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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Disclaimer: This report commits only to the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission.

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

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Introduction

This Impact Assessment summary report addresses a possible revision of the R&TTE[1] Directive, Directive 1999/5/EC on radio equipment and telecommunications terminal equipment[2]. The Directive covers an estimated €63 billion market (2007), inlcuding *inter alia* mobile phones, mobile network transmitters and fixed telephones[3]. It harmonises at EU level regulatory requirements for the protection of health and safety, electromagnetic compatibility, and the avoidance of harmful interference.

1. PROBLEM DEFINITION

1.1. Low level of compliance

A low level of compliance with the requirements of the Directive has been observed. Available evidence from EU Market Surveillance Authorities (MSAs) show values ranging between 28% and 56% for compliance with the essential requirements, and even lower values for administrative compliance.

Efficient enforcement by MSAs is strongly hindered by the limited **traceability** of products and of manufacturers. 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.

Also, the Directive is often **ambiguous and unnecessarily complex** (see 2.2 below), and demands a relatively high effort from manufacturers to understand their obligations.

1.2. Problems related to the legal provisions of the Directive

The Directive is considered to be too complex and ambiguous. Some isses subject to different interpretations are:

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1 R&TTE= Radio and telecommunications terminal equipment
2 Directive 1999/5/EC OJ L 91, 7.4.1999, p. 10–28
3 Non-radio telecommunications infrastructure such as switching systems is excluded from the scope of the R&TTE Directive

- Whether the essential requirement in article 3.2 ('effective use of spectrum... so as to avoid harmful interference') is applicable only to transmitters or also to the **performance of reception by radio equipment**

- Distinction between the obligation to affix the **'Alert Sign'** on products subject to restrictions of use and the obligation to **notify** the placing on the market of equipment operating in non-harmonised bands

These ambiguities and others lead to inconsistent application of the Directive and constitute a hindrance to the Internal Market.

The Directive also includes many **administrative provisions**, and the value of some of them is questionable, e.g. CE marking, Notified Body number and Alert Sign must be affixed on the equipment, on the package and on user instructions.

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

It is unclear how to apply the Directive to some particular categories of equipment, such as equipment modifiable by software and installations made up of multiple components.

The Directive does not allow to require equipment to interoperate with accessories, such a chargers. In the absence of voluntary industry agreements, lack of interoperability is an inconvenience for users and creates unnecessary waste[4].

Receivers (e.g. GPS or Galileo receivers) are generally included in the Directive. Sound and TV broadcast receivers, and also intentional radiators non-capable of communication (e.g. wireless chargers) are excluded from the Directive, and fall under the EMC Directive[5]. Different legal requirements for similar equipment create legal uncertainty.

1.3. Regulatory barriers to market entry of innovative radio equipment

Market access for new radio technologies requires compliance with the R&TTE Directive, two issues are relevant here:

- Excessive delays in the development of harmonised standards (up to several years) and in the publication of references in the OJEU[6] (up to 1 year)

- Difficulties in obtaining opinions from notified bodies (NBs) in the absence of approved rules for the use of spectrum.

Other issues affecting market access of innovations fall outside the scope of the R&TTE Directive, and include the lack of harmonisation of spectrum in the EU, and the relatively long, complex and uncertain process for the re-allocation of spectrum use.

1.4. Who is affected.

- Users of R&TTE equipment, public services and citizens in general exposed to non-compliant equipment.

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4 http://ec.europa.eu/enterprise/sectors/rtte/chargers/index_en.htm

5 Electromagnetic Compatibility Directive, Directive 2004/108/EC

6 Official Journal of the European Union

- Manufacturers affected by distortion of competition by non-compliant products, by the complexity and ambiguity of the Directive, and by difficulties in bringing innovations to the market

- Market Surveillance Authorities affected by difficulties in efficiently enforcing the Directive and by legal uncertainty

2. ANALYSIS OF SUBSIDIARITY

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 revised Directive shall be based on TFEU articles 26 (*Internal Market*) and 114 (*Approximation of Laws*). Action at EU level is necessary in order to adapt, clarify or simplify provisions which are the keystone of the Single Market in this area. This cannot be done by Member States on their own. A possible new obligation to register at EU level manufacturer and/or product (options A2, A3, A4) would affect the the whole EU market, its advantages with respect to similar measures at national level are clear. Option C2 affects spectrum regulation, an area largely within the competence of Member States, this is discussed below. For the other options considered, the EU right to act and the value-added of action at EU level can be considered uncontroversial.

3. OBJECTIVES

The review of the R&TTE Directive aims to ensure better implementation of the essential requirements in the Directive. It must preserve and improve the Single Market, avoid unnecessary costs and burden, in particular for SMEs, and support innovation. Specific and operational objectives 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 particular regarding traceability of products

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

- To clarify, simplify or suppress a number of provisions and administrative obligations; to improve the coherence with other EU legislation.

- To facilitate the application of the Directive some specific technologies; to enable harmonisation of interfaces between equipment and accessories

- To include within the scope of the Directive all equipment for which avoidance of harmful interference is relevant

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

- To simplify regulatory decision-making and reduce associated delays

4. POLICY OPTIONS

4.1. 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

-Option A2 includes Option A1 plus the obligation for manufacturers to register in a central EU registration system their contact data. A unique company registration number shall be affixed on all products placed on the EU market

-Option A3 includes Option A1 plus the obligation for the manufacturer to register in a central EU registration system each new product type and upload part of the technical file. A product specific registration number shall be affixed on each corresponding product

-**Option A4** includes Option A1 plus the possibility for the Commission, on the basis of delegated powers, to introduce product registration as in option A3 for some specific categories of equipment where a high level of compliance has not been achieved

4.2. Options addressing objective B

-Option B0 is the status quo

-Option B1 includes the alignment of definitions and obligations in the Directive with the NLF for the Internal Market for goods, the clarification of currently problematic provisions on the basis of the current 'Guide for the implementation of the Directive', and the simplification of some administrative obligations

-Option B2 includes option B1, plus the introduction of additional provisions to deal with some specific technologies, a new requirement for interoperability with accessories, and an extension of scope to all radio transmitters and receivers

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

4.3. Options addressing objective C

-Option C0 is no new EU action.

-Option C1 includes non-legislative measures: to set up a single EU point of request for experimental licences for use of radio equipment; an action plan to improve cooperation between regulators, notified bodies and standardisation bodies; and an information campaign towards companies and SMEs on the regulatory framework of radio equipment

-Option C2 includes option C1 and two legal changes: the creation of a special category of notified bodies focussing on the more innovative radio equipment; and the setting up of a central EU body 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

5. ASSESSMENT OF IMPACTS

All options are assessed in terms of effectiveness in achieving the objectives. Accrued compliance is expected to bring in positive **social impacts**, i.e. improved protection of health

and safety and better operation of equipment for the benefit of consumers, business and public services.

Economic impacts relate to the functioning of the internal market, the efficient use of spectrum and the administrative costs induced by the Directive, and some innovation aspects. **No significant specific impact on SMEs has been identified.**

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

Some 50% of Member States and most economic operators[7] expect a high impact of the alignment to the NLF (**Option 1**) on compliance in the R&TTE area.

Most MSAs consider that the additional effect on enforcement efficiency and on compliance of **Option A2** should be positive but limited. **Option A3** brings in an additional tool for enforcement, providing **quick access to the technical file** of registered products, **online availability of product-specific contact data** and therefore a reduction of delay enforcement. One MSA estimated an overall gain of up to 10-15% in time/resources allocated to market surveillance and an improvement in reaction time of several weeks. While focussing only on problematic product categories, **Option A4** should have a similar impact on effectiveness as option A3.

Negative 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) assess the impact as significant against only 10% for the NLF alignment. It seems that the current obligation to establish a technical file prior to the placing of a product on the market is often not complied with. Should it be the case, additional burden arising from collecting, formatting and uploading this information would be very limited. For **Option A4** additional administrative costs would be limited to those product categories subject to registration.

These and other impacts are summarised in the table below:

Table 1. Summary table comparing options addressing objective D

	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 improves coherence with 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	--/++ Perceived as a significant	+++/-- Idem NLF /

[7] In the course of the 2010 public consultation 71% of respondents (MSAs were excluded in this question) expected from the NLF alignment a medium to strong impact on compliance

	instrument for effective enforcement of obligations and education of companies	increase of burden by manufacturers Improves efficiency of MSAs Estimated 300000€ investment	Departs from New Approach legislation
Option A4	++ Additional instrument 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

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

Table 2. Summary table comparing options addressing objective B

	Effectiveness in achieving objective B	**Side effects**	**Cost and efficiency**	**Coherence**
Option B0	0	0	0	0
Option B1	++ -Significant clarification	+ -Improved compliance (objective A)	++ Some reduction of administrative requirements	++ -Improves coherence with other EU legislation
Option B2	++/- -Clarifies application of the Directive to specific technologies -A general requirement for interoperability with accessories may be inapplicable -Improves legal certainty - all receivers under the R&TTED -Improves protection of spectrum - all intentional radiators under the R&TTE D	+/- -More efficiency in the use of spectrum through regulatory requirements for receivers -A general requirement for interoperability with accessories may deter innovation	-- -Additional cost due to general interoperability obligation -Some additional cost for broadcast receivers and non-communicating intentional radiators	
Option B3	+++ -Commission powers allow to react to future technology/ market/ legal issues -Improves legal certainty: all receivers and fixed terminals under the EMCD -Improves protection of spectrum: all intentional radiators under the R&TTE	- -Performance of receivers left to voluntary standards -Essential requirements in article 3.3 not applied to pure receivers, e.g. Galileo receivers	+/- -Some additional cost non-communicating intentional radiators -Some reduction of cost for receive-only equipment and fixed terminals	++ -Improves coherence with other EU legislation on competition -Implementing powers facilitate consistent application of the Directive across the EU

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

Option C1 is expected to improve awareness of regulation among companies, to facilitate the role of notified bodies in assessing innovative products, and to achieve some reduction of delays to accommodate novel products within the regulatory framework.

The central EU body in **Option C2** would reduce time-to-market for innovative products, up to 1-2 years in some cases. Industry is reluctant to invest on the basis of temporary authorisations. The central EU body would need to be staffed, 10 persons full-time is a lower estimate[8]. Its powers raise subsidiarity issues with regard to national competences in this area.

This and other impacts are summarised in the table below:

Table 3. 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		+ -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 investment	-- -Special category of NBs may distort competition among NBs -Difficulties in reversing temporary authorisations	-- Important costs: -Operation of new accreditation of a special category of NBs -Set up of a new competence centre -High expenses for withdrawal of previously authorised equipment	-- -Double regime for authorisations -Raises subsidiarity issues

6. COMPARISON OF OPTIONS. PREFERRED OPTION.

Option A1 should increase compliance with limited increases in administrative cost. Manufacturer registration as per **Option A2** provides only limited value-added. Full product registration as per **Option A3** is a powerful additional instrument for improving the effectiveness of market surveillance, but is perceived by industry as a significant additional burden. **Option A4** provides a flexible and proportional approach: to perform the alignment with the NLF, and to introduce product registration as required by compliance in some specific product categories. **Option A4** is therefore the preferred option addressing objective A.

Option B1 achieves clarification, simplification, reduction of burden and improvement of coherence. **Option B2** further clarifies and improves the legal basis in dealing with some specific technologies, intentional radiators and receivers. Requirements on performance of reception bring in increase efficiency in the use of spectrum, but entail additional 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 costs, leaving. **Option B3** is therefore the preferred option addressing objective B.

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

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. **Option C1** is therefore the preferred option addressing objective C.

Overall, this package of preferred options is expected to increase compliance, 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 elements of the preferred option. 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.

7. MONITORING AND EVALUATION

The following table summarises the core indicators of progress towards meeting the objectives for the revision of the Directive:

Table 4. Core indicators of progress

	Indicator	**Approach**
Compliance	Compliance ratios	Periodic reports from Member States
Administrative simplification and legal adaptations	Induced administrative cost and burden, number of provisions in the Directive perceived as unclear	Regular exchange with stakeholders
Regulatory barriers to innovation	Perceived simplicity of introducing innovations	Regular exchange with stakeholders

In accordance with the proposal, **Member States** would have an obligation to send to the Commission biannual reports on the application of the Directive, providing information on levels of compliance with the Directive.

The **Commission** plans to regularly review the operation of this Directive and report thereon to the European Parliament and to the Council every five years.