ANEC position on prEN 50566 "Product standard to demonstrate compliance of radio frequency fields from handheld and body-mounted wireless communication devices (30 MHz - 6 GHz)"

Introduction

The draft standard (prEN 50566:2011) has been prepared by CLC/TC 106X, "Electromagnetic fields in the human environment", of which ANEC is a member. PrEN 50566:2011 is currently out for vote of Public Enquiry until 3 February 2012.

It has been prepared under a mandate (M/305 in the Field of Electrotechnology, Information Technology and Telecommunications, 7 September 2000), given to CENELEC by the European Commission and the European Free Trade Association and if approved it will provide presumption of conformity with the essential safety requirements of the R&TTE Directive 1999/5/EC as a harmonized standard.

prEN 50566 applies to any wireless communication devices intended to be used with the radiating part of the equipment in close proximity to the human body (i.e. less than 200 mm) including devices operated in front of the face. The frequency range covered is 30 MHz to 6 GHz.

General Comments

"Intended use" VS ""foreseeable use"

In the ANEC position paper on the revision of R&TTE Directive[1], we expressed the position that the safety concept of the directive should be in line with real life situations as it neglects the expectations of consumers in modern society. ANEC called to align the safety concept of the R&TTE Directive with the concept the General Product Safety Directive[2].

We suggested for the following wording of art. 16.2 of Regulation 765/2008[3] "products covered by Community harmonisation legislation which, *when used in accordance to their intended purpose or under the conditions which can be reasonably foreseen and when properly installed and maintained*" to be put in paragraph 1 of art. 6 of the revised R&TTE directive.

We also obviously endorse the additional note: "Intended use and use based on human behavior and anthropometric data".

It should be noted however that the present R&TTE directive only refers to the concept of "intended use".

The objective of this particular point of discussion has two aspects:

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[1] ANEC-ICT-2011-G-001

[2] Art. 2b) of the General Product Safety Directive (GPSD) 2001/95.

[3] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (

- The first objective is to protect the consumer (in the most generic and global sense of it) through a complete and transparent information on the products (and services) proposed on the market.
- The second objective is to get acceptance from the manufacturers (*or as appropriate … an obligation on the manufacturer*) in relation with the nature and the ways and means to make such information complete, transparent, accessible and understandable to all consumers.

The manufacturer has a protective legal approach which is concretized by the term: "intended use". We know that the main goal of this manufacturer approach is more to protect themselves than to protect consumers: "Should a consumer use products and services beyond what is defined as intended use, then the manufacturer would not endorse any responsibility on what could happen to the consumer". This is what we could define as a "non-information" approach since it describes only a border when the consumer needs to know what happens beyond this border.

The consumer has also a protective approach which is supported by the proposed term: "Foreseeable use". One of the basic marketing principles says that the success of a product is characterized by the number of item sold and, beyond that, by the misappropriation that consumers can make of it. In other words a manufactured product is not only a marketing concept but also a physical object owned by the consumers. As such the manufacturer shall also take all appropriate dispositions to keep the consumer informed on the consequences of using the said product outside the limitations defined under "intended use".

The consumer must be aware of the "***what if*** …?".

- What if .. I use my laptop in my garden and it suddenly rains?
- What if .. I put my mobile phone under my pillow during the night?
- Etc…

The above examples of consumer behaviors are not unrealistic and as such could be qualified as "reasonable foreseeable use". However, certain of these behaviors, even if reasonable, are difficult to predict.

This is where the notion of standard enters into consideration. Standards impose on manufactured products a certain number of technical, physical and administrative obligations which, among others, shall strongly limit (preferably eliminate) negative impacts on the consumer, whatever is the nature of this negative impact (physical, economical, psychological, ..).

For the time being, the implementation of a standard is mainly based on measurable characteristics to be met by the product accompanied by appropriate documentation including measurement procedures and conditions of use, the latter being reflected in the user guide.

However, certain products meet the standards only in certain circumstances beyond which it might become dangerous for, the consumer. These circumstances are delimited by the "intended use" defined by the manufacturer.

In other cases, certain parts of the standardized test measurement procedures are slightly modified to fit with the "intended use" of the product, since the

manufacturer considers that test measurement procedures must be relevant with what is defined as “normal” conditions of use according to the user manual.

In such cases, appropriate additional documentation ought to be provided by the manufacturer to clarify:

- Why specific limitations have been introduced for the use of the product?
- What could be the consequences when the user goes beyond these limitations under “reasonable foreseeable use” of the product?
- As appropriate, quantify the difference between test values measured under conditions fitting with the “intended use” of the product and test values measured strictly following standardized procedures.

Finally, the nature of this additional documentation required by the consumers shall also be considered by the manufacturer as an additional legal protection versus what would then be qualified as “exaggerated unforeseeable misuses”.

Specific Comments on prEN50566

prEN50566 is mainly (if not only) based on EN 62209-2 standard[4]. In this respect, an in-depth exam of prEN50566 implies a good knowledge of EN 62209-2.

REMINDER: test details and results shall be reported according to Clause 8 of EN 62209-2:2010 which is applicable to any wireless communication device capable of transmitting electromagnetic fields (EMF) intended to be used at a position near the human body, in the manner described by the manufacturer, with the radiating part(s) of the device at distances up to and including 200 mm from a human body.

It has been underlined that the concept of “reasonable foreseeable use” has a subjective nature while referring to “the existing basic standard EN 62209-2, which explicitly requests manufacturers to reflect in the user manual the conditions of use in case certain measurement distance has been used during SAR tests.”, where we take note of the unquantifiable character of the concept of: “certain measurement distance”.

It has also been said that:

- “to request manufacturers to reflect in the user manual the conditions of use in case certain measurement distance has been used during SAR tests” and,
- to ask the “the rationales of the separation distance relative to the use of the device under reasonably foreseeable conditions”,

are redundant information.

[4] Human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices - Human models, instrumentation, and procedures - Part 2: Procedure to determine the specific absorption rate (SAR) for wireless communication devices used in close proximity to the human body (frequency range of 30 MHz to 6 GHz)

Consumer behaviors are not under the control of manufacturers nor of the ANEC, in particular when using handheld and body-mounted wireless communication devices.

From the ANEC's point of view the first bullet proposed in prN50566, section 6, is only factual and does not necessarily help the consumer to avoid being in a critical situation as far as the EMF radiation levels are concerned.

ANEC considers that providing the rationales of the separation distance relative to the use of the device under reasonably foreseeable conditions would significantly clarify relationship between consumers and manufacturers.

In the specific case of the implementation of EN 62209-2 (section 6.1.4.1), the measurement distance between the device to be tested and the human body shall not be higher or equal to 200 mm. This section also mention that in the case measurement distance(s) have been specified by the manufacturer the device shall be tested at these specified distances.

This does not mean in any way that, when a measurement distance is specified and higher than 200 mm, the concerned manufacturer is exempted to proceed with SAR measurement at distances equal or lower than 200 mm.

This is exactly where the additional documentation, as requested in prEN50566 (section 6 second bullet) is absolutely necessary to insure the full compliance with EN 62209-2 in particular if (as appropriate) measurement distance(s) specified by the manufacturer are higher than 200 mm.