

# Product Compliance Newsletter

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Dear Readers,

In April 2014 we published the first issue of our Product Compliance Newsletter and we're proud to say that since then it has reached 2139 readers in its present format. In those four years we've examined the many important changes in the field of product compliance.

Our company, too, is subject to changes. It is with considerable sadness that we are saying goodbye to Ms Monika Krauth, our Corporate Communications and Public Relations Manager and the editor of this newsletter, who has been offered an opportunity in the field of education.

In a sense this represents somewhat of a watershed for us and we are therefore taking this opportunity to consider the format in which we would like to continue this newsletter. This depends not least on you and whether you regard this newsletter as a useful source of information. The new European General Data Protection Regulation (GDPR) also plays a not insignificant role here. In the past, we were able to request certain information from you during the newsletter subscription process that allowed us to better understand our subscribing client base. This is only possible to a limited extent now, hence we are currently considering a new format. One possibility would be a paid subscription format where we would correspondingly offer greater value in the form of more detailed information.

If you would like to take a few minutes, I would be interested to know whether you are interested in continuing to receive a monthly publication on Product Compliance. We would likewise also welcome any suggestions or feedback at this stage, whether it be on the topics, content or the format of this newsletter.

For now, however, we would like to take this opportunity to thank Ms Krauth for her untiring efforts and dedication in the past, and to wish her all the best in what will surely be a challenge of a truly different nature.

Europe is enjoying unusually hot weather this time of year. Once this subtropical summer is over, we would be pleased to welcome you at one of our upcoming GLOBALNORM events, such as our GLOBALNORM Product Compliance Conference on April 4th and 5th, 2019 in Berlin.

Sincerely,  
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## 1. EU: Update on the Radio Equipment Directive 2014/53/EU

On June 5, 2018 the Commission published an updated version of the Guide to the Radio Equipment Directive 2014/53/EU at <https://ec.europa.eu/docsroom/documents/29782>. Section 1.6.3.1 – Non-Radio Products which function with Radio Equipment / Electrical and Electronic Equipment with Non-Electrical Products – now has a further link to the Supplementary Guidance On The LVD / EMCD / RED (<https://ec.europa.eu/docsroom/documents/29121>).

Regarding this entire topic of so-called 'combined radio systems' (a wireless module installed in a non-wireless product), the following text passage in that Supplementary Guide is worth mentioning:

„It should be noted that this document is publicly available but is not binding, even if the word 'shall' is used in many parts. In the event of any inconsistency between the provisions of a EU law (e.g. LVD/EMCD/RED) and this document, the provisions of EU law prevail. National market surveillance authorities shall take action with respect to finished non-compliant products on the basis of the provisions of the applicable EU act (s).”

This topic was also one of many topics during the meeting of the Radio Equipment Directive Compliance Association (REDCA) in Copenhagen, Denmark (May 15-17, 2018). The status of individual Technical Guidance Notes (TGN) still to be published was discussed, including among others the TGN 01 – DRAFT Technical Guid-

ance Note on the RED Compliance Requirements for a Radio Module and the Final Product that integrates a Radio Module. Also of interest was the presentation by several notified bodies in cooperation with the Bundesnetzagentur (Federal Network Agency) on the Introduction to Risk Assessment regarding the RED.

The next meeting of the REDCA will take place in Berlin, Germany, on November 12-14, 2018.

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## 2. EU: EU Commission plans to revise the Low Voltage Directive

The EU Commission announced its intention to review the existing Low Voltage Directive 2014/35/EU in regard to any potential need for change, and plans to conduct a comprehensive investigation in the coming year 2019 that includes a public Internet survey as well as focus interviews. The first feedback period is closed since November 27, 2017 followed by the upcoming public consultation ([http://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5291384\\_en](http://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5291384_en)).

From a German perspective, and after consultation with the relevant department at the Bundesministerium für Arbeit und Soziales (BMAS / Federal Ministry of Labour and Social Affairs), there appears to be no compelling need for change. In contrast to the Machinery Directive 2006/42/EC, this Directive has

been adapted in line with Decision 768/2008/EC and risk assessment implementation and documentation was introduced (e.g. by applying the CENELEC Guide 32). The Low Voltage Directive certainly does have some special characteristics in relation to the applicable standards and the individual options (Article 12 to 14). But in and of itself, the Low Voltage Directive represents a piece of legislation that has proven itself in practice.

In practice, certain products may be difficult to place under any one Directive. This is the case, for example, when electronic products have certain functions of a machine, resulting in a conflict with Section 1(2)(k) of the Machinery Directive 2006/42/EC, if such products do not come under the list of products excluded from the scope of the Directive and if there are, for example, no applicable harmonized standards for such products under the Machinery Directive. An example of this is the IEC 61010-2-120:2016-10, which for various reasons could not be ratified yet as EN 61010-2-120.

There will certainly also be problems in relation to the new Radio Equipment Directive 2014/53/EU. However, this is more likely due to the general difficulties associated with how harmonized standards are published (we reported on this in connection with the James Elliott verdict in earlier editions of this newsletter).

In this respect, there does not appear to be a compelling need for a revision of the content of the Low Voltage Directive. Should the Commission decide otherwise, a draft

revision cannot reasonably be expected before 2020.

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### 3. EU: Implementation of the Regulation on Food Contact Materials

At the meeting on October 6, 2017 the European Parliament adopted the resolution on the implementation of Regulation 1935/2004 regarding food contact materials (Official Journal C 215, p. 57, Communication 2018/C 215/11).

This regulation allows for individual rulings on 17 food contact materials and objects (FCMs), pursuant to Annex 1 of the Regulation. However, individual rulings that apply across the EU have been issued for only 4 individual materials to date, namely plastics (including recycled plastics), ceramics, regenerated cellulose, and active or 'smart' materials. There is moreover, an urgent need to revise Directive 84/500/EEC on ceramic objects. EU Member States are free to adopt individual national provisions for the remaining 13 materials or not. Many Member States have already introduced or are actively working on various measures for the remaining food contact materials and objects. This, however, undermines the principle of mutual recognition and the effective functioning of the domestic market. Numerous other deliberations are mentioned in this resolution, aimed at ensuring a high level of protection of health and well-being. Parliament initially noted that

this general regulation provides a solid basis, the objectives of which continue to remain relevant. It emphasizes that even though the focus should be on issuing individual measures for the 13 materials that have not yet been regulated at the level of the European Union, all the relevant stakeholders are pointing out the shortcomings in the implementation and enforcement of existing legislation.

The Joint Research Centre of the Commission is going to review individual national provisions. Parliament therefore calls on the Commission to use this review as a starting point for drawing up the necessary measures. It also emphasizes the need to pay particular attention to those FCMs where there is a higher risk of transfer, irrespective of whether they come into contact with food directly or indirectly, and to also include materials that enclose liquids and food items with a high fat content as well as materials that come into contact with food over a long period of time. Other subjects covered by this resolution include risk assessment, traceability, compliance, enforcement and monitoring.

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### 4. USA: California Proposition 65 – New regulations on "clear and reasonable" warning notices

Proposition 65 in California in the United States requires companies

to warn people in California if they are being exposed to a significant amount of listed chemicals that can cause cancer, birth defects or other reproductive harm. Around 1,000 chemicals are listed at present.

Proposition 65 (Prop 65) is being made more stringent in terms of how to display warning notices. To date, warning notices only had to indicate that listed chemicals are contained in a product. Information as to exactly which chemical that was, where it could be found, how consumers were being exposed to it, the degree of risk or how to reduce exposure to the chemical was not provided. This resulted in Prop 65 warning notices being displayed as a precautionary measure at numerous locations across California where chemicals emission was considered fundamentally likely (e.g. on products and in hotels, coffee shops, offices). This approach, however, ran counter to the purpose of the provision, which was to protect and educate consumers and in particular raise awareness among businesses.

Now, in 2018, the new "clear and reasonable" warning notices have to have three key elements:

- A yellow and black triangle warning symbol displaying the word "WARNING".
- The name of at least one specific chemical, that triggered the need for a warning notice, has to be indicated as well as the risk it presents (e.g. carcinogenic).
- A clearly displayed link to a website that provides information on Proposition 65 and further information on health

effects and ways to reduce and/or eliminate exposure.

In addition, font size has to be at least size 6, but at the same time must not be smaller than the largest writing on the product.

Old and possibly unrecorded inventory with outdated warning notices (or none at all) can result in compliance issues for companies. Fines in the event of a lawsuit are high, about USD\$ 2,500 per day. So-called “bounty hunters”, resourceful lawyers who try to profit financially from catching companies that violate the regulations, are always looking for inadmissible or incorrect warning notices.

The new provisions enter into force on August 30, 2018.

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## 5. Standards News

### **New Low Voltage Directive (2014/35/EU) standards**

The European Commission has published a third list of harmonized standards for the current Low Voltage Directive (Communication 2018/C 209/04, Official Journal C 209 of June 15, 2018, p. 37), which has been in force since April 20, 2016. No new standard is cited in that list.

An important notice regarding this communication is that the Date of Termination of the Presumption of Conformity for the Replaced Standard (DoC) has been postponed for the EN 62368-1:2014-08 from June 20, 2019 to December 20, 2020 and applies to the replaced standards

EN 60065:2014 with AC and EN 60950-1:2006 with A11, A12, A1, A2 and AC.

### **New standards for the Electromagnetic Compatibility (EMC) Directive (2014/30/EU)**

The European Commission has published a new list of harmonized standards pertaining to the EMC Directive (Communication 2018/C 246/01, Official Journal C 246 of July 13, 2018, p. 1). This list replaces the previous lists published in the Official Journal of the European Union.

A total of 9 new standards and amendments were published:

EN 12895:2015  
EN 16361:2013 + A1:2016  
EN 50121-3-1:2017  
EN 50121-3-2:2016  
EN 50121-4:2016  
EN 50121-5:2017  
EN 50270:2015  
EN 50270:2015 + AC:2016-08 and  
EN 61000-6-5:2015.

### **New standards for the Radio Equipment Directive (2014/53/EU)**

The European Commission has published a new list of harmonized standards in regard to the Radio Equipment Directive 2014/53/EU (Communication 2018/C 246/02, Official Journal C 246 of July 13, 2018, p. 23). This list replaces the previous lists published in the Official Journal of the European Union. No new standards have been published. Numerous standards in regard to safety and EMC (e.g. EN 62368-1, EN 60950-1, EN 3014891-1 as well as the specific sections) are therefore unfortunately still missing, so that it is up to the manufacturers to decide on how to proceed here.

The important thing though is that despite a lack of relevant standards here, Module A – Internal Production Control can still be applied by the manufacturer, in accordance with Section 17(2), meaning the involvement of a notified body is not mandatory.

### **The new IEC/IEEE 82079-1 (Edition 2.0)**

The international standard IEC 82079-1 — Preparation of Instructions for Use: Structuring, Content and Presentation – Part 1: General Principles and Detailed Requirements — has been the central standard for technical editorial departments in companies since 2012. It is to be replaced in 2019 by the new and revised edition 2.0, which will also have a new title: IEC/IEEE 82079-1 — Preparation of Information for Use (Instructions for Use) of Products – Part 1: Principles and General Requirements.

In the current discussions and in sifting through the comments received, demarcation in regard to the planned ISO 20607 — Safety of Machinery – Instruction Handbook: General Drafting Principles, also plays an important role.

Website: <https://www.technical-communication.org/news/an-important-milestone-in-the-revision-of-the-standard-iecieee-82079-1-has-been-achieved.html>

### **Canada: ICES-Gen — General Requirements for Compliance of Interference-Causing Equipment (July 2018)**

Canada published the ICES-Gen in July 2018 (<https://www.ic.gc.ca/eic/site/smt-gst.nsf/eng/sf11413.html>). This document regulates both the technical requirements as

well as the placing on the market and the compliance assessment procedure.

What is interesting about this document is its broad scope:

“Interference-causing equipment is a device, machinery or equipment, other than radio apparatus or terminal equipment, that causes or is capable of causing interference to radiocommunication. ICES-Gen shall be used in conjunction with the ICES standard applicable to the specific type of interference -causing equipment, for assessing the equipment’s compliance with the ISED requirements, provided the applicable standard has been updated to refer to ICES-Gen for the common requirements. Where requirements in this standard are different from those in the applicable ICES standard, the latter shall take precedence.”

You can easily monitor such regulatory amendments in individual third party countries using the ROGER WILLCO Product Compliance portal.

If you have any questions, please do not hesitate to email our Compliance team at [team.compliance@globalnorm.de](mailto:team.compliance@globalnorm.de)

## 6. Product Compliance Officer training course

Three additional dates in 2018 are available for the Product Compliance Officer training course:

October 16th - 19th in Berlin, Germany

November 6th - 9th in Switzerland

December 11th - 14th in Austria

All these courses are held in German.

Further information on all training courses can be found by clicking on the link provided below or in the Events Calendar on our website.

» [Events Calendar](#)

## 7. Save the Date

The 7th GLOBALNORM Product Compliance Conference will take place on April 4th and 5th, 2019 in Berlin, Germany.

The conference will once again examine the current developments and issues regarding product compliance. The first day of the conference will focus on the most recent legislative developments, e.g. in the area of market surveillance. On the second day, we’ve once again scheduled workshops on important practical issues.

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