

## ROADMAP

Title of the initiative: **Revision of R&TTE Directive 1999/5/EC**

Lead DG: ENTR I4

Expected date of adoption of the initiative (month/year): Q4 2010

Date of modification: 24<sup>th</sup> March 2010

Version No: V5

### Initial IA screening & planning of further work

#### **A. Context and problem definition**

A-1 - What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

The R&TTE Directive 1999/5/EC (hereafter 'the 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 a large part of the €90bn market for telecommunications and radio equipment, covering inter alia mobile telephones, broadcast transmitters, fixed telephones and data transmission modems. Non-radio telecommunications infrastructure such as most internet routers and switching systems is excluded from its scope. The Directive is applied in the European Economic Area (EEA) and also in Turkey in application of the EU-Turkey Customs Union agreement. Switzerland has aligned its national legislation with the provisions of the Directive on a voluntary basis.

The Directive has been instrumental in the completion of the internal market for radio equipment, replacing thousands of national type-approval schemes and introducing a light-touch regulatory regime facilitating innovation and competition.

The products covered by the Directive are also strongly impacted by other European legislation such as the electronic communications regulatory framework, and in particular by the Radio Spectrum Decision and its implementing measures for the progressive harmonisation of spectrum.

Following the 2004 Commission Report on the Operation of the Directive (COM(2004)288), the Council already invited the Commission to propose a revision. The Commission has been working within TCAM, the standing committee of the Directive, in order to develop the objectives for a revision of the Directive, and a broad and deep public consultation was performed in 2007. The European Parliament has recently raised its interest in spectrum management for the provision of electronic communication services, a matter which as said above has an important impact on R&TTE equipment. The 2010 Commission Report on the Operation of the Directive (COM(2010)43) draws attention to some difficulties in the operation of the Directive in view to achieve its desired effects, and indicates the need to consider options to address them within a future revision of the Directive, for which a Commission proposal would be scheduled for end 2010.

## A–2 What are the main problems identified?

Overall, the regulatory framework set up by the Directive has allowed to achieve its intended goals, i.e. a high level of protection of health and safety for users, the electromagnetic compatibility for telecommunication terminals and radio equipment as well as the avoidance of harmful interference. Without a change in the approach, some adaptations are required in order to optimise operations, to provide better tools for market surveillance authorities and to align the Directive with the New Legal Framework for the Internal Market. There are a number of issues which present clear room for improvement:

- a. A low level of compliance in certain product categories with the technical and with the administrative requirements established by the Directive. Related to this, a limited traceability of the manufacturers and importers and other entities or persons responsible for placing a product on the market, which prevents market surveillance authorities from being efficient and effective
- b. the scope of the Directive includes equipment already covered by more specialised EU legislation or by international agreements, which creates issues of demarcation and consistency, in particular with equipment for maritime, terrestrial transport and aerospace applications.
- c. within the scope of the Directive is currently included equipment for which the provisions of the Directive are not well adapted (e.g. very low power radio equipment, complex installations, reconfigurable equipment, equipment likely to create cumulative effects)
- d. the Directive includes many administrative provisions, such as notifications to authorities of certain categories of equipment being placed on the market, and the clarity and the value-of some of them appear to be questionable. This creates unnecessary burden to business and administrations as well as dissimilar approaches among national administrations operating with the Directive. Provisions intended to support competition, such as the publication of radio interfaces, also seem to pay a limited contribution to their goal. Inconsistencies between the Directive and other New Approach (eg Toys Directive) and non-New Approach pieces of legislation (eg RoHS, WEEE, Eco Design Directive) covering the same products also create unnecessary difficulties. These problems are common to other Single Market legislation and are at the origin of the NLF (New Legislative Framework for the Internal Market). Alignment with the NLF is therefore the baseline to address these issues
- e. Market access for new radio technologies depends in practice on the availability of applicable harmonised standards facilitating compliance with the R&TTE Directive and of usable spectrum. Processes for putting in place regulatory decisions concerning spectrum use and harmonised standards are relatively complex, and market entrance for innovative radio technologies in the EU is consequently delayed or discouraged. Difficulties in the notified body route to market access have also been identified, as it appears that notified bodies would have difficulties in issuing opinions on the conformity of radio equipment with the essential requirements of the R&TTE Directive where an applicable harmonised standard is not available. Consequently, when moving from the research and development phase to commercial deployment, the lack of harmonised standards allowing to place innovative products on the market in compliance with legal requirements, and availability of suitable spectrum allocations and associated conditions of use may create legal uncertainty and thus can deter potential investors in technology.

Is EU action justified on grounds of subsidiarity?

The Single Market is an area of 'shared competence' according to article 4 of the Treaty of Lisbon (TFEU). The Directive to be revised, as one of 'New Approach' directives, has been instrumental in the completion of the internal market for radio and telecommunication terminal equipment. The EU level instrument setting harmonised requirements for the internal market is based on TFEU articles 26 (Internal Market) and 114 (Approximation of Laws). In general, it is not foreseen that the problems and objectives identified for the revision raise new subsidiarity issues. Some issues within problem d) regarding the common application of the Directive could be the exception and will therefore be the subject of specific analysis within the impact assessment

## **B. Objectives of EU initiative**

What are the main policy objectives?

The general objective of the revision of the Directive is to better protect health and safety, to ensure electromagnetic compatibility, non-interference, efficient use of spectrum and the other essential requirements for radio equipment and telecommunications terminal equipment in such a way that supports innovation and guarantees free circulation of these products in the EU.

Specific and operational objectives are the following:

### **A — To achieve improved enforcement and compliance with the Directive**

- To simplify and clarify the requirements stemming from the Directive, thus facilitating compliance by market operators
- To provide better tools for increased effectiveness of market surveillance authorities, such as improved cooperation, more effective safeguards, and in particular to improve the traceability of equipment covered by the Directive

### **B —To adapt the scope of the Directive in order to better consider the case of equipment already covered by specialised legislation or by international treaties**

This includes the cases of:

- Some radio equipment for air traffic management
- Some radio equipment for safety of sea-going vessels (eg non-SOLAS ships ) and of waterways , notably including some radars
- Some radio equipment for safety of terrestrial transport

### **C —To adapt the obligations and powers created by the Directive to a number of specific cases covered by the Directive**

This includes the cases of:

- Complex installations which are currently treated like compact equipment
- `Benign equipment`, very low power equipment for which the Directive may create excessive obligations
- Situations where the effect of multiple equipment cumulates (e.g. in-vehicle radars )
- Radio equipment of which the emission characteristics are modifiable by the user or may change according to the radio environment (reconfigurable radio equipment)

**D – Simplification, improvement of consistency among MSs, and with related EU legislation**

- To clarify, develop or suppress a number of unused provisions or administrative obligations which have proved to be ineffective or confusing. Some candidates for review are:
  - Notifications of radio interfaces under articles 4.1 (considering obligations under Directive 98/34 and RSD) and 4.2
  - Notifications of equipment being placed on the market under article 6.4
  - Use of the alert sign for equipment subject to restrictions of use
  - Inclusion of the Declaration of Conformity in the user documentation
- To simplify and harmonise the definition of terminal, which currently depends on national decisions, and to rationalise current exclusions from its scope, in particular of broadcast receivers
- To update obligations to facilitate competition in terminal equipment
- To review the scope and applicability of article 3.3 on additional essential requirements
- To clarify and simplify a number of provisions for market operators, notified bodies and market surveillance authorities on the basis of the NLF, to ensure a common approach with other New Approach legislation covering the same products, and to improve consistency with related legislation such as the Radio Spectrum Decision , the electronic communications regulatory framework RoHS or WEEE as well as with the implementing measures under the EcoDesign Directive
- To facilitate a more uniform application of the Directive across the EU, including inter alia on the concept of ‘intended use’, and the specific case of trade fairs. This objective could be extended in order to give a formal role to TCAM in facilitating a harmonised implementation of the EMC Directive, in particular when radio equipment is concerned

**E – To remove regulatory barriers to innovation:** to adapt the regulatory regime in order to facilitate the introduction in the market of innovative radio technologies, in particular at the pre-commercial and early commercial phases

Does the objective imply developing EU policy in new areas or in areas of strategic importance?

No, the Directive should remain a ‘New Approach’ Directive regulating the placing on the market and putting into service of radio equipment and telecommunications terminal equipment in the Single Market

## **C. Options**

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

### **Objective A — To achieve improved enforcement and compliance with the Directive**

-**Option A0** is the status quo

-**Option A1** is an alignment to the NLF for the Internal Market for goods.

-**Option A2** includes the NLF alignment and the obligation of the manufacturer (or authorised representative or importer) to register in an ad hoc registration system his contact data. The system would return a unique company registration number, which the manufacturer would have to affix on all products placed on the EU market

-**Option A3** includes the NLF alignment and the obligation of the manufacturer (or authorised representative or importer) to register in an ad hoc registration system each new product. The system would return a product-specific registration number, which the manufacturer would have to affix on each corresponding product. Such number would allow for quick identification of the product and the retrieval of the relevant technical file

### **B —To adapt the scope of the Directive in order to better consider the case of equipment already covered by specialised legislation or by international treaties**

-**Option B0** is the status quo

-**Option B1** would include in the Directive a '*lex specialis*' provision by which equipment already covered by specialised legislation or by international treaties would be excluded from the Directive

-**Option B2** would give powers to TCAM (the Committee of the Directive) or to the Commission to exclude certain categories of products from the scope of the Directive

### **C —To adapt the obligations and powers created by the Directive to a number of specific cases covered by the Directive**

-**Option C0** is the status quo

-**Option C1** would include in the Directive specific provisions for complex installations, for benign equipment, for reconfigurable radio equipment, and for equipment likely to create cumulative effects

-**Option C2** would give powers to TCAM or to the Commission to introduce specific obligations for specific cases broadly identified in the Directive

### **D – Simplification, improvement of consistency among MSs, and with related EU legislation**

-**Option D0** is the status quo

-**Option D1** is the alignment to the NLF for the Internal Market for goods.

-**Option D2** includes the NLF alignment, the clarification of currently problematic provisions, the improvement of consistency with related EU legislation, and the suppression of a number of unused provisions or administrative obligations which have proved to be ineffective

-**Option D3** is option D1 plus an EU wide homogeneous definition of terminal, also including broadcasting terminals

-**Option D4** is option D2 plus the detailed development of a number of obligations and powers, in particular in the area of notifications and market surveillance, currently left to national transposition and development

-**Option D5** is option D3 plus the conferral of powers to TCAM or to the Commission to take binding decisions on harmonised implementation of the Directive. A variation of this option would allow TCAM to also take decisions about the EMC Directive.

-**Option D6** is option D3 in the form of an EU regulation as opposed to a Directive

#### **E – To remove regulatory barriers to innovation in radio equipment:**

-**Option E0** is the status quo. Ongoing efforts in relation to the objective include fostering the development of more generic (less technology-specific) harmonised standards and increasing the flexibility and technology neutrality of spectrum allocation

-**Option E1** would fine-tune the current process for the update of harmonised standards and of spectrum regulation. The R&TTE Directive would clarify the concept of state of the art and the requirements for equipment to efficiently use spectrum according to the state of the art, and possibly address the efficiency of receivers

-**Option E2** is the creation of a special group of notified bodies, who would be required to engage with CEPT and with ETSI in order to acquire early expert knowledge on innovative technologies, and who would give opinions on the more innovative radio equipment

-**Option E3** is the creation of a regulatory group (eg RSC-TCAM) in charge of providing innovators with a perspective of access to the EU market. Under the current rules, the group would supervise pre-commercial deployments and facilitate early commercial deployments of innovative technologies in liaison with the special group of notified bodies

-**Option E4** implies legal changes for the creation of a temporary and reversible regulatory regime for innovation, possible on the basis of an EU level competence centre, allowing the placing in the market of a limited amount of equipment in a limited area and for a limited period of time which may be extended, but providing the conditions for a quick commercial uptake

-**Option E5** would revise and simplify the current institutional arrangement for spectrum and equipment regulation in the EU

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

-Proposed action to facilitate innovation in radio technology has very strong relation with spectrum policy led by DG INFSO

-The Directive fosters competition in the telecom equipment market, also covered by INFSO and by DG COMP

-Within R&TTE scope is equipment also covered by legislation managed by DG TREN and by DG ENV.

-Risks to health arising from electromagnetic fields (EMF) are managed by DG SANCO

- The Directive includes provisions enabling to impose additional essential requirements on accessibility, covered by DG EMPL
- The technical requirements in the Directive have an impact on external trade

Explain how the options respect the proportionality principle

The options considered remain within what is reasonable to achieve the objectives being considered. The impact analysis shall allow to evaluate more finely the balance between the actions and the expected level of performance

#### **D. Initial assessment of impacts**

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

- Option A1 (and D1) should provide for improved clarity and consistence. Nevertheless, the NLF includes new obligations for economic operators for which the proportionality needs to be assessed. Also the adaptation of existing R&TTE modules to the NLF should allow to improve consistency without losing the value of existing R&TTE specificities
- Options A2 and A3 should improve traceability of R&TTE products, and, depending on the specific registration mode considered, may create burden and costs both for business and for public administrations. In particular time-to-market must be considered.
- Options B1 and B2 should simplify R&TTE management but may create confusion and additional burden for business if heavy regulatory regimes replace the R&TTE Directive
- Options C1 and C2 should facilitate appropriate treatment of specific equipment, but might also render the Directive excessively complex
- Option C1, if excluding benign equipment from the Directive, may create a loophole for other equipment which must comply with the Directive
- Option C1, if introducing regulation on reconfigurable radio equipment, may create unnecessary burden and prevent market uptake
- Option D1 should provide for improved clarity and consistence. Nevertheless, the NLF includes new obligations for economic operators for which the proportionality needs to be assessed. Also the adaptation of existing R&TTE modules to the NLF should allow to improve consistency without losing the value of existing R&TTE specificities
- Options D2, D3 and D4 for simplification and improved coherence should reduce burden and further clarify obligations in the Directive
- Option E2 should improve reactivity of notified bodies to technologic innovation, but could create additional burden for them, and generate tensions within the community of notified bodies
- Option E4 should facilitate pre-commercial deployments, and would need the establishment of a specific authorisation process for spectrum and for compliance with

the essential requirements of the Directive, as well as procedures to reverse authorisations and to effectively withdraw pre-commercial equipment from the market. Effectiveness of reversing authorisations and cost, in particular of enforcement and of a possible competence centre, need to be assessed

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

Depending on the further development of options A2 and A3, putting in place a pan-European registration system might imply investments above the threshold. Should this options be further proposed, appropriate evaluation would take place

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

-The revision intends to significantly simplify the Directive and its application by market operators and public authorities

-The market for R&TTE equipment is global, and those affected by the revision are both within and outside the EU. In particular, the introduction of a registration system as per option 5 could be interpreted as a change of the regulatory approach of the EU in the area of harmonised legislation, possibly impacting harmonisation of technical regulations at multilateral and bilateral levels

Who is affected?

- Manufacturers, importers and distributors
- Entrepreneurs
- EU Market surveillance authorities
- Spectrum authorities
- Notified Bodies
- Standardisation Bodies
- Users of R&TTE equipment

## **E. Planning of further impact assessment work**

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

-A very broad and deep public consultation took place in 2007. 60 respondents answered to some 120 questions on the operation of the Directive. This allowed to identify the main problems in the operation of the Directive as well as the possible remedies

-A consultation within TCAM end of 2009 has allowed to fine-tune the objectives and the options for the revision of the Directive

-During 2009, Technopolis developed and finalised for the Commission a study on the impact of the introduction of a registration system (options A1 and A2)

-More information needs to be gathered on:

- Improvements in traceability expected from the NLF
- capital and operational expenses, and burden on time-to-market induced by a possible registration system
- improvements in traceability expected from a registration system
- impact of regulatory regimes replacing the R&TTE Directive for some specialised equipment
- impact of explicitly including installations in the Directive
- risks of a simplified regime for benign equipment
- risks of a specific regime for reconfigurable equipment
- potential benefits, risks and costs of a two-tier system of notified bodies
- potential benefits, risks and costs of a temporary regime for innovation

-To this aim, a public consultation is planned in Q3 2010, and several TCAM meetings will focus on the revision of the Directive during 2010

Which stakeholders & experts have been/will be consulted, how and at what stage?

- The 2007 public consultation by the Commission services (60 respondents), and the 2009 Technopolis study consulted all the relevant stakeholders in industry, administrations and the community of users
- The planned public consultation in 2010 will again address all key actors.
- TCAM includes the MSs as well as industry, notified bodies, standardisation bodies and consumer representatives