ORGALIME

Position Paper

Brussels, 29 January 2013

Orgalime comments on the European Commission Proposal for a Directive on the making available on the market of radio equipment (RED)

European Commission Proposal COM (2012) 584 final 2012/0238 (COD)

EXECUTIVE SUMMARY

While Orgalime welcomes the proposal for the revision of the Radio and Telecommunication Terminal Directive (R&TTED, 1999/5), we have some areas of concern, and especially with:

- **Application of the "*Lex Specialis*" principle**: the Directive should not apply where, for radio equipment, the essential requirements referred to in Article 3 are wholly or partly covered more specifically by other EU directives (not only the EMCD and LVD, but also ATEX, and directives on machinery or medical devices);
- **Scope**: we regret that the **definition of radio equipment** no longer refers to its capability of communication, thereby broadening the scope of the new Directive to equipment that was not intended to be under the scope: this brings legal uncertainty for manufacturers of such equipment (micro-wave ovens, industrial sensors…). We suggest re-introducing the communication criteria into the definition.
- **Scope exclusions**: in any case, **we recommend to exclude from the scope** of this revised Directive under annex II.2 the following product groups: **inductive heating appliances, inductive power transfer appliances, medical devices** such as high frequency surgery equipment**, and industrial sensing devices** that are based on physical principles of electromagnetic fields without communication ability**;**
- **Registration system: we call for the deletion of this requirement**, because such a system is in contradiction with the New Legislative Framework (e.g. LVD, EMCD), would raise **confidentiality questions, cause disproportionate costs to legitimate manufacturers and undermine the global competitiveness position of the EU.**
- **Declaration of conformity (DoC)**: we suggest that manufacturers **use the type, batch, serial number or any other element allowing for the identification of the products** covered by the DoC instead of a "unique identification number for each product covered".
- **Translation of the DoC**: Orgalime calls **for the deletion of** Article 21.5, as it requires manufacturers to translate the technical documentation necessary to demonstrate the conformity **into the language of all Member States where the product is circulated**, thereby **upsetting the current practice and adding costs which impact especially SMEs**.

Orgalime, the European Engineering Industries Association, speaks for 39 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 23 European countries. The industry employs some 10.2 million people in the EU and in 2011 accounted for some €1,666 billion of annual output. The industry not only represents some 28% of the output of manufactured products but also a third of the manufactured exports of the European Union.

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 414341438

1. INTRODUCTION

Orgalime welcomes the proposal of the European Commission for the revision of the Radio and Telecommunication Terminal Directive (R&TTED, 1999/5). Radio and telecommunication equipment is integrated in many electric and electronic appliances, as well as in machinery, improving their functionality and offering a better service to the user. Therefore, Orgalime supports the intention of the Commission to adapt the Directive to technological progress by taking into account the use of software and the interoperability of radio equipment in networks.

Orgalime welcomes in particular:

- the alignment of the Directive with the New Legislative Framework, as this can strengthen the legal certainty for economic operators and simplify the external trade of radio equipment.
- the inclusion of Chapter 5 on Union market surveillance and controls of products entering the Union market, which is a positive step forward as it clarifies the measures to be taken in case of non-conformity and underlines the value of administrative checks (article 43).

However, we have a number of serious concerns namely about changes to the scope of the Directive and the registration of products categories that would be discretionarily considered as showing a low level of compliance. We thereby encourage the European Parliament and Council to improve the text of this proposal on these issues, so as to introduce legal certainty and would not give rise to unjustifiable additional costs to legitimate manufacturers.

2. SCOPE

Orgalime welcomes the Commission's choice to keep the Radio Equipment Directive a full harmonisation directive, covering not only the harmful interference aspects, but also health and safety and electromagnetic compatibility risks. It is also useful that the provisions of the proposal explain which conformity assessment should be used for each category of essential requirements (Article 17).

a) Application of the "*Lex Specialis*" principle

Nevertheless, we consider that **the Radio Equipment Directive should not apply where, for radio equipment, the essential requirements referred to in Article 3 are wholly or partly covered more specifically by other EU directives**. The text of the Commission proposal makes this clear as regards the Electromagnetic Compatibility Directive (EMCD 2004/108/EC) and the Low Voltage Directive (LVD 2006/95). However, this exception should also apply to products already more specifically covered by other directives, as for example, the directive on equipment and protective systems intended for use in potentially explosive atmospheres (ATEX), the Machinery Directive (MD) which includes many safety components or the Directive on Medical Devices (MDD). Therefore, it is necessary to clarify to the manufacturer which conformity assessment procedure he should apply and, where relevant, which notified body he should address. Therefore, we believe the text should recall the principle of "*lex specialis*", with a similar formulation as in the Machinery Directive (2006/42, Art. 3).

Furthermore, we consider that **a clause exempting radio equipment falling under the EMC Directive should be added in a paragraph 5 under article 1**, similar to the clause exempting radio equipment falling under the LVD (Article 1 paragraph 4). We consider that this would reflect in the binding text of the Directive what is clearly called for in the recitals 8 and 9.

b) Clarification of the categories of products subject to the scope of the RED

Orgalime **regrets that the new definition of radio equipment no longer refers to its capability of communication** and possible utilisation of the radio spectrum, as is the case in Article 2 paragraph (c) of the R&TTED. We believe that the previous definition, although not ideal, has proved to be efficient at discriminating between products falling under the scope of the Directive or not.

ORGALIME aisbl | Diamant Building | Boulevard A Reyers 80 | B1030 | Brussels | Belgium
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The new definition expands the scope to almost all electrical products, as they practically all emit or use radio waves intentionally or unintentionally, although many entail a very low risk of localised interference with the radio spectrum. Therefore, the new definition blurs the demarcation line between the Radio Equipment Directive and the EMC directive. **This would in our view create legal uncertainty**, **especially for manufacturers of products that were not intended to be covered by the Radio Equipment Directive**, such as manufacturers of micro-wave ovens, industrial sensors or electric tooth brushes.

It would add costs for demonstrating their conformity with this additional piece of legislation, **without demonstrated benefits**: many product types that would fall under the scope of the new RED are already on the market for years without reported problems. Besides, there are solutions to address expected problems that may arise from products that use the spectrum for purposes other than communication. CENELEC and ETSI have confirmed in a report to the European Commission that this could be done through standardisation in the framework of the EMC Directive.

Therefore, Orgalime suggests re-introducing the criteria of "communication" into the definition of radio equipment and of radio waves.

3. EXCLUSIONS FROM THE SCOPE

Orgalime welcomes the list in annex II, which clarifies for some categories of radio equipment whether they fall under the scope of the Directive or not.

We consider however that **inductive heating appliances, inductive power transfer appliances, medical devices such as high frequency surgery equipment, and industrial sensing devices based on physical principles of electromagnetic fields without communication ability should also be excluded from the scope** of this revised Directive under annex II.2.

Other examples are public railways/trams, robot joints, chargers for portable electronic devices, inductive proximity switches etc… These products are based on physical principles of electromagnetic fields without communication ability. They have been extensively used in industrial applications for decades and do not fall under the scope of the current RTTE Directive. They are sufficiently regulated by the EMC Directive and the LVD. It would be therefore be contrary with the principle of proportionality to impose new requirements for placing these devices, appliances and equipment on the EU market.

4. REGISTRATION SYSTEM

The Commission's proposal (Article 5) introduces the possibility for the European Commission to impose the obligation on manufacturers of radio equipment to register their products in a central database and to mark these products with a registration number provided by the database, should the Commission decide that some types or categories of equipment are affected by a low level of compliance with the essential requirements. We call on the European Parliament and the Council to **delete this requirement to register for any equipment**, because such a system would raise **confidentiality questions,** would **cause disproportionate costs to legitimate manufacturers** and widen the gap in sales prices with unfair competitors. More effective and efficient market surveillance across the whole of the EU is the only way to improve the compliance level of products with this directive, as with any other harmonised legislation. We believe that the traceability requirements laid down in the proposal, in line with those of the LVD and EMCD and all other NLF legislation, should be effective enough to assist Member States in their task and duties. Furthermore, a registration obligation would **undermine the position of the EU against legal or de facto third-party certification of such radio equipment, as it is requested from trading partners of the EU, such as China or the USA**.

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5. TRANSITIONAL PERIOD

Given that the scope of the Directive will change and that it is not yet clear to manufacturers which products would fall under its scope, we consider that a longer transition period would be necessary in order to enable manufacturers to carry out the necessary risk assessment and technical adaptations to the new scope. Furthermore, the standards for these products would need to be revised. Therefore, we consider that a **3 years transition period would be necessary** before the implementation of this Directive.

6. UNIQUE IDENTIFICATION OF THE PRODUCT IN THE DECLARATION OF CONFORMITY

Orgalime calls for changes to Annex VII, which describes a possible model of the Declaration of Conformity (DoC), in such a way ***as to suggest manufacturers to use the type, batch, serial number or any other element allowing for the identification of the products covered by the DoC*** instead of a "unique identification number for each product covered". The requirement in Item 1 of Annex VII of a "number" or a "unique identification of the radio equipment" is redundant with item 4 "*Object of the declaration (identification of product allowing traceability. It may include a photograph, where appropriate)*".

It would **oblige manufacturers to issue a unique DoC for each product, whilst currently a single DoC may apply to variations of the same product**, in shape, colour or functionalities. It would bring a substantial and unjustified change to the common practice, where item 1 refers to the numbering of the DoC itself, in line with harmonised standard EN ISO/IEC 17050-1:2010, which serves manufacturers and market surveillance authorities alike. It would also add administrative burdens for manufacturers and therefore costs, which would undermine the competitiveness of manufacturers both on the internal and international markets.

7. TRANSLATION OF THE TECHNICAL DOCUMENTATION

Orgalime considers that Article 21.5 should be deleted, as it requires manufacturers to provide the technical documentation necessary to demonstrate the conformity of radio equipment, not only "*in a language which can be easily understood by that authority*" (as requested in Article 10 paragraph 11), but "*into the language of that Member State*". Such translation requirement would:

- upset the current practice of the internationalisation of the supply chain, whereby technical reports and third-party certificates are usually directly produced in well-understood languages by manufacturers and market surveillance authorities with the internationally used terminology for the construction of radio equipment.
- create unnecessary administrative burdens and costs for legitimate manufacturers, and in particular SMEs, which would be obliged to:
    - request from third parties the technical files for their components or software, while this is not always possible because technical files include elements subject to intellectual property rights and are therefore only communicated by such third parties to market surveillance authorities;
    - translate detailed documents, such as diagrams and circuits, in the very short allocated timeframe of 30 days.

We believe that the requirement of Article 10 paragraph 11, which is in line with the New Legislative Framework (Decision 768/2008, article R2.9), would be sufficiently serving the needs of market surveillance without excessive costs to manufacturers.

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Advisers in charge: Philippe Portalier (firstname.lastname@orgalime.org)
Efthymia Ntivi (firstname.lastname@orgalime.org)