ORGALIME

Position Paper

Brussels, 30 June 2010

Additional comments on the alignment of the LVD and the EMCD with the New Legislative Framework

During the LVD and EMC working party meetings the Commission has invited stakeholders for a final round of comments until 30 June 2010. Orgalime welcomes this opportunity to comment further on documents "*(15) 11 NLF- LVD.doc*" and "*EMC_16_16 EMC alignment NLF_rev2.doc*" which were respectively discussed during the LVD Working Party on 27 May 2010 and the EMC Working Party on 8 June 2010. We appreciate that the majority of our concerns, as expressed in our position paper "Alignment of the EMC Directive 2004/108/EC with the New Legislative Framework" (12/11/2009) and "Alignment of the LVD 2006/95/EC with the New Legislative Framework" (15/12/2009), have been addressed.

Orgalime welcomes the Commission approach to align the text of the LVD and EMCD as closely as possible to the model provided in the New Legislative Framework (Regulation 765/2008/EC and Decision 768/2008/EC), thereby striving to avoid any deviations that would not be duly justified.

However, we would like to provide the following detailed comments as further support to the alignment exercise:

1) Horizontal issues linked with the alignment

The commission has already announced that these issues will be addressed during the revision of the Blue Guide. We would very much welcome the opportunity to contribute to such a discussion and have prepared proposals accordingly. However, we would like to draw the attention to two issues that would require deviations from the texts:

Re: Article R34 of Decision 768/2008/EC

Formal non-compliance

1. Without prejudice to Article R31, where a Member State makes one of the following findings, it shall require the relevant *economic operator to put an end to the non-compliance concerned:*

(a) the conformity marking has been affixed in violation of Article R11 or of Article R12;
(b) the conformity marking has not been affixed;
(c) the EC declaration of conformity has not been drawn up;
(d) the EC declaration of conformity has not been drawn up correctly;
(e) technical documentation is either not available or not complete.

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2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or ensure that it is recalled or withdrawn from the market.

This article provides market surveillance authorities with an instrument to take action in formal cases of non-conformity. In the New Legislative Framework market surveillance is greatly facilitated thanks to requirements that improve the traceability of a product back to its original manufacturer. This is reflected in the obligations of manufacturers and importers (articles R2.6 and R4.6) to apply their name and address on the product. This formal requirement, which is now implemented in the directives, is not reflected in the list of formal non-conformities.

In order to strengthen the ability of market surveillance authorities to ensure a level playing field, we would, in this case, suggest deviating from the original text and adding this requirement to the list.

Article 5, Decision 768/2008/EC

EC declaration of conformity

Where Community harmonisation legislation requires a statement by the manufacturer that fulfilment of the requirements relating to a product has been demonstrated (EC declaration of conformity), the legislation shall provide that a single declaration shall be drawn up in respect of all Community acts applicable to the product containing all information required for the identification for Community harmonisation legislation to which the declaration relates, and giving the publication references of the acts concerned.

This is a requirement that has now been introduced into the documents of the aligned EMC and LV directives. During the LVD working party this issue was addressed by industry with a request to deviate from the 768/2008 requirement. One representative from market surveillance hinted that the sense of this paragraph is not clear and that the requirement would restrict the possibilities of manufacturers without giving additional benefit for market surveillance. Following this discussion the Commission invited industry to provide a good rationale for departing from the original text.

Orgalime prefers to address as far as possible non-specific issues in a horizontal manner, instead of modifying each individual directive during the alignment exercise. However, as industry was now been given this possibility we would support such a deviation for the following reasons:

- It is currently the manufacturer's choice whether to state all directives and relating harmonized standards in one DoC or to have individual DoCs for each directive. Depending on the product and the internal processes manufacturers choose one or the other. Since some products are in the scope of a relatively high number of directives at the same time, for example LVD, EMC, EUP and RoHS, stating all directives and the related harmonized standards in a single DoC extends the DoC to a relatively complex document, such that readability is compromised.

- Market surveillance is organised differently in the Member States. In some countries different authorities are responsible for the market surveillance of different directives whilst in others the same authority is responsible for a number of directives. In the first case a single DoC would not give added value to the market surveillance authorities as they focus on a single directive and require only information related to it. Additionally, it is our understanding market surveillance authorities when assessing a product, check until the first mistake. Here again, there would be no added value as the manufacturer provides all DoCs relating to one product and the authorities would start the process with one aspect, for example product safety.

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- Some Directives require that the DoC accompanies the product, i.e. Machinery Directive, ATEX, and Pressure Equipment Directive. For series products these DoCs are printed in large numbers and packed with each product in stock. If a single DoC has to be issued this could add significant problems for products that are covered by several directives. Given that with a change of harmonized standards the DoC has to be aligned, the requirement would significantly increase the frequency of changes of DoC and hence, the documentation accompanying the product. This means an additional burden for manufacturers.

For these reasons we request that the requirement of a single DoC in the alignment of the New Approach directives with the New Legislative Framework should be excluded and that the present possible choice of the manufacturer for one or several DoCs should be maintained.

2) Specific issues linked with the alignment of the EMCD

Orgalime proposes the deletion of art. 11A ("Compliant products which present a risk to health and safety").

Rationale: This article is in contradiction with the scope of the EMC Directive, as this Directive does not regulate safety according to article 1.5. In addition, safety aspects are covered by other Community legislation, e.g. Low Voltage Directive, General Product Safety Directive.

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