resolution of 7 May 1985 on the New Approach is quite clear about it²³. It gives a clear advantage to manufacturers that place a product covered by harmonisation legislation (e.g. a power grinder) compared to those that are not (e.g. an abrasive disk for the grinder).

The Blue Guide alludes to such a reversal of the burden of proof when it refers to “*practical consequences for the manufacturer who chooses not to use the harmonised standard or parts thereof*” (See Blue Guide page C 272/43). Practically, it would be more difficult for a manufacturer to demonstrate its bona fide by other means than harmonised standards made available to him by the New Approach: test reports, certificates and marks of conformity issued by a third party are expensive and a declaration of conformity under his own name without reference to harmonised standards would prompt enforcement authorities to call for the product’s whole technical file and other means of attestation, a cumbersome and time-consuming exercise if repeated too often.

9) Are there limitations to the legal effect of the presumption of conformity?

Yes, the presumption of conformity comes with several limitations in scope and relevance for those that claim that benefit:

1. The presumption of conformity is a **key indicator, but not proof** – The design of a product in compliance with a harmonised standard, enables the presumption of conformity to act as a “key indicator” (but not as proof) that the product complies with EU legislation. It contributes to building the bona fide of the manufacturer, like the affixing of the CE marking on products covered by harmonisation legislation (cf. Blue Guide p. C 272/59). Besides, “*refusal on the part of the manufacturer or the importer to communicate these data constitutes sufficient reason to doubt the presumption of conformity.*”²⁴

Besides, **The presumption of conformity is rebuttable**: “*it does not mean that the Member States cannot act if risks appear.*”²⁵ The New Approach made clear that “*Public authorities keep intact their responsibility for the protection of safety (or other requirements envisaged) on their territory*”²⁶. To do this authorities shall take the following steps: ascertain that there is a risk, take measures to withdraw or remove the product at issue from the market, and finally inform the Commission of any such measures (Cf. Regulation 1025/2012, Article 11.1).

²¹ Cf. Franck Gambelli, *Aspects juridiques de la Normalisation et de la Règlementation technique européenne*, Eyrolles 1994).

²² Cf. Corado Mattiuzzo: “*Ultimately, the presumption of conformity is no more than a reversal of the burden of proof*” in “Caution: presumption of conformity”, Kommission Arbeitsschutz und Normung, KAN Brief 1/10: <https://www.kan.de/en/publications/kanbrief/safety-of-machinery/caution-presumption-of-conformity/>; The New Safety Compendium (orientation guide) © Pilz GmbH & Co. KG, November 2008: “*In a formal, legal context this is called a reversal of the burden of proof. Where the manufacturer applies a harmonised standard, if there is any doubt, misconduct will need to be proven.*” http://www.eltron.pl/uploads/manufacturer_catalogs/16/10336/Compendium_EN_2009-08.pdf

²³ Council Resolution of 7 May 1985 OJEU C 136/4, Section B.II.2: “*In order to respect the general principle on which the outline Directive is based, which is to leave to the trade the choice of the means of attestation of conformity and thus to prohibit Member States from setting up any system of control prior to placing on the market.*”: [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:31985Y0604\(01\)](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:31985Y0604(01))

²⁴ Council Resolution of 7 May 1985, Section VIII§3.3, OJEU C 136, 04/06/1985, p. C136/8.

²⁵ C-470/03 A.G.M.-COS.MET Srl v Suomen valtio, judgment of 17-04-2007, paragraphs 62-63: <http://curia.europa.eu/juris/showPdf.jsf?text=&docid=63389&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=637359>

²⁶ Council Resolution of 7 May 1985 OJEU C 136, 04/06/1985, p. C136/3.

2. **Free circulation ≠ safety or compliance** – In the framework of Union harmonisation legislation, such a legal effect is limited to granting a right of free circulation of the product on the territory of all Member States without further administrative burden. The ECJ reminded us of this in the James Elliott Case²⁷.
By contrast, manufacturers of products not covered by Union harmonisation legislation (mutual recognition) are sometimes requested to demonstrate an equivalent level of protection of the public interest in the target country compared to the country of origin.
3. **Conformity to the standard ≠ conformity to the law** – The presumption of conformity reflects a ‘claim’ – from the manufacturer – not an assurance that the harmonised standard “fulfils the terms of the relevant request(s) [of the EC]” and “covers indeed the essential requirements which it claims to cover” (cf. Blue Guide 2016 p. C 272/47, third paragraph).
“**The standard is an eye-opener, a simple indication. But such indication is far from being foolproof. The failure to comply should be proven in itself. It would be wrong to consider the non-compliance with the standard as an irrefutable presumption of violation of regulations. This would lead to a reverse onus of proof in criminal matters and “canonize” a private document which is eminently fallible.**” (Franck Gambelli, *Aspects juridiques de la Normalisation et de la Règlementation technique européenne*, Eyrolles 1994).

10) Does the citation of harmonised standards in the OJEU make the European Commission liable in case of non-conformity?

This is very unlikely, as the decision to open the presumption of conformity by publishing the reference of a harmonised standard in the OJEU does not establish in itself a link between a particular product and the cited harmonised standard.

It is the choice and the responsibility of the manufacturer to adequately comply with applicable standards; in any case, he remains liable in full for the placing of a safe and otherwise compliant product on the market (under Regulation 765/2008). He is also liable for the damages that it could have caused to users or other parties (under the Directive on Product Liability for defective products).

In the case of a litigation about a product’s conformity with the technical specification of a harmonised standard, the only responsibility of the European Commission is vis-à-vis Member States for having opened – or not – the free circulation across all EU Member States to all products that would comply with a deficient standard.

Such verification is the responsibility of Member States authorities, not the European Commission²⁸. “When a Member State considers that a harmonised standard does not entirely satisfy the requirements which it aims to cover and which are set out in the relevant Union harmonisation legislation”, it is that Member State’s responsibility to request the Commission to decide “to publish or not to publish, to maintain or not to maintain (...) the reference to the harmonised standard” (Cf. Regulation 1025/2012, Article 11.1).

This is why this claim that the presumption of conformity holds could be challenged in a safeguard clause by Member States or even by the European Parliament to “control the presumption of conformity” for part or for the whole of the standard (Blue Guide page C 272/48, last paragraph and further), without affecting the existence of the standard, which remains under the responsibility of the ESOs (Blue Guide page C 272/48, last paragraph).

The implementation of the New Approach ought to remain what it has been for over three decades: simple, swift (as per Article 10.6 of Regulation 1025/2012) and effective. Adding bureaucratic pre-requisites to the citation of harmonised standards in the official journal “does not contribute (...) to facilitating the free movement of Goods” (ECJ Global Garden case, §67).

²⁷ ECJ Ruling in Case C-613/14 §57: “It follows that such a presumption of conformity seeks only to allow a construction product which meets the requirements laid down by a harmonised standard to circulate freely within the European Union”.

²⁸ Council Resolution of 7 May 1985 OJEU C 136/4, section B. II.1 General clause for placing on the market.