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Proposal for a

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on the harmonisation of the laws of the Member States relating to the making available  
on the market of radio equipment**

(Text with EEA relevance)

{SWD(2012) 300 final}

{SWD(2012) 329 final}

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

- **Context, objectives and grounds for the proposal**

The R&TTE 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, 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. The Directive entered into force in 1999 and has been crucial to achieving an internal market in this area.

The Directive includes essential requirements for the protection of health and safety, of electromagnetic compatibility and for the avoidance of harmful interference. These requirements are translated into technical requirements within non-mandatory harmonised standards, as in other ‘New Approach’ legislation. The regulatory approach is considered to remain valid, a fundamental revision of the Directive is therefore not necessary. Nevertheless, experience in the operation of the Directive has highlighted a number of issues to be addressed<sup>1</sup>. The main objectives of the draft proposal are:

- To improve the level of compliance with the requirements in the Directive, and to increase the confidence of all stakeholders in the regulatory framework;
- To clarify and simplify the Directive, including some limited adaptations of scope, so as to facilitate its application and eliminate unnecessary burden for economic operators and public authorities.

The proposed revision also allows to better integrate the Directive with other related EU legislation managed by DGConnect, in particular the Radio Spectrum Decision<sup>2</sup>. The proposed text is built on the alignment of the Directive with the new legislative framework for the marketing of products (NLF), with Regulation No 182/2011 on the Commission’s exercise of implementing powers and with the Treaty on the Functioning of the European Union (TFEU).

The proposal is based on Articles 26 (Internal Market) and 114 (Approximation of Laws) of the TFEU.

- **Existing provisions in the area of the proposal**

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 of 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

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<sup>1</sup> Second Progress Report on the operation of the R&TTE Directive, COM(2010)43 final, of 9.2.2010

<sup>2</sup> 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

on RoHS<sup>3</sup>, WEEE<sup>4</sup> and Batteries<sup>5</sup>, as well as implementing measures under the EcoDesign Directive<sup>6</sup>.

Putting into service and use of radio equipment is subject to national regulation. When exercising this competence, Member States must comply with applicable EU law, in particular:

- The general framework for spectrum policy set out in the Radio Spectrum Policy Programme<sup>7</sup>;
- General criteria laid down in Directive 2002/21/EC (Framework Directive<sup>8</sup>) within the regulatory framework for electronic communications;
- Conditions for authorisations for the use of spectrum laid down in Directive 2002/20/EC (Authorisation Directive<sup>9</sup>) within the regulatory framework for electronic communications;
- Implementing measures under Decision 676/2002/EC (Radio Spectrum Decision<sup>10</sup>) harmonising the technical conditions for the use of certain spectrum bands in the EU and that are binding on all Member States. Examples of bands harmonised at EU level include the bands for GSM, UMTS and short-range devices;
- Consistency with the other policies and objectives of the Union.

The proposal is consistent with the principles of the Commission's 'Smart Regulation' policy<sup>11</sup>, with the policy for Europe 2020, in particular as regards the regulatory review foreseen within the policy for an Innovation Union<sup>12</sup>, as well as with the Radio Spectrum Policy Programme<sup>13</sup>.

The initiative is consistent with the New Legislative Framework package approved in 2008, composed of Regulation 765/2008 on accreditation and market surveillance and of Decision 768/2008 establishing a common framework for the marketing of products. The Decision provides (Article 2) that its provisions are to be used when legislation is drafted or revised.

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<sup>3</sup> Directive 2002/95/EC on Restriction of Hazardous Substances.

<sup>4</sup> Directive 2002/96/EC on Waste of Electrical and Electronic Equipment.

<sup>5</sup> Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators.

<sup>6</sup> Directive 2009/125/EC establishing a framework for the setting of ecodesign requirements for energy-related products.

<sup>7</sup> Decision No 243/2012/EU of the European Parliament and of the Council of 14 March 2012 establishing a multiannual radio spectrum policy programme.

<sup>8</sup> 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)

<sup>9</sup> 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)

<sup>10</sup> 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)

<sup>11</sup> [http://ec.europa.eu/governance/better\\_regulation/key\\_docs\\_en.htm#\\_br](http://ec.europa.eu/governance/better_regulation/key_docs_en.htm#_br).

<sup>12</sup> [http://ec.europa.eu/research/innovation-union/index\\_en.cfm](http://ec.europa.eu/research/innovation-union/index_en.cfm), COM(2010) 546 final, Europe 2020 Flagship Initiative - Innovation Union.

<sup>13</sup> Decision No 243/2012/EU of the European Parliament and of the Council of 14 March 2012 establishing a multiannual radio spectrum policy programme.

## **2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS**

- Consultation of interested parties

A first public consultation on the operation of the Directive took place in 2007. Issues identified through this consultation were included in the Second Progress Report on the operation of the Directive<sup>14</sup>.

The Commission conducted a further public consultation in 2010 focusing on the impact of some of the measures under consideration. The Commission received contributions from 122 respondents, including 50 SMEs, 36 other economic operators, national authorities, notified bodies, and standardisation bodies<sup>15</sup>.

- Collection and use of expertise

During 2009, an external study was conducted on the impact of different options addressing the need to improve traceability of products and their compliance with the requirements in the Directive<sup>16</sup>.

Overall, there is a high level of consensus and support for aligning the Directive with the New Legislative Framework package and for clarifying and simplifying the Directive. Opinions are more divided on the possible introduction of a requirement to register products prior to their placing on the market, and on some measures for administrative simplification

## **3. LEGAL ELEMENTS OF THE PROPOSAL**

- Legal basis

Articles 26 and 114 TFEU.

- Subsidiarity and proportionality principles

Action at EU level is necessary in order to adapt, clarify or simplify provisions of Internal Market legislation in this area. The proposal harmonises essential and administrative requirements compliance with which enables access to the EU market, and its advantages compared to multiple similar measures by Member States acting individually are clear.

In accordance with the principle of proportionality, the proposed modifications do not go beyond what is necessary to achieve the objectives set. The new or modified obligations do not impose unnecessary burdens and costs on industry especially on small and medium sized

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<sup>14</sup> 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] - [http://ec.europa.eu/enterprise/sectors/rtte/documents/legislation/review/index\\_en.htm#h2-2](http://ec.europa.eu/enterprise/sectors/rtte/documents/legislation/review/index_en.htm#h2-2)

<sup>15</sup> 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](http://ec.europa.eu/enterprise/sectors/rtte/public-consultation/files-public-consultation/summary-2010-pc_en.pdf)

<sup>16</sup> 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](http://ec.europa.eu/enterprise/sectors/rtte/files/technop-ia-radio-finrep_en.pdf)

enterprises - or administrations. Where modifications have been identified as having negative impacts, their analysis has made it possible to provide the most proportionate response to the problems identified. A number of modifications concern the improvement of clarity of the existing Directive without introducing new requirements.

- Choice of instrument

The proposal is to replace current Directive 1999/5/EC with a new Directive, to be transposed by Member States by way of national legal instruments.

#### **4. BUDGETARY IMPLICATION**

The proposal is compatible with the current multiannual financial framework: all measures or actions included in the proposed directive are consistent and compatible with the current and the next multiannual financial framework (2014 to 2020) as proposed by the Commission.

The proposal includes the possibility of requiring registration of certain categories of radio equipment prior to their placing on the market. Were this possibility to come into effect, a database should be put in place and administered by the Commission. The available estimation of costs includes an investment of €300000 and an annual maintenance cost of €30000.

#### **5. OPTIONAL ELEMENTS**

- **Simplification and reduction of administrative costs**

The proposal aims to clarify the application of the Directive and to eliminate unnecessary administrative burden for businesses and administrations by increasing spectrum flexibility and easing administrative procedures for spectrum use. It is part of the Commission's rolling programme for updating and simplifying *acquis communautaire* and its Work and Legislative Programme under reference 2009/ENTR/021.

- **Review**

The proposal requires the Commission to review the operation of the Directive and report thereon 4 years after the entry into force of the Directive and every five years thereafter

- **Information from Member States**

Member States shall inform the Commission on the transposition of the Directive and send to the Commission a report on its application three years after the entry into force of the Directive and every two years thereafter.

- **European Economic Area**

The proposed act is of relevance to the EEA and should therefore extend thereto.

- **Detailed explanation of the proposal**

The most significant elements of the proposal for a revision of the Directive are the following:

1. Alignment with Decision 768/2008/EC on a common framework for the marketing of products:
  - Article 2 includes the definitions set out in chapter R1 of Decision 768/2008/EC
  - Articles 10-to-15 include the obligations of economic operators set out in chapter R2 of Decision 768/2008/EC
  - Article 17 and Annexes III, IV and V include three modules for conformity assessment set out in Annex II of Decision 768/2008/EC
  - Articles 22-to-38 include the obligations for the notification of conformity assessment bodies set out in chapter R4 of Decision 768/2008/EC
  - Articles 39-to-43 include the simplified safeguard procedures set out in chapter R5 of Decision 768/2008/EC
2. Article 2(1) sets out a new definition of ‘radio equipment’ which demarcates the modified scope of the Directive: this includes all and only equipment which intentionally transmits signals using radio spectrum, whether for the purpose of communication or other. The essential requirement in Article 3(2) has been correspondingly adapted and only refers to transmitted signals.

In consequence, the proposed new title for the Directive is: “Directive on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment”
3. Article 3(3) (a) makes it possible to require radio equipment to interoperate with accessories such as chargers
4. Article 3(3) (g) makes it possible to require software-defined radio equipment to ensure that only compliant combinations of software and hardware come together. Article 4 makes it possible to adopt measures to avoid that this regulatory requirement creates barriers to competition in the market for third-party software
5. Article 5 introduces the possibility to require the registration within a central system of products within categories showing low levels of compliance, on the basis of information on compliance provided by Member States in accordance with Article 47(1)
6. Article 7 clarifies the relation between the R&TTE Directive and EU and national legislation on the use of radio spectrum
7. Simplification and reduction of administrative obligations:

- The new definition of radio equipment set out in Article 2(1) establishes a clear demarcation of scope with Directive 2004/108/EC (the EMC Directive<sup>17</sup>);
  - Pure receivers and fixed-line terminals cease to fall within the scope of the Directive, falling instead within the scope of Directive 2004/108/EC and Directive 2006/95/EC<sup>18</sup>, or depending on their voltage falling within the scope of Directive 2004/108/EC and Directive 2001/95/EC<sup>19</sup>; this entails some reduction of administrative obligations;
  - The requirement to notify the placing on the market of equipment using frequency bands which are not EU-wide harmonised (current Article 6(4)) is removed;
  - The obligation to affix an equipment class identifier on the product (current Annex VII(5)) is removed;
  - The requirement to affix CE marking on user instructions (current Annex VII(3)) is removed;
  - Requirements supporting competition in the market for terminals (current Articles 4(2), 7(3)-to(5)) are removed from the text of the Directive. Similar requirements are in force under Directive 2008/63/EC<sup>20</sup>.
8. Alignment with the Treaty on the Functioning of the European Union and with Regulation No 182/2011 on the Commission's exercise of implementing powers:
- The procedures for the exercise of implementing and delegated powers are laid out in Articles 44 (Committee procedure) and 45 (Exercise of the delegation)
  - Implementing powers are proposed in Article 8(3) (determination of equipment classes) and Article 10(9) (presentation of information on geographical area for use and on restrictions to use of radio equipment)
  - Delegated powers are proposed in Article 2(3) (adaptation to technical progress of Annex II listing some equipment falling or not within the definition of radio equipment), Article 3(3) (additional essential requirements), Article 4(2) (provision of information on the compliance of software-defined radio equipment), and Article 5(2) (requirement to register radio equipment within some categories)

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<sup>17</sup> Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC

<sup>18</sup> Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits

<sup>19</sup> Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety

<sup>20</sup> Directive 2008/63/EC of 20 June 2008 on competition in the markets in telecommunications terminal equipment

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the Economic and Social Committee<sup>21</sup>,

After consulting the European Data Protection Supervisor<sup>22</sup>,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) 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<sup>23</sup> has been substantially amended several times. Since further amendments are to be made, it should be replaced in the interests of clarity.
- (2) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93<sup>24</sup> lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.
- (3) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council

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<sup>23</sup> OJ L 91, 7.4.1999, p. 10.

<sup>24</sup> OJ L 218, 13.8.2008, p. 30.



Decision 93/465/EEC<sup>25</sup> lays down a common framework of general principles and reference provisions intended to apply across the legislation harmonising the conditions for the marketing of products in order to provide a coherent basis for revision or recasts of that legislation. Directive 1999/5/EC should therefore be adapted to that Decision.

- (4) The essential requirements in Directive 1999/5/EC which are relevant to fixed-line terminal equipment, i.e. the protection of health and safety and the protection of electromagnetic compatibility, are appropriately covered by Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits<sup>26</sup> and 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC<sup>27</sup>. This Directive should therefore not apply to fixed-line terminal equipment.
- (5) Competition issues in the market for terminal equipment are appropriately covered by Commission Directive 2008/63/EC of 20 June 2008 on competition in the markets in telecommunications terminal equipment<sup>28</sup>, in particular through the obligation for national regulatory authorities to ensure the publication of details of technical interface specifications for network access. It is therefore not necessary to include in this Directive requirements facilitating competition in the market for terminal equipment covered by Directive 2008/63/EC.
- (6) Equipment which intentionally transmits radio waves in order to serve its purpose makes systematic use of radio spectrum. In order to ensure an efficient use of spectrum so as to avoid harmful interference, all such equipment should fall within the scope of this Directive, whether equipment is capable of communication or not.
- (7) Experience has shown the difficulty of establishing whether some products fall within the scope of Directive 1999/5/EC. In particular, in respect of products resulting from technological progress and presenting difficulties of categorisation, it is necessary to identify categories of products which fall or not within the definition of radio equipment. In order to supplement or amend certain non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amendments of Annex II so as to adapt it to technical progress.
- (8) The essential requirements in the area of safety laid down by Directive 2006/95/EC are sufficient to cover radio equipment, and should therefore be the reference and made applicable by virtue of this Directive. In order to avoid unnecessary duplications of provisions, other than the essential requirements, Directive 2006/95/EC should not apply to radio equipment.

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<sup>25</sup> OJ L 218, 13.8.2008, p. 82.

<sup>26</sup> OJ L 374, 27.12.2006, p. 10.

<sup>27</sup> OJ L 390, 31.12.2004, p. 24.

<sup>28</sup> OJ L 162, 21.6.2008, p. 20.

- (9) The essential requirements in the area of electromagnetic compatibility laid down by Directive 2004/108/EC are sufficient to cover radio equipment, and should therefore be the reference and made applicable by virtue of this Directive. In order to avoid unnecessary duplications of provisions, other than essential requirements, , Directive 2004/108/EC should not apply to radio equipment.
- (10) Efficient use of the radio spectrum, according to the state of the art, should be ensured so as to avoid harmful interference.
- (11) Although receivers do not themselves cause harmful interference, reception capabilities are an increasingly important factor in ensuring the efficient use of radio spectrum by way of an increased resilience of receivers against interference and unwanted signals on the basis of the essential requirements of Directive 2004/108/EC.
- (12) Receiver capabilities of receive-only equipment are subject to the essential requirements of Directive 2004/108/EC in particular with regard to unwanted signals resulting from the efficient use of shared or adjacent frequency bands, and it is therefore not necessary to include such equipment within the scope of this Directive.
- (13) In some cases interworking via networks with other radio equipment and connection with interfaces of the appropriate type throughout the Union may be necessary. Interoperability between radio equipment and accessories such as chargers may simplify use of radio equipment and reduce unnecessary waste.
- (14) The protection of personal data and privacy of users of radio equipment and the protection from fraud may be enhanced by particular features of radio equipment. Radio equipment should therefore in appropriate cases be designed in such a way that it supports those features.
- (15) Radio equipment can be instrumental in providing access to emergency services. Radio equipment should therefore in appropriate cases be designed in such a way that it supports those features required for access to those services.
- (16) Radio equipment is important to the well-being and employment of people with disabilities who represent a substantial and growing proportion of the population of Member States. Radio equipment should therefore in appropriate cases be designed in such a way that disabled people may use it without or with only minimal adaptation.
- (17) The compliance of some categories of radio equipment with the essential requirements may be affected by the inclusion of software or modification of its existing software. The user, the radio equipment or a third party should only be able to load software into the radio equipment where this does not compromise the subsequent compliance of the radio equipment with the applicable essential requirements.
- (18) It is necessary to provide for a possibility to introduce supplementary requirements addressing needs related to interoperability, user privacy, fraud prevention, use by users with a disability, access to emergency services or the prevention of non-compliant combinations of software and radio equipment. In order to supplement or amend certain non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of specification of categories or classes of radio equipment that need to comply with additional essential requirements

on interoperability, user privacy, fraud prevention, use by users with a disability, access to emergency services or the prevention of non-compliant combinations of software and radio equipment.

- (19) Verification by radio equipment of the compliance of its combination with software should not be abused in order to prevent its use with software provided by independent parties. The availability to public authorities, manufacturers and users of information on the compliance of intended combinations of radio equipment and software should contribute to facilitate competition. In order to supplement or amend certain non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of specifying categories or classes of radio equipment for which manufacturers need to provide information on the compliance of intended combinations of radio equipment and software, the information to be communicated and the rules on making that information available.
- (20) A requirement to register in a central database radio equipment to be placed on the market may enhance the efficiency and effectiveness of market surveillance and therefore contribute to ensure a high level of compliance with the Directive. Such a requirement entails additional burden to economic operators and should therefore be introduced only for those categories of radio equipment where a high level of compliance has not been attained. In order to supplement or amend certain non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of identifying the relevant categories of radio equipment to be registered in a central database on the basis of information on compliance to be provided by Member States, and of specifying the information to be registered, the rules applicable for registration and affixation of the registration number.
- (21) Radio equipment which complies with the relevant essential requirements should be allowed to circulate freely. Such equipment should be allowed to be put into service and used for its intended purpose, where applicable in accordance with rules on authorisations for the use of radio spectrum and the provision of the service concerned.
- (22) In order to avoid unnecessary barriers to trade in radio equipment within the Internal Market of the Union, Member States should notify under Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations<sup>29</sup> to other Member States and to the Commission their projects in the area of technical regulations, such as radio interfaces, but not where these allow Member States to comply with binding Union acts such as implementing measures under 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<sup>30</sup>.
- (23) The provision of information on the equivalence of regulated radio interfaces and their conditions of use reduces barriers for the access of radio equipment to the internal market. The Commission should therefore assess and establish the equivalence of

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<sup>29</sup> OJ L 204, 21.7.1998, p. 37.

<sup>30</sup> OJ L 108, 24.4.2002, p. 1.

those regulated radio interfaces and make available such information in the form of radio equipment classes.

- (24) In accordance with Commission Decision 2007/344/EC of 16 May 2007 on harmonised availability of information regarding spectrum use within the Community<sup>31</sup>, Member States have to use the ERO Frequency Information System (EFIS) set up by the European Radiocommunications Office (ERO) in order to make comparable information regarding the use of spectrum in each Member State available to the public via the Internet. Manufacturers can search in EFIS frequency information for all Union Member States prior to the placing on the market of radio equipment and so evaluate whether and under which conditions such radio equipment may be used within each Member State. Therefore in this Directive there is no need to include additional provisions, such as prior notification, allowing to inform manufacturers of the conditions of use of radio equipment using non-harmonised frequency bands.
- (25) For the purpose of promotion of research and demonstration activities it should be possible, in the context of trade fairs, exhibitions and similar events, to exhibit radio equipment which does not conform to this Directive and cannot be placed on the market, on the condition that exhibitors ensure sufficient information to the visiting public.
- (26) Economic operators should be responsible for the compliance of products, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of health and safety, of electromagnetic compatibility, an efficient use of spectrum so as to avoid harmful interference, and to guarantee fair competition on the Union market.
- (27) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market products which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each operator in the supply and distribution process.
- (28) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure. Conformity assessment should therefore remain the obligation of the manufacturer alone.
- (29) The manufacturer should provide sufficient information on the intended use of the equipment so as to allow its use in compliance with the essential requirements. Such information may need to include description of accessories such as antennas, components such as software and specifications of the installation process of the equipment.
- (30) The requirement in Directive 1999/5/EC to include an EU declaration of conformity with equipment has been found to simplify and to enhance the information and the efficiency of market surveillance. The possibility to provide a simplified EU declaration of conformity has allowed to reduce the burden associated with this requirement without reduction of its effectiveness and should be provided for within this Directive.

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<sup>31</sup> OJ L 129, 17.5.2007, p. 67.

- (31) It is necessary to ensure that products from third countries entering the Union market comply with the requirements of this Directive, and in particular that appropriate assessment procedures have been carried out by manufacturers with regard to those products. Provision should therefore be made for importers to make sure that the products they place on the market comply with the requirements of this Directive and that they do not place on the market products which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that product marking and documentation drawn up by manufacturers are available for inspection by the supervisory authorities.
- (32) The distributor makes radio equipment available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the radio equipment does not adversely affect the compliance of the radio equipment.
- (33) When placing radio equipment on the market, every importer should indicate on the radio equipment his name and the address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the equipment does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the radio equipment.
- (34) Any economic operator that either places radio equipment on the market under his own name or trademark or modifies radio equipment in such a way that compliance with the requirements of this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (35) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the radio equipment concerned.
- (36) Ensuring traceability of radio equipment throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant radio equipment available on the market.
- (37) This Directive should be limited to the expression of essential requirements. In order to facilitate conformity assessment with those requirements it is necessary to provide for presumption of conformity for radio equipment which is in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No [.../...] [*on European Standardisation*]<sup>32</sup> for the purpose of expressing detailed technical specifications of those requirements.
- (38) Regulation (EU) No [.../...] [*on European Standardisation*] provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy requirements of this Directive.

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<sup>32</sup> OJ L [...], [...], p. [...].

- (39) In order to enable economic operators to demonstrate and the competent authorities to ensure that radio equipment made available on the market conforms to the essential requirements it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules.
- (40) Manufacturers should draw up an EU declaration of conformity to provide detailed information on the conformity of radio equipment with the requirements of this Directive and of the other relevant Union harmonisation legislation.
- (41) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.
- (42) The requirement to affix the CE marking on products is important for the information of consumers and public authorities. The possibility in Directive 1999/5/EC to affix a reduced CE mark on small equipment, provided that it remains visible and legible, has allowed to simplify application of this requirement without reducing its effectiveness and should therefore be included in this Directive.
- (43) The requirement in Directive 1999/5/EC to affix the CE marking on the packaging of equipment has been found to simplify the task of market surveillance and should therefore be included in this Directive.
- (44) The conformity assessment procedures set out in this Directive require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.
- (45) Experience has shown that the criteria set out in Directive 1999/5/EC that the conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (46) In order to ensure a consistent level of conformity assessment quality it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.
- (47) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Directive.
- (48) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.

- (49) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out this evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.
- (50) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for radio equipment to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.
- (51) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (52) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (53) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.
- (54) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to radio equipment.
- (55) Directive 1999/5/EC already provides for a safeguard procedure which applies only in the event of disagreement between Member States over measures taken by a Member State. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard clause procedure, with a view to making it more efficient and drawing on the expertise available in Member States.
- (56) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to radio equipment presenting a risk to the health and safety of persons or to other aspects of public interest covered by the essential requirements in this Directive. It should also allow

market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such equipment.

- (57) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.
- (58) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers<sup>33</sup>.
- (59) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work of delegated acts, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and the Council.
- (60) The Member States should lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.
- (61) It is necessary to provide for transitional arrangements that allow making available on the market and putting into service radio equipment that have already been placed on the market in accordance with Directive 1999/5/EC.
- (62) Since the objective of this Directive, namely to ensure that radio equipment on the market fulfils requirements providing a high level of protection of health and safety, of electromagnetic compatibility and an efficient use of spectrum so as to avoid harmful interference while guaranteeing the functioning of the internal market, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.
- (63) In accordance with the Joint Political Declaration of Member States and the Commission on explanatory documents of 28 September 2011, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified.

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<sup>33</sup> OJ L 55 of 28.2.2011, p. 13.



HAVE ADOPTED THIS DIRECTIVE:

## CHAPTER I

### GENERAL PROVISIONS

#### *Article 1*

##### **Subject matter and scope**

1. This Directive establishes a regulatory framework for the making available on the market and putting into service in the Union of radio equipment.
2. This Directive shall not apply to equipment listed in Annex I.
3. This Directive shall not apply to radio equipment exclusively used for activities concerning public security, defence, State security, including the economic well-being of the State in the case of activities pertaining to State security matters, and the activities of the State in the area of criminal law.
4. Radio equipment falling within the scope of this Directive shall not be subject to Directive 2006/95/EC, except as set out in Article 3(1)(a) of this Directive.

#### *Article 2*

##### **Definitions**

1. For the purpose of this Directive the following definitions shall apply:
  - (1) ‘radio equipment’ means a product which intentionally emits radio waves in order to serve its purpose, or a product which must be completed with an accessory, such as antenna, so as to emit radio waves in order to serve its purpose;
  - (2) ‘radio waves’ means electromagnetic waves of frequencies from 9 kHz to 3000 GHz, propagated in space without artificial guide;
  - (3) ‘interface’ means an air interface specifying the radio path between radio equipment and their technical specifications;
  - (4) ‘radio equipment class’ means a class identifying particular categories of radio equipment which under this Directive are considered similar and those interfaces for which the equipment is designed;
  - (5) ‘harmful interference’ means harmful interference as defined in Directive 2002/21/EC of the European Parliament and of the Council<sup>34</sup>;

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<sup>34</sup> OJ L 108, 24.4.2002, p. 33.

- (6) ‘making available on the market’ means any supply of radio equipment for distribution, consumption or use in the European Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (7) ‘placing on the market’ means the first making available of radio equipment on the European Union market;
- (8) ‘manufacturer’ means any natural or legal person who manufactures radio equipment or has radio equipment designed or manufactured, and markets that equipment under his name or trademark;
- (9) ‘authorised representative’ means any natural or legal person established within the European Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- (10) ‘importer’ means any natural or legal person established within the European Union who places radio equipment from a third country on the European Union market;
- (11) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes radio equipment available on the market;
- (12) ‘economic operators’ means the manufacturer, the authorised representative, the importer and the distributor;
- (13) ‘technical specification’ means a document that prescribes technical requirements to be fulfilled by radio equipment;
- (14) ‘harmonised standard’ means harmonised standard as defined in Article 2(1)(c) of Regulation (EU) No [...] [on *European Standardisation*]<sup>35</sup>;
- (15) ‘accreditation’ means accreditation as defined in Regulation (EC) No 765/2008;
- (16) ‘national accreditation body’ means national accreditation body as defined in Regulation (EC) No 765/2008;
- (17) ‘conformity assessment’ means the process demonstrating whether the essential requirements relating to radio equipment have been fulfilled;
- (18) ‘conformity assessment body’ means a body that performs conformity assessment activities;
- (19) ‘recall’ means any measure aimed at achieving the return of radio equipment that has already been made available to the user;
- (20) ‘withdrawal’ means any measure aimed at preventing radio equipment in the supply chain from being made available on the market;
- (21) ‘CE marking’ means a marking by which the manufacturer indicates that radio equipment is in conformity with the applicable requirements set out in European Union harmonisation legislation providing for its affixing;

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<sup>35</sup> OJ L [...], [...], p. [...].

- (22) ‘ Union harmonisation legislation’ means any Union legislation harmonising the conditions for the marketing of products.
2. For the purposes of point 1 of paragraph 1 of this Article, products listed under point 1 of Annex II shall be deemed to be radio equipment, and products listed under point 2 of Annex II shall not be deemed to be radio equipment.
3. The Commission shall be empowered to adopt delegated acts in accordance with Article 45 modifying Annex II in order to adapt it to technical progress.

### *Article 3*

#### **Essential requirements**

1. Radio equipment shall be constructed so as to ensure:
- (a) the protection of the health and the safety of the user and any other person, including the objectives with respect to safety requirements set out in Directive 2006/95/EC, but with no voltage limit applying;
  - (b) the protection of electromagnetic compatibility as set out in Directive 2004/108/EC, including in particular levels of immunity which lead to improvements in the efficient use of shared or adjacent frequency bands.
2. Radio equipment shall be so constructed that its transmitted signals efficiently use the spectrum allocated to terrestrial/space radio communication and orbital resources so as to avoid harmful interference. Only radio equipment that can be operated in at least one Member State without infringing applicable requirements on the use of spectrum can comply with this requirement.
3. Radio equipment shall be so constructed that it complies with the following essential requirements:
- (a) radio equipment interworks with accessories, and/or it interworks via networks with other radio equipment, and/or it can be connected to interfaces of the appropriate type throughout the Union;
  - (b) radio equipment does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service;
  - (c) radio equipment incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected;
  - (d) radio equipment supports certain features ensuring avoidance of fraud;
  - (e) radio equipment supports certain features ensuring access to emergency services;
  - (f) radio equipment supports certain features in order to facilitate its use by users with a disability;

- (g) radio equipment supports certain features in order to ensure that software can only be loaded into the radio equipment where the compliance of the combination of software and the radio equipment has been demonstrated.

The Commission shall be empowered to adopt delegated acts in accordance with Article 45 specifying which categories or classes of radio equipment are concerned by each of the requirements (a) to (g) in the first subparagraph.

#### *Article 4*

### **Provision of information on the compliance of combinations of software and radio equipment**

1. Manufacturers of radio equipment and of software allowing radio equipment to be used as intended shall provide the Member States and the Commission with information on the compliance of intended combinations of radio equipment and software with the essential requirements set out in Article 3.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 45 specifying which categories or classes of radio equipment are concerned by the requirement in the paragraph 1, the required information and the operational rules for making the information on compliance available.

#### *Article 5*

### **Registration of radio equipment within some categories**

1. As from [date - *four years after the date of entry into force of the Directive*], manufacturers shall register radio equipment types within categories of equipment affected by a low level of compliance with the essential requirements set out in Article 3 within a central system referred to in paragraph 3 prior to radio equipment within those categories being placed on the market. The Commission shall allocate to each registered type a registration number, which manufacturers shall affix on radio equipment placed on the market.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 45 specifying which categories of radio equipment are concerned by the requirement set out in the paragraph 1, taking into account information on the compliance of equipment provided by Member States in accordance with Article 47(1), the information to be registered, the operational rules for registration and the operational rules for affixation of the registration number on radio equipment.
3. The Commission shall make available a central system allowing manufacturers to register the required information.

#### *Article 6*

### **Placing on the market**

Member States shall ensure that radio equipment is made available on the market only if it complies with this Directive when it is properly installed and maintained and used for its intended purpose.

#### *Article 7*

##### **Putting into service and use**

Member States shall allow the putting into service and use of radio equipment for its intended purpose where it complies with this Directive. Without prejudice to their obligations under Decision No 676/2002/EC, and to the conditions attached to authorisations for the use of frequencies in conformity with Union law, in particular under Articles 9(3) and 9(4) of Directive 2002/21/EC, Member States may only introduce additional requirements for the putting into service and/or use of radio equipment for reasons related to the efficient use of the radio spectrum, avoidance of harmful interference or matters relating to public health.

#### *Article 8*

##### **Notification of interface specifications and radio equipment classes**

1. Member States shall notify in accordance with the procedure set out in Directive 98/34/EC the interfaces which they intend to regulate.
2. When assessing correspondence between radio equipment and regulated interfaces, Member States shall take into account the equivalence with radio interfaces notified by other Member States.
3. The Commission shall establish the equivalence between notified interfaces and assign a radio equipment class, details of which shall be published in the Official Journal of the European Union. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 44(2).

#### *Article 9*

##### **Free movement of radio equipment**

1. Member States shall not prohibit, restrict or impede, for reasons relating to those aspects covered by this Directive, the placing on the market in their territory of radio equipment complying with this Directive.
2. At trade fairs, exhibitions, demonstrations and similar events, Member States shall not create any obstacles to the display of radio equipment which does not comply with this Directive, provided that a visible sign clearly indicates that such radio equipment may not be marketed or used until it has been made to comply.

## CHAPTER II

### OBLIGATIONS OF ECONOMIC OPERATORS

#### *Article 10*

##### **Obligations of manufacturers**

1. When placing radio equipment on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the essential requirements set out in Article 3.
2. Manufacturers shall draw up the technical documentation referred to in Article 21 and carry out the conformity assessment procedure referred to in Article 17 or have it carried out.

Where compliance of radio equipment with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after radio equipment has been placed on the market.
4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in radio equipment design or characteristics and changes in the harmonised standards or in technical specifications by reference to which conformity of apparatus is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by radio equipment, manufacturers shall carry out sample testing of radio equipment made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming radio equipment and radio equipment recalls, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that radio equipment bears a type, batch or serial number or other element allowing their identification, or, where the size or nature of radio equipment does not allow it, that the required information is provided on the packaging, or in a document accompanying radio equipment.
6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on radio equipment or, where the size or nature of radio equipment does not allow it, on its packaging, or in a document accompanying radio equipment. The address must indicate a single point at which the manufacturer can be contacted.
7. Manufacturers shall ensure that radio equipment is accompanied by instructions and safety information in a language which can be easily understood by consumers and other users, as determined by the Member State concerned. Instructions shall include the information required to use radio equipment in accordance with its intended use.

Such information shall include, where applicable, a description of accessories and/or components, including software, which allow the radio equipment to operate as intended.

The following information shall also be included:

frequency band(s) in which the radio equipment operates;

radio-frequency power transmitted in the frequency band(s) in which the radio equipment operates.

8. A copy of the full EU declaration of conformity shall accompany each piece of radio equipment. This requirement may also be fulfilled by the provision of a simplified EU declaration of conformity. Where only a simplified EU declaration of conformity is provided, it shall be immediately followed by the exact internet or e-mail address where the full EU declaration of conformity can be obtained.
9. Information available on the packaging shall allow to identify the Member States or the geographical area within a Member State where radio equipment can be put into service, and shall alert the user to potential restrictions or requirements for authorisation of use in certain Member States. Such information shall be completed in the instructions accompanying radio equipment. The Commission may adopt implementing acts specifying how to present this information. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 44(2).
10. Manufacturers who consider or have reason to believe that radio equipment which they have placed on the market is not in conformity with this Directive shall immediately take the necessary corrective measures to bring that radio equipment into conformity, to withdraw it or recall it, if appropriate. Furthermore, where radio equipment presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made radio equipment available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.
11. Manufacturers shall, further to a reasoned request from a competent national authority, provide it without delay with all the information and documentation necessary to demonstrate the conformity of radio equipment, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by radio equipment which they have placed on the market.

### *Article 11*

#### **Authorised representatives**

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 10(1) and the drawing up of technical documentation shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:
  - (a) keep the EU declaration of conformity and the technical documentation at the disposal of national surveillance authorities for 10 years after the radio equipment has been placed on the market;
  - (b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of radio equipment;
  - (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by radio equipment covered by the authorised representative's mandate.

## *Article 12*

### **Obligations of importers**

1. Importers shall place only compliant radio equipment on the market.
2. Before placing radio equipment on the market importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the radio equipment bears the CE marking and is accompanied by the information for users and regulatory authorities referred to in Article 10(7), (8) and (9), and that the manufacturer has complied with the requirements set out in Article 10(5) and (6).

Where an importer considers or has reason to believe that radio equipment is not in conformity with the essential requirements set out in Article 3, he shall not place the radio equipment on the market until it has been brought into conformity. Furthermore, where radio equipment presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the radio equipment or, where that is not possible, on its packaging or in a document accompanying the radio equipment. This includes cases where the size of radio equipment does not allow it, or where importers would have to open the packaging in order to indicate their name and address on radio equipment.
4. Importers shall ensure that the radio equipment is accompanied by instructions and safety information in a language which can be easily understood by consumers and other users, as determined by the Member State concerned.
5. Importers shall ensure that, while radio equipment is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Article 3.



6. When deemed appropriate with regard to the risks presented by radio equipment, importers shall, to protect the health and safety of consumers, carry out sample testing of radio equipment made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming radio equipment and radio equipment recalls, and shall keep distributors informed of such monitoring.
7. Importers who consider or have reason to believe that radio equipment which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that radio equipment into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the radio equipment presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the radio equipment available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.
8. Importers shall, for a period of ten years after the radio equipment has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.
9. Importers shall, further to a reasoned request from a competent national authority, provide it without delay with all the information and documentation necessary to demonstrate the conformity of radio equipment in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by the radio equipment which they have placed on the market.

### *Article 13*

#### **Obligations of distributors**

1. When making radio equipment available on the market distributors shall act with due care in relation to the requirements of this Directive.
2. Before making radio equipment available on the market distributors shall verify that the radio equipment bears the required CE marking, that it is accompanied by the required documents and by instructions and safety information in a language which can be easily understood by consumers and other users in the Member State in which the radio equipment is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 10(5) to (9), and Article 12(3).

Where a distributor considers or has reason to believe that radio equipment is not in conformity with the essential requirements set out in Article 3, he shall not make the radio equipment available on the market until it has been brought into conformity. Furthermore, where radio equipment presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3. Distributors shall ensure that, while radio equipment is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Article 3.
4. Distributors who consider or have reason to believe that radio equipment which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that radio equipment into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where radio equipment presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the radio equipment available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.
5. Distributors shall, further to a reasoned request from a competent national authority, provide it without delay with all the information and documentation necessary to demonstrate the conformity of radio equipment. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by radio equipment which they have made available on the market.

#### *Article 14*

#### **Cases in which obligations of manufacturers apply to importers and distributors**

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 10, where he places radio equipment on the market under his name or trademark or modifies radio equipment already placed on the market in such a way that compliance with the requirements of this Directive may be affected.

#### *Article 15*

#### **Identification of economic operators**

Economic operators shall, on request, identify the following to the market surveillance authorities:

- (a) any economic operator who has supplied them with radio equipment;
- (b) any economic operator to whom they have supplied radio equipment.

Economic operators shall be able to present the information referred to in the first paragraph for a period of 10 years after they have been supplied with the radio equipment and for a period of 10 years after they have supplied the radio equipment.

## CHAPTER III

### CONFORMITY OF RADIO EQUIPMENT

#### *Article 16*

##### **Presumption of conformity and harmonised standards**

1. Radio equipment which is in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential requirements covered by those standards or parts thereof, set out in Article 3
2. Where a harmonised standard satisfies the requirements which it covers and which are set out in Article 3 or Article 27, the Commission shall publish the references of those standards in the Official Journal of the European Union.

#### *Article 17*

##### **Conformity assessment procedures**

1. Manufacturers may demonstrate compliance of radio equipment with the essential requirements identified in Articles 3(1)(a) and (b) using any of the following conformity assessment procedures:
  - (a) internal production control procedure set out in Annex III;
  - (b) EU-type examination followed by the conformity to type procedure set out in Annex IV;
  - (c) full quality assurance procedure set out in Annex V.
2. Where in assessing the compliance of radio equipment with the essential requirements identified in Articles 3(2) and (3), the manufacturer has applied harmonised standards, the reference number of which has been published in the Official Journal of the European Union, he may use any of the following procedures:
  - (a) internal production control procedure set out in Annex III;
  - (b) EU-type examination followed by the conformity to type procedure set out in Annex IV;
  - (c) full quality assurance procedure set out in Annex V.
3. Where in assessing the compliance of radio equipment with the essential requirements identified in Articles 3(2) and (3), the manufacturer has not applied or has applied only in part harmonised standards the reference number of which has been published in the Official Journal of the European Union, or where such harmonised standards do not exist, radio equipment shall be submitted with regard to

those essential requirements to the procedure set out in either of the following procedures:

- (a) EU-type examination followed by the conformity to type procedure set out in Annex IV;
- (b) full quality assurance procedure set out in Annex V.

#### *Article 18*

#### **EU declaration of conformity**

1. The EU declaration of conformity shall state that the fulfilment of the essential requirements set out in Article 3 has been demonstrated.
2. The EU declaration of conformity shall have the model structure and shall contain the elements set out in Annex VII and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which market the radio equipment is placed or made available.

The simplified EU declaration of conformity referred to in Article 10(8) shall contain the elements set out in Annex VIII and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which market the radio equipment is placed or made available. The full EU declaration of conformity accessible through internet or e-mail address shall be available in a language or languages required by the Member State in which market the radio equipment is placed or made available.

3. Where the radio equipment is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the acts concerned including the publication references.
4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of radio equipment.

#### *Article 19*

#### **General principles of the CE marking**

1. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.
2. On account of the nature of radio equipment, the height of the CE marking affixed to radio equipment may be lower than 5 mm, provided that it remains visible and legible.

#### *Article 20*

#### **Rules and conditions for affixing the CE marking**

1. The CE marking shall be affixed visibly, legibly and indelibly to the radio equipment or to its data plate, unless that is not possible or not warranted on account of the nature of radio equipment. The CE marking shall also be affixed visibly and legibly to the packaging.
2. The CE marking shall be affixed before radio equipment is placed on the market.
3. The CE marking shall be followed by the identification number of the notified body where the conformity assessment procedure set out in Annex V is applied.

The identification number of the notified body shall have the same height as the CE marking.

It shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

### *Article 21*

#### **Technical documentation**

1. The technical documentation shall contain all relevant data or details of the means used by the manufacturer to ensure that radio equipment complies with the requirements set out in Article 3. It shall, at least, contain the documents listed in Annex VI.
2. The technical documentation shall be drawn up before radio equipment is placed on the market and shall be continuously updated.
3. The technical documentation and correspondence relating to any EU-type examination procedures shall be drawn up in an official language of the Member State in which the notified body is established or in a language acceptable to that body.
4. Technical documentation drawn up in accordance with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification shall be presumed to provide an adequate basis for the assessment of conformity.
5. Following a reasoned request from the market surveillance authority of a Member State, the manufacturer shall provide a translation of the relevant parts of the technical documentation into the language of that Member State.

When a market surveillance authority requests the technical documentation from a manufacturer, it shall be transmitted without delay. When a market surveillance authority requests from a manufacturer a translation of technical documentation or parts thereof, it may fix a deadline for receipt of such translation, which shall be 30 days, unless a shorter deadline is justified in the case of serious and immediate risk.

6. Where the technical documentation does not comply with paragraphs 1, 2 or 3 of this Article, and in so doing fails to present sufficient relevant data or means used to ensure compliance of radio equipment with the requirements set out in Article 3, the market surveillance authority may require the manufacturer to have a test performed

by a body acceptable to the market surveillance authority at the expense of the manufacturer within a specified period in order to verify compliance with the essential requirements set out in Article 3.

## **CHAPTER IV**

### **NOTIFICATION OF CONFORMITY ASSESSMENT BODIES**

#### *Article 22*

##### **Notification**

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Directive.

#### *Article 23*

##### **Notifying authorities**

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 28.
2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.
3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 24(1) to (6). In addition it shall have arrangements to cover liabilities arising out of its activities.
4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

#### *Article 24*

##### **Requirements relating to notifying authorities**

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.
2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.
4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.
5. A notifying authority shall safeguard the confidentiality of the information it obtains.
6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

#### *Article 25*

#### **Information obligation on notifying authorities**

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

#### *Article 26*

#### **Requirements relating to notified bodies**

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.
2. A conformity assessment body shall be established under national law and have legal personality.
3. A conformity assessment body shall be a third-party body independent of the organisation or the radio equipment it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of radio equipment which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the radio equipment which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed radio equipment that is necessary for the operations of the conformity assessment body or the use of such radio equipment for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of that radio equipment, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.
6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by this Directive in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of radio equipment in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of radio equipment technology in question and the mass or serial nature of the production process.

It shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner.

7. The personnel responsible for carrying out conformity assessment activities shall have the following:
  - (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;



- (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
  - (c) appropriate knowledge and understanding of the essential requirements set out in Article 3, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;
  - (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.
8. The impartiality of the conformity assessment bodies, their top level management and of the assessment personnel shall be guaranteed.
- The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.
9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.
10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under this Directive or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.
11. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities, the regulatory activities in the area of radio equipment and frequency planning, and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

#### *Article 27*

#### **Presumption of conformity of conformity assessment bodies**

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article 26 in so far as the applicable harmonised standards cover those requirements.

#### *Article 28*

#### **Subsidiaries of and subcontracting by notified bodies**

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or

the subsidiary meets the requirements set out in Article 26 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.
3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.
4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Directive.

#### *Article 29*

#### **Application for notification**

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.
2. That application shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and categories of radio equipment for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 26.
3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 26.

#### *Article 30*

#### **Notification procedure**

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 26.
2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.
3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and categories of the radio equipment concerned and the relevant attestation of competence.
4. Where a notification is not based on an accreditation certificate as referred to in Article 29(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 26.

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Directive.

6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

### *Article 31*

#### **Identification numbers and lists of notified bodies**

1. The Commission shall assign an identification number to a notified body.  
It shall assign a single such number even where the body is notified under several Union acts.
2. The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been allocated to them and the activities for which they have been notified.

The Commission shall ensure that that list is kept up to date.

### *Article 32*

#### **Changes to notifications**

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 26, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.
2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

### *Article 33*

#### **Challenge of the competence of notified bodies**

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.
3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.
4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including de-notification if necessary.

#### *Article 34*

##### **Operational obligations of notified bodies**

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes IV and V.
2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of radio equipment with this Directive.

Where a notified body finds that the essential requirements set out in Article 3 or corresponding harmonised standards or technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.

3. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that radio equipment no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.
4. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

#### *Article 35*

##### **Appeal against decisions of notified bodies**

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

## *Article 36*

### **Information obligation on notified bodies**

1. Notified bodies shall inform the notifying authority of the following:
  - (a) any refusal, restriction, suspension or withdrawal of a certificate;
  - (b) any circumstances affecting the scope of and conditions for notification;
  - (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
  - (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.
2. Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same categories of radio equipment with relevant information on issues relating to negative and, on request, positive conformity assessment results.
3. Notified bodies shall fulfil information obligations under Annexes IV and V.

## *Article 37*

### **Exchange of experience**

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

## *Article 38*

### **Coordination of notified bodies**

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral group of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.

## CHAPTER V

### UNION MARKET SURVEILLANCE, CONTROL OF PRODUCTS ENTERING THE UNION MARKET AND SAFEGUARD PROCEDURES

#### *Article 39*

##### **Union market surveillance and control of products entering the Union market**

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to radio equipment.

#### *Article 40*

##### **Procedure for dealing with radio equipment presenting a risk at national level**

1. Where the market surveillance authorities of one Member State have taken action pursuant to Article 20 of Regulation (EC) No 765/2008, or where they have sufficient reason to believe that radio equipment covered by this Directive presents a risk to the health or safety of persons or to other aspects of public interest protection covered by this Directive, they shall carry out an evaluation in relation to the radio equipment concerned covering all the requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities.

Where, in the course of that evaluation, the market surveillance authorities find that the radio equipment does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective action to bring the radio equipment into compliance with those requirements, to withdraw the radio equipment from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.
3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all radio equipment concerned that it has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict radio equipment being made available on their national market, to withdraw radio equipment from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant radio equipment, the origin of radio equipment, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to any of the following:
  - (a) failure of radio equipment to meet requirements relating to the health or safety of persons or to other aspects of public interest protection laid down in this Directive;
  - (b) shortcomings in the harmonised standards referred to in Article 16 conferring a presumption of conformity.
6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of radio equipment concerned, and, in the event of disagreement with the notified national measure, of their objections.
7. Where, within 8 weeks of receipt of the information referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.
8. Member States shall ensure that appropriate restrictive measures are taken in respect of the apparatus concerned without delay.

#### *Article 41*

#### **Union safeguard procedure**

1. Where, on completion of the procedure set out in Articles 40(3) and 40(4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant radio equipment is withdrawn or recalled from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.
3. Where the national measure is considered justified and the non-compliance of the radio equipment is attributed to shortcomings in the harmonised standards referred to in Article 16 of this Directive, the Commission shall apply the procedure provided for in Article [8] of Regulation (EU)No[../..] [on European Standardisation].

#### *Article 42*

##### **Compliant radio equipment which presents a risk to health and safety**

1. Where, having performed an evaluation under Article 40(1), a Member State finds that although radio equipment is in compliance with this Directive, it presents a risk to the health or safety of persons or to other aspects of public interest protection covered by this Directive it shall require the relevant economic operator to take all appropriate measures to ensure that the radio equipment concerned, when placed on the market, no longer presents that risk, to withdraw the radio equipment from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.
2. The economic operator shall ensure that corrective action is taken in respect of all the radio equipment concerned.
3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the radio equipment concerned, the origin and the supply chain of radio equipment, the nature of the risk involved and the nature and duration of the national measures taken.
4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not, and where necessary, propose appropriate measures.
5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

#### *Article 43*

##### **Formal non-compliance**



1. Without prejudice to Article 40, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:
  - (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 19 or 20 of this Directive;
  - (b) the CE marking has not been affixed;
  - (c) the EU declaration of conformity has not been drawn up;
  - (d) the EU declaration of conformity has not been drawn up correctly;
  - (e) technical documentation is either not available or not complete;
  - (f) product does not comply with the requirements set out in Articles 10(5), (6) and 12(3);
  - (g) information on intended use of radio equipment, EU declaration of conformity and usage restrictions as set out in Article 10(7), (8) and (9) does not accompany radio equipment;
  - (h) requirements on identification of economic operators set out in article 15 are not fulfilled;
  - (i) non compliance with Article 5.
2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit corresponding radio equipment being made available on the market or ensure that it is recalled or withdrawn from the market.

## **CHAPTER VI**

### **THE COMMITTEE, IMPLEMENTING ACTS AND DELEGATED ACTS**

#### *Article 44*

##### **Committee procedure**

1. The Commission shall be assisted by the Telecommunication Conformity Assessment and Market Surveillance Committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

## *Article 45*

### **Exercise of the delegation**

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The delegation of power referred to in Articles 2(3), 3(3), 4(2) and 5(2) shall be conferred for an indeterminate period of time from the [date of entry into force]
3. The delegation of power referred to in Articles 2(3), 3(3), 4(2) and 5(2) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Articles 2(3), 3(3), 4(2) and 5(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

## **CHAPTER VII**

### **FINAL AND TRANSITIONAL PROVISIONS**

## *Article 46*

### **Penalties**

Member States shall lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced.

The penalties provided for shall be effective, proportionate and dissuasive.

Member States shall notify those provisions to the Commission by [insert date – the date set out in the second subparagraph of Article **Transposition(1)**] at the latest and shall notify it without delay of any subsequent amendment affecting them.

## *Article 47*

### **Review and reporting**

1. Member States shall send the Commission regular reports on the application of this Directive by [date, - three years after the entry into force of this Directive] and at least every two years thereafter. The report shall contain a presentation of the market surveillance activities performed by the Member States and provide information on whether and to what extent compliance with the requirements of this Directive has been attained, including in particular requirements on identification of economic operators.
2. The Commission shall review the operation of this Directive and report thereon to the European Parliament and to the Council, by [date - 4 years after the entry into force of this Directive] and every five years thereafter. The report shall cover progress on drawing up the relevant standards, as well as any problems that have arisen in the course of implementation. The report shall also outline the activities of the Committee, assess progress in achieving an open competitive market for radio equipment at Union level and examine how the regulatory framework for the placing on the market and putting into service of radio equipment should be developed in order to achieve the following:
  - (a) ensure that a coherent system is achieved at Union level for all radio equipment;
  - (b) allow for convergence of the telecommunications, audiovisual and information technology sectors;
  - (c) enable harmonisation of regulatory measures at international level.

It shall in particular examine whether essential requirements are still necessary for all categories of radio equipment covered. Where necessary, further measures may be proposed in the report for full implementation of the aim of this Directive.

#### *Article 48*

#### **Transitional provisions**

Member States shall not impede the making available on the market and/or putting into service of radio equipment covered by Directive 1999/5/EC which is in conformity with that Directive and which was placed on the market before [date set out in the second subparagraph of Article **Transposition(1)**].

#### *Article 49*

#### **Transposition**

1. Member States shall adopt and publish, by [insert date - 18 months after adoption] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from [day after the date set out in the first subparagraph].

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

2. Member States shall communicate to the Commission the texts of the main provisions of national laws which they adopt in the field covered by this Directive.

#### *Article 50*

##### **Repeal**

Directive 1999/5/EC is repealed with effect from [date set out in the second subparagraph of Article **Transposition(1)** of this Directive].

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex IX.

#### *Article 51*

##### **Entry into force**

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

#### *Article 52*

##### **Addressees**

This Directive is addressed to the Member States.

## ANNEX I

### **EQUIPMENT NOT COVERED BY THIS DIRECTIVE**

1. Radio equipment used by radio amateurs within Article 1, definition 56, of the International Telecommunications Union (ITU) radio regulations unless the equipment is available commercially.

Kits of components to be assembled by radio amateurs and commercial equipment modified by and for the use of radio amateurs are not regarded as commercially available equipment.

2. Marine equipment falling within the scope of Council Directive 96/98/EC<sup>36</sup>.
3. Cabling and wiring.
4. Test equipment exclusively intended for the testing of radio equipment by professional users.
5. Aeronautical products, parts and appliances within the meaning of Article 3 of Regulation (EC) No 216/2008 of the European Parliament and of the Council<sup>37</sup>.

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<sup>36</sup> OJ L 46, 17.2.1997, p. 25

<sup>37</sup> OJ L 79, 19.3.2008, p. 1

## ANNEX II

### **PRODUCTS FALLING WITHIN THE DEFINITION OF RADIO EQUIPMENT**

1. For the purposes of this Directive the following products shall be deemed to be radio equipment:
  - (a) active antennas;
  - (b) jammers.
  
2. For the purposes of this Directive the following products shall not be deemed to be radio equipment:
  - (a) passive antennas;
  - (b) cochlear implants;
  - (c) microwave ovens.

## ANNEX III

### CONFORMITY ASSESSMENT

#### Module A (internal production control)

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that radio equipment concerned satisfies the requirements set out in Article 3 and where applicable other harmonisation legislation applying to them.

2. Technical documentation

The manufacturer shall establish the technical documentation according to Article 21.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured radio equipment with the technical documentation referred to in point 2 and with the relevant essential requirements in Article 3.

4. CE marking and declaration of conformity

4.1. The manufacturer shall affix the required CE marking according to Articles 19 and 20 to each piece of radio equipment that satisfies the applicable requirements.

4.2. The manufacturer shall draw up a written declaration of conformity for each radio equipment type and keep it together with the technical documentation at the disposal of the national authorities for 10 years after radio equipment has been placed on the market. The declaration of conformity shall identify the radio equipment for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

## **ANNEX IV**

### **CONFORMITY ASSESSMENT MODULES**

#### **Modules B + C**

##### **EU-Type examination + Conformity to type based on internal production control**

When reference is made to this Annex, the conformity assessment procedure shall follow Modules B (EU-Type examination) and C (Conformity to type based on internal production control) below.

#### **Module B**

##### **EU-type examination**

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of radio equipment and verifies and attests that the technical design of radio equipment meets the requirements of the legislative instrument that apply to it.
2. EU-type examination shall be carried out in the following manner:  
  
assessment of the adequacy of the technical design of radio equipment through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).
3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation. The technical documentation shall make it possible to assess radio equipment's conformity with the applicable requirements of the legislative instrument and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of radio equipment. The technical documentation shall contain, wherever applicable, the elements in Annex V to this Directive,
- the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate



laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall examine the technical documentation and supporting evidence to assess the adequacy of the technical design of radio equipment;
5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations as provided in paragraph 8 below, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.
6. Where the type meets the requirements of the specific legislative instrument that apply to radio equipment concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the assessed type. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured radio equipment with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of the legislative instrument, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of the legislative instrument, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the assessed type that may affect the conformity of radio equipment with the essential requirements of the legislative instrument or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authorities concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

Each notified body shall inform Member States of EU-type examination certificates it has issued and/or additions thereto in those cases where harmonised standards, the

reference of which have been published in the Official Journal of the European Union, are available and have not been fully applied. The Member States, the Commission and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Member States and the Commission may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer for a period of 10 years after radio equipment has been assessed or until the expiry of the validity of the certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after radio equipment has been placed on the market.
10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

## **Module C**

### **Conformity to type based on internal production control**

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that radio equipments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.
2. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured radio equipment with the approved type described in the EU-type examination certificate and with the requirements of the legislative instrument that apply to them.
3. **CE marking and declaration of conformity**
  - 3.1. The manufacturer shall affix the CE marking according to Articles 19 and 20 to each piece of radio equipment that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of the legislative instrument.
  - 3.2. The manufacturer shall draw up a written declaration of conformity for each radio equipment type and keep it at the disposal of the national authorities for 10 years after radio equipment has been placed on the market. The EU declaration of conformity shall identify the radio equipment type for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

## ANNEX V

### CONFORMITY ASSESSMENT

#### Module H

##### Full Quality Assurance

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that radio equipment concerned satisfies the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of radio equipment concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for radio equipment concerned.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- the technical documentation for one type of each category of radio equipment intended to be manufactured. The technical documentation shall contain, wherever applicable, the elements in Annex VI to this Directive,
- the documentation concerning the quality system, and
- a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of radio equipment with the requirements of the legislative instrument that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,
- the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or technical specifications will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to radio equipments will be met,
- the design control and design verification techniques, processes and systematic actions that will be used when designing radio equipment pertaining to radio equipment category covered,
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.,
- the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2 of this Annex.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant radio equipment field and radio equipment technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1, second indent, to verify the manufacturer's ability to identify the applicable requirements of the legislative instrument and to carry out the necessary examinations with a view to ensuring compliance of radio equipment with those requirements.

The manufacturer or his authorised representative shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

- 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

#### 4. Surveillance under the responsibility of the notified body

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

- the quality system documentation,
- the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.,
- the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out radio equipment tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

#### 5. CE marking and declaration of conformity

- 5.1. The manufacturer shall affix the CE marking according to Articles 19 and 20 and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each piece of radio equipment that satisfies the applicable requirements set out in Article 3.

- 5.2. The manufacturer shall draw up a written EU declaration of conformity for each type of radio equipment and keep it at the disposal of the national authorities for 10 years after radio equipment has been placed on the market. The EU declaration of conformity shall identify the radio equipment type for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending at least 10 years after radio equipment has been placed on the market, keep at the disposal of the national authorities:
- the technical documentation referred to in point 3.1,
  - the documentation concerning the quality system referred to in point 3.1,
  - the change referred to in point 3.5, as approved,
  - the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

## ANNEX VI

### **Contents of Technical Documentation**

The technical documentation shall, wherever applicable, contain at least the following elements:

- (a) a general description of the radio equipment including: photographs or illustrations showing external features, marking and internal layout; versions of software or firmware affecting compliance with essential requirements; user information and installation instructions;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits and other relevant similar elements;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the radio equipment;
- (d) a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements in Article 3 where those harmonised standards have not been applied; in the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- (e) copy of the EU declaration of conformity;
- (f) where the conformity assessment module in Annex IV has been applied, copy of the EU-type examination certificate and its annexes as delivered by the involved notified body;
- (g) results of design calculations made, examinations carried out, and other relevant similar elements;
- (h) test reports.

**ANNEX VII**

**Declaration of Conformity**

1. No ... (unique identification of the radio equipment):
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of the radio equipment allowing traceability. It may include a photograph, where appropriate):
5. The object of the declaration described above is in conformity with the relevant European Union harmonisation legislation:

Radio Equipment Directive XXXX/xx

Other European Union harmonisation legislation where applicable

6. References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared. References shall be listed with their identification number and version and where applicable date of issue:
7. Where applicable, the notified body ... (name, number) ... performed ... (description of intervention) ... and issued the EU-type examination certificate: ...
8. Additional information:

Where applicable, description of accessories and/or components, including software, which allow the radio equipment to operate as intended and covered by the Declaration of Conformity

Signed for and on behalf of: .....

(place and date of issue):

(name, function) (signature):



## **ANNEX VIII**

### **Simplified Declaration of Conformity**

The simplified EU declaration of conformity referred to in the third subparagraph of Article 10(8) shall be provided as follows:

Hereby, [Name of manufacturer] declares that the radio equipment type [designation of type of radio equipment] is in compliance with Radio Equipment Directive XXXX/xx.

**ANNEX IX**  
**Correlation table**  
**CORRELATION TABLE**

<b>Directive 1999/5/EC</b>	<b>This Directive</b>
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3, with the exception of Article 3(3)(g)
Article 4(1)	Article 8
Article 4(2)	<i>deleted</i>
Article 5	Article 16
Article 6(1)	Article 6
Article 6(2)	<i>deleted</i>
Article 6(3)	Article 10(7), 10(8), 10(9)
Article 6(4)	<i>deleted</i>
Article 7(1), 7(2)	Article 7
Article 7(3), 7(4), 7(5)	<i>deleted</i>
Article 8	Article 9
Article 9	Articles 39-43
Article 10	Article 17
Article 11	Articles 22-38
Article 12	Articles 19, 20, 10(5), 10(6)
Articles 13 to 15	Article 44
Article 16	<i>deleted</i>
Article 17	Article 47
Article 18	Article 48
Article 19	Article 49
Article 20	Article 50
Article 21	Article 51
Article 22	Article 52
Annex I	Annex I

Annex II	Annex III
Annex III	<i>deleted</i>
Annex IV	Annex IV
Annex V	Annex V
Annex VI	Article 26
Annex VII(1) to (4)	Articles 19, 20
Annex VII(5)	Article 10(9)
New Articles	Article 3(3)(g)
	Article 4
	Article 5
	Articles 10(1) to (4), 10(10), 10(11), Articles 11 to 15
	Article 18
	Article 21
	Article 45
	Article 46
	Annex II
	Annex VI
	Annex VII
	Annex VIII

**LEGISLATIVE FINANCIAL STATEMENT**

**1. FRAMEWORK OF THE PROPOSAL/INITIATIVE**

**1.1. Title of the proposal/initiative:**

**1.2. Policy area(s) concerned in the ABM/ABB structure**

**1.3. Nature of the proposal/initiative:**

**1.4. Objective(s):**

*1.4.1. The Commission's multiannual strategic objective(s) targeted by the proposal:*

*1.4.2. Specific objective(s) and ABM/ABB activity(ies) concerned*

**1.5. Grounds for the proposal/initiative:**

**1.6. Duration and financial impact:**

**1.7. Management method(s) envisaged:**

**2. MANAGEMENT MEASURES**

**2.1. Monitoring and reporting rules**

**2.2. Management and control system**

**2.3. Measures to prevent fraud and irregularities**

**3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE**

**3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected:**

**3.2. Estimated impact on expenditure**

*3.2.1. Summary of estimated impact on expenditure*

*3.2.2. Estimated impact on operational appropriations*

*3.2.3. Estimated impact on appropriations of an administrative nature:*

*3.2.4. Compatibility with the current multiannual financial framework*

*3.2.5. Third-party participation in financing*

**3.3. Estimated impact on revenue**

## LEGISLATIVE FINANCIAL STATEMENT

### 1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

#### 1.1. Title of the proposal/initiative

Proposal for a Directive of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to radio equipment (the Radio Equipment Directive), and repealing Directive 1999/5/EC, Directive on Radio and Telecommunications Terminal Equipment, the R&TTE Directive

#### 1.2. Policy area(s) concerned in the ABM/ABB structure<sup>38</sup>

Title 2 – Enterprise – Chapter 02 03: Internal Market for Goods and Sectoral Policies

#### 1.3. Nature of the proposal/initiative

The proposal/initiative relates to **a new action**

The proposal/initiative relates to **a new action following a pilot project/preparatory action**<sup>39</sup>

The proposal/initiative relates to **the extension of an existing action**

The proposal/initiative relates to **an action redirected towards a new action**

#### 1.4. Objectives

1.4.1. *The Commission's multiannual strategic objective(s) targeted by the proposal/initiative*

1.4.2. *Specific objective(s) and ABM/ABB activity(ies) concerned*

Specific objective No.1.

To continually renew existing internal market acquis and propose new legislative or non-legislative action whenever appropriate [IP, IU, DA]. See 1.5.1 below for further detail.

ABM/ABB activity(ies) concerned

02 03

1.4.3. *Expected result(s) and impact*

*Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.*

<sup>38</sup>  
<sup>39</sup>

ABM: Activity-Based Management – ABB: Activity-Based Budgeting.  
As referred to in Article 49(6)(a) or (b) of the Financial Regulation.

The proposed legislative revision is expected to increase compliance of radio equipment with the essential requirements in the Directive, namely the protection of health and safety, electromagnetic compatibility, and the avoidance of harmful interference. It should therefore improve protection of users and of fair competition, to bring increased legal certainty, smoother and more consistent application of the Directive and more comprehensive prevention of harmful interference, with limited additional burden for market operators

#### 1.4.4. Indicators of results and impact

Specify the indicators for monitoring implementation of the proposal/initiative.

Core indicators of progress towards meeting the objectives for the revision of the Directive are the following:

	<b>Indicator</b>	<b>Approach</b>
<b>Compliance</b>	Administrative and technical compliance ratios	Periodic reports from Member States
<b>Administrative simplification and legal adaptations</b>	Induced administrative cost and burden, number and relative relevance of issues of interpretation	Regular exchange with stakeholders — economic operators, authorities and notified bodies
<b>Regulatory barriers to innovation</b>	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 laid down in the Directive

Further information is to be collected through regular exchanges within TCAM, the standing committee set up by 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.

### 1.5. Grounds for the proposal/initiative

#### 1.5.1. Requirement(s) to be met in the short or long term

The Directive has been essential to achieve a single market for radio equipment and for telecommunication terminals. It includes essential requirements for the protection of health and safety and for the prevention of harmful interference. These requirements are translated into technical requirements within non-mandatory harmonised standards, as in other 'New Approach' legislation.

The regulatory approach is considered to remain valid, a fundamental revision of the Directive is therefore not necessary; Nevertheless, experience in the operation of the

Directive has highlighted a number of issues to be addressed<sup>40</sup>. The main objectives of the draft proposal are:

- to redress the current situation of low level of compliance with the requirements in the Directive, and to increase the confidence of all stakeholders in the regulatory framework,

- to clarify and simplify the Directive including some limited adaptations of scope so as to facilitate its application and eliminate unnecessary burden for economic operators and public authorities.

#### 1.5.2. *Added value of EU involvement*

The revised Directive is to be based on Articles 26 (Internal Market) and 114 (Approximation of Laws) TFEU. 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 achieved by Member States acting individually. A possible new obligation to register at EU level manufacturers and/or equipment would enable access to the EU market, and its advantages compared to multiple similar measures at national level are clear

#### 1.5.3. *Lessons learned from similar experiences in the past*

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 (EMC) for telecommunication terminals and radio equipment as well as the avoidance of harmful interference. The main issues to be addressed are the low level of compliance with the Directive and the ambiguity and complexity of some provisions in the Directive.

#### 1.5.4. *Coherence and possible synergy with other relevant instruments*

The proposed revision will be consistent with the principles of the Commission's 'Smart Regulation' policy, with the policy for Europe 2020, in particular as regards the regulatory review foreseen within the policy for an Innovation Union, as well as with the proposed Radio Spectrum Policy Programme.

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 sets out 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 deals with 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,

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<sup>40</sup> Second Progress Report on the operation of the R&TTE Directive, COM(2010)43 final, of 9.2.2010



individuals or Member States, and provides (Article 2) that its provisions are to be used when legislation is drafted or revised.

**1.6. Duration and financial impact**

Proposal/initiative of **limited duration**

- Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY
- Financial impact from YYYY to YYYY

Proposal/initiative of **unlimited duration**

- Implementation with a start-up period from **2013**
- followed by full-scale operation.

**1.7. Management mode(s) envisaged<sup>41</sup>**

**1.8.  Centralised direct management by the Commission**

**Centralised indirect management** with the delegation of implementation tasks to:

- executive agencies
- bodies set up by the Communities<sup>42</sup>
- national public-sector bodies/bodies with public-service mission
- persons entrusted with the implementation of specific actions pursuant to Title V of the Treaty on European Union and identified in the relevant basic act within the meaning of Article 49 of the Financial Regulation

**Shared management** with the Member States

**Decentralised management** with third countries

**Joint management** with international organisations (*to be specified*)

*If more than one management mode is indicated, please provide details in the "Comments" section.*

Comments

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<sup>41</sup> Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: [http://www.cc.cec/budg/man/budgmanag/budgmanag\\_en.html](http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html)

<sup>42</sup> As referred to in Article 185 of the Financial Regulation.

## **2. MANAGEMENT MEASURES**

### **2.1. Monitoring and reporting rules**

*Specify frequency and conditions.*

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 laid down in the Directive.

Further information is to be collected through regular exchanges within TCAM, the standing committee set up by 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.

### **2.2. Management and control system**

#### **2.2.1. Risk(s) identified**

-Divergent implementation of the revised Directive by Member States might become an issue.

-EU-level expenses associated to the revised Directive are limited to human resources and possibly to the creation of a database for registration of some categories of products prior to their placing on the market where following the entry into force of the revised Directive a high level of compliance has not been achieved.

#### **2.2.2. Control method(s) envisaged**

-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.

-The possible set-up of database for the registration of products for an estimated budget of 300000 EUR would be subject to tendering under the rules of the Financial Regulation.

### **2.3. Measures to prevent fraud and irregularities**

*Specify existing or envisaged prevention and protection measures.*

-No specific measures beyond the application of the Financial Regulation

### 3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

#### 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing expenditure budget lines

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Description.....]	Diff./non-diff. <sup>(43)</sup>	from EFTA <sup>44</sup> countries	from candidate countries <sup>45</sup>	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
1a Competitiveness for growth and employment	02.03.01, Operation and development of the internal market, particularly in the fields of notification, certification and sectoral approximation.	Diff.	NO	NO	NO	NO

- New budget lines requested: NO

*In order of multiannual financial framework headings and budget lines.*

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Heading.....]	Diff./non-diff.	from EFTA countries	from candidate countries	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
	[XX.YY.YY.YY]		YES/NO O	YES/NO O	YES/NO O	YES/NO

<sup>43</sup> Diff. = Differentiated appropriations / Non-diff. = Non-Differentiated Appropriations

<sup>44</sup> EFTA: European Free Trade Association.

<sup>45</sup> Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

### 3.2. Estimated impact on expenditure

#### 3.2.1. Summary of estimated impact on expenditure

EUR million (to 3 decimal places)

<b>Heading of multiannual financial framework:</b>	Number	1a. Competitiveness for growth and employment
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DG: ENTR			Year N <sup>46</sup>	Year N+1	Year N+2	Year N+3	... enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL
• Operational appropriations										
02.03.01, Operation and development of the internal market, particularly in the fields of notification, certification and sectoral approximation.	Commitments	(1)	0	0	0	0.3	0.03	0.03	0.03	Proposal of unlimited duration
	Payments	(2)	0	0	0	0.3	0.03	0.03	0.03	Proposal of unlimited duration
Number of budget line	Commitments	(1a)								
	Payments	(2a)								
Appropriations of an administrative nature financed from the envelope for specific programmes <sup>47</sup>										
Number of budget line		(3)								
<b>TOTAL appropriations</b>	Commitments	=1+1a +3	0	0	0	0.3	0.03	0.03	0.03	Proposal of unlimited duration

<sup>46</sup> Year N is the year in which implementation of the proposal/initiative starts.

<sup>47</sup> Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

<b>for DG ENTR</b>	Payments	=2+2a +3	0	0	0	0.3	0.03	0.03	0.03	Proposal of unlimited duration
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• TOTAL operational appropriations	Commitments	(4)								
	Payments	(5)								
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)								
<b>TOTAL appropriations under HEADING 1a. Competitiveness for growth and employment of the multiannual financial framework</b>	Commitments	=4+ 6	0	0	0	0.3	0.03	0.03	0.03	Proposal of unlimited duration
	Payments	=5+ 6	0	0	0	0.3	0.03	0.03	0.03	Proposal of unlimited duration

**If more than one heading is affected by the proposal / initiative: NO**

• TOTAL operational appropriations	Commitments	(4)								
	Payments	(5)								
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)								
<b>TOTAL appropriations under HEADINGS 1 to 4 of the multiannual financial framework (Reference amount)</b>	Commitments	=4+ 6								
	Payments	=5+ 6								

<b>Heading of multiannual financial framework:</b>	<b>5</b>	" Administrative expenditure "
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		Year N	Year N+1	Year N+2	Year N+3	... enter as many years as necessary to show the duration of the impact (see point 1.6)			<b>TOTAL</b>
<b>DG: ENTR</b>									
• Human resources		0.635	0.635	0.635	0.635	0.635	0.635	0.635	Proposal of unlimited duration
• Other administrative expenditure		0.092	0.092	0.092	0.092	0.092	0.092	0.092	Proposal of unlimited duration
<b>TOTAL DG ENTR</b>	Appropriations	0.727	0.727	0.727	0.727	0.727	0.727	0.727	Proposal of unlimited duration

<b>TOTAL appropriations under HEADING 5 of the multiannual financial framework</b>	(Total commitments = Total payments)								
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3.2.2. *Estimated impact on operational appropriations*

- The proposal/initiative does not require the use of operational appropriations
- The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to 3 decimal places)

Indicate objectives and outputs  ↓			Year N	Year N+1	Year N+2	Year N+3	... enter as many years as necessary to show the duration of the impact (see point 1.6)								TOTAL			
	OUTPUTS																	
	Type of output <sup>48</sup>	Average cost of the output	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Total number of outputs	Total cost
SPECIFIC OBJECTIVE No 1: <b>To continually renew existing internal market acquis and propose new legislative or non-legislative action whenever appropriate</b> <sup>49</sup> ...																		
Delivery of an IT database for product registration								1	0.3									

<sup>48</sup> Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

<sup>49</sup> As described in Section 1.4.2. "Specific objective(s)..."

Maintenance of an IT database for product registration										1	0.03	1	0.03	1	0.03		Proposal of unlimited duration
- Output																	
Sub-total for specific objective N°1																	
SPECIFIC OBJECTIVE No 2...																	
- Output																	
Sub-total for specific objective N°2																	
<b>TOTAL COST</b>									0.3		0.03		0.03		0.03		Proposal of unlimited duration



### 3.2.3. Estimated impact on appropriations of an administrative nature

#### 3.2.3.1. Summary

- The proposal/initiative does not require the use of administrative appropriations
- The proposal/initiative requires the use of administrative appropriations, as explained below:

EUR million (to 3 decimal places)

	Year N <sup>50</sup>	Year N+1	Year N+2	Year N+3	... enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL
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<b>HEADING 5 of the multiannual financial framework</b>								
Human resources	0.635	0.635	0.635	0.635	0.635	0.635	0.635	<i>Proposal of unlimited duration</i>
Other administrative expenditure	0.092	0.092	0.092	0.092	0.092	0.092	0.092	
<b>Subtotal HEADING 5 of the multiannual financial framework</b>	<b>0.727</b>	<b>0.727</b>	<b>0.727</b>	<b>0.727</b>	<b>0.727</b>	<b>0.727</b>	<b>0.727</b>	<i>Proposal of unlimited duration</i>

<b>Outside HEADING 5<sup>51</sup> of the multiannual financial framework</b>								
Human resources								
Other expenditure of an administrative nature								
<b>Subtotal outside HEADING 5 of the multiannual financial framework</b>								

<b>TOTAL</b>	<b>0.727</b>	<b>0.727</b>	<b>0.727</b>	<b>0.727</b>	<b>0.727</b>	<b>0.727</b>	<b>0.727</b>	<i>Proposal of unlimited duration</i>
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<sup>50</sup> Year N is the year in which implementation of the proposal/initiative starts.

<sup>51</sup> Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

### 3.2.3.2. Estimated requirements of human resources

- The proposal/initiative does not require the use of human resources
- The proposal/initiative requires the use of human resources, as explained below:

*Estimate to be expressed in full amounts (or at most to one decimal place)*

	Year N	Year N+1	Year N+2	Year N+3	... enter as many years as necessary to show the duration of the impact (see point 1.6)		
<b>• Establishment plan posts (officials and temporary agents)</b>							
02 01 01 01 (Headquarters and Commission's Representation Offices)	5	5	5	5	5	5	5
XX 01 01 02 (Delegations)							
XX 01 05 01 (Indirect research)							
10 01 05 01 (Direct research)							
<b>• External personnel (in Full Time Equivalent unit: FTE)<sup>52</sup></b>							
XX 01 02 01 (CA, INT, SNE from the "global envelope")							
XX 01 02 02 (CA, INT, JED, LA and SNE in the delegations)							
<b>XX 01 04 yy</b> <sup>53</sup>	- at Headquarters <sup>54</sup>						
	- in delegations						
<b>XX 01 05 02</b> (CA, INT, SNE - Indirect research)							
10 01 05 02 (CA, INT, SNE - Direct research)							
Other budget lines (specify)							
<b>TOTAL</b>	<b>5</b>	<b>5</b>	<b>5</b>	<b>5</b>	<b>5</b>	<b>5</b>	<b>5</b>

**XX** is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary agents	1 official as desk officer of the Directive, 3 officials in charge of specific areas: legal issues, secretariat of the Standing Committee, communication, coordination with DG Information Society on Spectrum Policy, assessment of Member States notifications of
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<sup>52</sup> CA= Contract Agent; INT= agency staff ("*Intérimaire*"); JED= "*Jeune Expert en Délégation*" (Young Experts in Delegations); LA= Local Agent; SNE= Seconded National Expert;

<sup>53</sup> Under the ceiling for external personnel from operational appropriations (former "BA" lines).

<sup>54</sup> Essentially for Structural Funds, European Agricultural Fund for Rural Development (EAFRD) and European Fisheries Fund (EFF).

	relevant technical regulations, coordination of enforcement by market surveillance authorities, screening of legislation by EU candidate/associated countries, support to DG Trade on negotiations with third countries -1 official as secretary of the team and responsible for logistics
External personnel	

3.2.4. *Compatibility with the current multiannual financial framework*

- Proposal/initiative is compatible the current multiannual financial framework: all measures or actions included in this Directive are consistent and compatible with the current and the next multiannual financial framework (2014 to 2020) as proposed by the Commission.
- Proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts.

- Proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework<sup>55</sup>.

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.2.5. *Third-party contributions*

- The proposal/initiative does not provide for co-financing by third parties
- The proposal/initiative provides for the co-financing estimated below:

Appropriations in EUR million (to 3 decimal places)

	Year N	Year N+1	Year N+2	Year N+3	... enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
<i>Specify the co-financing body</i>								
TOTAL appropriations cofinanced								

**3.3. Estimated impact on revenue**

- Proposal/initiative has no financial impact on revenue.
- Proposal/initiative has the following financial impact:
  - on own resources
  - on miscellaneous revenue

EUR million (to 3 decimal places)

Budget revenue line:	Appropriation	Impact of the proposal/initiative <sup>56</sup>
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<sup>55</sup> See points 19 and 24 of the Interinstitutional Agreement.

	s available for the ongoing budget year	Year N	Year N+1	Year N+2	Year N+3	... insert as many columns as necessary in order to reflect the duration of the impact (see point 1.6)		
Article .....								

For miscellaneous assigned revenue, specify the budget expenditure line(s) affected.

Specify the method for calculating the impact on revenue.

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<sup>56</sup> As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25% for collection costs.