

Brussels, 12 November 2009

Alignment of the EMC Directive 2004/108/EC with the New Legislative Framework (NLF)

Orgalime welcomes the opportunity to comment on the documents presented at the EMC Working Party meeting of 30 June 2009 with regard to the alignment of the EMC Directive 2004/108/EC with the New Legislative Framework (NLF), Decision 768/2008/EC mainly.

The EMC Directive 2004/108/EC is an important piece of product legislation as it affects almost all electrical and electronic equipment. It resulted from a thorough review process where, based on the experience with its predecessor 89/336/EEC, the conformity assessment procedures were adapted in a way that was acceptable to all stakeholders and provisions were introduced to ensure a better enforcement of the Directive.

Orgalime believes that the existing modules and the subsequent involvement of notified bodies as defined in 2004/108/EC fully meet the will of the legislator to ensure protection against electromagnetic disturbance and do not need to be amended. Therefore Orgalime prefers a partial alignment with the NLF which maintains the EMC specificities as proposed in Document "EMC/15/20".

In addition we would like to provide the following detailed comments on Document EMC/15/20 as further support for the proposal for partial alignment.

Orgalime, the European Engineering Industries Association, speaks for 34 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 22 European countries. The industry employs some 11.1 million people in the EU and in 2008 accounted for some €1,885 billion of annual output. The industry not only represents more than one quarter of the output of manufactured products but also a third of the manufactured exports of the European Union.

Document EMC/15/20	ORGALIME comment & proposal
<p>Article 2 – Definitions</p> <p>12. "conformity assessment" shall mean the process demonstrating whether specified requirements relating to equipment;</p>	<p>Editorial alignment with NLF provision</p> <p>12. "conformity assessment" shall mean the process demonstrating whether specified requirements relating to equipment have been fulfilled;</p>
<p>Article 6 – Harmonised standards</p> <p>1. "Harmonised standard" means a technical specification adopted by a recognised European standardisation body under a mandate from the Commission in conformity with the procedures laid down in Directive 98/34/EC for the purpose of establishing a European requirement. Compliance with a "harmonised standard" is not compulsory.</p>	<p>Alignment of first sentence with the definition of a harmonised standard in order to ensure coherence</p> <p>1. "Harmonised standard" is a standard as defined in article 2.9. Compliance with a "harmonised standard" is not compulsory.</p>
<p>Article 6 – Harmonised standards</p> <p>3. Where a Member State or the Commission considers that a harmonised standard does not entirely satisfy the essential requirements referred to in Annex I, it shall bring the matter before the Standing Committee set up by Directive 98/34/EC (hereinafter "the Committee"), stating its reasons. The Committee shall deliver an opinion without delay</p>	<p>Proposal to <u>fully align with the NLF provision R9.1</u></p> <p>3. When a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements which it covers and which are set out in ... [reference to the relevant part of the legislation], the Commission or the Member State concerned shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC, giving its arguments. The Committee shall, having consulted the relevant European standardisation bodies, deliver its opinion without delay.</p>
<p>Article R2 – Obligations of manufacturers</p> <p>6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the equipment or, where that is not possible, on its packaging or in a document accompanying the equipment. The address must indicate a single point at which the manufacturer can be contacted.</p>	<p>Proposal to <u>delete article R2.6</u> as the requirements are already covered by article 9.2</p>
<p>Article R2 – Obligations of manufacturers</p> <p>In the proposed NLF alignment the NLF term "product" has been replaced by the EMC term "equipment" in articles R2.2 (second paragraph), R2.3, R2.4 (first and second paragraph), R2.5, R2.7, R2.8, R2.9</p>	<p>Proposal to <u>replace "equipment" by "apparatus"</u>. The EMC Directive has a different regime for apparatus and for fixed installations. The alignment as proposed in EMC/15/20 would affect the meaning of EMC Directive 2004/108/EC.</p>

Document EMC/15/20	ORGALIME comment & proposal
Article R2 – Obligations of manufacturers	Editorial alignment with NLF provision (and taking into account the previous comment)
R2.4 – second paragraph :keep a register of complaints, of non-conforming equipment recalls, and	R2.4 – second paragraph :keep a register of complaints, of non-conforming apparatus and apparatus recalls, and
Article R2 – Obligations of manufacturers	Alignment with the period specified in EMC 2004/108/EC Annex II (clause 4)
R2.3 ... [period to be specified in proportion to the lifecycle of the product and the level of risk]	
Article R2 – Obligations of manufacturers	EMC Directive 2004/108/EC does not – according to article 1.5 – regulate the safety of equipment in respect of people, domestic animals or property. Proposal to <u>delete “to protect the health and safety of consumers”</u> in R2.4 and <u>“and safety information”</u> in R2.7
R2.4 – second paragraph : When deemed appropriate with regard to the risks presented by equipment, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of marketed products, ...	
R2.7 ... is accompanied by instructions and safety information	
Article R3 – Authorised representatives	Alignment with the period specified in EMC 2004/108/EC Annex II (clause 4)
R3.2a ... [period to be specified in proportion to the lifecycle of the product and the level of risk]	
Article R3 – Authorised representatives	Proposal to replace <u>“equipment”</u> by <u>“apparatus”</u> . The EMC Directive has a different regime for apparatus and for fixed installations. The alignment as proposed in EMC/15/20 would affect the meaning of EMC Directive 2004/108/EC.
In the proposed NLF alignment the NLF term “product” has been replaced by the EMC term “equipment” in article R3.2b	
Article R4 – Obligations of importers	Change <u>“equipment”</u> to <u>“apparatus”</u> for consistency with the other provisions in R4.
1. Importers shall place only compliant equipment on the Community market.	
Article R4 – Obligations of importers	EMC Directive 2004/108/EC does not – according to article 1.5 – regulate the safety of equipment in respect of people, domestic animals or property. Proposal to <u>delete “to protect the health and safety of consumers”</u> in R4.6
R4.6 : When deemed appropriate with regard to the risks presented by apparatus, importers shall, to protect the health and safety of consumers, carry out sample testing of marketed products, ...	
Article R4 – Obligations of importers	Editorial alignment with NLF provision
R4.6 :....keep a register of complaints, of non-conforming apparatus recalls, and	R4.6 :....keep a register of complaints, of non-conforming apparatus and apparatus recalls, and

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<p>Article R4 – Obligations of importers</p> <p>R4.8 ... [period to be specified in proportion to the lifecycle of the product and the level of risk]</p>	<p>Alignment with the period specified in EMC 2004/108/EC Annex II (clause 4)</p>
<p>Article R5 – Obligations of distributors</p> <p>R5.2 ...that it is accompanied by the required documentation and by instructions and safety information</p>	<p>EMC Directive 2004/108/EC does not – according to article 1.5 – regulate the safety of equipment in respect of people, domestic animals or property.</p> <p>Proposal to <u>delete</u> “<u>and safety information</u>” in R5.2</p>
<p>Article R11 – General principles of the CE marking</p> <p>3. The CE marking shall be followed by the identification number of the notified body, where that body is involved in the production control phase.</p> <p>The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.</p>	<p>The tasks of notified bodies are specified in Annex III of EMC Directive 2004/108/EC.</p> <p>As these tasks are not related to the production control phase, it is suggested to <u>delete R11.3</u>.</p>
<p>Article R31 – Procedure for dealing with apparatus presenting a risk at national level</p> <p>R31.1 : ... that apparatus covered by this Directive presents a risk to the health or safety of persons or to other aspects of public interest protection covered ...</p>	<p>EMC Directive 2004/108/EC does not – according to article 1.5 – regulate the safety of equipment in respect of people, domestic animals or property.</p> <p>Proposal to <u>delete</u> “<u>health or safety of persons or to other aspects of</u>” in R31.1</p>
<p>Article R31 – Procedure for dealing with apparatus presenting a risk at national level</p> <p>R31.5a : failure of the apparatus to meet requirements relating to the health or safety of persons or to other aspects of public interest protection laid down in this ... [act]; or</p>	<p>EMC Directive 2004/108/EC does not – according to article 1.5 – regulate the safety of equipment in respect of people, domestic animals or property.</p> <p>Proposal to <u>delete</u> “<u>health or safety of persons or to other aspects of</u>” in R31.5a</p>
<p>Article R33 – Compliant apparatus which present a risk to health and safety</p>	<p>EMC Directive 2004/108/EC does not – according to article 1.5 – regulate the safety of equipment in respect of people, domestic animals or property.</p> <p>Proposal to <u>delete R33</u></p>
<p>Article 13 – Fixed installations</p> <p>13.1 – second paragraph : However, the provisions of Articles 5, 7, 8 and 9 shall not be compulsory in the case of</p>	<p>Editorial update due to alignment with NLF</p> <p>13.1 – second paragraph : However, the provisions of Articles 5, 7, R12 and 9 shall not be compulsory in the case of</p>

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