

# Product Compliance Newsletter

## Content

### Editorial

1. EU: Does conformity to Standards equal legal conformity?
2. USA: Amended regulations regarding radio services safety
3. Inaugural meeting of the Product Compliance Working Group
4. Review of the 6<sup>th</sup> GLOBALNORM Product Compliance Conference

Authors of this edition

Legal Notice

## Editorial

Dear readers,

GLOBALNORM can look back on a very successful 2017. Undoubtedly one of its highlights was the 6<sup>th</sup> GLOBALNORM Product Compliance Conference of which we present a [retrospective in this Newsletter](#).

The newly designed GLOBALNORM website went online just in time for the conference. The redesigned website allows us on the one hand to present to you in an even more transparent and accessible way than before how comprehensive our range of services involving Standards and Product Compliance are – from consulting via software solutions to continuing education and professional development.

On the other hand, we can present in detail how individual focus sectors or industries and economic operators can profit from our knowledge, expertise and services.

Right now the website is not yet available in English. However, the translation is already in progress and we're confident that also our English-speaking clients will soon be able to once again find all the information they need on the [GLOBALNORM website](#).

We would also like to take this opportunity to wish all our readers a blessed and peaceful Christmas and a safe and happy New Year!

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## 1. EU: Does conformity to Standards equal legal conformity?

Ever since the James Elliott judgment by the European Court of Justice (ECJ: C-613/14 James Elliott Construction Limited vs Irish Asphalt Limited) the matter of the presumption of conformity in the application of harmonized standards has become a 'hot topic' indeed. On July 21, 2017 the Commission published the Implementing Decision (EU) 2017/1357 in OJ L 190 on publication with a restriction in the Official Journal (OJ) of the European Union of the reference of standard EN 60335-2-9:2003, as last amended by A13:2010, on the Particular Requirements for Grills, Toasters and Similar Portable Cooking Appliances under Regulation (EU) No 1025/2012 of the European Parliament and of the Council.

Hence facts in connection with hot surfaces were established in that Implementing Decision. The presumption of conformity restriction applies to the following content of the harmonized standard:

- Section 11, Table Z101, Footnote b,
- those parts of Section 7.1 that refer to Table Z101, Footnote b,
- those parts of Section 11.Z10x that refer to ventilation openings.

Upon enquiry to the competent Standards Committee at the DKE, the German Commission for Electrical, Electronic & Information Technologies of DIN and VDE, it is unlikely that any changes will be made to the standard before the end of 2018 at best. Under normal

circumstances, however, it is more likely going to be at the end of 2019. Accordingly, manufacturers will have to forge new paths as to how they can demonstrate compliance with the fundamental requirements of Annex 1 of the Low Voltage Directive 2014/35/EU. A detailed risk assessment is therefore necessary here (e.g. as per CENELEC Guide 32), which has to form part of the technical documentation. We would also direct you to the Blue Guide, Chapter 4.1.2.2 in this regard. It contains a diagram illustrating how the manufacturer should proceed. This clarifies that it is the responsibility of the manufacturer to first carry out a risk assessment in which the manufacturer specifies the basic requirements relevant to a particular product and whether harmonized standards exist for the individual safety objectives, or whether these cover all safety objectives. If this is not the case, the manufacturer has to either apply other specifications or render evidence of compliance with the essential requirements directly by means of a risk assessment, meaning: documentation. In that case, the burden of proof also reverses. Hence the manufacturer can therefore no longer claim the presumption of conformity, because it is reserved for harmonized standards.

Such restrictions on the presumption of conformity are found more and more in the Official Journal in the references or sources of harmonized standards. As such, this increasingly puts the future of the presumption of conformity of harmonized standards into question. It can be noted that European standards, at a growing rate, are either

not published in the Official Journal (as is the case with the Radio Equipment Directive, which is still missing numerous standards on EMC and safety) or with a considerable delay. Or, as was described above, they are published in the Official Journal with a restriction on the presumption of conformity.

On October 23, 2017 the Commission published an announcement in regard to the James Elliott judgment. Among other things, it once again refers to the fact that the ECJ has confirmed that the obligation and responsibility of the Commission to monitor whether harmonized standards comply with the fundamental requirements of the relevant harmonization legislation and/or the relevant standardisation mandate, before they are published in the Official Journal in accordance with Article 10 (5) and (6) of Regulation (EU) 1025/2012. This judgment has led the Commission to examine European standards in a very strict and legalistic manner in accordance with a document entitled "Verification of conditions for the publication of references of harmonised standards in the Official Journal" (November 23, 2016), to ensure they comply with the formal requirements for publication in the Official Journal. The Commission is aware that this can result in problems regarding deadlines for the publication of the references of harmonized standards. In order to streamline and formalize publication practices, an Action Plan entitled 'Structural solutions to decrease the stock of non-cited harmonized standards' has been published on the EU website (see link below).

The action plan focuses on three aspects in particular:

1. Improvement in the support of so-called New Approach Consultants, with the aim of achieving an alleviation of the administrative burden on European standardization organizations and to fundamentally integrate New Approach Consultants in the process of establishing standards more efficiently.  
(More about the function of the New Approach Consultants: [ftp://ftp.cencenelec.eu/EN/EuropeanStandardization/Guides/15\\_CENCLCGuide15.pdf](ftp://ftp.cencenelec.eu/EN/EuropeanStandardization/Guides/15_CENCLCGuide15.pdf))
2. Improvement in the common understanding of the assessment and publication process of the references of harmonized standards. The Commission and the European standardization organizations have adopted a review mechanism which has a clear allocation of roles and responsibilities as well as strict target dates.
3. E1. The internal database of harmonized standards is to be updated. In particular, this is intended to simplify the verification processes and the maintenance and integration of relevant data (e.g. transition periods) that are required prior to publication in the EU Official Journal. In the past, it was often at precisely this point that errors arose in regard to the references of harmonized standards. This step is therefore a very welcome one.

[https://ec.europa.eu/growth/content/european-commission-launches-action-plan-improve-publication-harmonised-standards-industry\\_en](https://ec.europa.eu/growth/content/european-commission-launches-action-plan-improve-publication-harmonised-standards-industry_en)

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## 2. USA: Amended regulations regarding radio services safety

In the USA, radio frequency (RF) devices and industrial, scientific and medical (ISM) devices and equipment are, among other things, subject to the provisions of the Federal Communication Commission (FCC) agency. These provisions can be found in the Code of Federal Regulations (CFR), Title 47, Part 2, 15 and 18. To ensure radio services operation is as interference-free as possible, compliance of specific RF and ISM devices with the relevant requirements has to be guaranteed before they are placed on the market or imported.

It is precisely these requirements that have now been amended by Official Journal Notice FR/Vol. 82, No. 211, which took effect on November 2, 2017. The transitional period has been set at one year. Preparations for this had been in progress for a long time. The proposed amendments were published in the Official Journal on August 6, 2015 in the form of a Notice of Proposed Rulemaking (NPRM). Comments were invited. Three out of five FCC commissioners posted an initial report on the matter on July 14, 2017 on the FCC website.

The amendments now announced in the Official Journal concern the following topics:

1. **Two become one:** In future, there will only be one self-verification procedure. The Declaration of Conformity (DoC) procedure and the Verification procedure merge into a new process called the Supplier's Declaration of Conformity (SDoC). (Note: The Certification procedure is not affected by this.)  
For the SDoC, the economic operator who is responsible for compliance with conformity requirements is, as before, requested to either conduct EMC readings himself or to provide one of the other types of evidence of compliance with appropriate technical standard(s) acceptable to the FCC. Samples and test reports are to be sent to the relevant government office upon request. A minimum labeling requirement is to affix a label which, in the event of a certification, also displays the FCC Identifier.
2. **Electronic Identification:**
  1. In future, in addition to warning notices or other information, such an FCC identifier may also be provided in electronic form (e.g. on an integrated display screen). In doing so, however, it is important that
    - a. the information is readily accessible,
    - b. it does not require any special access codes,
    - c. it is clearly legible without the aid of magnification,
    - d. it cannot be modified by a third party, and

- e. it may only be in addition to a label on the device or the packaging.

This may in individual cases result in changes to the labeling of radio frequency (RF) devices.

Moreover in future, the technical standard ANSI C63.4-2014: American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz must be observed in full.

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### 3. Inaugural meeting of the Product Compliance Working Group

On November 21, 2017 the inaugural meeting of the newly founded Product Compliance Work Group at Netzwerk Compliance e.V. ([www.netzwerk-compliance.de](http://www.netzwerk-compliance.de)) was held in Berlin. Netzwerk Compliance e.V. is a non-profit association of Corporate Compliance experts from a variety of companies. More than 350 corporations and medium-sized companies from a wide variety of industries are represented. The aim of Netzwerk Compliance e.V. is to promote and support the exchange of experience among leading companies in Germany, to discuss current challenges and to provide knowledge in a targeted way. The new Product Compliance Work Group closes a gap, since ensuring product compliance when placing products on the market plays an important role. It addresses manu-

facturers and importers, but also traders and distributors. The kick-off event was attended by industry representatives, corporate lawyers as well as law firm representatives (32 participants). The industry advocates represented a range of sectors, including mechanical engineering, electrical/electronic engineering, consumer goods and retail, information and communication technology as well as branches of industry such as fire alarm systems and other construction products.

In addition to promoting the exchange of expertise, the inaugural project of the Work Group is the development of a guideline on the subject of Product Compliance. Such a guideline is intended to serve as an introduction to this subject for beginners from a variety of perspectives as well as to illustrate the importance of this subject to other professionals and their respective agents working in, for example, management, purchasing, sales and marketing or product management.

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### 4. Review of the 6<sup>th</sup> GLOBALNORM Product Compliance Conference

The 6<sup>th</sup> GLOBALNORM Product Compliance Conference was held on November 22-23, 2017 in Berlin. In his opening words, Michael Loerzer noted the increased awareness of Product Compliance, as evi-

denced also by the growing number of participants at GLOBALNORM conferences:

Our first conference was held June 8-9, 2009 in Berlin with just on 30 participants. This year, we were pleased to welcome over 80 participants from a wide variety of industry sectors. Furthermore, the subscriber base to this Newsletter of over 2,000 also suggests a rise in interest. Add to that the fact that since 2016, the Product Compliance Officer certificate program (ISO/IEC 17024 certified) offered by GLOBALNORM ACADEMY has been reliably booked out and 83 participants have successfully completed the program and been awarded certification to date.

Here are some examples that illustrate the complexity of Product Compliance:

- Kitchen appliances with cooking function
- Personal weighing scales with smartphone connection
- Industry 4.0 and the requirements arising from the networking of subsystems
- All possible radio frequency applications in a car, such as a distance radar

In his opening speech, Mr. Loerzer used a well-known shop manufacturer as an example to illustrate how a simple wooden table can turn into a high-tech product if it has LED, Wi-Fi and a driving motor, which illuminated that mastering the regulatory and normative requirements of convergent technology will be one of the central challenges in the future.

Following on from that, Mr. Dieudonné of Heraeus Noblelight GmbH

spoke on how the subject of Product Compliance has evolved at Heraeus Noblelight over the past 20 years. These days, a Product Compliance Officer (in association with Quality Management, Coordinator) is actively involved in projects. Another Product Compliance Officer has been integrated into Research and Development directly as a contact partner. Furthermore, corresponding measures in PDM as well as the Cluster concept have been implemented.

Next, Dr. Honnacker of the Bavarian Ministry for the Environment and Consumer Protection illustrated in his lecture how the New Approach has evolved over the last few years due to Decision 768/2008/EC and Regulation (EC) 765/2008 (New Legislative Framework). He emphasized the high degree of autonomy economic operators have, yet also noted the correspondingly high degree of personal accountability. In the subsequent discussion it became clear that some economic operators struggle with the personal accountability that this high degree of freedom entails. Market surveillance as a safety net plays quite a substantial role in this issue. Yet the monitoring authorities view themselves also as advisory partners to the economic operators. Neither the authorities nor the economic operators want any non-compliant or unsafe products on the market. In some segments, more intensive market surveillance would even be considered desirable in order to ensure a level playing field.

Professor Stefan Bracke of the Faculty of Mechanical Engineering and

Safety Technology at the University of Wuppertal (Department of Reliability Engineering and Risk Analysis) gave a very entertaining talk on the subject of "Faulty product series in the real world: Reaction and prevention from a statistical perspective". On the basis of two case studies – the recall of Philips Senseo coffee machines in 2009 and VW motors – he illustrated how to calculate and forecast faulty behaviour using statistical methods.

Mr. Schaber of SICK AG (Dept. of External Standards and Regulations) presented their approach to the automated creation of EU Conformity Declarations. The project was initiated in response to the immense database maintenance effort required in regard to EU Conformity Declarations for over 40,000 product variations. The fundamental idea here was that an EU Conformity Declaration represents a module in the product structure or bill of materials and Standards and EU Directives are individual components in that module.

As a second public service representative, Mr. Meinders of the Federal Network Agency in Germany (Bundesnetzagentur) introduced the Radio Equipment Directive 2014/53/EU. Since it came into force on June 13, 2017 it continues to cause issues here and there, such as for example, how to handle the matter of 'combined equipment'. The lively Q&A following the presentation underscored the impact of the Radio Equipment Directive on industry. Subsequent to his presentation, Mr. Meinders forwarded the information that according to a colleague who had participated at

the most recent TCAM meeting, the deadline to comment on 'combined equipment' will be extended to the end of January 2018. Orgalime and DIGITALEUROPE are also likely to be involved.

Attorney-at-law Inken Green listed the most recent developments in the area of Environmental Compliance, whereby she presented an almost up to the minute report on amendments to the RoHS Directive, which was published as Directive (EU) 2017/2102 in Official Journal L 305 on November 21, 2017. Additional topics included the new Energy Labeling Ordinance as well as a review of 10 years of REACH and the challenges ahead.

On the second day of the conference, six focus topics were on offer to participants:

- Standards Management – Practical issues, Organization and Goals from a Company Perspective
- Product Compliance in Business – As much as necessary and as little as possible
- Market Access requirements for Electrical Products in the global transport of goods
- Products with integrated Radio Modules – Legally compliant application of the Radio Equipment Directive
- Dialogue between Economic Operators and Public Service Agencies – Current issues surrounding CE labels, Obligations of Economic Operators and Liability Issues
- Application of the Conformity Assessment Procedure in the absence of a specific Product Standard

At the Products with Integrated Radio Modules Workshop it was established that a Recommendation for Action together with a template Declaration of Conformity (in German and English) is to be made available on the website for purchase. The examples presented by Mr. Loerzer were deemed very accomplished by Mr. Meinders, who took the opportunity to reiterate that if the European Standards published in the Official Journal are not applied in the Conformity Assessment procedure, the principle of the presumption of conformity is no longer given (see Article 16 of Directive 2014/53/EU, also the article "Does conformity to Standards equal legal conformity?" in this Newsletter). However, as has already been correctly pointed out, it is then no longer mandatory to involve a notified authority.

On behalf of Globalnorm GmbH, we would like to thank our staff, the participants, the Hotel and Conference team and above all the speakers for their contribution to the success of this event that has become a firm fixture in our calendar.

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The Product Compliance Newsletter is available in German as well.

### **Legal Notice**

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