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IMPACT ASSESSMENT

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Accompanying the document

Proposal for a Directive of the European Parliament and of the Council on the harmonisation of laws of the Member States to the making available on the market of radio equipment

{COM(2012) 584 final}
{SWD(2012) 300 final}

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1. INTRODUCTION

The object of this Impact Assessment report is a possible revision of the R&TTE[1] Directive, Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity[2].

The R&TTE Directive establishes a framework for the placing on the market, free movement and putting into service in the EU of radio equipment and telecommunications terminal equipment. It addresses an estimated €63 billion market (2007[3]), covering *inter alia* mobile phones, mobile network transmitters and fixed telephones[4]. The Directive entered into force in 1999, replacing a wealth of national type-approval schemes and other regulations, and has been essential to achieve an internal market in this area.

The Second Progress Report on the operation of the R&TTE Directive, dated February 2010 *(see reference [2][5]),* has highlighted a number of emerging problems and margins for improvement to be addressed through legislative revision or other means.

This Impact Assessment report analyses these problems, presents the policy options that are being considered to address them, evaluates their impact and on that basis proposes recommended measures.

2. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

2.1. Identification

The lead Directorate-General for this impact assessment is DG Enterprise and Industry.

Other Directorate-Generals involved have been DG Information Society and Media, DG Competition, DG Internal Market and Services, DG Health and Consumers, DG Justice, DG Mobility and Transport, DG Environment, DG Taxation and Customs Union, DG Trade, Secretariat General.

The proposal is included in the Commission Work Programme 2011[6]. The reference of this proposal in Agenda Planning is 2009/ENTR/021 - Amendments to the R&TTE Directive.

2.2. Organisation and timing

The Impact Assessment Steering Group (IASG) met three times in order to discuss the preparation of this impact assessment: 1st March 2010, 6th October 2010 and 28th April 2011.

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1 R&TTE= Radio and telecommunications terminal equipment. A list of acronyms used and a glossary can be found in Annex I

2 Directive 1999/5/EC OJ L 91, 7.4.1999, p. 10–28

3 Basic economic data of the EU market covered by the R&TTE Directive can be found in Annex III.

4 Non-radio telecommunications infrastructure such as switching systems is excluded from the scope of the R&TTE Directive. More information about the product scope of the R&TTE Directive can be found in Annex II.

5 A list of all references can be found in annex XIII.

6 COM(2010) 623 final VOL. II ANNEXES to the COMMUNICATION FROM THE COMMISSION Commission Work Programme 2011

2.3. Consultation and expertise

Issues raised by the operation of the Directive and possible solutions to them have been discussed within TCAM[7], the standing committee of the Directive, since its establishment in 2000. In addition to Member States and the Commission, TCAM includes representatives from industry, European Standards Organisations, CEPT[8], notified bodies and consumer organisations.

A first public consultation took place in 2007, where 60 respondents answered some 120 questions on the operation of the Directive (*see Annex IV*). This consultation allowed to identify the main problems in the operation of the Directive as well as the possible remedies. Issues identified through this consultation were included in the Second Progress Report on the operation of the R&TTE Directive *(see ref. [2])*.

During 2009, an external contractor Technopolis developed for the Commission a study on the impact of different options addressing the need to improve traceability of products and their compliance with the requirements in the Directive. In the framework of the study, the consultant also carried out 49 interviews with different stakeholders, including SMEs *(see ref. [8] and Annex V)*.

During 2010, three TCAM ad hoc working groups[9] were put in place in order to assess the impact of the different options pursuing the following objectives:

(1) To improve the traceability of R&TTE products and their compliance with the provisions in the Directive.

(2) To align the R&TTE Directive with the provisions of the New Legislative Framework (NLF[10]) in order to achieve its intended goals: improved coherence of legal texts with regard to market surveillance and notification of conformity assessment bodies, clarification of obligations for economic operators, harmonisation of conformity assessment procedures, simplification of EU safeguard measures

(3) To make the regulatory environment for placing on the market and putting into use radio equipment more receptive to innovative radio technologies

All three ad hoc working groups included the participation of public authorities and other interested stakeholders, namely companies, notified bodies, consumer representatives and standards organisations.

The Commission conducted a further public consultation between 16.07.2010 and 15.09.2010 focussing on the impact of some of the measures under consideration. The questions covered the following topics: improved compliance with the Directive, clarification of the Directive and reduction of administrative obligations, issues of scope and accessibility of R&TTE products for all kinds of users. An adapted consultation specifically sought the views of SMEs

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7 Telecommunications Conformity Assessment and Market Surveillance Committee

8 European Conference of Postal and Telecommunications Administrations

9 See reference of the three final reports in Annex XIII, references [9], [10] and [11]

10 The NLF consists of 2 regulations and a decision:
-Regulation (EC) No 764/2008 of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State
-Regulation (EC) No 765/2008 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products;
-Decision No 768/2008/EC of 9 July 2008 on a common framework for the marketing of products

through the network Enterprise Europe[11]. The Commission received contributions from 122 respondents, including 50 SMEs, 36 other economic operators, national authorities, notified bodies, standardisation bodies and other respondents. *(see Annex VI and ref. [12]).*

During four meetings of TCAM in 2010, the Commission has consulted the Committee on the considered approach to address the issues subject to review.

There is a high level of consensus and support for aligning the Directive with the NLF and for clarifying and simplifying the Directive. Opinions are more divided on the possible introduction of compulsory registration, on some measures of administrative simplification such as the suppression of current article 6.4 (see 4.2.1 below), and on adaptations of scope such as those potentially affecting broadcast receivers (see 4.2.2 below).

2.4. Scrutiny by the Commission Impact Assessment Board

The Impact Assessment Board of the European Commission assessed a draft version of the present impact assessment report and issued its opinion on 27th June 2011. The Impact Assessment Board made several recommendations and, in the light of the latter, the final impact assessment report:

- Clarifies the relation between compliance with the R&TTE Directive and a more efficient use of spectrum, taking into account other legislation at EU and national level affecting the use of radio equipment
- Makes explicite all elements underlying Option A4, in particular the procedure for identification of categories of equipment to be subject to registration
- Indicates the positions of the main stakeholders with regard to the options considered
- Makes more explicite social impacts and impacts on consumers
- Clarifies how the proposed Options A1 to A4 facilitate and/or incentivise compliance by manufacturers based outside the EU

3. CONTEXT

The R&TTE Directive fully harmonises the **placing on the EU market** of the products falling within its scope. Only equipment complying with the requirements in the Directive may be placed on the market, and Member States may not introduce further restrictions addressing at national level the same requirements, namely the protection of health and safety, electromagnetic compatibility, and the avoidance of harmful interference. Other EU legislation on environmental aspects also applies to these products, in particular the directives on RoHS[12], WEEE[13] and Batteries[14], as well as implementing measures under the EcoDesign Directive[15].

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11 http://www.enterprise-europe-network.ec.europa.eu/index_en.htm

12 Directive 2002/95/EC on Restriction of Hazardous Substances

13 Directive 2002/96/EC on Waste of Electrical and Electronic Equipment

14 Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators

15 Directive 2009/125/EC establishing a framework for the setting of ecodesign requirements for energy-related products

With regard to **putting into service** of radio equipment, the legal environment is more complex. Radio equipment makes use of spectrum, the management of which is largely a national competence. Whereas equipment complying with the R&TTE Directive can in principle be used in the EU, national regulations, some of them harmonised at EU level, may introduce further restrictions on the use of radio equipment. When exercising this competence, Member States shall comply with applicable EU legislation *(see Annex VIII and section 4.5 below for a more detailed description).*

The Commission has issued **two progress reports** on the R&TTE Directive:

– A First Progress Report, of 22.4.2004, collecting the experience of the first five years of operation of the Directive *(see ref.[1])* and announcing the intention of the Commission to examine the need for revising the Directive and to make proposals

The Telecommunications, Transport and Energy Council of 9-10 December 2004 adopted Conclusions on this first report and invited the Commission to examine the need for revising provisions of the R&TTE Directive and make the appropriate proposals

– A Second Progress Report, of 9.2.2010 *(see ref.[2])* which, building on further experience on the operation of the Directive and on the 2007 public consultation, highlighted a number of emerging problems and margins for improvement to be addressed through legislative revision or other means

4. PROBLEM DEFINITION

4.1. Low level of compliance

A low level of compliance with the requirements of the Directive has been observed, affecting both the essential requirements in the Directive (the protection of health and safety, electromagnetic compatibility, and the avoidance of harmful interference) and the related administrative requirements (e.g. CE marking, information on restrictions to use, Declaration of Conformity). The Second Progress Report *(see ref.[2])* states:

> "a very low level of compliance to the provisions of the Directive was observed among low power radio devices and to a lesser extent in other areas. A number of importers and manufacturers of this equipment are not aware of the Directive or deliberately ignore it"

This conclusion is based on evidence available from national Market Surveillance Authorities (MSAs) who cooperate within the administrative co-operation group ADCO-R&TTE[16]. Since the Directive entered into force, ADCO-R&TTE coordinated four EU-wide market surveillance campaigns (*see ref. [3], [4], [5] and [6]*).

The first campaign covered a broad range of products, subsequent campaigns focussed on a particular category: short-range devices, Private Mobile Radio (PMR[17]) and 2.4 GHz

[16] Administrative Cooperation in the R&TTE area

[17] PMR offers mobile radio communication to specific organisations such as the police, fire brigade and civil protection

devices[18], and low-power FM[19] transmitters. The table in next page summarises the results of the 4 campaigns:

The campaigns have found values ranging between 28% and 56% for compliance with the essential requirements, and even lower values for administrative compliance.

The most recent consolidated report available, i.e. the 2009 final report of ADCO-R&TTE *(see ref. [7])* also shows low levels of compliance. Of 6168 R&TTE pieces of equipment inspected, 68 % were compliant with the essential requirements and only 56% were compliant with both essential and administrative requirements.

Table 1. Summary of R&TTE market surveillance campaigns

	1st campaign 9/2002-10/2003	**2nd campaign 1/2005-1/2006**	**3rd campaign 9/2008-5/2009**	**4th campaign 6/2009-10/2009**
Product area	Broad range of products	Short-range devices	PMR (Private Mobile Radio) and 2.4GHz devices	Low-power FM radio transmitters
Sampled products	>1000	180	259	60
Observed administrative compliance	24%	42% only 12% compliant including requirements on technical documentation	40% only 15% compliant including requirements on technical documentation	17%
Observed compliance with essential requirements	Not included in the campaign	56%	53% (60% for radio aspects)	28%
Observed overall compliance	24%	6%	16% -22% for PMR -9% for 2.4 Ghz devices	10%
Other elements	-Missing DoC and area of intended use particularly severe	-Missing design schemes in technical file was a major cause for non-compliance	-Missing design schemes in technical file was a major cause for non-compliance	

MSAs have found that for a non-negligible part of equipment non-complying with the essential requirements, no evidence was available of a conformity assessment having taken place. Absence of a complete technical documentation has been a recurrent issue. Also basic requirements such as CE marking (15% absent/incorrect for equipment inspected in 2009) and a correct Declaration of Conformity (DoC) (33 % absent/incorrect for equipment inspected in 2009) are often not complied with. In many cases the equipment concerned consists of low-cost products for consumers, such as some toys with short-range radio features. However, the market surveillance campaigns also detected low levels of compliance for professional equipment such as PMR.

[18] 2.4 GHz devices includes WiFi radio local access Networks (RLANs), remote control equipment, Bluetooth communications equipment, etc

[19] Frequency Modulation

This situation affects consumers, law-abiding manufacturers, and public services. The following consequences can be identified:

(4) **Low compliance prevents law-abiding companies from competing in a level-playing field** with companies that do not comply with the legal requirements of the Directive. Products not complying with the Directive and/or the conformity of which has not been assessed benefit from lower costs and thereby gain competitive advantage over compliant products, thus distorting competition

(5) Low compliance **exposes citizens to possibly unsafe products,** thus potentially entailing accidents and negative health impacts. In this respect, three aspects are to be considered:

- Electrical safety hazards arising from insufficient assessment of risks associated to the electrical characteristics of the equipment. As most R&TTE products used by consumers, many of them battery-powered, are of relatively low-risk, direct consequences of non-compliance for human health and safety are usually limited

- Public **exposure to electromagnetic fields** (EMF) is a matter of concern. Primary responsibility in this area remains with Member States. At EU level Council Recommendation 1999/519/EC[20] includes recommended limits for the exposure to EMF of the general public. Harmonised standards giving presumption of conformity with the essential requirements in the R&TTE Directive are designed to ensure that the public is not exposed beyond the limits of the Council Recommendation. Compliance with the R&TTE Directive is important for public confidence in the effective surveillance of public exposure to EMF radiation, which in turn supports further deployment of radio technologies (e.g. base stations for mobile communications)

- Non-compliant radio equipment may create **harmful interference with critical communication services** such as those of security services, air traffic management or public safety. Nuisances on such critical communications may have fatal consequences or contribute to criminal activity, and several such cases have been reported within ADCO-R&TTE (e.g. long-range walkie-talkies interfering with aeronautical communications)

(6) Low compliance of radio equipment with the Directive also **prevents a more intensive and efficient use of radio spectrum**, negatively affecting the potential for economic growth and innovation in this area[21]. The R&TTE Directive is the only legal instrument with requirements on the use of radio spectrum (e.g. power, width of frequency band used, spurious emissions) to be complied with by radio equipment placed on the EU market. Though other EU-level and national regulations (see Annex VIII) often set further requirements on the use of spectrum, ensuring that only equipment complying with the R&TTE Directive is placed on the market is very important for an effective and efficient use of spectrum:

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[20] COUNCIL RECOMMENDATION of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz) (1999/519/EC)

[21] COM/2010/0471 final - Proposal for a DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing the first radio spectrum policy programme

-First, through the interaction between the R&TTE Directive and other EU/national regulations on the use of radio spectrum: where confidence in the enforcement of the Directive is poor, national authorities are reluctant to authorise more intense uses of radio spectrum in their regulations

-Second, influencing the behaviour of users and manufacturers: equipment non-complying with the relevant R&TTE requirements creates harmful interference and dissuades users and manufacturers from using affected frequency bands; for example non-compliant walki-talkies interfering aeronautical communications oblige aviation authorities to reserve several frequency bands for these critical communications

Different elements concur in **explaining the low level of compliance** observed:

A) The current text of the R&TTE Directive is considered to be ambiguous and unnecessarily complex *(see Annex IV and ref. [2]).* Section 4.2 below develops these aspects. A relatively high effort is required from manufacturers in order to understand their obligations under the Directive.

B) Insufficient or inefficient **enforcement** by Market Surveillance Authorities:

– The relative **low riskiness of the product area** covered by the Directive, and the fact that phenomena such as excessive exposure to electromagnetic fields or interference among radio equipment are particularly difficult to ascertain, makes the detection by MSAs of the placing on the market of non-compliant products particularly difficult

– Market Surveillance is a national competence. MSAs monitor the market in order to detect and withdraw non-compliant products. Member States currently commit very different amounts of **resources** to market surveillance[22]. Under chapter III of Regulation 765/2008/EC[23], Member States shall entrust market surveillance authorities with the powers, resources and knowledge necessary for the proper performance of their tasks. Tight budgetary conditions and the limited political visibility of MSAs have not allowed to fully implement this requirement up to this date, and no fundamental change is foreseeable in the near future. **Lack of cooperation** among MSAs also reduces the efficiency and the dissuasive power of their action. This point is being addressed as well under NLF Regulation 765/2008/EC.

– **Efficiency and effectiveness of MSAs** is strongly hindered by the limited **traceability** of products and of manufacturers. Current provisions in the 'Guide for the implementation of the Directive[24]' include the obligation to provide the name and address of the manufacturer or his authorised representative in the DoC accompanying the product. Nevertheless, this non-legal obligation is not always followed, and often the data provided do not allow an effective contact *(see ref. [9] and [3] to [6])*. When a valid contact point cannot be found, MSAs are obliged to unfurl the distribution chain in order to contact the person responsible for placing the product in the EU market. As an illustration, a market surveillance authority mentioned difficulties for contacting the responsible entity in 50% of the cases, entailing a

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22 It needs to be pointed out that low compliance is also observed within Member States with relatively substantial resources available for market surveillance in the R&TTE area, e.g. Germany, France or The Netherlands

23 See footnote 10 above

24 http://ec.europa.eu/enterprise/sectors/rtte/documents/guidance/index_en.htm

time effort ranging between 0.25 and 0.75 manXdays. *(see ref. [9])*. Many MSAs devote large amounts of time and resources in order to trace products and the manufacturer or the importer responsible for the product on the EU market, which are subtracted from the limited resources of MSAs. This can be also illustrated by the following statement given in an interview by another MSA:

"*When we find a product and suspect it to be non-compliant, we first try to contact the person responsible for the market introduction. Frequently, such information is lacking, e.g. in the packaging or on the product. We then ask the retailer where we found the product from whom he/she got the device. We continue with this contact provided to us and ask the supplier where he obtained the product from. The story can repeat itself for so long till we get to the very first importer of the product… this is extremely in-efficient and also in-effective*" (see ref. [8]).

Responsibilities of economic operators other than manufacturers, i.e. **importers and distributors** and other intermediators such as web-platforms, are absent in the current Directive. This creates difficulties in obtaining their cooperation in the enforcement of the Directive, cooperation which is particularly important when manufacturers are based outside the jurisdiction of the MSA.

The **incentive matrix** with which manufacturers are currently confronted is characterised both by a high perceived cost of compliance, driven by the complexity of the Directive, and a low risk of sanctions in case of non-compliance, taking into account the limited resources and efficiency of enforcement. Such an incentive matrix does not sufficiently encourage manufacturers to comply with the legal requirements, especially those manufacturers with an ephemeral presence on the market.

Table 2. Incentive matrix for compliance under the R&TTE Directive

Barrier/Incentive for compliance		**Probability of effective sanction[25] in case of non compliance**	
		High	**Low**
Perceived cognitive barrier to compliance	**High**		**X**
	Low		

4.2. Problems related to the legal provisions of the Directive

4.2.1. Ambiguity and complexity of the Directive

The Directive is generally considered to be too complex and ambiguous. The cases below have been identified within the 2007 consultation *(see Annex IV and ref. [2])* and within TCAM[26].

There are different interpretations among MSs and industry on whether the essential requirement in article 3.2 ('effective use of spectrum... so as to avoid harmful interference') is only applicable to radio equipment when transmitting or also to the **performance of reception by radio equipment**. The community of standardisation is divided, with

[25] Sanctions depend on national legislation and may include fines, product withdrawal and criminal sanctions

[26] Annex VII lists other elements in the Directive adding to its ambiguity and complexity

consequences on harmonised standards conferring presumption of conformity with the requirement[27]. This ambiguity also affects the possibility of systematically introducing harmonised standards setting requirements for all radio receivers in view of a more intensive and efficient use of radio spectrum.

The **'alert sign'** must be affixed on products where restrictions on their use are applicable in one or more Member States. As indicated by consumer representatives within TCAM, the practical value of this sign for consumers is very limited. There have been extensive discussions on the distinction between this requirement and the obligation to notify to authorities the intention to place on the market equipment operating in non-harmonised bands, as per **article 6.4**[28]. Yet the distinction remains unclear for many companies. National authorities use these notifications in very different ways. While some consider that they facilitate informing manufacturers on possible restrictions on use of the equipment, other authorities do not make any use of such notifications. They add to administrative burden for industry *(*43 % of respondents consider a suppression of this requirement to bring in some or significant reduction of burden*, see ref. [12])*.

Member States have different interpretations on how to apply the requirements in the Directive to products and economic operators in the case of **internet sales and other distance sales,** as shown by discussions within TCAM. For example, the applicability to web-platforms based outside the EU of the concept of person responsible for placing on the market and ensuing obligations is unclear.

The ambiguities and redundancies above and others cited in Annex VII result in scarce resources of authorities and economic operators being consumed in interpretative discussions, lead to different approaches to the application of the Directive, and constitute a hindrance to the Internal Market.

The Directive also includes many **administrative provisions** and experience has shown that there is scope for administrative **simplification.** This refers in particular to the obligation to affix in 3 places, namely on the equipment, on the package and on user instructions the following elements, where applicable to a piece of equipment:

(a) CE marking

(b) Notified Body number

(c) Alert sign

These obligations create burden for businesses that have to adapt the design of labelling, packaging and accompanying documentation for products, and also for public administrations in charge of monitoring them.

Many R&TTE products are also covered with regard to other requirements by other pieces of EU Harmonising Legislation, e.g. for **Toys, Machinery, Lifts, etc**. The fact that many definitions, obligations and procedures are **similar but slightly different** is a source of difficulties and undue burden for economic operators.

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[27] ETSI TR 102 914 - Aspects and implications of the inclusion of receiver parameters within ETSI standards

[28] See for instance TCAM (29)34 Proposed approach to the provision of information on equipment classes, restrictions to use and notifications 6_4

4.2.2. Problems with the scope of the R&TTE Directive

- ***Problems arising from the application of the Directive to certain equipment***

Within the scope of the Directive is currently included **equipment for which the provisions of the Directive are not well adapted**, in particular in the following cases:

Software-defined radio (SDR) is a technology allowing to modify key operating parameters of radio equipment (e.g. frequency range, modulation, output power) by changing its software. These parameters are central to compliance with all three essential requirements of the R&TTE Directive. SDR emerged in the military environment and has until now had a limited impact on the civil market. Most SDR products, in particular for base stations in mobile networks, remain today under the control of a single manufacturer. However, a foreseeable increased presence of SDR, in particular when independent software is uploaded on equipment, raises questions on conformity assessment of combinations of hardware and software, on marking and information requirements for products and, on allocation of responsibilities for non-compliance. Lack of appropriate provisions in the Directive creates **legal uncertainty** both for public authorities and for equipment manufacturers, and **barriers to market uptake** of these products.

Complex installations, e.g. a high power TV broadcasting transmitter, are often continuously modified, and include pieces of equipment that are not placed on the market. However, as the Directive does not include any specific provision for them, installations and their components should be treated like normal products, which creates some legal and practical problems. For example the application of the obligation of both the complete installation and its components to comply with the essential requirements is problematic. One third of respondents to the 2007 public consultation considered that installations where not sufficiently addressed in the Directive, while half of them considered this was not an issue.

The effects of multiple pieces of individually compliant equipment may cumulate (e.g. in-vehicle radars in congested traffic) and create risk to health or harmful interference. The Directive does not easily allow to deal with risk arising from these situations.

In the absence of voluntary industry agreements, lack of **interoperability** is an inconvenience for users and creates unnecessary waste of resources, as illustrated by the protracted inability of the market to generate a common standard for chargers for mobile telephones. The Directive already allows the Commission to take Decisions requiring certain equipment classes to interoperate with emergency services and with network interfaces, but not with accessories. As shown by requests from the public and from the European Parliament, there is a strong societal support for the ongoing Commission initiative to harmonise chargers for mobile telephones[29], and for extending such harmonisation to other equipment, e.g. laptops.

The definition of '**terminal**', a constitutive element of the scope of the Directive, depends on national decisions on the location of the Network Termination Point (NTP). **A fixed terminal may be considered a 'terminal' for the purposes of the Directive in some Member States but not in others:** equipment such as an ADSL router may fall within the scope of the R&TTE D in a Member State and within the scope of EMCD[30] and LVD[31] in another one. Although the applicable essential requirements are the same in both cases, different

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29 Memorandum of Understanding to harmonise chargers for data-enabled mobile phones, http://ec.europa.eu/enterprise/sectors/rtte/chargers/index_en.htm

30 Electromagnetic Compatibility Directive, 2004/108/EC, requires electrical equipment to comply with an adequate level of electromagnetic compatibility.

31 Low Voltage Directive, Directive 2006/95/EC, requires electrical equipment to be safe

administrative requirements and legal basis create burden for manufacturers (e.g. Declaration of Conformity for both R&TTE D and EMCD/LVD) and regulators, and prevent a more integrated Internal Market. This problem was highlighted by manufacturers and public authorities in the context of a related question within the 2010 consultation *(see section 3 in ref. [12])*

- ***Issues arising from products currently outside the scope of the Directive***

Receive-only radio equipment (e.g. GPS or Galileo receivers, receiver side of car-openers) is generally included within the scope of the Directive[32]. Sound and TV broadcasting receivers, the most important category of such receivers, are excluded from the Directive, and are generally covered by the LVD and the EMCD or, in particular in the case of battery powered equipment, by the GPSD[33] and EMCD. The same equipment, if able to receive other data, falls within the scope of the Directive. Similar equipment is therefore subject to **different legal frameworks and essential requirements,** creating legal uncertainty and adding legal complexity to market surveillance.

Also outside the Directive are **intentional radiators** which transmit energy through radio waves for other purposes than communication. They include equipment such as frequency jammers, wireless chargers, heating applications, sensors and other usually falling under the denomination ISM (industrial, scientific and medical applications). Such equipment is not covered by the R&TTE Directive but by the LVD and the EMCD, or, in the case of battery powered equipment, by the GPSD and EMCD. If able to communicate, such equipment is however covered by the R&TTE Directive. Different equipment having the potential to create harmful interference is subject to **different legal frameworks and essential requirements,** adding legal complexity to market surveillance and also to market access for products not clearly falling within legal definitions.

4.3. Regulatory barriers to market entry of innovative radio equipment

Market access for new radio technologies depends on the possibility for manufacturers to comply with the R&TTE Directive, in particular through the availability of harmonised standards or of notified body opinions, but also on the availability of an appropriate allocation of spectrum and authorisation regime in the Member State where the equipment is intended for use, in particular where frequency bands are not harmonised by implementing measures under the Radio Spectrum Decision[34]. As identified within the public consultation held in 2007, a number of issues delay or discourage market entrance for innovative radio technologies in the EU *(see ref. [11])*. Within the scope of the R&TTE Directive are the following:

- Conformity with the Essential Requirements in article 3.2 of the R&TTE Directive[35] is usually based on **harmonised standards** the references of which have been published in the Official Journal of the European Union (OJEU). In past years, it has been the case that the delay for publication of references in the OJEU has been excessive, up to one year in some cases

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32 See 4.2 above for a discussion on whether essential requirement in article 3.2 ('effective use of spectrum.. so as to avoid harmful interference') applies to receive-only radio equipment

33 General Product Safety Directive, Directive 2001/95/EC, requires consumer products not covered by more specific legislation to be safe

34 Decision 676/2002/EC on a regulatory framework for radio spectrum policy in the European Community

35 'effective use of spectrum… so as to avoid harmful interference'

- Manufacturers may place equipment on the market without following harmonised standards, provided that a positive opinion has been obtained from a **notified body (NB).** Difficulties in obtaining opinions from NBs have been reported in the absence of technical conditions defined for the use of spectrum . It is challenging for some notified bodies to be continuously updated on deliberations on rules for the use of spectrum and on compatibility studies developed by CEPT (*see ref [11]).*

Other issues fall mainly outside the scope of the R&TTE Directive:

- Lack of harmonisation of spectrum in the EU reduces economies of scale and makes national markets unattractive for innovators

- Excessive level of detail in the technical conditions for use of spectrum, as opposed to more flexible conditions allowing different technologies to share frequency bands

- A long and uncertain process for the re-allocation of spectrum when this is necessary for innovative use. The time necessary to complete the process depends on the complexity of the systems being considered and the presence of existing users of the bands to be re-allocated. Such a process and constellation of entities is in contrast with the more centralised and agile decision processes of trade partners and competitors such as US and Japan

- Lack of awareness among companies and SMEs of the regulatory decision-making processes for the placing on the market and the use of radio equipment

These issues reflect the complex processes involving the several entities responsible for different regulatory steps for the placing on the market and the putting into service of equipment using spectrum.

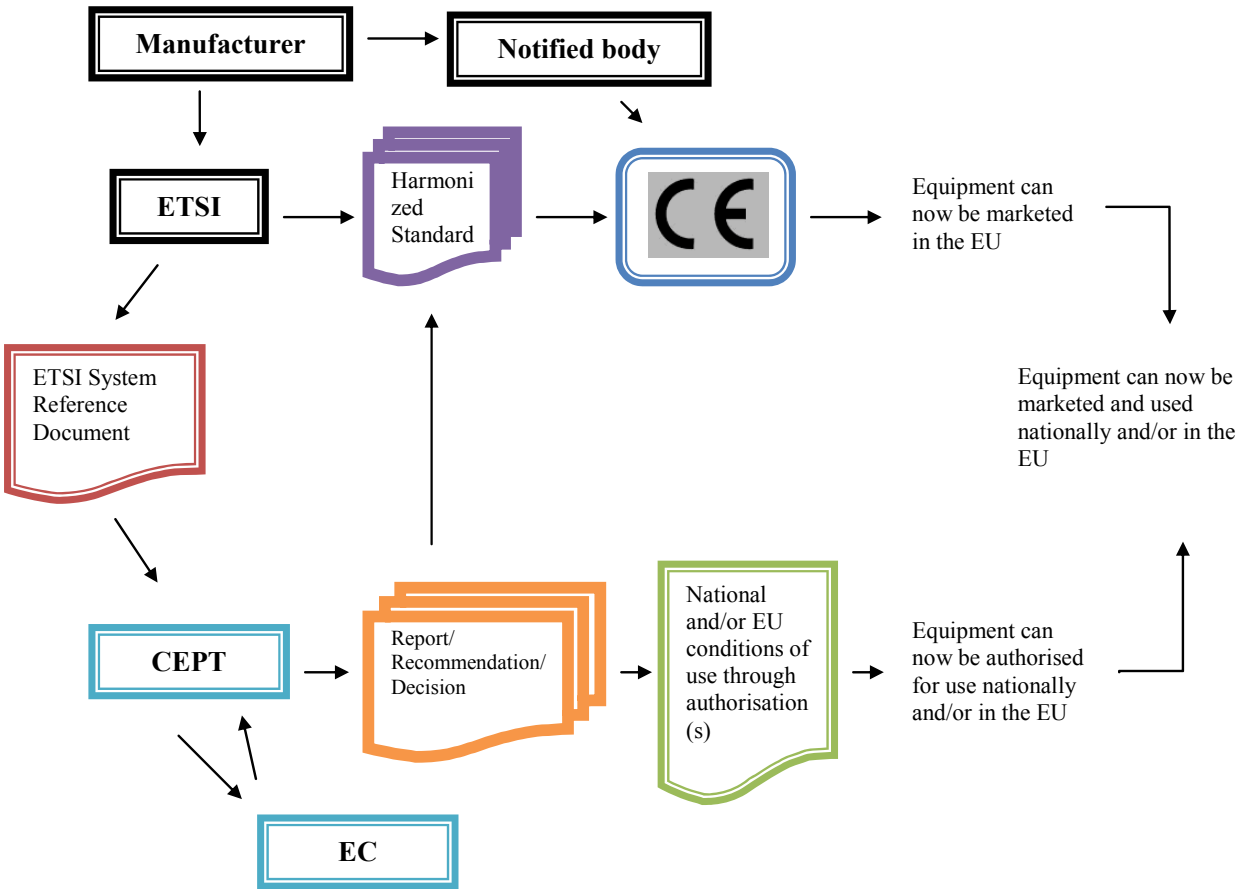
Technical conditions for use of spectrum are issued by Member States and may be harmonized either through binding EU Decisions pursuant to the Radio Spectrum Decision, or through non-binding CEPT Decisions or Recommendations (*see Annex VIII for a more detailed discussion*).

Relevant **authorisation regimes** under which radio equipment will operate are defined at national level according to the principles of the Authorisation Directive[36], which covers Electronic Communications.

The following figure presents a simplified view of the regulatory steps allowing the placing on the market and putting into service of radio equipment *(see ref. [11])* where no harmonised standard is available and the frequency bands are not harmonised at EU level:

Figure 1: Simplified diagram for the preparation of harmonised standards and regulatory decisions allowing the placing on the market and putting into service of radio equipment

[36] Directive 2002/20/EC of the European Parliament and of the Council of 7 March 2002 on the authorisation of electronic communications networks and services (Authorisation Directive), OJ L 108, 24.4.2002, p. 21–32



The current repartition of responsibilities involves a number of entities both at European and at national levels. Progress in the decision-making process usually needs iterative exchanges among the different entities, with associated delays necessary to ensure transparency and due consultation of interested parties, in particular users of spectrum.

Since 2007, the EU has taken a number of measures aimed at facilitating market access for innovative radio technologies. Such measures include:

- the improvements in the second part of 2010 of the process for the publication of references of harmonised standards in the Official Journal of the EU has allowed to achieve a substantial reduction of delays
- the review of the Framework Directive in 2009[37] has strengthened the emphasis on flexibility in regard to the use of spectrum for electronic communications services
- the harmonisation of a number of frequency bands introducing flexible usage conditions under the regime introduced by the Radio Spectrum Decision (e.g. for Short Range Devices[38])

[37] DIRECTIVE 2002/21/EC of 7 March 2002 on a common regulatory framework for electronic communications networks and services (Framework Directive)

[38] Commission Decision 2010/368/EU amending Decision 2006/771/EC on harmonisation of the radio spectrum for use by short-range devices

– the proposed Radio Spectrum Policy Programme[39] provides a strategic framework for the next 4-5 years in spectrum management, in particular in promoting innovation and encouraging efficient use of spectrum

As a summary to this section, market entrance for innovative radio technologies in the EU has to cope with a relatively complex and slow-moving system. Where innovative technologies do not fit within existing harmonised standards and regulatory conditions for use of spectrum, legal uncertainty arises, and can deter potential investors and innovators. Some limited issues regarding development/publication of harmonised standards and information of notified bodies on regulatory developments can be tackled within the framework of the R&TTE Directive and are addressed by the objectives and policy options below, but the most important issues arise in the area of spectrum regulation.

4.4. Other issues

Articles 3.1 and 3.2 contain the essential requirements at the core of the Directive. Article 3.3 allows the Commission to take Decisions in order to introduce additional essential requirements applying to categories of equipment to be defined. Since the entry into force of the Directive, the Commission has taken 5 decisions on the basis of article 3.3.e on access to emergency services. Article 3.3.f addresses support to *'certain features in order to facilitate* ***its use by users with a disability'.*** Until present, this article has not been the subject of a Commission Decision. In the course of the 2010 public consultation *(see ref. [12])*, stakeholders were invited to discuss whether this provision needed to be amended in order to make it more supportive of accessibility. Most respondents agreed on the potential value of article 3.3.f, while some called upon the Commission to take decisions on the basis of this article, and others preferred to focus on other instruments such as the Universal Service Directive[40], which addresses *inter alia* services for special categories of population. The conclusion is that article 3.3.f may be valuable in the future and should be kept as it is. Therefore, this aspect will not be discussed further under this impact assessment.

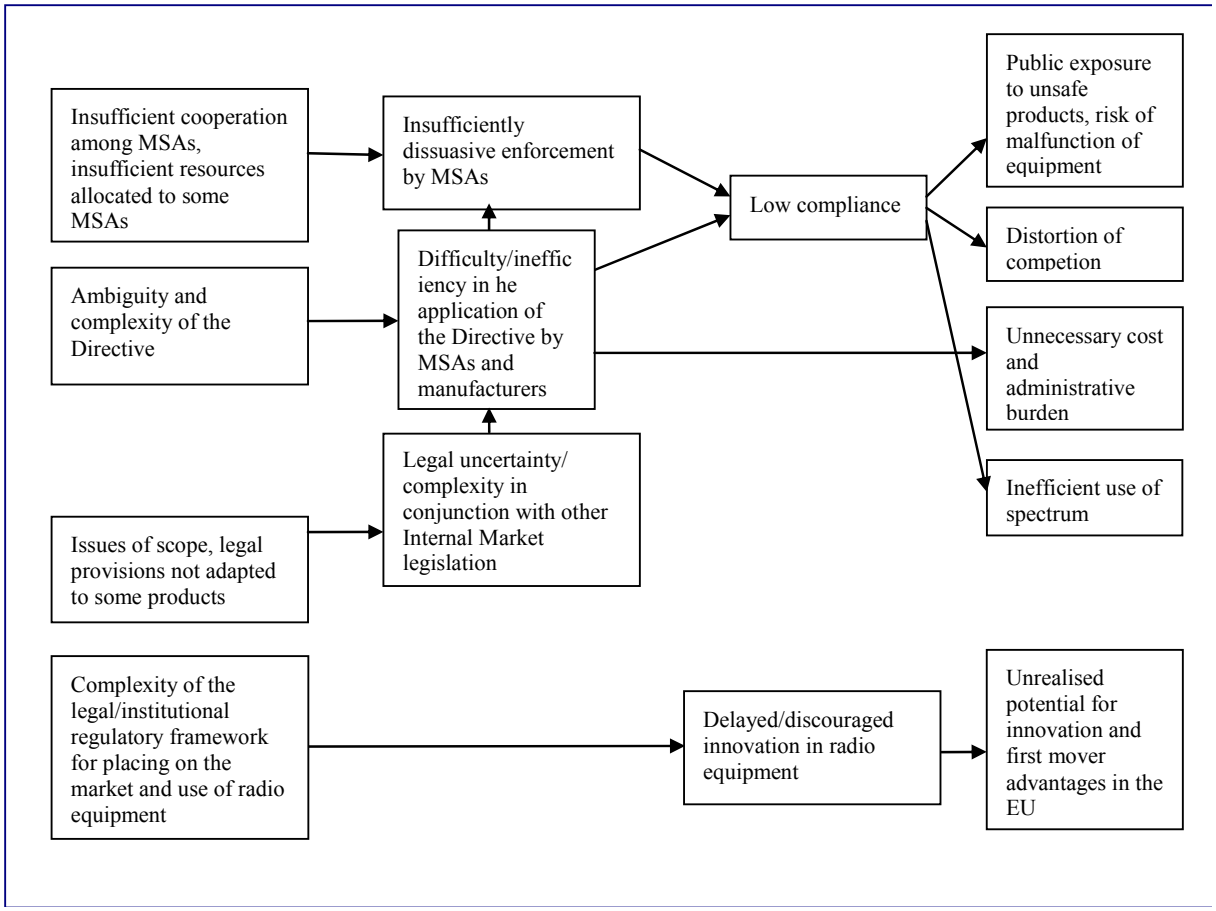
4.5. Problem tree

The following problem tree presents a stylised view of the causality links between the problems identified within the operation of the R&TTE Directive and their main consequences:

Figure 2: Problem tree identified within the operation of the R&TTE Directive

[39] COM/2010/0471 final - Proposal for a DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing the first radio spectrum policy programme

[40] DIRECTIVE 2002/22/EC of 7 March 2002 on universal service and users' rights relating to electronic communications networks and services (Universal Service Directive)



4.6. Underlying drivers of the problem

As noted above key drivers of the problems of non-compliance and complexity are the following:

(7) insufficient resources of MSAs, and inefficiencies in their use due to inappropriate legal instruments for enforcement and lack of operational cooperation among MSAs

(8) a diversity of interpretations by economic operators and Member States of the scope and requirements laid down in the Directive

(9) economic operators face an incentive matrix for compliance with the Directive which combines a relatively high complexity with a low probability of sanctions

(10) increasing proportion of manufacturers non located in the EU, in particular in East Asia, who have more difficulties in understanding the EU legal framework and the Directive

For the other problems, the drivers are:

(11) technological change driving the appearance of software-defined radio and the growing presence or radio components in many different products raising the issue of cumulative effects of technology

(12) different regulatory approaches raising the issue of specialised equipment falling within the R&TTE scope and other legislations

(13) a multiplicity of entities regulating the use of spectrum at EU and at national level, and an only partial harmonisation of spectrum; the revision of the R&TTE Directive only offers limited opportunity to address this issue

4.7. Who is affected.

As already mentioned in sections 4.1 to 4.6, several categories of stakeholders are affected by the current framework put in place by the R&TTE Directive and its implementation:

(14) **Users of R&TTE equipment**, public services and citizens in general are exposed to an important share of non-compliant equipment.

(15) **Manufacturers** are affected by distortion of competition, by the complexity and ambiguity of the Directive, by issues of scope and by difficulties in bringing innovations to the market

(16) **Market Surveillance Authorities** are affected by difficulties in efficiently enforcing the Directive, in dealing with its complexity and ambiguity and with issues of scope

4.8. Foreseen evolution of the problem

NLF Regulation 765/2008, which became applicable on 1 January 2010, should lead to a certain improvement of the current situation. It strengthens the obligations of Member States on market surveillance and provides for reinforced cooperation and information exchange on non compliant products. It also requires controls of imported products. Market surveillance should hence become more effective and more visible and deter those operators who have been encouraged by a perceived absence of market surveillance activities to take advantage of the system. However, even under the best functioning market surveillance system, authorities can only control a relatively limited amount of products on the market. Certain operators will still try their luck, in particular as long as the consequences of "being caught" (fines, withdrawal, effect on reputation, etc) are relatively minor in relation to the economic savings they can achieve.

While the NLF Regulation might lead to a certain improvement of the current situation, at the same time certain trends suggest a worsening of the problem. Whereas when the Directive entered into force in 1999 a significant part of the products covered were manufactured in Europe, **most products today (80%, see Annex III) are imported** from trading blocks where awareness of EU legal requirements is limited, and this trend seems to be sustained. Increased delocalisation of production will also make the tasks of market surveillance authorities more complex and difficult. In many instances they will not be able to identify or directly contact the manufacturer. Consequently they will need to rely increasingly on the information provided by importers and distributors. The lack of traceability in the supply and distribution chain will then become an even bigger problem. With no action, compliance with the Directive should remain low.

The presence of wireless communication devices has been significantly increasing in the last ten years. An increasing amount of other products such as machinery, vehicles and toys incorporate radio modules. In all probability this trend will not change. No action would increasingly allow for situations of risk to good operation of devices and prevent a more efficient use of radio spectrum.

Technological progress and market developments continously present new challenges to the application of the Directive. The 'Guide for the implementation of the Directive' agreed by Member States and the Commission is a common reference for consistent application of the Directive, and maybe regularly updated. However, as it is not legally binding, Member States follow it to different degrees. In particular increasing amounts of equipment modified by software are expected to be placed on the EU market, lack of adequate provisions would render the application of the Directive difficult or impossible in this case.

Further **harmonisation of spectrum** under the Radio Spectrum Decision and the impulse of the Radio Spectrum Policy Programme should simplify regulatory conditions for market access of radio equipment in general, enhance the flexibility and technology neutrality of spectrum allocation, and provide more opportunities for license-free access to spectrum by innovative products in particular. The Commission plans to issue a Communication on collective and shared use of spectrum.

Continuous efforts by the European Standards Organisations and the Commission to reduce delays in development and publication of **harmonised standards,** and to develop technology-neutral harmonised standards are expected to facilitate their timely correspondence with the state of the art and thus enable market access for innovative products.

4.9. EU right to act

The Single Market is an area of 'shared competence' according to article 4 of the Treaty on the Functioning of the European Union (TFEU). The current R&TTE Directive, as one of the 'New Approach' directives setting EU-wide harmonised requirements, has been instrumental in the completion of the internal market for radio and telecommunication terminal equipment. The objective of creating an open competitive single market for telecommunications and radio equipment could not sufficiently be achieved by the Member States acting individually, as different national requirements for the placing on the market of equipment fragment the EU market.

The revised Directive shall be based on TFEU articles 26 (*Internal Market*) and 114 (*Approximation of Laws*). Action at EU level is necessary on order to adapt, clarify or simplify provisions which are the keystone of the Single Market in this area. This cannot be achieved by Member States acting individually. A possible new obligation to register at EU level manufacturer and/or equipment as part of options addressing objective A would enable access to the EU market, and its advantages with respect to multiple similar measures at national level are clear. The changes of scope considered within options addressing objective B are limited, and affect other EU legislation rather than national competences. Some of the options considered for a revision of the regulatory environment of radio equipment (Objective C) affect spectrum regulation, an area largely within the competence of Member States, and this is addressed in section 7.4. The other options considered propose simplification or limited adaptation of the current Directive to some technologies, and therefore the EU right to act and the value-added of action at EU level can be considered uncontroversial for them.

5. OBJECTIVES

5.1. General objectives

As a general objective, the review of the R&TTE Directive aims to ensure better implementation of the essential requirements in the Directive, i.e. to ensure a high level of

protection of health and safety for users and any other person, to ensure the electromagnetic compatibility of equipment, and to ensure an effective use of spectrum so as to avoid harmful interference. This must be achieved in a way that preserves free circulation of these products in the EU, does not create unnecessary costs and burden, in particular for SMEs, and supports innovation.

5.2. Specific and operational objectives

Specific and operational objectives in line with the problems identified in section 4 are the following:

A To achieve improved enforcement and compliance with the Directive:

- To reinforce the obligations of economic operators, and to improve the legal tools available to MSAs in order to improve their efficiency and effectiveness, in particular regarding traceability of products

- To simplify and clarify the requirements in the Directive in order to facilitate compliance by economic operators. This is also part of objective B

B To make available a sound legal basis for the implementation of the essential requirements:

- To clarify and simplify a number of provisions for economic operators, notified bodies and market surveillance authorities. To improve the coherence of definitions and requirements with other Internal Market legislation and with other related legislation such as the Radio Spectrum Decision and the regulatory framework for electronic communications. To modify or suppress a number of administrative obligations which create burden but bring in only limited value-added

- To facilitate the application of the Directive to equipment within the scope of the Directive which because of its nature, technology or patterns of use creates difficulties in the operation of the Directive, i.e. software defined radio, complex installations, equipment prone to generate cumulative effects; to enable harmonisation of interfaces between equipment and accessories

- To rationalise the scope of the Directive so that it includes all equipment for which avoidance of harmful interference (the essential requirement in article 3.2) is relevant

C To remove regulatory barriers for the access to the market of innovative radio equipment:

- To simplify regulatory decision-making processes and to reduce associated delays conditioning market access of new technologies

5.3. Consistency with other policies and objectives

The initiative will be consistent with the principles of the 'Smart Regulation' policy of the Commission[41], with the policy for Europe 2020, in particular with the regulatory review foreseen within the policy for an Innovation Union[42], as well as with the proposed Radio Spectrum Policy Programme[43].

The initiative will also be consistent with the New Legislative Framework package, approved in 2008. This consists of two complementary instruments, Regulation 765/2008 on accreditation and market surveillance and Decision 768/2008 establishing a common framework for the marketing of products. The Decision complements the Regulation. While the latter basically contains the obligations on Member States and their authorities to ensure that products on their market are safe and comply with the legal requirements, the Decision contains the relevant obligations imposed on economic operators such as manufacturers, importers and distributors, as well as the bodies testing and certifying products. Hence, the two instruments are inextricably linked and their elements mutually support and complement each other. Unlike the Regulation, the Decision does not have immediate legal effects on economic operators, individuals or Member States, and provides (article 2) that its provisions are to be used when legislation is drafted or revised.

6. POLICY OPTIONS

6.1. Options addressing objective A

-Option A0 is the status quo.

-Option A1 is an alignment with the New Legislative Framework (NLF) for the marketing of goods. Alignment of Single Market harmonising legislation with the NLF is a commitment of the EU Council, Parliament and the Commission. One of the main objectives of the NLF is to improve compliance with legal requirements in the Internal Market, and in particular to strengthen market surveillance. Alignment with the NLF would include the following elements from NLF Decision 768/2008/EC[44]:

- obligations for manufacturers, importers and distributors to check at the different steps in the supply chain that compliance of equipment has been assessed
- traceability obligations for manufacturers, importers and distributors: to mark their identity on the equipment, to keep a register of from whom they buy, to whom they sell (with the exception of consumers) at the different steps in the supply chain
- easier to use and more effective safeguard clauses
- penalties for administrative non-compliance

This option also includes the improvement of cooperation with MSAs in countries exporting to the EU so that they contribute to raise awareness of EU regulatory requirements among those manufacturers within their jurisdiction. This cooperation will be sought within

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41 http://ec.europa.eu/governance/better_regulation/key_docs_en.htm#_br

42 http://ec.europa.eu/research/innovation-union/index_en.cfm, COM(2010) 546 final, Europe 2020 Flagship Initiative - Innovation Union

43 See footnote 10 above

44 A more detailed description of these elements can be found in annex IX.

regulatory dialogues between the Commission and third countries, as it has been the case in the area of toys.

-Option A2 includes Option A1 plus the obligation for manufacturers to register. The manufacturer shall register in an ad hoc EU central registration system his contact data, and keep them updated. The system returns a unique company registration number, which the manufacturer shall affix on all products placed on the EU market.

-Option A3 includes Option A1 plus the obligation to register individual product types. The manufacturer shall register in an ad hoc central EU registration system each new product type, and upload part of the technical file. The system returns a number specific to each product type, which the manufacturer shall affix on each corresponding product. Product registration intends a quick identification of products and online retrieval of the technical file by MSAs. This obligation could be applied as follows:

– The manufacturer registers, and is allocated a unique manufacturer identifier (mID)

– The manufacturer assigns a unique product identifier (pID) to each product type. This may be performed well in advance of placing a product on the market, so that details of both mID and pID are available when product design takes place

– The manufacturer assesses the conformity of the product, and affixes the product identifier (mID+pID) to his product

– The manufacturer uploads in a central registration system a subset of the technical file of the product which has to be put together as part of conformity assessment

-Option A4 includes Option A1 plus the possibility for the Commission, through the use of delegated powers conferred on the basis of article 290 TFEU, to introduce product registration for some specific categories of equipment, where following the entry into force of the revised Directive a high level of compliance has not been achieved in those categories.

– The Commission, following consultation with Member States and interested parties, would decide on a regular basis whether and for which product categories registration would become mandatory or would cease to become mandatory. Categories of products to be considered for product registration would be identified on the basis of evidence provided by MSAs, and taking into account other circumstances such as particular market/technology situations and availability of alternative enforcement measures. Depending on the situation of the categories of equipment covered by the delegated act, this may be accompanied by a specific impact assessment

– All manufacturers producing equipment within those categories would be required to register relevant products as long as the measure is in force. Exceptions could be considered for those manufacturers implementing the most comprehensive conformity assessment module, i.e. Full Quality Assurance module according to Annex V of the Directive

– The Commission would be in charge of implementing and operating the central EU registration system

A clear majority of industry representatives have favoured option A1, and strongly opposed options including product registration (options A3 or A4), alledging that it would bring significant additional burden upon law-abiding manufacturers but could still be circumvented

by other manufacturers . Consumer representatives support option A3. Market surveillance authorities are equally split among those who value the increased efficiency and effectiveness of enforcement under option A3, and those who consider it unnecessary burden (*see section 7.2 for more detail, as well as Annex VI and refs. [9] and [12]*)

6.2. Options addressing objective B

-Option B0 is the status quo including the regular update of the 'Guide for the implementation of the Directive'

-Option B1 includes:

- **alignment** of definitions, obligations and conformity assessment procedures **with the NLF** for the Internal Market for goods[45]
- the **clarification of currently problematic provisions** on the basis of the current 'Guide for the implementation of the Directive'; inclusion of obligations of internet-based economic operators
- **simplification** of administrative obligations including the 'Alert Sign' informing users of restrictions to use, and the suppression of a number of administrative obligations (*see section 4.2*) including notifications as per article 6.4
- the improvement of **consistency** with the Regulatory Framework for Electronic Communications and the Radio Spectrum Decision. This includes the alignment of definitions in the area of electronic communications and the introduction of explicit references in the Directive to other EU requirements for use of radio equipment

Suppression of notification to Member States of the placing on the market of equipment using non-harmonised bands, as currently provided for by article 6.4, is compensated with an enhancement of existing non-legislative measures providing information to stakeholders on regulation on the use of spectrum at EU and national level, namely the R&TTE sub-classes[46] under article 4.1 and the EFIS database[47].

-Option B2 includes option B1, plus the introduction of additional provisions to deal with some specific technologies and to address interoperability with accessories, and an **extension of scope** so that it includes all radio transmitters, radio receivers, and fixed terminals:

- introduce specific provisions for complex installations, for software defined radio equipment, and for equipment likely to create cumulative effects; a new general essential requirement for interoperability with accessories
- clarify that the essential requirement in article 3.2 applies to reception performance of radio equipment, and include within the scope of the Directive

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45 e.g. Definitions of common terms like "manufacturer", "importer", "placing on the market" set out in Article R2 of Decision 768/2008 are introduced in the R&TTE Directive. Existing conflicting definitions are removed

46 http://www.ero.dk/rtte

47 ECO Frequency Information System (EFIS), http://www.efis.dk/

all equipment which intentionally emits or receives radio waves; this would add to the current scope receive-only TV and sound broadcast equipment and intentional radiators non-capable of communication

-Option B3 includes option B1, plus the introduction of additional provisions to deal with some specific technologies**, an empowerment to the Commission** to facilitate the application of the Directive and to address interoperability with accessories, and a **scope restricted to radio transmitters:**

- introduce specific provisions for software defined radio equipment and for equipment likely to create cumulative effects (but not for installations)

- confer delegated powers to the Commission on the basis of article 290 TFEU in two areas to introduce additional requirements in two areas: conformity assessment of software defined radio equipment, and interoperability between specific categories of equipment and accessories

- confer implementing powers to the Commission on the basis of article 291 TFEU to take binding decisions on consistent application of the Directive to future products and technologies in matters such as definitions, scope and requirements

- clarify that the essential requirement in article 3.2 applies to transmitters but does not apply to reception performance of radio equipment; include within the scope of the Directive intentional radiators non-capable of communication, and exclude all receive-only equipment.

Improvement in the performance of receivers, left outside the essential requirement in article 3.2, is to be pursued through voluntary standards reflecting the state of the art. When necessary the Commission may issue standardisation mandates requesting the development of such standards

- remove fixed terminals from the scope of the Directive, which would become a Directive for radio equipment; leave competition issues affecting terminals to general competition law and to Directive 2008/63/EC[48]

Both industry and MSAs generally support simplification measures in Option B1, as well as adaptations to specific cases in options B2 and B3. Opinions are more divided with regard to the inclusion of broadcast receivers within the scope of the Directive: manufacturers are clearly opposed, network operators and frequency managers are clearly supportive (*see also section 7.3, as well as AnnexVI and ref. [12]*).

6.3. Options addressing objective C

-Option C0 is no new EU action.

-Option C1 includes several non-legislative measures:

- to put in place a single point of contact for the request of EU-wide experimental licences for use of radio equipment

[48] COMMISSION DIRECTIVE 2008/63/EC on competition in the markets in telecommunications terminal equipment

– an action plan led by the Commission to achieve a stronger relationship between responsible entities within the regulatory framework for radio equipment, in particular CEPT, notified bodies and standardisation bodies. This would include measures such as the systematic exchange of information on planning and operational processes, exchange of personnel, co-located meetings, etc

– an information campaign improving awareness by companies and SMEs on the regulatory framework for the use of radio equipment

-Option C2 includes option C1 and two legal changes: the creation of a **special category of notified bodies**, who would give opinions on the more innovative radio equipment, and who would be required to engage with CEPT and with ETSI in order to have access to an appropriate level of information; second, the **setting up of a central EU body** which would be empowered to allow the placing in the market and the use of a limited amount of radio equipment within well defined geographical areas and periods of time, so as to provide the conditions for a quick commercial start and uptake. The body would be supported by an EU level competence centre which might be attached to an existing body (e.g. BEREC[49]),. Temporary authorisations could be extended, made permanent or be reversed, including a possible withdrawal of previously authorised equipment.

Industry and public authorities generally support the measures included in Option C1. Measures in Option C2 have been proposed by individual companies and authorities, but are not clearly supported by a category of stakeholders (*see also section 7.4 and ref. [11]*).

7. ANALYSIS OF IMPACTS

The Impact Assessment report uses data collected during 2 public consultations, numerous formal and informal exchanges with stakeholders and the external study carried out by Technopolis on the impacts of a possible registration system for R&TTE equipment. While every effort has been undertaken to base the proposed analysis on evidence, it must be recognized that some data are not available or have not been sufficiently agreed by stakeholders, in particular with regard to the administrative costs and benefits of a possible registration system.

The impacts of the three respective baseline options have been described in detail in chapter 4, in particular section 4.8, and will not be repeated here. They are consistently used as the benchmark for comparison of the options involving new EU action and are therefore also included in the summary tables.

7.1. Identifying impacts

All options will be assessed in terms of effectiveness in achieving the objectives.

Further, the main impacts to be assessed are **social impacts**, driven by the improvement of compliance with requirements protecting the the good operation of communications equipment used by consumers, business and public service and the health and safety of users and other citizens. Reduction of regulatory barriers for innovation facilitates access to the market of new products, enhances consumer choice and increases value-added for consumers.

[49] Body of European Regulators for Electronic Communications, Regulation (EC) No 1211/2009

According to present knowledge, **no significant impact on employment** of the options considered can be foreseen.

Economic impacts consist of an improvement in the functioning of the internal market, an efficient use of spectrum and the administrative costs induced by the Directive, as well as some competition and innovation aspects. Many of these impacts are indirect, driven by intended **improvements in simplicity in the operation of the Directive and in legal certainty**. Specific impacts on **SMEs** are described as appropriate[50].

Due to the overall limited impact on the costs resulting from the options considered, it is not expected that it creates **price** increases that may negatively affect consumers. If on specific products moderate price increases were nevertheless to materialise, in particular under options B2 and B3, it is expected that the latter would be largely offset by the benefit of greater reliance on the product quality.

With regard to **environmental impacts**, disposal of R&TTE equipment is already regulated by a number of existing pieces of legislation (*see section 3*). Options considered in this report do not present significant environmental impacts.

7.2. Options addressing objective A: To achieve improved enforcement and compliance with the Directive

Four impacts are relevant here: impact on compliance – and through compliance on the social benefit of improved and safe operation of equipment-, administrative costs for companies and administrations, direct cost of a registration system, and impact on trade with third-countries.

7.2.1. Effectiveness:

In spite of significant efforts undertaken by the Commission together with Member States and economic operators in order to assess the impact on compliance of the different options[51], views on this matter of different stakeholders have remained very divergent. Furthermore, though product registration applies to different subsets of radio equipment in countries such as US, Canada and Singapore, they do not provide information on resulting levels of compliance. It is therefore important to explain which and to what extent elements in each option contribute to improved compliance.

Option A1 – alignment of the Directive to the NLF

The improved legal tools (obligations of importers and distributors, traceability, safeguards, penalties) intend to increase the effectiveness of enforcement by MSAs. Stakeholders have provided the following estimation of the impact of the NLF alignment on compliance:

– Some 50% of Member States and most economic operators expect a high impact of the alignment to the NLF on compliance in the R&TTE area (*see ref. [9]*). In the course of the 2010 public consultation a majority of respondents expected from the NLF alignment a medium (43%) to strong (28%) impact on compliance. SMEs were equally positive with 60% indicating a medium impact and 12% a strong impact (*see ref. [12]*)

[50] An overview (SME-test) can be found in Annex XII.

[51] These efforts included a study commissioned to an independent consultant, see reference [8]

– A similar fraction of Member States (ca 50%) considers that, taking into account current difficulties to allocate more resources to market surveillance, in the absence of other instruments allowing to improve efficiency of MSAs only a limited positive improvement with regard to the current situation can be expected (*see ref. [9])*

With regard to the growing share of imports in the R&TTE area, the obligations of importers and distributors to check that appropriate conformity assessment has been carried out, and their role in providing feedback on enforcement measures (e.g. market withdrawals) are expected to have a positive impact on compliance by manufacturers based outside the EU. In addition to this, improving cooperation between EU authorities and those in the main exporting countries, i.e. China, US, Japan and Korea *(see Annex III)* is also necessary in order to educate extra-EU manufacturers and importers and to dissuade them from placing non-compliant products on the EU market. Considering the divergence of economic interests among trading partners, a significant additional contribution to compliance as a result of such cooperation is however uncertain.

Taking into account the elements above, the conclusion is that this option should provide an improvement of compliance ranging between moderate and significant.

Option A2 – NLF alignment +manufacturer registration - includes two additional elements for MSA efficiency on top of option A1: the **online availability of up-to-date manufacturer's contact data** in a central database facilitates a reduction of delay in contacting manufacturers responsible for R&TTE products; as the contact data are not product specific, the reduction would in some cases be more effective than in others. Also, MSAs can easily **withdraw from the market products without manufacturer registration number**.

The additional effect on the efficiency of MSAs and therefore on compliance should be positive but limited, as seen by most MSAs *(see ref. [9]).*

Option A3 - NLF alignment + product registration - provides improved efficiency in market surveillance and has an educational impact on manufacturers:

First, product registration provides **quick access to the technical file** of registered products; this should allow in most cases to check whether conformity assessment has been performed or not. When necessary, **online availability of product-specific manufacturer's contact data** in a central database facilitates a reduction of delay in obtaining further details about the process. Though no common picture of the potential improvement could be obtained, one MSA provided the following estimation *(see ref. [9]):*

– Difficulties for contacting the responsible entity arise in 50% of the cases, entailing a time effort ranging between 0.25 and 0.75 manXdays. Taking into account time spent analysing the technical documentation and planning lab tests (average 1.5 days), the MSA estimates an overall gain of up to 10-15% in time/resources allocated to market surveillance. Product registration also allows to eliminate the current delay for obtaining the technical documentation for the product, which is currently estimated to be of 4 weeks on average, and therefore reaction time of MSAs would be improved by several weeks.

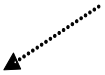
Second, product registration allows MSAs to easily detect and **withdraw from the market non-registered products, and products identified as non-compliant.**

Third, on the basis of the aggregate set of registered products, MSAs obtain an **overview of the market to be surveyed**. This allows devise programmes for market surveillance accordingly, and to request appropriate means from budgetary authorities

Fourth, a user-friendly online product registration tool obliges manufacturers to go step by step through all necessary regulatory steps specific to each product. This is expected to **improve awareness by manufacturers of their obligations under the Directive**, and is particularly relevant for the majority of manufacturers located outside the EU.

Respondents to the 2010 stakeholder assessed the impact of product registration on compliance as medium 31% (48% for SMEs) or significant 34% (18% for SMEs). The incentive matrix with which manufacturers are confronted evolves with option 3:

Table 3. Evolved incentive matrix for compliance under R&TTE Directive under option 3

Barrier/Incentive for compliance		**Probability of effective sanction in case of non compliance**	
		High	**Low**
Perceived cognitive barrier to compliance	**High**		
	Low		

The new matrix is characterised by a lower perceived cognitive cost of compliance, and a higher risk of sanctions in case of non-compliance. The change in the incentive matrix should drive compliance further up from the levels attained with options A1 and A2. Some allowance for inefficiency and forgery in the product registration system itself should however moderate the increase in compliance resulting from this option.

Option A4 should have similar impact as Option A3 on effectiveness addressing compliance in those equipment categories which become subject to product registration. For other equipment categories, impact of effectiveness is similar as for Option A1. As Option A4 only brings in the obligation to register products for those categories where a high level of compliance has not been attained, a better cost/benefit ratio is expected.

7.2.2. Impact on administrative costs

Option A1 entails some additional administrative costs, resulting for example from the obligation of economic operators to keep a register of suppliers and buyers of equipment, which are perceived as non-problematic by manufacturers *(see ref. [9], [12]*[52]*)*.

With regard to **Option A2**, manufacturers consider that effort associated to a one-time registration of the manufacturer itself would be negligible. Adding an additional manufacturer ID to all products would create design problems since there are already many global labelling requirements and limited space on product labels *(see ref. [9]).*

[52] 16% of all respondents (30% of SMEs) of the 2010 public consultation indicated no or no significant administrative burden; 45% (38% of SMEs) indicated some administrative burden linked to option A1

The impact of **Option A3** on administrative burden is perceived as much more significant than for the other options. 32% respondents to the 2010 consultation (but only 12% of SMEs[53]) assess the impact as significant against only 10% for the NLF alignment. Main burdens generated by this option are the following *(see ref. [9])*:

– Training staff to become acquainted with the system: this is a one-time investment, also common to option A2 above, and not considered significant by industry

– Upload manufacturer information, obtain manufacturer Id and a range of product Ids. This is again considered not significant by industry

– Upload product specific information: this implies selecting appropriate information, formatting, performing confidentiality checks and actually uploading the information. This is considered to be significant by industry, actual effort would depend on the precise subset of technical documentation required

– Manage correspondence between product Id, technical file and product labelling: this is again considered significant. In the case of supply chains involving subcontractors, this may imply revision of legal agreements in order to allocate responsibilities under the product registration scheme

– Design equipment to accommodate a new label, and organise production to ensure correspondence between products and product Ids. This is considered problematic, mainly because of already existing labelling requirements in the EU and other economic areas, and the limited space on products

Manufacturers have not been able to provide a systematic estimation of resources required to cope with these tasks. Both written and oral requests on behalf of the Commission to provide such estimation were declined by companies and industry associations[54]. Some elements gathered were the following:

– For a large manufacturer with many products, industry representatives indicated that the additional workload could mean several additional full-time staff. *(see ref. [9]).*

– A large manufacturer indicated the need to recruit 2 additional employees, an additional cost of ca. 1500000 €/year to cope with obligations under Option A3.

– Additional burden is expected to be lesser for SMEs with fewer products on the market and for whom the operation of the system presents less challenges of complexity *(see ref. [8])*

– Additional burden arising from collecting, formatting and uploading product specific information seems to derive from the way in which companies comply in practice with their obligations under the Directive:

"*It seems that while firms (especially large companies) collect all necessary data as expected by the regulation when a new product is introduced onto the market, they do not edit a fully*

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53 This might be linked to the fact that they produce less different types of products

54 A first systematic effort was conducted by Technopolis, see ref. [8], a second by TCAM ad hoc group on Traceability and Compliance, see [9], several direct Commission contacts were also undertaken with manufacturers in 2010 and 2011

comprehensive report every time. Rather, and although manufacturers have all information on their databases, such fully comprehensive reports are only edited 'on demand', i.e. when an MSA asks for the required information. That way, the companies in question save the work to actually produce reports in most cases (i.e., the work needed to copy and paste the information, create table of contents etc.) and are able to implement higher 'internal' (information) *security standards (e.g., by implementing separate access barriers for certain employees to certain types of information). The additional time needed is seen in this context in the need to hire extra persons only tasked to handle the creation of the reports, and the extra time needed to assemble the information in a readable way. Additional costs would be negligible if the companies were to create the Documentation in such a way every time, i.e. also when no MSA is requiring the information (which is what many MSAs seem to expect from the companies). However, in practice cost increases would occur (although they would likely also be present if the current system could be enforced more stringently). (see ref [8])*

Should the current obligation to establish a technical file prior to the placing of a product on the market be systematically fulfilled, additional costs would be limited.

There is no impact on time to market: provision of a pool of product Ids to a company can be done in advance, allowing companies to plan for their use. Product registration can be designed to integrate existing notifications as per article 6.4 *(see section 4.2.4 above)*, so that registration facilitates market access without additional procedures.

An obligation to register products as in option A3 is already in place in countries such as US, Canada and Singapore. In view of their experience, no relevant impact on product diversity and consumer choice in the EU market is foreseen.

For **Option A4**, additional administrative burden linked to product registration (i.e. training, formatting and upload of information, labelling, etc) would only apply for those product categories required to apply registration, i.e. those showing persistently low compliance levels. The total administrative costs would therefore be much more limited than for Option A3. As Option A4 targets problematic product categories and implies less burden for industry as a whole, its overall efficiency is expected to be higher than for Option A3.

7.2.3. Direct costs of the options

Options A2, A3 and A4 entail direct costs for the implementation and maintenance of a registration system. A conservative estimate of these costs for option 3, implying the most complex system yields estimated investment costs of 300000 € and estimated annual maintenance costs of: 30000 € (*see Annex X for the assumptions considered)*. A system limited in scope to some categories of products, as in **Option A4,** would of course imply lower costs; the reduction need not be proportional. As for the system in option A2, costs would be very limited.

7.2.4. Impact on third countries:

Some 80% of equipment placed on the EU market is manufactured abroad, and manufacturers outside the EU would have to comply with an obligation to register in case the relevant options are adopted. In the case of option A4, observed low compliance shows that some categories of low-cost products manufactured in East Asia might become subject to registration. Associated administrative burden and cost would particularly apply to them.

A Commission proposal to introduce registration in the R&TTE area would have an impact on the role of the EU as an effective model of liberal regime in the area of technical barriers to

trade. Introducing registration in the R&TTE area may be perceived as questioning the effectiveness of the New Approach regime in protecting public interests, and could make less attractive the adoption of the EU regulatory approach by our trading partners.

7.2.5. Comparing the options addressing objective A. Preferred option

The table below summarises the impacts assessed[55].

As a summary, the alignment to the NLF and the improved cooperation among MSAs (**Option A1**) should increase compliance with limited increases in administrative cost. The simplification measures considered below under objective B should further contribute to the improvement of compliance. Manufacturer registration as per **Option A2** provides only limited value-added to market surveillance tasks. Full product registration as per **Option A3** may provide significant improvement of effectiveness and efficiency of market surveillance, but is perceived by industry as a significant additional burden. **Option A4** allows to adopt a flexible and proportional approach: to perform the alignment of the R&TTE Directive to the NLF, and to introduce registration in some specific product categories where a high level of compliance has not been attained as shown by careful examination. **Option A4** provides the best balance between the social benefit of improved compliance and the economic imperative to avoid unnecessary burden, and is **therefore the preferred option.**

Table 4. Summary table comparing options addressing objective A

	Effectiveness in achieving objective A	**Cost and efficiency**	**Coherence**
Option A0	0	0	0
Option A1	+/++ Moderate to significant	- Increase of administrative requirements, in particular for importers and distributors	+++ NLF alignment improves coherence with other New Approach legislation
Option A2	+/++ Limited impact on top of A1	-/+ Perceived as a small increase of burden by manufacturers Limited improvement in the efficiency of MSAs	+++/- Idem NLF / Slight depart from New Approach legislation
Option A3	+++ Additional instrument for effective enforcement of obligations and education of companies	--/++ Perceived as a significant increase of burden by manufacturers Improves efficiency of MSAs Estimated 300000€ investment	+++/-- Idem NLF / Departs from New Approach legislation
Option A4	++ Additional measures only for problematic categories	-/+++ Smaller increase in burden for industry than Option A3 Higher overall efficiency than Option A3	+++/- Idem NLF / Departs from New Approach legislation in justified cases

[55] For the assessed impact of the options, the symbols are to be read as follows: 0 no impact, + weak positive, ++ moderate positive, +++ significant positive, - weak negative, -- moderate negative, --- strong negative

7.3. Options addressing objective B: To make available a sound legal basis for the implementation of the essential requirements

7.3.1. Effectiveness.

Option B1: the NLF intends, among other objectives, to clarify and to bring consistency to many definitions and obligations common to New Approach legislation such as the R&TTE Directive. This is an aspect which benefits from an important consensus among the R&TTE constituency *(see ref. [10])*. Avoiding current confusion between the obligation to affix the alert sign and the obligation to notify equipment using non-harmonised bands (article 6.4) is important for manufacturers, as shown by numerous discussions within TCAM. We may therefore speak of a significant clarification and improvement of coherence from Option B1.

Many Member States use notifications in article 6.4 to communicate with manufacturers on applicable spectrum regulation, and to identify needs for further spectrum harmonisation. Suppression of this communication channel is to be compensated by currently ongoing improvements in information provided to manufacturers by the list of R&TTE equipment sub-classes, which provide information on available restrictions to use, in the EFIS database, which provides some information on spectrum allocation and designation at European and national level but which is yet incomplete and not up-to-date, and by other non-legislative measures considered under objective C in section 6.3.

Option B2, with the introduction in the Directive of provisions specific to the cases of software defined radio, installations and cumulative effects, provides in general companies and authorities with a clearer, more fit-for-purpose legal basis. Specific issues and possible drawbacks to take into account are the following:

- In the area of software defined radio, there are yet important unknowns about the actual risks created by software uploads, about the future extent of competition in the provision of third-party software, and in general about future technology and its market uptake. New provisions may not be future-proof

- Installations are not placed on the EU market. There is less value-added in harmonising legislation applicable to them than it is the case for products. Co-existence with national legislation for installations may still be necessary in many cases, making the case for harmonisation weaker

- A general requirement for interoperability with accessories may be inapplicable due to disagreements within industry on technology. Systematic intervention by the Commission would mean a counterproductive interference with technology choices in the market

Option B2 brings the benefit of unifying interpretation of the essential requirement 3.2, which would include performance of reception. This facilitates the task of ETSI in developing harmonised standards, and also allows to plan a more efficient use of spectrum. This is important in view of the increased demand for this scarce resource, and in particular for the coexistence in the same bands of broadcast services and other electronic communication services. It ensures that consumers only have access to receivers with sufficient performance to work properly in situations of intense use of spectrum, and therefore brings the social benefit of protecting user experience. This approach is strongly supported by mobile network operators and by spectrum authorities *(see ref. [12])*. Including within the scope of the

Directive intentional radiators non-capable of communication and broadcast receivers brings under the same legislation all equipment concerned by the essential requirement, which allows to unify requirements on equipment using spectrum for different purposes and simplifies market surveillance.

Option B3 brings in the benefits of option B2 with regard to application of the Directive to challenging technologies, but tries to avoid its drawbacks through the use of Commission implementing and delegated powers, allowing to timely react to future developments in technology or in the market. This is particularly valuable in the case of software defined radio, where the technology and the forms of cooperation between manufacturers of hardware and software are yet to be developed. With regard to interoperability with accessories, the possibility in option B3 to introduce requirements in the future provides an incentive to market actors to solve the issue by themselves, thus making EU intervention exceptional, which is desirable in order to avoid hampering innovation.

Option B3 also brings the benefit of unifying interpretation of the essential requirement 3.2 with regard to reception, though in a different direction than in option B2: the requirement would not be applicable to receive-only equipment, which would be excluded from the Directive. Performance of receivers would be left to voluntary standards and to the market, as it is currently taking place for co-existence of services in the 800 Mhz band. This option is clearly preferred by manufacturers (*see ref. [12])*. In the context of a more intense use of radio spectrum, some consumers having purchased underperforming receivers may suffer a degradation of their experience.

Again, bringing within the scope of the Directive intentional radiators non-capable of communication brings under the same legislation all equipment intentionally using spectrum and therefore concerned by avoidance of interference, which unifies requirements and simplifies market surveillance.

In addition, Option B3 unifies and simplifies the legal framework for fixed terminals *(see 4.2.2)*, which would be the EMCD[56] and the LVD[57] (or GPSD[58] in some cases). The R&TTE Directive would become a simpler Directive on Radio Equipment with a clearer scope. A side effect of this simplification is to remove the possibility of introducing additional interoperability or accessibility requirements for fixed terminals and for pure receivers (e.g. Galileo/GPS receivers) on the basis of currently applicable article 3.3.

7.3.2. Impact on administrative and compliance cost

Alignment with the NLF (Option B1) involves some reduction of administrative cost for manufacturers (see table below).

Other elements in **Option B1** further provide reduction of administrative cost for manufacturers. Suppressing article 6.4 has been referred in the context of the 2010 public consultation (*see ref. [12]*) as a significant reduction of burden. Less important was considered the suppression of the Alert Sign. SME participating in the consultation did not present any specificity in their valuation of this impact.

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56 See footnote 29 above
57 See footnote 30 above
58 See footnote 32 above

Table 5. Administrative obligations under Current R&TTE Directive and NLF

Administrative obligations for manufacturers	**Option B0 - Current R&TTE D**	**Option B1 (NLF)**
-CE marking	3x:(equipment, package, user instructions)	1x : (equipment)
-Notified Body number	3x:(equipment, package, user instructions)	1x : (equipment)
-Alert Sign	3x:(equipment, package, user instructions)	1x (equipment)
-Manufacturer's name, product id, unique id	1x (equipment)	
-Indication of the countries where the equipment is to be used	2x (package, user instructions)	
-Indication of restrictions of use	1x	
-Indication of relevant interfaces for use	1x	not required
-Provision of a DoC with the product	1x	
-Prior notification of equipment using non-harmonised bands	-required	

Option B2 creates some additional compliance cost for manufacturers of software defined radio, i.e. an obligation to introduce mechanisms which ensure that only compliant software is uploaded, and for installers of fixed installations if explicitly covered by the Directive. Systematic requirements on interoperability with accessories may bring in important transitional costs for manufacturers obliged to adapt to new technical specifications.

Under option B2, a number of R&TTE D obligations would become applicable to intentional radiators and to broadcast receivers, what entails some **compliance costs** (*see table below*).

- complying with the essential requirement in article 3.2 may entail some additional testing and costs, ranging between quasi-nil for those products already subject to comprehensive testing, and a range of 2000-4000 EUR[59] per product type where the manufacturer opts for the introduction of external testing in order to assess compliance with the requirement. In the short term, in the absence of specific harmonised standards for these products, the opinion of a notified body would be required, with additional costs ranging between 500 and 1500 EUR[60] per product type. An appropriate mitigation measure to avoid such worst-case situations would be an additional delay for implementation allowing for the development of harmonised standards which would make consultation of a notified body optional
- the R&TTE Directive removes the voltage limitation (50 AC, 75 DC) of the LVD, therefore the LVD safety requirements are of application. Manufacturers have indicated that this entails additional testing and costs. However, under the GPSD safety of products also has to be tested and therefore the change of applicable legislation should only bring some limited additional administrative cost

The impact of these additional compliance costs on individual products may be estimated as ranging between practically nil for products which already are comprehensively tested by manufacturers and up to 50 € in the extreme case of products sold in small quantities when

[59] source: direct targeted consultation of some notified bodies by Commission services
[60] source: direct targeted consultation of some notified bodies by Commission services

full testing and the opinion of a notified body is newly required. (*see Annex XI for the assumptions considered*). Leaving aside exceptional situations, those products for which lower quantities are sold are also products incorporating higher value added and more expensive products, therefore the possible increase in prices is not substantial in relative terms, even in the absence of mitigation measures. Sufficient delays for the entry into force of the new scope should in practice eliminate the need for manufacturers to contract external testing and to consult with notified bodies, leaving them the option to declare conformity on the basis of harmonised standards and in-house tests.

As for additional **administrative burden**:

- article 6.3 obliges to provide the DoC with the product; this obligation can currently be fulfilled in the form of a standard simplified DoC
- article 6.3 obliges to provide information to the user on available interfaces, on the geographical area for intended use of radio terminals (and on possible restrictions to use, not applicable to broadcast receivers)
- one-time costs for referring to the R&TTED in the DoC of product types already present on the market under EMCD and LVD/GPSD; an additional delay for implementation limits the need for this adaptation to product types not phased out by manufacturers within the given delay

Table 6. Additional requirements under R&TTE Directives compared to EMCD + LVD/GPSD

	R&TTE D requirements additional to EMCD + LVD/GPSD
Substantive requirements	-essential requirement 3.2 (avoidance of harmful interference) -safety requirements of LVD apply also for equipment outside the 50V-1000V AC / 75V-1500V DC voltage range, in particular for battery-powered equipment
Administrative obligations	-provide the DoC with the product -inform the user about available interfaces and geographical areas for use -alert on restrictions to use (not applicable to pure receivers)

Negative impacts on cost and burden with regard to broadcast receivers were highlighted by a majority of manufacturers during the 2010 public consultation, where no specific SME issues where apparent.

The use of delegated powers in **option B3** allows to limit additional cost generated by requirements on SDR equipment and on interoperability with accessories to those cases where the benefits are clearly justified. Option B3, like option B2, would create some additional cost for intentional radiators non capable of communication, which would fall under the scope of the R&TTE Directive (*see above the discussion of additional cost for broadcast receivers under option B2*) . This option would reduce some administrative cost for receive-only radio equipment and for fixed terminals which would become excluded from the scope of Directive.

7.3.3. Comparing the options addressing objective B. Preferred option

The table below summarises the impacts assessed above:

In summary, **Option B1** achieves clarification, simplification, reduction of burden and improvement of coherence. **Option B2** further clarifies and improves the legal basis in dealing with SDR, intentional radiators and receivers. Requirements on performance of reception may be used to increase efficiency in the use of spectrum and improving user

experience, but entailing additional compliance and administrative costs. **Option B3** allows to clarify the application of the Directive to current and future specific cases, sets clear criteria for its scope in relation to the EMCD, and reduces or avoids regulatory requirements on the performance of receivers and associated compliance costs, leaving performance of receivers to the choice of manufacturers and consumers. It provides a good balance between protecting the good operation of radio equipment by consumers, businesses and public services and avoiding to regulate issues which may be left to the market, **Option B3 is therefore the preferred option.**

Option B3 is therefore the preferred option.

Table 7. Summary table comparing options addressing objective B

	Effectiveness in achieving objective B	**Side effects**	**Cost and efficiency**	**Coherence**
Option B0	0 -Guide to the Directive provides non-binding interpretations	0	0	0 -Different approaches among Member States
Option B1	++ -Significant clarification of existing provisions	+ -Improved compliance (objective A) -Removing article 6.4 may reduce information to manufacturers on spectrum regulation	++ Some reduction of administrative requirements	++ -Improves coherence with other internal market legislation and the Regulatory Framework for Electronic Communications
Option B2	++/- -Clarifies application of the Directive to specific technologies -Limited value-added of a EU-wide legislation for installations. -A general requirement for interoperability with accessories may be inapplicable due to disagreements within industry -Improves legal certainty bringing all receivers under the R&TTE -Improves protection of spectrum bringing all intentional radiators under the R&TTE D	+/- -May be used to deal with receiver aspects in improving efficiency in the use of spectrum -A general requirement for interoperability with accessories may deter innovation	-- -Some additional cost for SDR manufacturers and for installators -Additional cost due to general interoperability obligation -Some additional cost for manufacturers of broadcast receivers and intentional radiators non capable of communication	
Option B3	+++ -Commission powers allow to react to technology/ market/ legal issues arisen during application of the Directive -Improves legal certainty bringing all receivers and all fixed terminals under the EMCD -Improves protection of	- -Requires other measures to support efficient use of spectrum by receivers, e.g. voluntary standards Removes application of additional essential requirements 3.3 to fixed terminals and receive-only	+/- -Some additional cost for SDR manufacturers -Some additional cost for manufacturers of intentional radiators non capable of communication -Some reduction of cost for	++ -Improves coherence with other EU legislation on competition issues for terminals -Implementing powers facilitate consistent application of the Directive across the

	spectrum bringing all intentional radiators under the R&TTE	equipment (e.g. GPS/Galileo receivers)	manufacturers of receive-only equipment and of fixed terminals	EU

7.4. Options addressing objective C: to remove regulatory barriers to innovation in radio equipment

7.4.1. Effectiveness.

It is important to remind that, according to the report of the TCAM ad hoc group on innovation *(see ref. [11])*, the R&TTE Directive does not present major barriers to the use of radio equipment, it is in the area of regulation for the use of spectrum where the main issues lie, and the EU has already addressed and continues to address these issues within its Radio Spectrum Policy.

The non-legislative elements in **Option C1** are expected to improve awareness among innovators of the regulatory system and to achieve better coordination of the current processes necessary for the placing on the market and putting into service of radio equipment. This entails a reduction of delays to accommodate novel products within the regulatory framework and to bring them to the market *(see ref. [11])*. Taking into account the nature of these elements, improvements are expected to be incremental rather than radical with regard to the current situation.

Option C2 introduces a regime for temporary authorisation of the commercialisation and use of radio equipment. This regime would provide a visible EU-wide focal point for innovators and would allow a significant reduction in time-to-market, of up to 1-2 years in some cases. However, industry, in particular larger companies, is reluctant to invest in commercial deployment without regulatory certainty *(see ref. [11])*. Coherence with the current process for assessing technical compatibility of use of spectrum is also an issue, in particular regarding overlaps between the new competence centre supporting the regime and CEPT, which is currently in charge of formal compatibility assessments. Empowering a central EU authority to issue authorisations for the use of spectrum also raises subsidiarity issues with regard to national competences in this area.

As for the creation of a special category of notified bodies, this could facilitate that innovative equipment receives opinions with sufficient credibility among authorities. A foreseeable drawback is the possible degradation of the perceived value of opinions issued by 'normal' notified bodies not belonging to the special category, leading to distortions of competition.

7.4.2. Administrative and other costs

Option C1 involves investment in an Internet portal for experimental licensing[61] and in an information campaign, which could take place in the context of communication on the revised R&TTE Directive. Improved communication between CEPT, notified bodies and standardisation bodies, and better information of companies and SMEs should bring efficiency improvements for all stakeholders and largely compensate for those investments.

Option C2 involves the creation of new procedures for accreditation and monitoring of a special category of Notified Bodies, in parallel to existing procedures. This implies additional

[61] In principle to be funded by Member States and/or CEPT, not by the EU

cost for notified bodies and may imply additional human resources in public authorities (0-2 additional headcount per national authority is an estimation – source: Commission services).

Also within **Option C2**, a European competence centre advising the central EU body on temporary authorisations would need to be staffed, a headcount of 10 persons full-time is a lower estimate[62]. Withdrawal from the market of temporarily authorised equipment may be impossible or require very substantial costs for authorities (*see ref. [11]*).

7.4.3. Comparing the options

The following table summarises the impacts assessed above:

Table 8. Summary table comparing options addressing objective C

	Effectiveness in achieving objective C	**Side effects**	**Cost and efficiency**	**Coherence**
Option C0	0	0	0	0
Option C1	+ -Incremental improvement of regulatory delays in access to the market for innovations		+ -Some additional administrative costs -Incremental efficiency improvements	+ -Improves coherence of the current institutional arrangement
Option C2	+/++ -Improves credibility of opinions of 'special' NBs -Important reduction of regulatory delays in access to the market -Temporary authorisation not attractive for commercial investment	-- -Special category of NBs may distort competition among notified bodies - -Important practical difficulties in reversing temporary commercial authorisations	-- Important costs to consider: -Operation of new scheme for accreditation of a special category of NBs -Set up of a new competence centre for temporary authorisations -Withdrawal of previously authorised equipment may be very expensive	-- -Special category of NBs is not foreseen in NLF -Double regime for authorisations, uncertainty among incumbent users of spectrum -Overlaps current role of CEPT -Raises subsidiarity issues

Option C1 provides incremental improvements in time-to-market and efficiency gains for economic operators, regulators and other entities. Option C2 provides shorter time–to-market but involves non-negligible additional costs, as well as some institutional drawbacks and uncertainties with regard the benefits for industry of temporary equipment authorisations. **Option C1 is therefore the preferred option**.

8. PREFERRED OPTIONS

On the basis of the analysis in chapter 7, the recommended package includes options A4, B3 and C1:

The **combination of options A4 and B3 allows to increase compliance** through simplification and clarification of the requirements in the Directive and the improvement of

[62] For reference, ECO, the Secretariat of CEPT, employs a staff of 14 people including 7 experts

the legal instruments for enforcement. The NLF alignment implies a moderate increase of burden, in particular for importers and distributors. **Option A4** also allows the Commission to introduce product registration for specific product categories if required by persistently low levels of compliance, additional burden would only apply to these categories.

Option B3 provides clarification and simplification in the legal text and a few administrative simplifications compatible with the main goals of the R&TTE Directive. Option B3 also allows to adapt the legal basis to some specific technologies, and to set out a scope more consistent with the objective of preventing harmful interference. A full implementation of this option B3 requires complementary instruments (outside the R&TTE Directive) to improve information to manufacturers on national spectrum regulation, to foster efficiency of receivers in the use of spectrum and possibly to address competition issues raised by terminals. Commission delegated and implementing powers in this option add the benefit of a timely legal response to technology and market developments and to issues of consistent application, also further contributing to improve compliance.

Option C1 provides an incremental reduction of regulatory barriers to innovation, as well as efficiency gains within the current framework. Option C2 would provide more important gains in time-to-market but would also bring uncertainties for investment and additional cost for authorities

Table 9. Preferred options

Preferred option	Strengths/advantages	Drawbacks/costs
A4	Flexible and proportional approach to improve compliance: to perform the alignment with the NLF, and if necessary to complement it with product registration in some specific product categories where a high level of compliance has not been attained	Possible additional product registration is perceived by industry as additional burden, not foreseen within NLF obligations Direct implementation and maintenance cost of registration system estimated at maximum 300k€ and 30k€ respectively
B3	Provides clarification and simplification of legal provisions, and future-proof adaptation of scope and requirements in line with the goals of a more focussed Directive covering all intentional radio transmitters Some reduction of burden and cost for pure receivers and fixed terminals, which move out of the scope of Directive	Non-significant additional cost for non-communicating intentional radiators, which would enter within the scope of the Directive (up to a maximum of a fraction of a Euro per product in common cases)
C1	Improves access by companies to regulators and coordination within the current regulatory system for radio equipment	Does not fundamentally streamline the currently existing complex regulatory system

Overall, this package of preferred options is expected to increase compliance and therefore improve protection of users and of fair competition, to bring increased legal certainty, a smoother and more consistent application of the Directive and a more comprehensive

prevention of harmful interference, with limited additional burden for market operators. Beyond the synergies between Options A4 and B3 explained in chapter 7 no other interaction effects are expected between the three preferred options. Therefore, an additional in-depth assessment of the package is not considered necessary.

At the end of the impact assessment, there was no indication that the selected options might result in a disproportionate burden for SME. Consequently, there is no element showing the need for SME specific measures in order to ensure compliance with the proportionality principle

9. IMPLEMENTATION, MONITORING AND EVALUATION

9.1. Transposition and implementation

In order to facilitate the transposition of the Directive in a way which is consistent across Member States and with the intention of the EU legislator, the Commission plans to organise one or more workshops with responsible national ministries during the period provided for transposition of the Directive by Member States.

9.2. Reporting and review

The table below summarises the core indicators of progress towards meeting the objectives for the revision of the Directive.

Table 10. Core indicators of progress

	Indicator	**Approach**
Compliance	Administrative and technical compliance ratios	Periodic reports from Member States
Administrative simplification and legal adaptations	Induced administrative cost and burden, number and relative relevance of issues of interpretation	Regular exchange with stakeholders - economic operators, authorities and notified bodies
Regulatory barriers to innovation	Perceived simplicity of introducing innovations	Regular exchange with stakeholders

In accordance with the proposal, **Member States** would have a new obligation to send to the Commission biannual reports on the application of the Directive. The reports should cover market surveillance activities performed and provide information on the level of **compliance with the essential requirements in the Directive.** This obligation would consolidate common practice and should not increase administrative costs.

Further information is to be collected through regular exchanges within **TCAM**, the standing committee of the Directive, which in addition to Member States includes representatives from industry, European Standards Organisations, Notified Bodies and consumer organisations. The **Commission** plans to review the operation of this Directive and report thereon to the European Parliament and to the Council every five years.

ANNEX I. LIST OF ACRONYMS AND GLOSSARY

List of acronyms:

- ADCO R&TTE: Administrative Co-operation group in the R&TTE area
- CEPT: European Conference of Postal and Telecommunications Administrations
- DoC : Declaration of Conformity
- EFIS: European Communications Office Frequency Information System
- EMC: Electromagnetic Compatibility
- EMCD: Electromagnetic Compatibility Directive, Directive 2004/108/EC
- GPSD: General Product Safety Directive, Directive 2001/95/EC
- ISM: industrial, scientific and medical
- ITU: International Telecommunications Union
- LVD: Low Voltage Directive, Directive 2006/95/EC
- MSA: Market Surveillance Authority
- NB: Notified Body
- OSN: One Stop Notification
- PMR: Private Mobile Radio
- RSD: Radio Spectrum Decision, Decision 676/2002/EC
- R&TTE : Radio and telecommunications terminal equipment
- SDR: Software Defined Radio
- TCAM : Telecommunications Conformity Assessment and Market Surveillance Committee

Glossary:

Some definitions from the R&TTE Directive:

- **harmful interference:** interference which endangers the functioning of a radionavigation service or of other safety services or which otherwise seriously degrades, obstructs or repeatedly interrupts a radiocommunications service operating in accordance with the applicable Community or national regulations
- **interface:** can mean

(a) a network termination point, which is a physical connection point at which a user is provided with access to public telecommunications network, and/or

(b) an air interface specifying the radio path between radio equipment

– **radio equipment:** a product, or relevant component thereof, capable of communication by means of the emission and/or reception of radio waves utilising the spectrum allocated to terrestrial/space radiocommunication

– **radio waves:** electromagnetic waves of frequencies from 9 kHz to 3000 GHz, propagated in space without artificial guide

– **telecommunications terminal equipment:** a product enabling communication or a relevant component thereof which is intended to be connected directly or indirectly by any means whatsoever to interfaces of public telecommunications networks (that is to say, telecommunications networks used wholly or partly for the provision of publicly available telecommunications services)

Some definitions from ITU Radio Regulations 2008:

– **broadcasting service:** a radiocommunication service in which the transmissions are intended for direct reception by the general public. This service may include sound transmissions, *television* transmissions or other types of transmission

– **industrial, scientific and medical (ISM) applications** (of radio frequency energy)*:* operation of equipment or appliances designed to generate and use locally radio frequency energy for industrial, scientific, medical, domestic or similar purposes, excluding applications in the field of *telecommunications*

– **radiodetermination:** the determination of the position, velocity and/or other characteristics of an object, or the obtaining of information relating to these parameters, by means of the propagation properties of radio waves

– **telecommunication:** any transmission, emission or reception of signs, signals, writings, images and sounds or intelligence of any nature by wire, radio, optical or other electromagnetic systems

ANNEX II. PRODUCT SCOPE OF THE R&TTE DIRECTIVE

The following codes and categories under NACE/Prodcom classification contain most products falling within the scope of the Directive:

Table A2.1 Product scope of the R&TTE Directive

26.20.18.00	Machines capable of facsimile transmission, capable of connecting to an automatic data processing machine or to a network
26.30.11.00	Transmission apparatus for radio-broadcasting and television, with reception apparatus
26.30.12.00	Transmission apparatus for radio-broadcasting and television, without reception apparatus
26.30.21.00	Line telephone sets with cordless handsets
26.30.22.00	Telephones for cellular networks or for other wireless networks
26.30.23.10	Base stations
26.30.23.20	Machines for the reception, conversion and transmission or regeneration of voice, images or other data, including switching and routing apparatus
26.30.23.30	Telephone sets (excluding line telephone sets with cordless handsets and telephones for cellular networks or for other wireless networks); videophones
26.30.23.70	Other apparatus for the transmission or reception of voice, images or other data, including apparatus for communication in a wired or wireless network (such as a local or wide area network), other than transmission or reception apparatus of HS 84.43, 85.25, 85.27 or 85.28
26.30.30.00	Parts of electrical telephonic or telegraphic apparatus
26.30.40.40	Aerials and aerial reflectors of all kinds for apparatus of HS 85.17; parts suitable for use therewith

ANNEX III. BASIC ECONOMIC DATA OF THE EU MARKET COVERED BY THE DIRECTIVE

Some basic data of the EU economic sector manufacturing products falling within the scope of the R&TTE Directive are shown below. Unless otherwise stated, the data have been obtained from Eurostat[63] in accordance with Annex II above.

Table A3.1 . EU production, consumption and trade. Values in million €

	2007	**2008**	**2009 (estimation)**
EU27 production	54290	52052	43131
EU27 imports	48696	49216	47781
EU27 exports	40294	40138	39260
EU27 internal consumption	62692	61130	51652

Some 75% of EU production is exported, and 80% of EU consumption is imported. This means that **ca 80% of equipment placed on the EU market is manufactured abroad.**

Trade balance is negative and the trade deficit (-8402 million €) amounts to ca 15% of production. The main trading partners are US and Asia (China, Korea, Japan). Trade deficit with China (*-12905 million €)* offsets a positive trade balance with the rest of the world (+4503 million €). Imports are more geographically concentrated than exports.

Table A3.2 . EU trade with selected countries in 2007. Values in million €

	Imports	**Exports**	**Balance**
China	14590	1685	-12905
Japan	2375	1330	-1045
South Korea	5817	581	-5236
US	13903	8558	-5345

The number of people employed in manufacturing companies is about 250000 employees

Table A3.3. Number of employees in the EU

	2004	**2007**
Number of employees	293900	257,400

As in other EU industrial sectors, most companies (99%) belong in the SME category.

Table A3.4. Size of companies

[63] http://epp.eurostat.ec.europa.eu

Number of employees/company	Number of EU companies (percentage) - 2007
> 250	120 (0.87 %)
50 - 250	385 (2.90 %)
1 - 50	13,270 (96.33 %)
Total	13775 (100%)

Larger companies concentrate up to 76% of total production, on the basis of statistics from 6 countries accounting for 89% of EU production:

Table A3.5. Size of companies

Country	Share of production by companies >250 employees[64]
Germany	88%
Finland	94%
France	78%
Italy	50%
Sweden	93%
UK	76,2
Total for 6 countries	**76%**

Estimations of the number of different products subject to the R&TTE Directive which are available in the market range between 3000 and 10000 products.

Table A3.6 Total market size for products falling within the scope of the R&TTE Directive Source: Technopolis survey

Market Surveillance Authority	Estimated market size (2008) in terms of number of product types on the market subject to R&TTE Directive

[64] Data correspond to products within NACE Code 332 - Manufacture of television and radio transmitters and apparatus for line telephony and line telegraphy

Market Surveillance Authority	Estimated market size (2008) in terms of number of product types on the market subject to R&TTE Directive
MSA 01	3,000
MSA 02	4,000
MSA 03	5,200
MSA 04	7,000
MSA 05	10,000
Average of estimations	5,840

ANNEX IV. SUMMARY OF THE 2007 PUBLIC CONSULTATION

A public consultation took place in 2007, allowing to identify the main problems in the operation of the Directive as well as the possible remedies. The consultation used the "IPM" (Interactive Policy Making)[65] tool and was closed on 30 September 2007.

Some 120 questions addressed the following topics:

- A regulatory framework conducive to investment and product innovation
- Simplification
- Compliance
- Standard-setting
- Scope of the Directive
- Software-defined radio
- Optimisation of the running of the directive and coherence with other community legislation

Responses were contributed by 60 respondents from the categories of large company (17), SME (7), regulators (15), notified bodies (4) and others.

Some of the issues highlighted were:

- Difficulties in market entrance for innovative radio technologies due to the existing process for putting in place the necessary regulatory decisions concerning spectrum use and harmonised standards
- The Directive is unnecessaritly complex and its application is confronted to a number of ambiguous provisions
- Some stakeholders expressed the wish that, for some details of the operation of the Directive, TCAM conclusions be binding on all Member States.
- There are eighteen administrative provisions in the Directive and the relevance of some of them was questioned
- Lack of traceability of the manufacturer or the person responsible for placing products on the market needed to be addressed
- Very few cases in which presumption of conformity conferred by harmonised questions was questioned
- Particularly challenging appeared to be the case of equipment reconfigured during operations by users and/or an entity other than the initial manufacturer, such as 'Software Defined Radio' (SDR), or cognitive radio

65 HTTP://EC.EUROPA.EU/YOURVOICE/IPM/

- One third of respondents considered that installations where not sufficiently addressed in the Directive, half of respondents considered this was not an issue

- In practice most NB opinions concerned products which use harmonised standards to ensure compliance with the essential requirements of the Directive, but for which manufacturers - due to the often high technical complexity of conformity assessment - preferred to seek an endorsement from an experienced and qualified body

- Some arbitrary demarcations of scope, e.g. broadcast receivers, lacked a real justification

Issues identified through this consultation were included in the Second Progress Report on the operation of the R&TTE Directive *(see ref. [2])*.

ANNEX V. LIST OF INTERVIEW PARTNERS FOR THE TECHNOPOLIS STUDY

'Impact Assessment concerning a proposed mandatory registration system in the scope of directive 1999/5/EC' FINAL REPORT 5.10.2009. Technopolis Group[66]. (ref. [8])

Table 1. List of interview partners

Nr.	(Primary) interview partner	Organisation	Country
Market surveillance authorities			
1	Edmund Palkovich et al.	Federal Ministry of Transport, Innovation and Technology	Austria
2	Stefan Winkelmann et al.	Bundesnetzagentur (BNetzA), German federal Network Agency	Germany
3	Per G Andersson	Swedish Post and Telecom Agency	Sweden
4	Loredana Le Rose	Department of Communications, Ministry of Economic Development	Italy
5	CliveCorrie et al.	Ofcom	UK
6	Maria Sarantopoulou	National Telecommunications and Post Committee (EETT)	Greece
7	Hakim LaTrache et al.	Agence Nationale de Fréquences	France
8	Bert van Dijk	Netherlands Radiocommunications Agency	The Netherlands
9	Tanel Vinkel	Estonian Technical Surveillance Authority	Estonia
10	Kati Heikkinen	Finnish Communications Regulatory Authority	Finland
11	Lucio Cocciantelli	OFCOM/BAKOM – Federal Office of Communication	Switzerland
12	Albinas Visockas	Communications Regulatory Authority (RRT)	Lithuania
13	Tor Bringsverd	Norwegian Post and Telecommunications Authority	Norway
14	Pedro Martins	ICP-ANACOM	Portugal
Companies			
1	Matt Hansson/Jose Prats	Sony Ericsson	Sweden
2	Mr Esa Barck	Nokia Siemens Networks	Finland

[66] http://ec.europa.eu/enterprise/sectors/rtte/files/technop-ia-radio-finrep_en.pdf

3	Ms Marita Latovehmas	Satel OY *)	Finland
4	Mr Stewart Polley	Nokia oyj	Finland
5	Ms Kristine Kiltgaard Pedersen	Oticon *)	Denmark
6	Gerhard Doujak	Emporia GSM *)	Austria
7	Ken Simpson	Belkin Ltd (UK)	UK
8	Stylianos Tsatalas et al.	INTRACOM TELECOM	Greece
9	Armin Schoeller/Paul Guckian	QUALCOMM	Germany/US
10	Dimitrios Scribas	Marac Electronics	Greece
11	Mario Protopappas	PARISINO *)	Greece
12	Sergio Pastori	Alcatel-Lucent	Italy
13	Alessandro Tacchini	Reggio Emilia Innovazione/Laboratorio Nobili	Italy
14	Francesco Segato	Duolabs	Italy
15	Andrew Little	Raymarine	UK
16	Steven Clegg	Mira	UK
17	Iain King	Link Research *)	UK
18	Edgar Vangeel	CISCO Systems	Belgium
19	Tim Cull	Motorola Ltd.	United Kingdom
20	Stuart Graves	SAMSUNG	UK/Korea
21	Marion Rühle	ELDAT GmbH *)	GER
22	Erwin Schmidt	Pepperl & Fuchs GmbH	GER
23	Antoine Fruhauf	VEGA Grieshuber	GER
24	Andre Malitte	SHARP	GER/Japan
25	Per Döfnäs	Ericsson	Sweden
26	Mats Lindkvist	Ondico *)	Sweden
27	Nils-Åke Rosenberg	Swedish Radio Systems AB *)	Sweden
28	Ian van Zyl	Siemens Milltronics	GER/Canada

Industry associations and other			
1	George Tannahill	Federal Communications Commission	FCC (USA) representative
2	Tony Graziano	DIGITALEUROPE	Europe
3	Stefan Herzog	BITKOM	Germany
4	Alexandra Schleier	ZVEI	Germany
5	Joshua Rosenberg	ITIC - Information Technology Industry Council	United States (International)
6	Feodora von Franz	TechAmerica Europe	United States (International)
7	Marc Cumps	AGORIA	Belgium

**) Firm is an SME according to EU definition.*

ANNEX VI. SUMMARY OF THE 2010 PUBLIC CONSULTATION

0. Introduction

As part of the preparation of the review of the R&TTE Directive[67], the Commission collected information in an extensive public consultation in 2007, in the 2009 Technopolis study "Impact assessment study on the option of a mandatory registration for placing radio equipment on the market which could be introduced in Directive 1995/5/EC[68]" and within the standing committee of the Directive (TCAM). The Commission launched a second public consultation in 2010 in order to collect additional information on the impact of some of the measures under consideration for the revision of the Directive and also to reach out to stakeholders who may not have been able to express their views on the issues and measures under consideration. This annex presents an overview of the responses obtained.

The questionnaire was online between 16.07.2010 and 15.09.2010 and included 20 questions relative to the following issues:

- Compliance with the Directive
- Clarification of the Directive and reduction of administrative obligations
- Scope of the Directive in relation to specific legislation
- Other issues: accessibility of R&TTE products

A simplified version of the questionnaire was also available for SMEs and was distributed through the Commission SME Network, which resulted in the high level of participation of this category.

This document summarises some elements of the responses received. For the statistical analysis of the responses, please refer to Annex I in *ref [12]*.

1. Identification and characterisation of the respondents

There was an important participation in this public consultation as the Commission received 122 replies with a significant contribution from economic operators (36 companies + 50 SMEs).

Participation of public authorities was more limited, owing to the fact that public authorities have other means to convey their views on the legislative review to the Commission, in particular through their participation in TCAM (4 meetings in 2010).

2. Compliance with the Directive

Respondents expected from the **NLF alignment** a medium to strong impact on **compliance with the Directive** (71% in the categories ‘some impact’ or ‘significant impact’ in general

[67] Radio and Telecommunications Terminal Equipment, Directive 1999/5/EC OJ L 91, 7.4.1999, p. 10–28

[68] http://ec.europa.eu/enterprise/sectors/rtte/files/technop-ia-radio-finrep_en.pdf

comparing to 72% for SMEs). The measure is considered to entail a moderate increase of burden.

Respondents highlighted that the newly introduced provisions of the NLF especially obligations for importers and distributors, together with the introduction of traceability requirements will introduce a positive impact on surveillance activities and will consequently produce a significant improvement of compliance with the R&TTE Directive. It will also contribute to create a fair market environment for all economic operators.

Industry mentioned that the positive impact will depend on whether the NLF will be uniformly applied to all relevant Directives.

Some negative **effects on administrative burden** of the NLF alignment mentioned were the new requirements on traceability information, the possibility to ban compliant products presenting a risk to health and safety or the translation of the DoC and the technical documentation.

Concerning a possible mandatory **product registration** under the Directive, it was also expected that this system would have a medium to strong impact on compliance (65% in the categories ‘some impact’ or ‘significant impact’ in general comparing to 66% for SMEs) but entailing a strong increase of burden (66% in the categories ‘some increase' or ‘significant increase of administrative burden' in general comparing to 62% for SMEs). It is to be highlighted that on 12% of SMEs anticipate a ‘significant increase’ the overall value is 32%.

Some respondents mentioned that the obligation of a registration would allow Market Surveillance Authorities to easily comply with their new tasks under the NLF but some manufacturers were sceptical with regard to the possibilities of registration to counter criminal behaviour.

It was also said that a registration scheme would just add additional administrative burden by collating, uploading and updating product information without solving the original concern identified traceability and compliance since it does not prevent deliberate false registration. The issue of confidentiality of information uploaded in the registration database was also pointed out. Furthermore a registration scheme under the R&TTE Directive will only address one Directive while the NLF takes a more horizontal and harmonized approach and this would be critical for products falling under the scope of several Directives.

Respondents also highlighted that resources for market surveillance are an important key in order to achieve a higher compliance with the Directive.

3. Clarification of the Directive and reduction of administrative obligations

There was a moderately positive perception of the **impact on clarity of the inclusion of all radio receivers within the scope of the Directive**. The perception was slightly more positive among SMEs (60% in the categories 'some clarification' or 'significant clarification') than among respondents in general (48%). It was highlighted by several respondents that the Commission should consider carefully consequences for broadcast receivers if this option should be applied.

The definition of **performance requirements for radio reception** was considered beneficial for the efficiency in the use of spectrum by many stakeholders, in particular by network operators and spectrum authorities. Industry in general did not consider that changing the

scope of the Directive would bring any positive impact but only additional administrative and technical burden to manufacturers, which does not seem to be justified comparing to the limited potential added value. Industry also pointed out that during the last 15 years the application of the EMCD and LVD for audio and TV broadcast receivers has been proven to be sufficient and appropriate as no problems have been reported. For cases where the performance of receivers might have an impact on the performance of transmitters, industry proposed the development of appropriate Harmonised Standards and compatibility studies which will be more appropriate as a modification of the essential requirements.

Regarding the possibility to **exclude indirectly connected terminal equipment**, the impact on clarity is moderately positive. For greater clarity, it was proposed that the Commission should consider removing fixed terminals from the scope of the Directive as a way to avoid having similar equipment under the R&TTE Directive and under the LVD and EMCD.

On the option to include the definitions of fixed and mobile **installations** and clarify the application of the R&TTE Directive to both cases there was a general moderately positive impact (48% in the categories 'some clarification' or 'significant clarification' in general comparing to 50% for SMEs). Several comments pointed to the difficulty to apply EU level legislation to the many specific cases which could be considered to be installations, to the difficulties of defining installations, and to overlaps with national legislation.

The possibility to **incorporate** agreements and clarifications agreed in TCAM and collected in **the Guide in the revised Directive** was welcomed in a very positive way (66% in the categories 'some clarification' or 'significant clarification' in general comparing to 52% for SMEs) as the Guide has been very useful for economic operators.

A positive impact on the reduction of administrative burden is also to be noted by the possible suppression of **notifications under Article 6.4**: 43 % of respondents consider a suppression of this requirement to bring in some or significant reduction of burden

There was a strong reservation on the suppression of Article 4.2 which obliges operators to **publish technical specifications of public interfaces** prior to provision of services, due to competition issues. It was mentioned that this obligation for operators should be mirrored with an obligation for terminal manufacturers, in particular with regard to creating a level playing field for software applications for terminals, and with regard to access to contents from terminals.

Finally the option to suppress the **obligation to affix the "Alert Sign"** on radio equipment for which Member States apply restrictions on the putting into service had a moderate positive impact in the reduction of burden (31% in the categories 'some reduction' or 'significant reduction of administrative burden' in general, 28% for SMEs). A number of respondents insisted that it is very important to alert user on restrictions to use of radio equipment.

Some respondents also referred to the necessity to revise the proportionality of current obligations for operators in Article 7.5 of the Directive in case of a situation of emergency.

4. Scope of the Directive in relation to specific legislation

The possible positive impact on simplification of excluding from the scope of the Directive radio equipment covered by other more specific EU legislations or by international treaties (e.g. equipment for Air Traffic Management or radars for inland waterways) was considered as non-significant by more than half of respondents in the 2010 public consultation *(30% no*

simplification, 16 % no simplification). This view is even clearer among SME *(52% no simplification, 28 % no simplification).*

Some of the responses pointed to the stability of the current legal framework for equipment for Air Traffic Management and to the importance of managing all equipment liable to create harmful interference under the R&TTE Directive

5. Other issues

Regarding the accessibility of equipments for users with a disability, the general opinion was that there was no need to amend Article 3.3f of the Directive. Some associations mentioned the need to implement this Article with the enactment of relevant Commission Decisions, others were of the opinion that the R&TTE Directive was not the good legal instrument for this issue and that the Universal Service Directive was a more appropriate horizontal instrument to deal with this.

ANNEX VII. ADDITIONAL ITEMS AFFECTING THE AMBIGUITY AND COMPLEXITY OF THE DIRECTIVE

-Notifications of national technical regulations covering R&TTE equipment under **Article 4.1** of the Directive coincide with similar obligations under Directive 98/34.

-Notification by operators to national authorities of the technical characteristics of their public interfaces under **Article 4.2** coincide with a similar obligation under **Directive 2008/63/EC** on competition in the markets in telecommunications terminal equipment.

-The Directive includes a number of provisions fostering the emergence of a **competitive market for terminals** (article 4.2 on publication of interfaces by operators, article 6.3 on information to the user on available interfaces, articles 7.3-7.5 on the right to connect a terminal to a network). These obligations were included to avoid that operators unilaterally determine the specifications of terminals compatible with their networks, which would enable them to transfer its market power in the area of services to the market for terminals. However, the Directive does not contain provisions to prevent possible distortions of competition created by manufacturers of terminals on electronic communications markets such as the following:

- In the mobile market, closed on-line application stores linked to an operating system or a particular terminal, which bind the consumer to the choice of application, contents and/or network operator of his/her device manufacturer;

- In the TV market, the presence within TV receivers of closed browsers with technical characteristics which condition access to particular contents

ANNEX VIII. LEGISLATION AFFECTING THE PUTTING INTO SERVICE OF RADIO EQUIPMENT

Equipment complying with the requirements in the R&TTE Directive can be put into service in the EU (article 7.1 of the Directive). However, article 7.2 of the Directive allows Member States to introduce further restrictions in order to ensure and effective use of the spectrum, avoid harmful interference or protect public health.

Conditions for the use of spectrum are only partially harmonised across the EU. In practice **regulation of radio spectrum is largely a national competence**. Member States publish national frequency plans, 'radio interfaces' which are technical conditions laid out in national regulations, and other conditions for use of the spectrum such as individual licences or general authorisations. When exercising this competence, Member States shall comply with **applicable EU law**, in particular:

- General criteria laid down in the Directive 2002/21/EC (Framework Directive[69]) within the regulatory framework for electronic communications

- Conditions for authorisations for the use of spectrum laid down in Directive 2002/20/EC (Authorisation Directive[70]) within the regulatory framework for electronic communications

- More specific are the implementing measures under Decision 676/2002/EC (Radio Spectrum Decision[71]). Such measures harmonise in detail the technical conditions for the use of certain spectrum bands in the EU, and are binding to all Member States. Examples of bands harmonised at EU level include the bands for GSM, UMTS and short-range devices.

EU Member States cooperate in **CEPT** (European Conference of Postal and Telecommunications Administrations) with other countries in the European area in the use of spectrum, including in some cases its harmonisation. CEPT is an intergovernmental organisation which makes recommendations and non-directly binding decisions, the implementation of which depends on legal acts by its member states.

Finally, EU Member States are members of the International Telecommunications Union (**ITU**), which develops the Radio Regulations setting a frame to regional and national regulations on the use of spectrum, and which ITU member states commit to abide by.

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69 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), OJ L 108, 24.4.2002, p. 33–50

70 Directive 2002/20/EC of the European Parliament and of the Council of 7 March 2002 on the authorisation of electronic communications networks and services (Authorisation Directive), OJ L 108, 24.4.2002, p. 21–32

71 Decision No 676/2002/EC of the European Parliament and of the Council of 7 March 2002 on a regulatory framework for radio spectrum policy in the European Community (Radio Spectrum Decision), OJ L 108, 24.4.2002, p. 1–6

ANNEX IX. DETAILED DESCRIPTION OF OPTION A1

Under Option A1, the R&TTE Directive would take on board the solutions set out in the NLF Decision 768/2008 to address problems relating to non-compliance. The measures in the Decision designed to resolve these problems are as follows:

- Introduction of **obligations for importers and distributors:** Both must check that products bear the CE marking, are accompanied by the required documents and carry the name of the manufacturer and the importer (if relevant). **Importers** must furthermore check that the manufacturer outside the EU has applied the correct conformity assessment procedure and establish a link to the manufacturer that allows the technical documentation to be obtained when it is requested by authorities. They must carry out sample tests on products which they have supplied, when this is appropriate in the light of the risks presented by a product to the health and safety of consumers. If necessary, they must also keep a register of complaints, non-conforming products and product recalls and keep distributors informed about such monitoring (Articles R4 and R5 in Annex 1 of Decision 768/2008).

- Additional **manufacturer obligations**: In addition to the obligations that the current legislation already imposes on **manufacturers,** they must provide instructions and safety information in a language easily understood by consumers and end-users. Furthermore, they are subject to the same obligations on sample testing and product monitoring as importers (Article R3 in Annex 1 of Decision 768/2008).

- Introduction of traceability requirements: New obligations are introduced for all economic operators to ensure **traceability** of products throughout the whole distribution chain. Manufacturers and importers must put their name and address on the product or, where this is not possible, on the packaging or an accompanying document. Furthermore every economic operator must be able to inform the authorities from whom he purchased a product and to whom he supplied it. This obligation does not include sales to end-users (Article R7 in Annex 1 of Decision 768/2008).

- Reorganisation of safeguard clause procedure (market surveillance): The safeguard clause procedure has been reorganised and streamlined. The new procedure ensures that the relevant enforcement authorities are informed about dangerous products and that similar action is taken against that product in all Member States (Articles R31-33 in Annex 1 of Decision 768/2008).

ANNEX X. ESTIMATION OF THE DIRECT COST OF A PRODUCT REGISTRATION SYSTEM

Some assumptions on the system to be introduced according to Option A3 are the following:

– The highest available estimation of the number of product types on the market subject to R&TTE Directive is 10000 products *(see in Annex III the estimation of MSAs).* A conservative assumption is that all product are renewed every 2 years

– Compliance data to be uploaded in a central database do not need to include company sensitive data, therefore no complex access protection needs to be implemented

– The Commission services would not perform vetting of the uploaded information in order to verify that the submitted files are genuine and valid

On this basis, a pan-European registration system would have the following characteristics:

– Database of circa 5000 types/year of maximum 50MB per product, i.e. additional 250 GB/year *[Source: Commission services]*

– A simple registration system can be developed on the basis of the current OSN[72] system, of which the investment cost was 100000 € and maintenance cost is below 10000 €/year *[Source: Commission services]*

– A more powerful system including communications is necessary in order to allow for heavier and more frequent transactions and for a user-friendly interface for the functions of allocation of registration numbers, upload of product information and consultation.

Taking into account these characteristics, a conservative **estimate of costs** is *[Source: Commission services]* :

– Estimated investment costs: 300000 €

– Estimated annual maintenance costs: 30000 €

A system limited to registration of some categories of products as in **Option A4** would of course imply lower costs, the reduction would be less than proportional.

[72] One Stop Notification system for notifications according to article 6.4 of the Directive, see section 4.2.4

ANNEX XI. ESTIMATION OF ADDITIONAL COST POR SOME INDIVUAL PRODUCTS UNDER OPTION B2

Possible additional costs stemming from B-options are identified on page 34, in particular for those products currently covered by the EMC Directive which would fall within the scope of R&TTE D under option B2.

A possible repercussion of such costs upon individual products considering different scenarios is included in the table below:

Table A10.1 . Range of additional cost per individual product (€)

	Additional cost per product type (see page34 – option B2)		
Nb of products sold of a certain type	100 (no new test, just re-formatting of existing test)	2000 (intermediate case)	5000 (additional radio and safety testing plus Notified Body opinion, no mitigation measure)
100	1	20	50
1000	0.1	2	5
10000	0.01	0.2	0.5
100000	0.001	0.02	0.05

Sufficient delays for entry into force of the new scope should in practice eliminate the need for manufacturers to contract external testing and to consult with notified bodies, leaving them the option to declare conformity on the basis of in-house tests.

ANNEX XII. SME TEST

(1) Consultation with SME representatives	Interviews with SMEs have been carried out in the framework of the external study done by Technopolis. A specific consultation on the impact on measures under consideration took place through the Enterprise Europe Network in 2010. 50 SMEs participated in the exercise. See section 2.3, as well as Annex V.
(2) Preliminary assessment of businesses likely to be affected	Some 99% of EU manufacturers in the area of products covered by the Directive fall within the SME category (*see Annex III*). SMEs contribute some 25% of EU production in this area (*see Annex III*).
(3) Measurement of the impact on SME	Available evidence does not show specificities in the impact on SMEs of the options under consideration. This applies in particular to cost and administrative burden. The exception is option A3 on product registration, for which the impact on administrative burden was perceived as less significant by SMEs than by larger companies.
(4) Assess alternative options and mitigating measures	At the end of the impact assessment, there was no indication that the selected option might result in a disproportionate burden for SME. Consequently, there is no element showing the need for SME specific measures in order to ensure compliance with the proportionality principle.

ANNEX XIII. SELECTED REFERENCES

[1] Report from the Commission to the Council and the European Parliament of 22 April 2004 – First Progress Report Directive 1999/5/EC on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity. [COM(2004) 288 final – Not published in the Official Journal].

[2] 2nd Report from the Commission to the Council and the European Parliament second Progress Report on the operation of Directive 1999/5/EC, on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity. [COM/2010/0043 final - Not published in the Official Journal].

[3] Report to TCAM and ECC on R&TTE Market Surveillance Campaign carried out by ADCO and RA11 Survey Dates: September 2002 - October 2003. Date: 28 November 2003

[4] Report on the second joint cross border R&TTE Market Surveillance campaign carried out in 2005/06 by European Market Surveillance Authorities Survey Dates: 1. September 2005 – 1. June 2006 Report date: February 2007 final Version

[5] Report on the Third Joint Cross Border R&TTE Market Surveillance Campaign by the European Market Surveillance Authorities in 2008/2009 Survey Dates: 1. September 2008 – 31. May 2009 final Version Report date: 8th October 2009 / Rev. 4th November 2009

[6] Report on the Fourth Joint Cross Border R&TTE Market Surveillance Campaign (low power FM Transmitter), by the European Market Surveillance Authorities in 2009. Survey Dates: 15. June 2009 – 02. October 2009. Final Version. Report date: 13th April 2010

[7] TCAM (30)18 - ADCO-RTTE surveillance statistics for 2009

[8] Impact Assessment concerning a proposed mandatory registration system in the scope of directive 1999/5/EC FINAL REPORT 5.10.2009. Technopolis Group.
http://ec.europa.eu/enterprise/sectors/rtte/files/technop-ia-radio-finrep_en.pdf

[9] TCAM Ad Hoc Working Group on Traceability & Compliance. Final report. 17th June 2010

[10] TCAM Ad-hoc working group Alignment NLF. Final report on alignment of the R&TTE Directive with the Decision 768/2008/EC. 1st June 2010

[11] Final report of the TCAM Ad hoc Working Group on making radio equipment regulation more innovation friendly (INNOV WG). 20th October 2010

[12] Summary of the 2010 public consultation on the impact of options under consideration for the revision of the R&TTE Directive. May 2011.
http://ec.europa.eu/enterprise/sectors/rtte/public-consultation/files-public-consultation/summary-2010-pc_en.pdf