Group of Administrative Co-operation Under the R&TTE Directive

EMC Working Group on Administrative Co-operation

EMC ADCO

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Dear all,

The New Legislative Framework (NLF) lays down provisions in order to ensure that an effective and consistent system of market surveillance is established across the Union. The Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 sets out the requirements for accreditation and market surveillance relating to the marketing of products and repeals Regulation (EEC) No 339/93.

This Regulation provides a framework for the market surveillance of products to ensure that those products fulfil requirements providing a high level of protection of public interests, such as health and safety in general, health and safety at the workplace, the protection of consumers, protection of the environment and security.

The EU legislation does not aim to protect health and safety exclusively, but also other public interests such as protection of the consumer, worker, or the environment, the avoidance of electromagnetic compatibility by limiting disturbances or the correct measurement in legal metrology, etc. These issues must therefore also be considered to be covered by the notion of risk.

For the electronic communication domain the R&TTE (1999/05/EC) Directive and EMC Directive (2004/108/EC) are affected.

Member States shall ensure that products which present a serious risk requiring rapid intervention, including a serious risk the effects of which are not immediate, are recalled, withdrawn or that their being made available on their market is prohibited, and that the Commission is informed without delay thereof. If a product presenting a serious risk has been made available on the market, Member States shall notify the Commission of any voluntary measures taken and communicated by an economic operator, named RAPEX[1] procedure.

[1] Commission Decision 2010/15/EU of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive)

The decision whether or not a product represents a serious risk shall be based on an appropriate risk assessment which takes account of the nature of the hazard and the likelihood of its occurrence. The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering that a product presents a serious risk.

In accordance with articles 6.1 and 7.1 of the R&TTE Directive (1999/05/EC) and article 3 of the EMC directive (2004/108/EC), all products should fulfil the essential requirements and the other relevant provisions of the applicable directive before they can be placed on the market and put into service. Market surveillance authorities have to take appropriate measures to withdraw non compliant products from their market. The non-compliance of a product can be caused by:

- failure of equipment to meet the essential requirements or other requirements laid down in the Directive;
- shortcomings in the harmonised standards
- incorrect application of the harmonised standards;
- incorrect execution of the conformity assessment procedure.

Non-compliant products can cause interference. In some situations the operation is completely impossible, and in other situations the effect of disturbance is sporadic. For example a non-compliant product can disturb completely the radio communications of a vital mobile communications network (e.g. police, ambulance, fire brigade or air traffic), but in another situation this non-compliance product will not disturb radio communications. The circumstance of the radio-spectrum determines the level of risk in this case.

In principle, every non-compliance situation is unique and therefore each product should be assessed, separately by the market surveillance administration. The concept of 'risk' underpinning regulated sectors is closely linked to the legislator's choice of essential requirements of the different product Directives. The latter indeed constitute important benchmarks for the risk assessment. This also means that the fact that the legislator has accepted a certain level of risk should be taken into account.

Based on these considerations, the ADCO R&TTE and ADCO EMC decided to develop a harmonised risk assessment approach covering R&TTE and EMC products. The idea is to develop a methodology for analysing and assessing the level of risk of a product.

ADCO R&TTE and EMC ADCO are of the opinion that the level which represents a serious risk should be developed in close cooperation with the organisations which are in charge of spectrum management and standardisation (ECC, ETSI TC-ERM and CENELEC).

With that we are looking forward for a fruitful cooperation with you.

Best regards,

Chairman ADCO R&TTE

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