ORGALIME

Position Paper

Brussels, 6 December 2010

Revision of the R&TTE-Directive comments on the second proposal by the Commission TCAM 32 (10)

Orgalime highly welcomes the possibility to comment on the second proposal on a revised R&TTE directive as presented in TCAM document 32 (10). We submit our comments in an extra document in form of a table directly related to the text but would like to present the aspects of main concern summarized in this general position paper.

Deviation from NLF

ORGALIME represents product groups for which various directives apply simultaneously. We therefore, very much welcomed the New Legislative Framework as a means to align the elements of the directives as much as possible. This was also the reason why European industry took many efforts to contribute to the development of the NLF. Given this background we are very much disappointed by the high number of deviations from the NLF to be noted in the proposal for a new R&TTE-directive, which we have listed below. These even concern critical issues like the DoC, the CE-marking or a newly created article on technical documentation. We urge the commission to further align the R&TTE directive to the NLF and thus enable it to function as foreseen.

Deviations from the NLF

1. Article 2 (13) – conformity assessment body; part of the definition is missing
2. Article 2 (16) – CE marking – text added
3. Article R2 (5) / R4 (3) – Obligations of manufacturers and importers - "where that is not possible" was changed to "where the size and nature of equipment does not allow it" – this is already an interpretation of the New Legislative Framework. This matter should be clarified in the Blue Guide.
4. Article R5(5) – obligation of distributors - text added
5. Article R5 (6) – obligation of distributors – new article added
6. Article R8 – harmonized standards, text changed.
7. Article R12 (1) – Rules and conditions for affixing the CE marking – text reformulated
8. Article R12 (2) – Rules and conditions for affixing the CE marking – text deleted
9. Article R12 (4) – Rules and conditions for affixing the CE marking - NLF text not introduced.
10. Article R12B – Technical documentation - New article added
11. Article R17 (6) – Notified bodies - text missing.
12. Article R17 (10) – Notified bodies - text added
13. Article R17 (11) –Notified bodies - text added
14. Annex III – Module B (3) – text changed
15. Annex III – Module B (8) ; requirement for notified bodies added
16. Annex V – Contents of Technical documentation was taken from the modules: to the general description was added photographs etc. and copy of DoC was added.

Orgalime, the European Engineering Industries Association, speaks for 33 trade federations representing some 130,000 companies, mostly SMEs, in the mechanical, electrical, electronic, metalworking & metal articles industries of 22 European countries. The industry employs some 10.6 million people in the EU and in 2009 accounted for some €1,427 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.

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Registration of some categories of radio equipment
The first proposal of the new R&TTE-D did not contain a mandatory registration, which we highly welcomed. In the recent proposal it is introduced as a requirement to be imposed on products with high rates of non-compliance. We still welcome that not a full registration system covering all products is introduced. Nonetheless we have to state clearly, that to this kind of registration system the same arguments apply as already given during the meetings of the ad-hoc working group traceability. Also in this case the gap between honest manufacturers and manufacturers willing to circumvent legal requirements widens.

In addition to these arguments, the following problems arise:

- There are no fair criteria for the classification of product groups and the decision to which products this requirement should apply.
- Basing such a decision on market surveillance campaigns requires this campaigns to reflect the complete market representatively. This is in contradiction of the necessity to conduct market surveillance efficiently. In particular given the scarce resources market surveillance should concentrate on finding non-compliant products which is current practice.
- If such decisions are based on market surveillance campaigns an unfair situation arises because the decision whether the registration is imposed on a product depends on the choice of products for market surveillance campaigns.
- As a result of the whole system honest manufacturers again will be punished for the illegal action of others which widens the gap and their competitiveness will decrease.

We strictly oppose to introduce such a system. We at least request to conduct an impact assessment.
See also previous ORGALIME position paper.

Receivers included into the directive
Orgalime has already expressed its great concerns about bringing **pure broadcast receivers** under the scope of the R&TTE directive. TV receivers currently fall under the Low Voltage Directive (LVD) and the EMC Directive. Our concerns remain and we ask the commission to not include pure broadcast receivers. The problems to be addressed by this new legal requirement can be solved satisfactorily in standardisation and this process has already started. Choosing an approach through legislation leads to a situation where the burden has to be carried by one sector while through standardization a balanced situation can be reached. Receiving broadcast services is a matter of quality experience for the end user: This is mainly a competitive concern for companies rather than for regulators because there is no risk of creating interference.
It will also have impact on broadcast receivers' safety requirements that have a voltage lower than 50 volts for AC current and lower than 75 volts for DC current. They are outside the scope of the LVD. Low cost receiver equipment (e.g. the radio function in an MP3 player or alarm clock) may disappear simply because of the added cost, which is not in the interest of consumers nor of the trade as it will unnecessarily narrow choice.

See also previous position paper

Relation to other Directives article 3.2 – specificity clause
In our previous position commenting on the first proposal TCAM 31 (15) we proposed to introduce a lex-specialis clause with the purpose to clarify which safety requirements and related conformity assessment procedures should apply in case that the same product is subject to two safety-related directives, e.g. machinery and R&TTE. Unfortunately, this proposal was not considered. Rather the generalized formulation as it was chosen in TCAM 32 (10) leads to perfect double regulation for safety aspects.

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> *"Where equipment as defined in Article 2(a) falls within the scope of other European Union legislation, it shall comply both with the requirements in this Directive and in that legislation".*

We, therefore, repeat our proposal to substitute article 2.2 by a lex-specialis clause as formulated in our position.

> *"Where for equipment, the requirements referred to in this article are wholly or partly covered more specifically by other Community Directives, this Directive shall not apply, or shall cease to apply, to that equipment in respect of such requirements from the date of implementation of those other Directives."*

Article 2 - definition of radio equipment
The proposed definition does not refer to communication anymore, but to using (emitting or receiving) radio waves in order to serve its purpose. This could cause misunderstandings as whether equipment using radio waves internally (e.g. professional wood drying machines using microwaves, household microwave ovens) is considered in the scope of R&TTE equipment, which in our view cannot be the intention. We propose to keep the current definition.

Alert sign – Article R2 (7)
This solution for the information for users on geographical area and possible restrictions is not practicable. It is not possible to add the required information in written form on the packaging in all languages. We propose to introduce a pictogram to alert the user and give the required information in the accompanying documentation. Additionally, the proposed formulation leads to the requirement for the manufacturer to analyze where his equipment can be operated instead of informing the user where it is intended to be operated. This does not seem justified burden in particular for SMEs.

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Annex 1 to document TCAM(32)10

DG Enterprise and Industry Non Paper

(with changes accepted)

DRAFT

DIRECTIVE XXXX/XX OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of YYYY

on radio and electronic communications terminal equipment

CHAPTER I GENERAL ASPECTS Article 1	**ORGALIME comments**
SCOPE AND AIM	
2. Where equipment as defined in Article 2(a) falls within the scope of other European Union legislation, it shall comply both with the requirements in this Directive and in that legislation.	The paragraph as it is formulated now leads to double regulation for products that fall under different directives covering safety aspects, as the R&TTE-Directive regulates not only the efficient use of the spectrum but safety aspects and aspects of electromagnetic compatability as well. This double regulation leads to confusion on the market regarding the harmonized standards and conformity assessment procedures applicable. This is the case for machinery, medical devices, personal protection equipment. We, therefore, propose to delete this article and introduce a lex specialis clause. See previous ORGALIME position and general comments

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Article 2	**ORGALIME comments**
Definitions	
(b)'electronic communications terminal equipment' means a device which enables communication and which is intended to be connected directly to interfaces of public communications networks as defined in Directive 2002/21/EC1 ;	Reference to 2002/21/EC leads to a broadening of scope to CATV connected devices. We ask for clarification and intention of this change.
(c)'radio equipment' means a device which intentionally emits or receives radio waves in order to serve its purpose. All ancillary elements, including software, which may affect compliance of the radio equipment with the essential requirements in article 3 of this Directive are considered as part of the radio equipment. **Other active devices which enable the emission and/or reception of radio waves are also considered as radio equipment**;	The proposed definition does not refer to communication anymore, but to using (emitting or receiving) radio waves in order to serve its purpose. This could cause misunderstandings as whether equipment using radio waves internally (e.g. professional wood drying machines using microwaves, household microwave ovens) is considered in the scope of R&TTE equipment, which in our view cannot be the intention. We propose to re-introduce a reference to communication in order to avoid misunderstanding. This text has the possibility to include all apparatus connected to a radio module and could thus include all equipment sending data to, or enabling/disabling, the module. As a minimum we would like this to be clarified in a guide that this inclusion is not intended, or preferably that the text in bold be deleted.
Note: *NLF definitions below:*	
13. "conformity assessment body" shall mean a body that performs conformity assessment activities;	"including calibration, testing, certification and inspection" from NLF is missing. We propose to stick to the NLF formulation.
16. "CE marking" shall mean a marking by which the manufacturer indicates that equipment is in conformity with the applicable requirements set out in European Union harmonisation legislation providing for its affixing, and in particular R11 and R12 of this Directive	Delete and in particular R11 and R12 of this Directive. The reference is redundant. We propose to stick to the NLF.

[1] *Directive 2002/21/EC of the European Parliament and of the Council of 7 March 2002 on a common regulatory framework for electronic communications networks and services (Framework Directive*)

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CHAPTER II

OBLIGATIONS OF ECONOMIC OPERATORS

Article R2	ORGALIME comments
Obligations of manufacturers	
5. Manufacturers shall ensure that their equipment bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of equipment does not allow it, that the required information is provided on the packaging, or in a document accompanying the equipment.	This is a significant deviation from the NLF and represents an interpretation of the NLF text. We propose to introduce the original text and clarify the issue of "where not possible" in a horizontal manner in the Blue Guide.
Where it concerns radio equipment, information available on the packaging shall allow to identify the Member States or the geographical area within a Member State where the equipment can be put into service, and shall alert the user to potential restrictions or requirements for authorisation of use in certain Member States. Such information shall be completed in the instructions accompanying the equipment.	This solution for the information for users on geographical area and possible restrictions is not practicable. It is not possible to add the required information in written form on the packaging in all languages. We propose to introduce a pictogram to alert the user

Article R4	
Obligations of importers	
3. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on equipment or, where that is not possible, on its packaging or in a document accompanying equipment. This includes cases where the size of equipment does not allow it, or where importers would have to open the packaging in order to indicate their name and address on equipment	See comment on R2.5

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Article R5	ORGALIME comments
Obligations of distributors	

5. Distributors shall, further to a reasoned request from a competent national authority, provide it without delay with all the information and documentation necessary to demonstrate the conformity of equipment. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by equipment which they have made available on the market.	"without delay" was added to this paragraph as compared to the NLF text We propose to stick to the NLF and delete "without delay"
6. Distributors shall ensure that the CE marking and all information displayed on the package according to Article R2.7 is available to the buyer prior to purchase irrespective of the selling technique, including distance and electronic selling.	All requirements towards distributors in this paragraph are already included in the previous paragraphs. Distributors using electronic selling can be considered distributors in the sense of this article. Therefore, this article in our view is redundant and we propose to delete it.

Article 3	
Essential requirements	

2. In addition, radio equipment shall be so constructed so as to efficiently use the spectrum allocated to terrestrial/space radio communication and orbital resources and so as to avoid harmful interference. These requirements apply both to emission and reception,	These requirements apply both to emission and reception. This makes spectrum efficiency applicable for receivers. We ask for clarification and justification. See ORGALIME position on inclusion of receivers.

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Article 3 bis'	ORGALIME comments
Registration of some categories of radio equipment	
1. Where a high level of compliance with the essential requirements in the Directive has not been achieved for one ore more categories of equipment, the Commission may decide that manufacturers shall register types of such categories of equipment within a central system administered by the European Commission prior to such equipment being allowed to be placed on the market. 2. In taking such a Decision, the Commission shall determine the category or categories of equipment concerned, the modalities of registration and the information to be registered. In taking such a Decision the Commission shall also determine the date of its application. Such Decision shall be adopted in accordance with the procedure referred to in Article (15a). 3. Where such a Decision is taken, and before it enters into force, the Commission shall make available and operate a central system allowing manufacturers to register in an efficient way. Manufacturers shall affix the registration number on the equipment. 4. Where such a decision is taken, products non-complying with a Decision issued in accordance with this article can be withdrawn from the market by market surveillance authorities.	To this kind of registration system the same arguments apply as discussed in the traceability working group. The gap between honest manufacturers and manufacturers willing to circumvent legal requirements widens. In addition to these, the following problems arise. There are no fair criteria for the classification of product groups and the decision to which products this requirement should apply. Basing such a decision on market surveillance campaigns requires this campaigns to reflect the complete market representatively. This is in contradiction of the necessity to conduct market surveillance efficiently. In particular given the scarce resources market surveillance should concentrate on finding non-compliant products which is current practice. If such decisions are based on market surveillance campaigns an unfair situation arises because some products will be covered much earlier than others. As a result of the whole system honest manufacturers again will be punished for the illegal action of others which widens the gap. We strictly oppose to introduce such a system. We at least request that an impact assessment should be conducted. See previous ORGALIME position paper

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Article 5 – Articles R8 R9	**ORGALIME comments**
Harmonised standards	

2. Where a Member State or the Commission considers that conformity with a harmonised standard does not ensure compliance with the essential requirements referred to in Article 3 which the said standard is intended to cover, the Commission or the Member State concerned shall bring the matter before the Committee in article 13 , giving its arguments. The Committee shall, having consulted the relevant European standardisation bodies, deliver its opinion without delay.	The formulation in the NLF is: "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." We consider the NLF formulation more precise and propose to stick to the NLF and introduce the respective paragraph.

Article 8	
Free movement of equipment	
1. Member States shall not prohibit, restrict or impede the placing on the market and putting into service in their territory of equipment complying with this Directive. This shall be without prejudice to Articles 7.1 and R33.	
2. At trade fairs, exhibitions, demonstrations, etc., Member States shall not create any obstacles to the display of equipment which does not comply with this Directive, provided that a visible sign clearly indicates that such equipment may not be marketed **or put into service until it has been made to comply**.	In order to facilitate easier and faster access to the European market for new and innovative products it would be beneficial to add the following text to the end of Article 8(2): "**Temporary operation of such equipment shall not be unnecessarily restricted, especially if it uses radio interfaces which are already harmonised or designated for use in member states**." (.../...)

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	Also it would be useful to add to Recital 33: "***whereas procedures to request and control operation during trade fairs, exhibitions, demonstrations, tests, etc., should be proportionate and should not constitute a conformity assessment procedure; whereas it is desirable that those procedures should be harmonised and preferably implemented by electronic means and one-stop-shopping***."

CHAPTER IV

CONFORMITY ASSESSMENT

Article R10	

1. The EU declaration of conformity shall state that the fulfilment of requirements specified in this Directive has been demonstrated.	
Where the equipment is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the acts concerned including the publication references.	See ORGALIME position on alignment with NLF

Article R12	ORGALIME comments
Rules and conditions for affixing the CE marking	
1. The CE marking shall be affixed visibly, legibly and indelibly to equipment or to its data plate, unless that is not possible or not warranted on account of the nature of equipment. On account of the nature of the equipment, the size of the CE marking affixed to equipment may be reduced. The CE marking shall also be affixed visibly and legibly to the packaging.	The original text in the NLF is: .. Where that is not possible or not warranted on account of the nature of the product, it shall be affixed to the packaging and to the accompanying documents, where the legislation concerned provides for such documents." This is in contradiction of the idea of the NLF and represents an interpretation of the NLF which is task of the Blue Guide. We propose to stick to the NLF.
2. The CE marking shall be affixed before equipment is placed on the market.	In the NLF the formulation "It may be followed by a pictogram" follows. We propose to stick to the NLF.
3. The CE marking shall be followed by the identification number of the notified body, where that body is involved in the procedure for conformity assessment process according to Annex IV to this Directive.	
The identification number of the notified body shall have the same height as the CE marking.. It shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.	
	4. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and take appropriate action in the event of improper use of the marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use. Paragraph 4. From the NLF is not introduced. We consider this paragraph important and ask for reasoning.

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Article R12B	ORGALIME comments
Technical documentation	
1. The technical documentation referred to in Article R2(2) shall contain all relevant data or details of the means used by the manufacturer to ensure that equipment comply with the requirements set out in this Directive. It shall, at least, contain the documents listed in Annex V.	All requirements defined in this paragraph are already specified in other parts of this legislation. Therefore, this article is redundant and should be deleted.

6. If the manufacturer does not comply with the requirements of paragraphs 1, 2, 3, the market surveillance authority may require him to have a test performed by a body acceptable to the market surveillance authority at the expense of the manufacturer within a specified period in order to verify compliance with the essential requirements.	If technical documentation is missing, the manufacturer has to provide it. In this case no tests are necessary. If this is not possible because of non-compliance of the product it should be withdrawn from the market. Legislation provides market surveillance authorities with the means to enforce this. Costs for test are a matter of national law. We propose to delete this article and stick to the NLF.

CHAPTER V

NOTIFICATION OF NOTIFIED BODIES

Article R17	
Requirements relating to notified bodies	

6. (c) Paragraph 2 (...) It shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner.	"And shall have access to all necessary equipment and facilities" from NLF text is missing. We propose to stick to the NLF.

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	ORGALIME comments
10. Without prejudice to the obligations of notified bodies under annexes III and IV, The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under this Directive or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.	"Without prejudice to the obligations of notified bodies under annexes III and IV" relates to additional requirements as compared to the NLF which in our view are not acceptable. We propose to stick to the NLF and delete this sentence

ANNEX I

EQUIPMENT NOT COVERED BY THIS DIRECTIVE AS REFERRED TO IN ARTICLE 1(4)

4. Test equipment **exclusively** intended for the testing of radio equipment	We propose to delete "exclusively" and add **electronic communications terminal equipment** to this paragraph

6. Note: Deleted	
	We oppose the deletion of pure broadcast receivers from the annex. See our general comments and previous ORGALIME position

ANNEX II

CONFORMITY ASSESSMENT

Module A (internal production control)

2. Technical documentation	
The manufacturer shall establish the technical documentation according to article R12B.	We propose to reintroduce the documentation requirements into the annex and stick to the NLF. In our view there are not reasons for the changes in article R12B and the consequent cross-references to Annex V.

ANNEX III

CONFORMITY ASSESSMENT

Modules B + C

EC Type examination + Conformity to type based on internal production control

	ORGALIME comments
Module B	
EU-type examination	
8. Each notified body shall inform its notifying authorities concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.	
Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.	
Each notified body shall inform Member States of EU-type examination certificates it has issued and/or additions thereto in those cases where harmonised standards, the reference of which have been published in the Official Journal of the European Union, have not been fully applied. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer for a period of 10 years after equipment has been assessed or until the expiry of the validity of the certificate.	Each notified body shall inform Member States of EU-type examination certificates it has issued and/or additions thereto in those cases where harmonised standards, the reference of which have been published in the Official Journal of the European Union, have not been fully applied This addition to the requirements foreseen in the NLF text deeply touches confidentiality issues in the relation between notified bodies and manufacturers. Furthermore, there is no obligation for manufacturers to fully apply harmonized standards. Consequently, in our view there is no reason why this information should be reported. This requirement is unacceptable. We propose to delete it.

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ANNEX V

	ORGALIME comments
Contents of Technical Documentation	
The technical documentation referred to in article R12b shall, wherever applicable, contain at least the following elements:	We propose to reintroduce these requirements into the modules with the purpose to avoid cross-reference and reach clarity
– a general description of the equipment including: photographs or illustrations showing external features, marking and internal layout; versions of software or firmware affecting compliance with essential requirements; user information and installation instructions,	"photographs or illustrations showing external features ..... " was added as compared to the NLF text. We propose to stick to the NLF and delete this addition.
– conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.	
– descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the equipment,	
– a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,	
– copy of the declaration of conformity,	We propose to delete this addition to the NLF text. It is redundant.
– where the conformity assessment module in Annex III of this Directive has been applied, copy of the EU-type examination certificate and its annexes as delivered by the involved notified body,	
– results of design calculations made, examinations carried out, etc., and	
– test reports	

ANNEX VI

Declaration of Conformity

8. Additional information for radio equipment:	
o Frequency band(s) or discrete frequencies in which the equipment operates (not necessary for those licensed frequencies where the equipment operates under the control of a network) o Radio-frequency power linked to the frequency band(s)	This additional requirement goes far behind the idea of the NLF. Firstly, it is not possible to state in a simple way the frequency bands and radio-frequency power linked to frequency bands when equipment may operate in different bands. Secondly, other directives could follow this example and require additional information. Given this possibility and the requirement of a single DoC for all directives the simple statement of conformity would develop into an unreadable booklet. Delete this paragraph and stick to the NLF.