ORGALIME

Position Paper

Brussels, 11 September 2014

Orgalime's questions on the implementation of Directives aligned with the New Legislative Framework

1. INTRODUCTION

Orgalime welcomes the European Commission's plan to organise seminars on the implementation of Low Voltage Directive (LVD 2014/35/EU), Electromagnetic Compatibility Directive (EMC 2014/30/EU) and Radio Equipment Directive (RED 2014/53/EU). We consider that such seminars could contribute to a more consistent implementation of the Directives by market surveillance authorities and economic operators across the EU and hope that additional seminars for all the other Directives aligned with Decision 768/2008 will follow.

However, manufacturers have also raised an important number of horizontal questions. Therefore, we invite the Commission to organise a seminar which would tackle horizontal questions. We strongly believe that these questions should not be dealt with during the Directive-specific seminars, as this could result in diverging interpretations among the Directives.

Moreover, we expect the Commission to revise parts of the Blue Guide to include the seminars' results and eliminate any remaining room for misinterpretation of the aligned provisions.

Therefore, please find included in the annex a list of points where the text of the Blue Guide could confuse or misinform the reader.

2. HORIZONTAL QUESTIONS

2.1. OPTIONS FOR ISSUING DECLARATIONS OF CONFORMITY UNDER THE NEWLY ALIGNED DIRECTIVES DURING TRANSITIONAL PERIODS

Orgalime requests the European Commission to allow for pragmatic solutions to the question of which Directives should manufacturers indicate on Declarations of Conformity (DoC) issued during the transitional period.

Orgalime suggests allowing manufacturers to choose between three solutions which were used in the recent revisions of New Approach directives to avoid any negative impact on business. More information on this topic is available in a separate position paper (Orgalime's NLF interpretative fiche n°19) which is included in the annex.

www.orgalime.org

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
Tel: +32 2 706 82 35 | Fax: +32 2 706 82 50 | e-mail: secretariat@orgalime.org
Ass. Intern. A.R. 12.7.74 | VAT BE 0414 341 438

2.2. UPDATES OF CONFORMITY ASSESSMENT CERTIFICATES FOR PRODUCT VARIATIONS AFTER THE REPEAL OF ALIGNED DIRECTIVES

Orgalime requests the Commission to ensure that, in cases which involve third party certification bodies, manufacturers should still be able to receive updates of existing conformity assessment certificates on product variations, even after the repeal of revised or aligned Directives, under which the original certificates were issued.

More information on this topic is available in a separate position paper (Orgalime's NLF interpretative fiche n°20) which is included in the annex.

2.3. REFERENCE OF THE DIRECTIVE IN THE DECLARATION OF CONFORMITY

Orgalime requests the Commission to clarify that the provision of the Directives' text requiring the Declaration of Conformity (DoC) to "*contain the identification of the Union acts concerned including their publication references*" does not oblige manufacturers to add the number of the Official Journal of the European Union (OJEU) in which the Directives were published in the DoC.

On the contrary, it should be sufficient to state the Directive's numbering, as this is indicated in the OJEU. This is in line with current practices and is already illustrated in the Radio Equipment Directive (Annex VI, 2014/53).

2.4. PRODUCTS IN EXCHANGE

Orgalime requests the Commission to clarify which legislation is applicable to spare-parts and sub-assemblies supplied in exchange (for example, delivered following a return caused by a defective product or in the framework of a repair by the manufacturer).

The Blue Guide (Chapter 2.1) specifies that these parts are not to be considered as new for the purposes of Union harmonisation legislation. However, manufacturers need to know whether:

- such parts should be considered as outside of the scope of Union harmonisation legislation altogether **or** whether
- these parts have to comply with the requirements that were applicable to the products that they are replacing. Thereby, the products supplied in exchange should conform with the harmonisation legislation and state of technology (standards) applicable when the product to be repaired or exchanged was placed on the market.
  In this case, manufacturers would have to ensure that these products bear the CE marking, issue a DoC referring to the repaired / exchanged product and would be able to use harmonised standards applicable at the time that the initial product was placed on the market.

2.5. SAMPLE TESTING

Orgalime requests the Commission to provide further guidance on how sample testing should be conducted in practice and to what extent. We consider that sample testing only has to take place if the manufacturer and or the importer have reason to believe that the product already placed on the market may no longer be in conformity.

2.6. REASONED REQUEST

Orgalime requests the Commission to clarify what constitutes as a "*reasoned request*" according to which manufacturers would have to provide to market surveillance authorities with all the information and documentation necessary to demonstrate a product's conformity.

Manufacturers consider that stating that the information is necessary for normal market surveillance activities is not a sufficient reason for them to provide this information. On the

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
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contrary, authorities should state specific reasons why such information would be necessary and define which parts of the technical file they need.

3. INSTRUCTIONS AND SAFETY INFORMATION FOR PRODUCTS (e.g. LVD ART. 6; EMCD ART. 7)

3.1. OBLIGATION TO ACCOMPANY THE PRODUCT WITH INSTRUCTIONS

According to the recast aligned Directives, "*Manufacturers shall ensure that the [Product] is accompanied by instructions and [safety information]*".

Orgalime requests the Commission to clarify that the scope of application of the obligation to accompany the product with instructions depends both on the product's intended use and end-user. In particular:

a. B2B products for use by professionals

A professional user should in many cases have all the necessary knowledge to install, setup and operate the product. Therefore, besides the safety information and warnings on the product, there would be no need for further user instructions.

b. Consumer products

A large number of products are so simple that consumers and other end-users can install, use and operate them intuitively without user instructions (for example a simple switch).

Therefore, the obligation to accompany the product with instructions should be restricted to products which it can be assumed that consumers and other end-users do not have the knowledge to install, use and operate.

3.2. INSTRUCTIONS' CONTENT

Orgalime requests the Commission to clarify that the instructions, which should accompany the product, need only to contain information relevant to compliant use, operation and disposal of the product.

In other words, it is necessary to clarify the relationship between the general obligation contained in the list of obligations for manufacturers (and importers) and the specific provisions contained in the essential requirements of some Directives (for example LVD, Article 6 (7) and 8 (4) versus LVD Annex I (1) (a) or EMC, Article 7 (7) versus EMC Article 18 (3)).

For example, manufacturers need to know whether the general obligation contained in Article 6 (7) of the LVD is to be applied in accordance with Annex I (1) (a). This would imply that the obligation to provide instructions and safety information is limited to what is required by the essential requirements (e.g., Annex I (1) (a): "*the essential characteristics, the recognition and observance of which will ensure that electrical equipment will be used safely and in applications for which it was made, shall be marked on the electrical equipment, or, if this is not possible, on an accompanying document*").

Orgalime considers this to be the most reasonable solution, given that instructions would need to accompany the product and be translated into a large number of languages.

Further information related to the operation of the product and its functionalities, such as an extensive user manual, may be provided on a public website or on any other data storage medium accessible to the end-user.

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3.3. PRODUCTS SOLD IN BULK

Orgalime requests the Commission to confirm that when products are sold in bulk, namely to professional users, the obligation to accompany the product with instructions applies to the main package and not to each and every product part.

4. QUESTIONS REGARDING MANUFACTURERS CONTACT DETAILS

4.1. SINGLE CONTACT POINT

According to the Directives aligned with the New Legislative Framework, manufacturers have to affix a postal address that indicates a single point at which the manufacturer can be contacted to the product.

Orgalime requests the Commission to clarify that manufacturers can establish contact points for each product category. Thereby, they would have the possibility to define specialised contact points for each product category instead of being obliged to have a single point of contact for all their product ranges.

We consider that this would not only facilitate the work of manufacturers, but would also make it easier for users and market surveillance authorities to reach the right contact for a specific product.

4.2. LANGUAGE IN WHICH CONTACT DETAILS WOULD BE EASILY UNDERSTOOD

According to the Directives aligned with the New Legislative Framework, products should bear the manufacturer's contact details in a language easily understood by end users and market surveillance authorities.

Orgalime requests the Commission to clarify which languages can be considered as "easily understood" in this context given that contact details are not as complex to understand as other information, such as instructions for use.

We consider that "easily understood" means in this case, "easily read and easily used for postal communication". Therefore, we believe that contact details in Latin characters can be considered as easily understood throughout the internal market.

Moreover, we consider that it should be clarified that addresses should be kept in their original language, in order to be in line with postal practices. For example, a street's name in Czech should not be translated to English or any other language.

4.3. MANUFACTURERS NAME AND TRADENAME ON THE PRODUCT

Orgalime requests the Commission to clarify, with the use of examples, that it is sufficient to indicate on the product either the name or the registered trade name.

This is necessary, because the wording of the Directives only states that manufacturers have to indicate on the product "*their name, registered trade name or registered trade mark and the postal address at which they can be contacted*".

Moreover, the Blue Guide (Chapters 3.1, 3.3) states that manufacturers have "*to indicate the following three elements: their (1) name, (2) registered trade name or registered trade mark and (3) the address at which they can be contacted*".

Both these statements do not specify if the product should bear both the name and trade name or only one of these elements.

Therefore, it is necessary to clarify that either the name or the registered trade name along with the address and the trademark are sufficient elements for the manufacturer's identification. Otherwise, products would bear the same identification element twice as the name and registered trade name are largely identical.

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5. CUSTOM BUILT EVALUATION KITS

"*Custom built evaluation kits, that are destined to be used by professionals solely at research and development facilities for such purposes*" are excluded from the scope of the aligned LVD, EMC and RED.

Therefore, Orgalime requests the Commission to clarify the criteria and conditions under which custom built evaluation kits would be excluded. A possible solution would be to adapt the guidance given on the issue in the ROHS 2 FAQ as follows:

"A custom built evaluation kit is intended to be used in the conceptual, developmental, design or pre-production stage and is as such designed solely for R&D use. This type of equipment is supplied only from a corporation to another corporation (B2B context) or a public institution, to be used by professionals at research and / or development facilities. The purpose of these kits is to be used in facilities that include for example the test/evaluation/further development/improvement of the function under development or research".

Therefore all devices/equipment used on a regular basis (such as laboratory equipment) to perform these evaluations are not covered by this exemption.

When the development/research process is finished, the custom built evaluation kit must not be delivered to the end-user – as it is no longer covered by this exemption - unless it has been brought into conformity with the applicable harmonised legislation.

6. RADIO EQUIPMENT DIRECTIVE

6.1. SCOPE OF LVD SAFETY REQUIREMENTS FOR RADIO EQUIPMENT

Orgalime requests the Commission to clarify whether the LVD safety provisions apply to radio equipment, under the new RED in the same way as under the current R&TTED (Recital 10), that is "*with no lower voltage limit applying*".

6.2. SOFTWARE DEFINED PROPERTIES OF RADIO EQUIPMENT (RED ART. 4)

Orgalime requests the Commission to clarify if manufacturers of radio equipment and of software allowing radio equipment to be used as intended shall provide:

- one Declaration of Conformity for all intended HW/SW combinations of radio equipment and software or
- one Declaration of Conformity for each intended combination

6.3. INTENDED OPERATING CONDITIONS (RED ART. 17)

Orgalime requests the Commission to clarify that the requirement that "*the conformity assessment shall take into account all intended operating conditions*" (article 17) refers to all intended operating conditions that may alter the product behaviour with respect to the conformity of the product.

Otherwise the conformity assessment procedure would be too lengthy.

Advisers in charge: Philippe Portalier and Efthymia Ntivi
Email: firstname.lastname@orgalime.org