

# THE GOVERNMENT OF ROMANIA DECISION

# on electromagnetic compatibility

On grounds of the provisions of the Art. 108 of the Constitution of Romania, republished, of art. 22 paragraph (1¹) of the Government Ordinance no. 111/2011 on the electronic communications, approved with amendments and completions, by Law no. 140/2012, with subsequent amendments and completions, as well as of art. II of Government Ordinance no. 8/2012 amending the Government Ordinance no. 20/2010 on the establishment of some measurements for the harmonized enforcement of the European Union legislation which harmonizes the rules on products marketing, approved with amendments and completions by Law no. 55/2015,

# Romanian Government adopts the present decision

# Chapter I

#### General provisions

- **Art. 1.** (1) The subject matter of the present decision is to lay down:
- a) electromagnetic compatibility equipment requirements defined in art. 2 paragraph (1) point 5;
- b) conditions for placing on the market, making available on the market and/or putting into service of equipment defined in art. 2 paragraph (1) point 5;
  - c) conditions and requirements in order to notify the conformity assessment bodies.
- (2) Equipment, in accordance with their definition in art. 2 paragraph (1) point 5 below, shall comply with the essential requirements under Annex no. 1 hereto.
  - (3) The present decision shall not apply to:
- a) equipment regulated by the Directive 2014/53/EU of the European Parliament and of the Council, as of 16 April 2014 on the harmonisation of the laws of the Member States

relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC:

- b) products, parts and appliances referred to in 216/2008/EC Regulation of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and the establishing of an European Aviation Safety Agency and repealing the Directive 91/670/EEC of the Council, of the Regulation (EC) no. 1592/2002 and of the Directive 2004/36/EC, amended by Regulation (EC) no. 1108/2009 of the European Parliament and of the Council of 21 October 2009;
- c) radio equipment used by radio amateurs, as used by the rules adopted under the Constitution and Convention of the International Telecommunication Union signed in Geneva and ratified by Law no. 76/1993 ratifying the Constitution and Convention of the International Telecommunication Union signed in Geneva on 22 December 1992, with subsequent amendments, unless they are not made available on the market; radio kits for assembly and use by radio amateurs and the equipment modified by and for the use of radio amateurs shall be regarded as not being available on the market;
- d) equipment which, by its very nature and physical characteristics, cannot generate or contribute to generating electromagnetic emissions which exceed a level allowing radio and electronic communications and other equipment to operate as intended, and having no unacceptable degradation of service in the presence of electromagnetic disturbances which normally result during their use as intended;
- e) custom-built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.
- (4) This decision is the common regulatory framework law in the field of electromagnetic compatibility and does not preclude national or European Union legislation regulating the safety of equipment.
  - **Art. 2.** (1) For the purposes of this decision, the following definitions apply:
- 1. accreditation within the meaning of art. 2 point 10 of the 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 products marketing and repealing Regulation (EEC) no. 339/93;
- 2. apparatus any finished appliance or combination thereof made available on the market as a single functional unit, intended for the end-user and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance;

- 3. *electromagnetic compatibility* the ability of equipment to function satisfactorily in its electromagnetic environment without causing unacceptable electromagnetic disturbances themselves to other equipment in that environment;
- 4. *distributor* any natural or legal person in the distribution and supply chain, other than the manufacturer or the importer, who makes radio equipment available on the market;
  - 5. *equipment* any radio equipment or fixed installation;
- 6. *conformity assessment* the process which examines how the essential requirements provisioned in this decision relating to an apparatus were fulfilled;
- 7. *importer* any natural or legal person, established within the Union who places radio equipment from a third country on the Union market;
- 8. *immunity* the ability of equipment to perform as intended without degradation thereof in the presence of electromagnetic disturbances;
- 9. *fixed installation* a specific combination of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently in a predetermined location;
- 10. placing on the market means the first making available of the apparatus on the Union:
- 11. Union harmonisation legislation in accordance with the definition provided by art. 2 point 21 of the Regulation (EC) no. 765/2008;
- 12. *CE marking* means a marking by which the manufacturer indicates that the apparatus is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;
- 13. *electromagnetic environment* all electromagnetic phenomena observable in a given location
  - 14. safety reasons reasons of protection of human life or property;
- 15. *economic operators* means the manufacturer, the authorised representative, the importer and the distributor;
- 16. conformity assessment body means a body that performs a public service under the public power, consisting of conformity assessment activities including calibration, testing, certification and inspection;
- 17. *national accreditation body* means national accreditation body as defined in point 11 of Art. 2 of Regulation (EC) no. 765/2008;

- 18. harmful interference any electromagnetic phenomenon which may degrade the performance of equipment, such as, but not limited to electromagnetic noise, an unwanted signal or a change in the propagation medium itself;
- 19. *manufacturer* means any natural or legal person who manufactures an apparatus or has radio equipment designed or manufactured, and markets that equipment under his name or trade mark;
- 20. making available on the market means any supply of an apparatus for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- 21. *putting into service* means the first use of radio equipment in the Union by its end-user:
- 22. *recall* means any measure aimed at achieving the return of an apparatus that has already been made available to the end-user;
- 23. authorised representative means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- 24. *withdrawal* means any measure aimed at preventing an apparatus in the supply and distribution chain from being made available on the market;
- 25. *technical specification* means a document that prescribes technical requirements to be fulfilled by radio equipment;
- 26. harmonised standard means harmonised standard as defined in art. 2 point 1 letter c) of Regulation (EU) no. 1.025/2012 of the of the European Parliament and of the Council of 25 October 2012 on European standardization, with amendments to Directives 89/686/EEC and 93/15/CEE of the Council and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and Decision no. 1673/2006/EC of the European Parliament and of the Council;
- 27. *traceability* identification of persons responsible for the manufacturing, import, intra-Community purchasing, marketing and placing on the market of an apparatus.
  - (2) It is considered as an apparatus according to paragraph (1) point. 2:
- a) components or sub-assemblies intended for incorporation into an apparatus by the end-user, which are liable to generate electromagnetic disturbances or which is liable to be affected by such disturbances;
- b) mobile installations defined as a combination of apparatus and, where applicable, other devices, intended to move and function in different locations.

- (3) In this decision there are applicable as well, definitions provided by Regulation (EC) no. 765/2008.
- Art. 3. (1) An apparatus can be made available on the market by operators, put into service and/or used only if they comply with the requirements of this decision, when properly installed, maintained and used in accordance with their destination.
- (2) Notwithstanding the provisions of paragraph (1) display and/or demonstration, temporary, at trade fairs, exhibitions or similar events of equipment which does not comply with this Directive, provided that a visible sign clearly indicates that such equipment may not be made available on the market and/or put into service until it has been brought into conformity with this Directive.
- (3) Demonstration may only take place provided that adequate measures have been taken to avoid electromagnetic disturbances, under the rules settled by National Authority for Management and Regulations in Communications in Romania, hereinafter referred to as *ANCOM*.
- **Art. 4.** Making available on the market, putting into service or use of equipment which meet the requirements of this decision cannot be prohibited by ANCOM, for reasons relating to electromagnetic compatibility.
- **Art. 5.** (1) ANCOM may apply, by decision, measures relating to the putting into service or use of equipment:
- a) measures for resolving a situation of existing or predicted electromagnetic compatibility at one location;
- b) measures taken for safety reasons, to protect public electronic communications networks, the transmitters or receivers, when used for safety reasons in defined situations on the use of radio frequencies.
- (2) ANCOM informs the Commission and the similar authorities for the relevant area in the Member States on special measures provided in paragraph (1).
- (3) The information provided in paragraph (2) is done outside the exchange of information on standards and technical regulations made pursuant to Government Decision no. 1016/2004 on measures for the organization and exchange of information on technical standards and regulations and of rules on information society services between Romania and the Member States and the European Commission, with subsequent amendments and completions.

#### Chapter II

#### **OBLIGATIONS OF ECONOMIC OPERATORS**

# **Art. 6.** – Obligations of the manufacturers:

- a) When placing their apparatus on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential requirements set out in Annex no. 1:
- b) Manufacturers shall draw up the technical documentation referred to in Annex no. 2 or Annex no. 3 and carry out the relevant conformity assessment procedure referred to in art. 13 or have it carried out by the authorised representative;
- c) Where compliance of apparatus with the applicable requirements has been demonstrated by that procedure specified in art. 13, manufacturers shall draw up an EU declaration of conformity in accordance with art. 14 and affix the CE marking;
- d) Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the apparatus has been placed on the market;
- e) Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive;
- f) Changes in apparatus design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of apparatus is declared shall be adequately taken into account;
- g) Manufacturers shall ensure that apparatus which they have placed on the market bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the apparatus does not allow it, that the required information is provided on the packaging or in a document accompanying the apparatus;
- h) Manufacturers shall indicate, on the apparatus, their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the apparatus; the address shall indicate a single point at which the manufacturer can be contacted, and the contact details shall be clear, understandable, intelligible, relevant and in Romanian;
- i) Manufacturers shall ensure that the apparatus is accompanied by instructions and the information referred to in Art. 16 in Romanian; such instructions and information, as well as any labelling, shall be clear, understandable, intelligible and relevant;
- j) Manufacturers who consider or have reason to believe that an apparatus which they have placed on the market is not in conformity with this Directive shall immediately

take the corrective measures necessary to bring that apparatus into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the apparatus presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the apparatus available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;

- k) where the apparatus presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the apparatus available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;
- I) Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the apparatus with this Directive, in Romanian;
- m) They shall cooperate with those authorities, at their request, on any action taken to eliminate the risks posed by apparatus which they have placed on the market;
- n) The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the apparatus with the essential requirements of this Directive or the conditions for validity of that certificate.
- **Art. 7.** (1) A manufacturer may, by a written mandate, appoint an authorised representative.
- (2) The obligations laid down in Art. 6 letter a) and the obligation to draw up technical documentation referred to in Art. 6 letter b) shall not form part of the authorised representative's mandate.
- (3) The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in a mandate. The mandate shall allow the authorised representative to do at least the following:
- 1. The manufacturer shall draw up a written EU declaration of conformity for each apparatus model and keep it at the disposal of the national authorities for 10 years after the apparatus has been placed on the market.
- 2. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form, necessary to demonstrate the conformity of the apparatus;
- 3. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by apparatus which are under the obligations specified in the mandate of the authorized representative.

## **Art. 8.** – Obligations of importers:

- 1. Importers shall place only compliant apparatus on the market;
- 2. Before placing apparatus on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in art. 14 has been carried out by the manufacturer;
- 3. They shall ensure that the manufacturer has drawn up the technical documentation, that the apparatus bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in art. 6 letters g)-h);
- 4. There an importer considers or has reason to believe that apparatus is not in conformity with the essential requirements set out in Annex I, he shall not place the apparatus on the market until it has been brought into conformity and for safety reasons, shall inform the manufacturer and the market surveillance and control authorities to that effect;
- 5. Importers shall indicate on the apparatus their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the apparatus; the contact details shall be clear, understandable, intelligible, relevant and in Romanian;
- 6. Importers shall ensure that the apparatus is accompanied by instructions and the information referred to in Art. 16; instructions and information shall be in Romanian, accessible, intelligible, correct and complete;
- 7. Importers shall ensure that, while apparatus is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I;
- 8. Importers who consider or have reason to believe that apparatus which they have made available on the market is not in conformity with this Directive shall take immediately any corrective measures necessary to bring that apparatus into conformity, to withdraw it or recall it, if appropriate;
- 9. Furthermore, where the apparatus presents a risk that may affect its operation or operation of other equipment, importers shall immediately inform the competent national authorities of the Member States in which they made the apparatus available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken;
- 10. Importers shall, for 10 years after the apparatus 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;

- 11. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form, necessary to demonstrate the conformity of the apparatus; information shall be clear, understandable, intelligible, relevant and in Romanian;
- 12. They shall cooperate with the surveillance and control authorities, at their request, on any action taken to eliminate the risks posed by apparatus which they have placed on the market.

#### **Art. 9.** – Obligations of distributors:

- 1. When making apparatus available on the market distributors shall act with due care in relation to the requirements of this Directive.
- 2. Before making apparatus available on the market distributors shall verify that the apparatus bears the EC marking, that it is accompanied by the required documents and by instructions and the information referred to in art. 16, drawn up in Romanian;
- 3. They shall ensure that the manufacturer and the importer have complied with the requirements set out in art. 6 letters g)-h) and art. 8 point 5;
- 4. Where a distributor considers or has reason to believe that apparatus is not in conformity with the essential requirements set out in Annex I, he shall not make the apparatus available on the market until it has been brought into conformity and for safety reasons, shall inform the manufacturer and the market surveillance and control authorities to that effect;
- 5. Distributors shall ensure that, while apparatus is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I;
- 6. Distributors who consider or have reason to believe that apparatus which they have made available on the market is not in conformity with this Directive shall take immediately any corrective measures necessary to bring that apparatus into conformity, to withdraw it or recall it, if appropriate;
- 7. Furthermore, where the apparatus presents a risk that may affect its operation or operation of other equipment, distributors shall immediately inform the competent national authorities of the Member States in which they made the apparatus available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

- 8. Distributors shall, further to a reasoned request from the surveillance and control authorities, provide them with all the information and documentation in paper or electronic form, necessary to demonstrate the conformity of the apparatus; information shall be clear, understandable, intelligible, relevant and in Romanian;
- 9. They shall cooperate with the surveillance and control authorities, at there request, on any action taken to eliminate the risks posed by apparatus which they have made available on the market.
- **Art. 10.** 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 art. 6, where he places apparatus on the market under his name or trade mark or modifies an apparatus already placed on the market in such a way that compliance with this Directive may be affected.
- **Art. 11.** (1) Economic operators shall, on request, identify the following to the market surveillance authorities:
  - a) any economic operator who has supplied them with apparatus;
  - b) any economic operator to whom they have supplied apparatus.
- (2) Economic operators shall be able to keep and present the information referred to in the first paragraph for 10 years after they have been supplied with the apparatus or after they have supplied the apparatus.

#### Chapter III

#### **CONFORMITY OF EQUIPMENT**

- **Art. 12.** (1) 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 set out in Annex I, covered by those standards or parts thereof.
- (2) The harmonized standards set out at paragraph (1) shall not be compulsory, other conformity assessment procedures being allowed.
- (3) Whether it is considered the a harmonised standard set out at paragraph (1) not fully meets the essential requirements set out in Annex no.1, ANCOM shall inform the Standing Committee provisioned in art. 13 paragraph (1) of the Government Decision no. 1016/2004, with subsequent amendments and completions.
- (4) In the situation provisioned at paragraph (3), ANCOM will specify with arguments in his information, the reasons on which it is based, too.

- **Art. 13.** (1) Compliance of apparatus with the essential requirements set out in Annex I shall be demonstrated by means of either of the following conformity assessment procedures:
  - a) internal production control set out in Annex 2;
- b) EU type examination that is followed by Conformity to type based on internal production control set out in Annex 3.
- (2) The manufacturer may choose to restrict the application of the procedure referred to in paragraph (1) letter (b) of the first paragraph to some aspects of the essential requirements, provided that for the other aspects of the essential requirements the procedure referred to in paragraph (1) letter a) is applied.
- **Art. 14.** (1) EU declaration of conformity shall state, as it is drawn up by the manufacturer, that the fulfilment of the essential requirements set out in Annex I has been demonstrated.
- (2) EU declaration of conformity shall have the model structure set out in Annex 4, shall contain the elements specified in the relevant modules set out in Annexes 2 and 3 and shall be continuously updated.
  - (3) EU declaration of conformity is drawn up in Romanian.
- (4) Where apparatus is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up by the manufacturer in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.
- (5) By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the apparatus with the requirements laid down in this Directive.
- **Art. 15.** (1) The CE marking shall be subject to the general principles set out in Art. 30 of Regulation (EC) no. 765/2008.
  - (2) The EC marking shall be affixed before the apparatus is placed on the market.
- (3) The EC marking shall be affixed visibly, legibly and indelibly to the apparatus or to its data plate. Where that is not possible or not warranted on account of the nature of the apparatus, it shall be affixed to the packaging and to the accompanying documents.
- **Art. 16.** (1) Apparatus shall be accompanied by information on any specific precautions that must be taken when the apparatus is assembled, installed, maintained or used, in order to ensure that, when put into service or make available on the market, the apparatus is in conformity with the essential requirements set out in point 1 of Annex 1.

- (2) Apparatus for which compliance with the essential requirements set out in point 1 of Annex 1 is not ensured in residential areas shall be accompanied by a clear indication of such restriction of use, where appropriate also on the packaging.
- (3) The information required to enable apparatus to be used in accordance with the intended purpose of the apparatus shall be included in the instructions accompanying the apparatus.
- (4) All information in paragraph (1) is provided to end-users as a user manual in Romanian in paper. Information may also be provided in electronic format only after end-user' consent is received.
- **Art. 17.** (1) Apparatus which has been made available on the market and which may be incorporated into a fixed installation shall be subject to all provisions set out in this Directive.
- (2) However, the requirements of art. 1 paragraph (2), art. 6-11 and art. 13-16 shall not be compulsory in the case of apparatus which is intended for incorporation into a particular fixed installation and is otherwise not made available on the market.
  - (3) For the apparatus specified in paragraph (2), the accompanying documents:
- a) shall identify the fixed installation and its electromagnetic compatibility characteristics;
- b) shall indicate the precautions to be taken for the incorporation of the apparatus into the fixed installation in order not to compromise the conformity of that installation;
  - c) shall also include the information referred to in 6 letter g)-h) and art. 8 point 5.
- (4) The good engineering practices referred to in point 2 of Annex 1 shall be documented and the documentation shall be held by the person or persons responsible at the disposal of the surveillance and control national authorities for inspection for as long as the fixed installation is in operation.
- (5) Where there are indications of non-compliance of the fixed installation, in particular, where there are complaints about disturbances being generated by the installation, the surveillance and control authorities of the Member State concerned:
  - a) may request evidence and/or information of compliance of the fixed installation;
  - b) initiate an evaluation of conformity;
- c) impose appropriate measures to bring the fixed installation into compliance with the essential requirements where non-compliance is established.
- (6) Where non-compliance of the fixed installation is established, the surveillance and control authorities shall impose appropriate measures to bring the fixed installation into

compliance with the essential requirements set out in Annex 1, in a certain time, as the case may be.

- (7) Member States shall set out the necessary provisions for identifying the person or persons responsible for the establishment of compliance of a fixed installation with the relevant essential requirements, based on scenarios that take into account the nature and locations of fixed installations.
- (8) Where the fixed installation is not brought into conformity to the conditions provisioned at paragraph (6), the surveillance and market control authorities dispose the application of the main sanctions for contravention and the complementary sanction provisioned at art. 45, paragraph (1), letter d).

## **Chapter IV**

#### NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

- **Art. 18.** (1) Ministry of Communications and Information Society hereinafter referred to MCSI, is the notifying authority and 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, in electromagnetic compatibility.
- (2) MCSI shall notify the European Commission and other relevant authorities of the Member States the authorised bodies to perform the conformity assessment.
- (3) MCSI informs the European Commission on carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, as well as on any completions, as the case may be.
  - **Art. 19. –** (1) MCSI, as the notifying authority shall:
  - a) ensure that no conflict of interest with conformity assessment bodies occurs.
- b) safeguard the objectivity and impartiality of its activities on assessment, notifying, appointment and monitoring the conformity assessment bodies;
- c) that each decision relating to notification of a conformity assessment body is taken on the grounds of the evidence or results of the analyses performed by competent persons with training or qualifications required in electronic communications, electronics or their equivalents.
- d) not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.
- e) safeguard the confidentiality of the information it obtains in the process of assessment and notification of conformity assessment bodies and their monitoring

- f) have a sufficient number of competent personnel at its disposal holding training or qualifications needed to verify the proper performance of the requirements in Art. 20, as well as an adequate number of persons for the performance of its attributions. (2) Provisions established in paragraph (1) letter a) are properly subject to the provisions of Law no. 161/2003 on measures to ensure transparency in the exercise of public dignities, public functions and in business, prevent and punish corruption, with subsequent amendments and completions.
- **Art. 20.** (1) In the notification, the conformity assessment body meets the following requirements:
  - 1. are established by law and have legal personality;
- 2. there shall be a third-party body independent of the organisation or the apparatus 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 apparatus which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body;
- 3. does not act as the manufacturer, supplier, fitter, purchaser, owner, user or in maintenance of those apparatus or represents the parties engaged in activities of their conformity assessment; this requirement extends to its top level management and the personnel responsible for carrying out the conformity assessment tasks; this shall not preclude the use of assessed apparatus that are necessary for the operations of the conformity assessment body or the use of such apparatus for personal purposes;
- 4. 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 those apparatus it assesses, or represent the parties engaged in those activities and this shall in particular apply to consultancy services;
- 5. a conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not engage in any activity that affect their impartiality or professional integrity with regard to conformity assessment activities for which they are notified and this requirement shall in particular apply to consultancy services;
- 6. shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities, as the case may be;

- 7. shall carry out the conformity assessment activities with 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; this requirement extends as well, to the personnel responsible for carrying out the conformity assessment tasks;
- 8. shall be capable of carrying out all the conformity assessment tasks assigned to it by annex 3 and 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;
- 9. at all times and for each conformity assessment procedure and each kind or category of apparatus in relation to which it has been notified, 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/another 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 the apparatus technology in question and the mass or serial nature of the production process.
- 10. shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities;
- 11. shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group;
- 12. the personnel responsible for carrying out conformity assessment tasks shall meet the requirements in paragraph (2);
- 13. the impartiality of the top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed and their remuneration

shall not depend on the number of assessments carried out or on the results of those assessments:

- 14. shall take out liability insurance for the performed activities.
- (2) The personnel responsible for carrying out conformity assessment tasks shall have the following:
- a) a sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- b) a 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 annex 1, of the applicable harmonised standards provided in art. 12 paragraph (1) and of the relevant provisions of Union harmonisation legislation and of national legislation;
- d) the necessary ability to draw up EU type examination certificates, records and reports demonstrating that assessments have been carried out;
- e) shall observe professional secrecy with regard to all information obtained in carrying out their tasks under annex 3 or any provision of national law giving effect to it, except in relation to the competent authorities of the Member States in which its activities are carried out; intellectual proprietary rights shall be protected.
- **Art. 21.** –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 art. 20 in so far as the applicable harmonised standards cover those requirements.
- **Art. 22.** (1) A conformity assessment body may, with the agreement of his client, decide to subcontract specific tasks connected with conformity assessment or has recourse to a subsidiary.
- (2) In the case under paragraph (1), the conformity assessment body shall ensure the following:
- a) that the subcontractor or the subsidiary meets the requirements set out in Art. 20 and shall inform MCSI accordingly;
- b) shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established:
- c) shall keep at the disposal of MCSI the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under annex 3.

- **Art. 23.** (1) The application for notification of conformity assessment body submitted at MCSI shall be accompanied by:
- a) a description of the conformity assessment activities, the conformity assessment module or modules and the apparatus for which that body claims to be competent;
- b) an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in art. 20.
- (2) Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide MCSI with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Art. 20.
- **Art. 24.** (1) MCSI may notify only conformity assessment bodies which have satisfied the requirements laid down in Art. 20.
- (2) The notification pursuant to paragraph (1) is forwarded to the Commission and the other relevant authorities from the Member States using the electronic notification tool developed and managed by the Commission.
  - (3) The notification shall include:
- a) full details of the conformity assessment activities, the conformity assessment module or modules and apparatus concerned and the relevant attestation of competence of the conformity assessment body;
- b) where a notification is not based on an accreditation certificate, the 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 Art. 20.
- (4) 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:
  - a) two weeks of a notification where an accreditation certificate is used;
  - b) two month in the case pursuant to paragraph (3) letter b).
- (5) MCSI shall notify the Commission and the other relevant authorities from the Member States of any subsequent relevant changes to the notification under paragraph (1)-(4).
- **Art. 25.** (1) Where MCSI has ascertained, following the regular monitoring, or has been informed that a notified body no longer meets the requirements laid down in art. 20, or that it is failing to fulfil its obligations, it shall restrict, suspend or withdraw notification as

appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations.

- (2) In the event of any disposition of the measures referred to in paragraph (1), MCSI shall immediately inform the Commission and the relevant authorities from the Member States accordingly.
- (3) In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, MCSI shall take all appropriate steps to ensure that the files of that body are:
  - a) either processed by another notified body
- b) or kept available for MCSI, ANCOM and/or National Authority for Consumer Protection hereinafter referred to as ANPC at their request;
- (4) The measures provided in paragraph (1) shall be ordered by the Minister of Communications and Information Society, which will state the same time, the type of the measure from those referred to in paragraph (1) and its/their length. An appeal procedure against the order can be taken in court under Administrative Court Proceedings Law no. 554/2004 with subsequent amendments and completions.
- Art. 26. If an investigation by the European Commission take place, according to Art. 31 paragraph (1) of Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the approximation of the laws of the Member States relating to electromagnetic compatibility, 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, MCSI will send on request information on the basis of notification or the maintenance of the competence of the notified body concerned.
- **Art. 27.** (1) Notified bodies carry out conformity assessments according to conformity assessment procedures set out in annex 3, proportionate, taking into account the criteria in paragraph (2).
  - (2) Conformity assessment bodies shall perform their activities:
- a) taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the apparatus technology in question and the mass or serial nature of the production process;
- b) respecting nevertheless the degree of rigour and the level of protection required for the compliance of the apparatus with this Directive;
- c) requiring to manufacturer to take appropriate corrective measures and not issuing a certificate where it finds that the essential requirements set out in annex 1,

corresponding harmonised standards, provisioned in art. 12 paragraph (1) or other suitable technical specifications have not been met by a manufacturer;

- d) requiring the manufacturer to take appropriate corrective measures and suspending or withdrawing the certificate, if necessary, where, in the course of the monitoring of conformity following the issue of a certificate, finds that an apparatus no longer complies.
- (3) Where corrective measures are not taken, pursuant to paragraph (2) letter d), or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificate, as appropriate. In this situation, the notified body shall inform MCSI, ANCOM and/or ANPC, as the case may be.
- **Art. 28.** –An appeal procedure against decisions of the conformity assessment bodies can be taken in court under Administrative Court Proceedings Law no. 554/2004 with subsequent amendments and completions.
- **Art. 29.** (1) The notified conformity assessment bodies shall inform MCSI of the following:
- a) any refusal, restriction, suspension or withdrawal of the conformity assessments certificates;
  - b) any circumstances affecting the scope of or conditions for notification;
- c) any request for information which they have received from market surveillance and control authorities regarding conformity assessment activities;
- d) conformity assessment activities performed within the scope of their notification and any other activity performed, including cross border activities and subcontracting.
- (2) The information provided in paragraph (1) letter d) is made available at the request of MCSI.
- (3) The notified conformity assessment bodies are under the obligation of providing the other bodies notified under EU, carrying out similar conformity assessment activities covering the same apparatus with relevant information on issues relating to negative and, on request, positive conformity assessment results.
- **Art. 30.** –Notified conformity assessment bodies are required to participate, directly or through a designated representative, at sectorial group of notified bodies coordinated by the European Commission.

## **Chapter V**

#### **Market Surveillance and Control**

- **Art. 31.** (1) Market surveillance and control in order to ensure compliance with this decision and the obligations of economic operators deriving from EU regulations and to identify traceability of equipment in the supply chain is conducted by ANCOM and ANPC, hereinafter referred to as market surveillance and control authorities acting by specialized personnel or specialized personnel authorized for this purpose.
- (2) ANPC surveillance and control activity refers to the compliance of equipment belonging to consumer under Government Ordinance no. 21/1992 on consumer protection, republished, with subsequent amendments and completions.
- (3) ANCOM and ANPC shall organise and carry out the surveillance and control activity in accordance with the provisions of art. 15 paragraph (3) and art. 16-29 of Regulation (EC) No. 765/2008.
- (4) In view of enforcing the present decision, ANCOM and ANPC may conclude a collaboration protocol aimed at ensuring the exchange of information in order to improve the non-compliant product identification measures and to carry out the necessary actions for the removal of such products.
- **Art. 32.** The end-user, legal or natural person, has the obligation to communicate, following the reasoned request of the surveillance and control authorities personnel, the name of importer or the distributor of equipment, as the case may be.
- **Art. 33.** (1) At any time, ANCOM or ANPC may take the reasoned decision to perform technical tests in order to verify the conformity of the apparatus with the applicable essential requirements, based on the relevant standards or technical specifications mentioned in the EC declaration of conformity. If the EU declaration of conformity standards or specifications shall be referred inappropriately or are missing or the EU declaration of conformity does not exist, ANCOM performs technical tests by the harmonised standards referred to in art. 12 paragraph (1).
- (2) For the purpose of performing the tests as per paragraph (1), the manufacturer, his authorised representative established within the European Union, the importer or the distributor, as the case may be, has the obligation to allow the control personnel to retain, based on an official report, for free, an adequate number of samples of the apparatus to be submitted to testing. Retain of samples can be ordered on the apparatus at the end-user, legal or natural person, if there are sufficient indications that the apparatus produce electromagnetic interference.

- (3) The costs resulting from performing the tests identified under paragraph (1) shall be borne by ANCOM or ANPC, from the approved budget intended as such.
- (4) Where the results of the tests show that the apparatus does not comply with the essential requirements, all costs resulting from the performance of the tests identified under paragraph (1) shall be fully borne by the manufacturer or by his authorised representative. Where the manufacturer or his authorised representative is not established on the Romanian territory, the costs shall be fully borne by the importer or the distributor, as the case may be.
- (5) Where the importer is not identifiable or the controlled person does not provide information likely to lead to his identification, the costs shall be borne by the controlled undertaking.
- (6) In case of costs borne by ANCOM, their individualization in view of establishing the amount to be recovered in accordance with the provisions under paragraph (4) or (5) above shall be made through a decision of the president of ANCOM, and the provisions or art. 14 paragraph (2) of Government Emergency Ordinance no. 22/2009 on the establishment of the National Authority for Management and Regulation in Communications, approved by Law no. 113/2010, with the subsequent amendments and completions, shall apply.
- (7) If the tests provisioned in paragraph (1) are performed in ANCOM own laboratory, the provisions of paragraph (4) and (5) shall not apply for the surveillance and control activities carried out by specialized personnel of ANCOM.
- **Art. 34.** (1) Subsequently to carrying out technical tests under art. 33, the apparatus shall be returned to the person from whom it was taken.
- (2) Where, due to technical tests, the apparatus is unusable or is destroyed for reasons of exclusive fault of the personnel who carried out technical tests, the equivalent costs of the apparatus shall be borne by the market surveillance and control authority that performed its monitoring.
- **Art. 35.** (1) If ANCOM or ANPC, as appropriate, considers that an apparatus involves a risk that can affect the public interest protected by the this decision, they shall make an assessment on the apparatus in question.
- (2) The assessment provisioned in paragraph (1) covers all the relevant requirements established by this decision.
- (3) It is the obligation of the relevant economic operators over which control actions are taken in the context of paragraph (1)-(2) to cooperate at the request of the market surveillance and control authority, if necessary, for that purpose.

- **Art. 36.** (1) Where, in the course of the evaluation referred to in accordance with art. 35, ANCOM or ANPC, as the case, find that the apparatus 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 actions to bring the apparatus into compliance with those requirements or to withdraw the apparatus from the market, and/or to recall it within a reasonable period, commensurate with the nature of the risk, as ANCOM or ANPC may prescribe.
- (2) In the situation provided in paragraph (1), ANCOM or ANPC, as the case, shall inform the relevant notified body on the measures taken, accordingly.
- (3) Art. 21 of Regulation (EC) no 765/2008 shall apply to the measures referred to in paragraph (1).
- (4) Corrective measures determined under paragraph (1) shall apply by a decision or by order, as appropriate.
- **Art. 37.** If ANCOM or ANPC, as appropriate, considers that non-compliance of the apparatus affects products which were or can be delivered in other Member States of the European Union, 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.
- **Art. 38.** The economic operator against whom the corrective measures provisioned under article 36 shall ensure that all corrective actions are taken in respect of all the apparatus concerned that it has made available on the market.
- **Art. 39.** (1) Where the relevant economic operator does not take adequate corrective measures set in accordance with art. 36 paragraph (1) and (4), ANCOM or ANPC, as the case, shall take any appropriate provisional measure to prohibit or restrict the apparatus's being made available on their national market or to withdraw the apparatus from that market or to recall it. Measures are established by decision or by order, as appropriate.
- (2) The market surveillance and control authority that initiated the measures shall inform the Commission and the other Member States, without delay, of those measures.
- (3) The information referred to in paragraph (2) shall include at least the following details:
  - a) the data necessary for the identification of the non-compliant apparatus;
  - b) the origin of the apparatus;
  - c) the nature of the noncompliance alleged and the risk involved;
  - d) the nature and duration of the national measures taken;

- e) the arguments put forward by the relevant economic operator;
- f) whether the non-compliance is due to failure of the apparatus to meet the requirements relating to aspects of public interest protection covered by this Directive;
- g) whether the non-compliance is due to shortcomings in the harmonised standards referred to in art. 12 paragraph (1), conferring a presumption of conformity.
- (4) The measures provisioned under paragraph (1) shall be deemed justified where, within three months no objection has been raised by either a Member State or the Commission in respect of the provisional measures taken.
- (5) If the European Commission adopts an act establishing that the provisional measure or measures are considered unjustified, the market surveillance and control authorities concerned shall withdraw that measures.
- (6) Where the measures are considered justified, the market surveillance and control authorities shall provide that measures provisioned in paragraph (1) should be applied permanently.
- **Art. 40.** –Without excluding measures ordered under art. 35-39, ANCOM or ANPC shall require the relevant economic operator to put an end to the non-compliance concerned, within 15 working days, if the following findings:
- a) the CE marking has been affixed in violation of art. 30 of Regulation (EC) No 765/2008 or of art. 15 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) the information referred to in art. 6 letter h) or art. 8 point 5) is absent, false or incomplete;
- g) any other administrative requirements provided for in art. 6 or art. 8 are not fulfilled as the case.
- **Art. 41.** (1) In the implementation of this Decision, authorized personnel of ANCOM or ANPC, as the case, shall require economic operators or any end user natural or legal person any information necessary to exercise powers relating to market surveillance.
- (2) Persons provided in paragraph (1) shall make the information available to ANCOM or ANPC, as the case, within the term and conditions set by these authorities.
- **Art. 42.** –ANCOM or ANPC personnel, as the case, may decide to apply seals on equipment or batches of apparatus on which measures have been taken under this decision.

## **Chapter VI**

#### **Sanctions**

- **Art. 43.** (1) The following deeds shall be deemed contraventions; insofar they are not committed under such conditions that might cause them to be considered, under the criminal law, as offences:
- 1) the producer or importer placed on the market equipment that is not compliant with the essential requirements provisioned in annex 1;
- 2) failure by the manufacturer to draw up the technical specifications, provisioned under annex no. 2 or no. 3, in accordance with art. 6 letter b), EU declaration of conformity or affixing the CE conformity marking according to art. 6 letter c);
- 3) failure by the manufacturer to fulfil the requirement under art. 6 letter c) to carry out the relevant conformity assessment procedure provisioned in art. 13;
- 4) the deed of the manufacturer, his authorised representative or importer not to be able to keep the technical specifications and/or EU declaration of conformity, as the case, according to with art. 6 letter d), art. 7 paragraph (3) point 1 or art. 8 point 10;
- 5) the deed of the manufacturer not to develop procedures that ensures continued conformity of series production with the provisions of this decision, as appropriate, according to art. 6 letter e);
- 6) failure by the manufacturer or his authorised representative to observe the requirement provisioned under art. 6 letter f);
- 7) the deed of the manufacturer or his authorised representative to place on the market equipment without having affixed on it the elements or being accompanied by the information provisioned under art. 6 letter g);
- 8) the deed of the manufacturer or his authorised representative not to specify on the apparatus name, registered trade name or registered trade mark and the postal address at which they can be contacted under art. 6 letter h);
- 9) failure by the manufacturer, his authorised representative or importer to comply with the requirement to ensure instructions and information set in accordance with art. 16, in the form and conditions provisioned in art. 6 letter i), as well as in art. 8 point 6;
- 10) the deed of the economic operator not to take immediately any necessary corrective measure necessary to bring that apparatus into conformity, to withdraw it or recall it, if appropriate, where he holds clues and information that an apparatus he placed on the market is not compliant with the provisions of this decision, in accordance with art. 6 letter j), art. 8 point 8 or art. 9 point 6, as the case;

- 11) failure to inform ANCOM or ANPC, as the case, in accordance with art. 6 letter k), art. 8 point 9 and art. 9 point 7, where the economic operator considers that the apparatus placed on the market or available on the market presents a risk;
- 12) failure by the economic operator to provide further to ANCOM or ANPC at their request, with all the information and documentation, as the case, under conditions provided in art. 6 letter I), art. 7 paragraph (3) point 2, art. 8 point 11 or art. 9 point 8;
- 13) refusal of the economic operator to cooperate with ANCOM or ANPC, as the case, on any action taken to eliminate the risks posed by apparatus which they have placed on the market or made available on the market under conditions of art. 6 letter m), art. 7 paragraph (3) point 3, art. 8 point 12 or art. 9 point 9;
- 14) failure by the importer to comply with the obligation provisioned under art. 8 point 2;
- 15) the deed of the importer to skip the verification provisioned in art. 8 point 3 on the obligation of the manufacturer to draw up the technical specification, the fact that the apparatus bears the CE marking, that it is accompanied by the required documents or that the manufacturer has complied with the requirements set out in Art. 6 letters g)-h);
- 16) failure by the importer to comply with the obligation to inform the manufacturer where the apparatus placed on the market presents a risk, according to art. 8 point 4;
- 17) the deed of the importer not to indicate on the apparatus his name, registered trade name or registered trade mark and the postal address at which he can be contacted under conditions provisioned in art. 8 point 5;
- 18) the deed of the importer or distributor to jeopardise the compliance of the apparatus with the essential requirements set out in annex 1 due to improperly storage or transport conditions, according to art. 8 point 7 or art. 9 point 5;
- 19) failure by the distributor to comply with the obligations provisioned under art. 9 point 1;
- 20) failure by the distributor to comply with the obligations provisioned under art. 9 points 2 and 3;
- 21) the deed of the importer or distributor to place on the market, as well as to make available on the market an apparatus, where he holds clues and information that apparatus is not compliant with the essential requirements provisioned in annex no. 1, previous to bring that apparatus into conformity, in accordance with the obligation provisioned in art. 8 point 4, as well as in art. 9 point 4, and to inform the producer, as well as the importer, as the case, and the market surveillance and control authorities the apparatus presents a risk;

- 22) failure by the conformity assessment body of the obligations provisioned under art. 22 paragraph (2);
- 23) failure by the conformity assessment body of the obligations provisioned under art. 29 paragraph (1) and (3);
- 24) refusal of the end-user to make available for the market surveillance and control authorities, under the provisions of art. 32, data and/or information needed to verify that they comply with the provisions of this decision;
- 25) failure by the economic operators to comply with the obligations provisioned under art. 11 or art. 40;
- 26) failure by the person or persons having under his/their responsibility a fixed installation to assume the obligation provisioned under art. 17 paragraph (4);
- 27) the deed of the economic operators or end-user to refuse or to prevent to retain apparatus according to art. 33 paragraph (2);
- 28) the deed of the controlled economic operator not to take the measures set in accordance with art. 39 paragraph (1), under conditions provisioned in art. 39 paragraph (6);
- 29) the deed of the manufacturer or his authorised representative to affix the CE marking without complying with the provisions set in art. 15;
- 30) the deed of the importer or distributor to place on the market, as well as to make available on the market an apparatus where the EC marking does not comply with the provisions set in art.15;
- 31) the deed of the manufacturer not to inform the notified body in accordance with art. 6 letter n);
- 32) the deed of the end-user to put into service and/or to use equipment that is non-compliant with the requirements of this decision.
  - (2) The contraventions identified under paragraph (1) shall be sanctioned as follows:
- 1) that under paragraph (1) points 1-3, with fine ranging from RON 20.000 to RON 50.000;
  - 2) that under paragraph (1) pct. 4, with fine ranging from RON 5.000 to RON 15.000;
- 3) that under paragraph (1) points 5 and 6, with fine ranging from RON 7.500 to RON 15.000:
- 4) that under paragraph (1) points 7 and 8, with fine ranging from RON 10.000 to RON 20.000;
- 5) that under paragraph (1) point 9 and point 31 with fine ranging from RON 5.000 to RON 10.000;

- 6) that under paragraph (1) point 10, with fine ranging from RON 10.000 to RON 50.000:
- 7) that under paragraph (1) points 11-13, with fine ranging from RON 5.000 to RON 15.000:
- 8) that under paragraph (1) point 14, with fine ranging from RON 2.500 to RON 10.000:
- 9) that under paragraph (1) points 15 and 19, with fine ranging from RON 5.000 to RON 10.000;
- 10) that under paragraph (1) point 16, with fine ranging from RON 15.000 to RON 50.000 lei;
- 11) that under paragraph (1) point 17, with fine ranging from RON 5.000 to RON 10.000:
- 12) that under paragraph (1) point 18, with fine ranging from RON 2.500 to RON 20.000:
- 13) that under paragraph (1) point 20, with fine ranging from RON 2.500 to RON 15.000:
- 14) that under paragraph (1) point (1), points 21 and 30, with fine ranging from RON 10.000 to 50.000;
- 15) that under paragraph (1) points 22 and 23, with fine ranging from RON 2.500 to RON 10.000;
  - 16) that under paragraph (1) point 24, with fine ranging from RON 500 to RON 5.000;
- 17) that under paragraph (1) point 25, with fine ranging from RON 1.000 to RON 5.000;
- 18) that under paragraph (1) points 26 and points 32, with fine ranging from RON 500 to RON 3.500;
- 19) that under paragraph (1) point 27, with fine ranging from RON 10.000 to RON 50.000;
- 20) that under paragraph (1) point 28, with fine ranging from RON 20.000 to RON 50.000:
- 21) that under paragraph (1) point 29, with fine ranging from RON 7.000 to RON 50.000.
- Art. 44. (1) The contraventions herein shall be assessed by the control personnel of the market surveillance and control authorities, by means of the official report establishing the contravention and applying the sanction.
  - (2) The sanctions for the contraventions identified herein shall be applied:

- a) by means of the official report establishing the contravention and applying the sanction by the specialised personnel of the market surveillance and control authorities for the contraventions identified under art. 43 paragraph (1) points 10, 11, 13, 16, 18, 19, 21, 24, 28 and 31;
- b) by means of written resolution of the president of ANCOM, inscribed on the official report establishing the contravention and applying the sanction, for the contravention assessed by the personnel of ANCOM, in those cases referred to under art. 43 paragraph (1) point 1-9, 12, 14, 15, 17, 20, 25-27, 29-30 and 32 where the end-user is a legal person;
- c) by means of the official report establishing the contravention and applying the sanction by the ascertaining agent, for the contravention assessed by ANPC personnel, in those cases referred to under art. 43 paragraph (1) point 1, 21, 24 and 32 where the enduser is a legal person;
- d) by means of the official report establishing the contravention and applying the sanction by empowered staff of MCSI, in those cases referred to under art. 43 paragraph (1) points 22 and 23.
- **Art. 45.** (1) In case of the deeds provisioned under art. 43 paragraph (1) points 1-9, 12, 14, 15, 17, 20, 25-27, 29-30 and 32, ANCOM or ANPC, as the case, also decides as an additional sanction by means of the official report establishing the contravention and applying the sanction, one of the following:
  - a) to restrict or prohibit the apparatus's being placed on the market;
  - b) to restrict or prohibit the apparatus's being made available on the market;
  - c) to withdraw the apparatus from that market and/or to recall it, as the case;
  - d) to prohibit the usage of the apparatus.
- (2) The additional sanction shall be applied by the persons specified in accordance with art. 44 paragraph (2) letters b)-c).
- **Art. 46.** –Where the sanctions provisioned in this decision are applied, ANCOM and ANPC shall inform each other on thereon, within 15 working days from the date of communication of the official report establishing the contravention and applying the sanction.
- **Art. 47.** The provisions of the Government Ordinance no. 2/2001 on the legal regime of contraventions, approved, with amendments and completions, by Law no. 180/2002, with the subsequent amendments and completions, shall apply to the contraventions identified herein.

# Chapter VII -

## Transitional and final provisions

- Art. 48. Annexes no. 1-4 are part of the present decision.
- **Art. 49.** Equipment placed on the market before the entry into force of this decision, which complies with the essential requirements of Government Decision no. 57/2015 regarding electromagnetic compatibility can be made available on the market and/or in operation.
- **Art. 50.** (1) The present decision shall enter into force within 30 days after it is published in the *Romanian Official Journal*, Part I.
- (2) The Government Decision no. 57/2015 on electromagnetic compatibility, published in the *Romanian Official Journal*, Part I, no. 119 as of 16 February 2015, is hereby repealed as from the date the present decision enters into force.
- (3) Whenever another previously law refers to the repealed law in paragraph (2) the reference shall be deemed to be made to the corresponding provisions of this decision.

The present decision transposes Directive 2014/30/EU of the European Parliament and of the Council as of 26 February 2014 on the approximation of the laws of the Member States relating to electromagnetic compatibility, published in the *Official Journal of the European Union* (JOUE) series L, no. 96 as of 29 March 2014.

# PRIME MINISTER DACIAN JULIEN CIOLOŞ

**Countersigned:** 

Minister of Communications and Information Society

**Marius-Raul Bostan** 

Deputy Prime Minister,

Minister of Economy, Trade and Relationships with Business

**Costin Grigore Borc** 

Minister of the Public Finance

Anca Dana Dragu

Bucharest, 6 July 2016 No. 487

# Annex no. 1:

# **Essential requirements**

# 1. General requirements

Equipment shall be so designed and manufactured, having regard to the technical state of the art, as to ensure that:

- a) the electromagnetic disturbances generated do not exceed the level above which radio, electronic communications equipment or other equipment cannot operate as intended;
- b) it has a level of immunity to the electromagnetic disturbances to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.
- 2. Specific requirements for fixed installations installation and intended use of components

A fixed installation shall be installed applying good engineering practices and respecting the information on the intended use of its components, with a view to meeting the protection requirements set out under point 1.

#### Annex no. 2:

# **Module A: Internal Production Control**

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2-5 of this Annex, and ensures and declares on his sole responsibility that the apparatus concerned satisfy the requirements of this Directive that apply to it.

## 2. Electromagnetic Compatibility Assessment

The manufacturer shall perform an electromagnetic compatibility assessment of the apparatus, on the basis of the relevant phenomena, with a view to meeting the essential requirements set out in point 1 of Annex 1 hereto.

The electromagnetic compatibility assessment shall take into account all normal intended operating conditions. Where the apparatus is capable of taking different configurations, the electromagnetic compatibility assessment shall confirm whether the apparatus meets the essential requirements set out in point 1 of Annex 1 hereto in all the possible configurations identified by the manufacturer as representative of its intended use.

#### 3. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the apparatus conformity to the relevant requirements, 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 the apparatus.

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

- a) a general description of the apparatus;
- b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits etc.;
- c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus;
- d) a list of the harmonised standards provisioned in art. 12 paragraph (1) hereto, applied in full or in part the references of which have been published in the Official Journal of the European Union and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards provisioned in art. 12 paragraph (1) hereto, the technical documentation shall specify the parts which have been applied;
  - e) results of design calculations made, examinations carried out etc.;
  - f) test reports.

#### 4. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured apparatus with the technical documentation referred to in point 3 of this Annex and with the essential requirements set out in point 1 of Annex 1 hereto.

# 5. CE marking and EU declaration of conformity

- 5.1 The manufacturer shall affix the CE marking to each individual apparatus that satisfies the applicable requirements of this Directive.
- 5.2 The manufacturer shall draw up a written EU declaration of conformity for each apparatus model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the apparatus has been placed on the market. The EU declaration of conformity shall identify the apparatus 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. Authorised representative

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

Annex no. 3

#### Part A

# **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 an apparatus and verifies and attests that the technical design of the apparatus meets the essential requirements set out in point 1 of Annex 1 hereto.
- 2. EU-type examination shall be carried out by assessment of the adequacy of the technical design of the apparatus through examination of the technical documentation and the documents referred to in point 3, without examination of a specimen (design type). It may be restricted to some aspects of the essential requirements as specified by the manufacturer or his authorised representative.
- 3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall specify the aspects of the essential requirements for which examination is requested and shall include:

- a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- b) a written declaration that the same application has not been lodged with any other notified body;
  - c) the technical documentation.

The technical documentation shall make it possible to assess the apparatus conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risks. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the apparatus.

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

- i.) a general description of the apparatus;
- ii.) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- iii.) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus;
- iv.) a list of the harmonised standards, provisioned in art. 12 paragraph (1), applied in full or in part the references of which have been published in the Official Journal of the European Union, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, provisioned in art. 12 paragraph (1), the technical documentation shall specify the parts which have been applied;
  - v.) results of design calculations made, examinations carried out, etc.;
  - vi.) test reports.
- 4. The notified body shall examine the technical documentation to assess the adequacy of the technical design of the apparatus in relation to the aspects of the essential requirements for which examination is requested.
- 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 vis-à-vis the notifying authorities, the notified body shall not release the content

of that report, in full or in part. The release of the content of that report, in full or in part, is possible only with the agreement of the manufacturer.

6. Where the type meets the requirements of this Directive that apply to the apparatus concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the aspects of the essential requirements covered by the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

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

Where the type does not satisfy the applicable requirements of this Directive, 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, generally acknowledged which indicate that the approved type may no longer comply with the applicable requirements of this Directive, 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 approved type that may affect the conformity of the apparatus with the essential requirements of this Directive or the conditions for validity of that 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 authority 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 authority the list of such 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 such certificates and/or additions thereto which it has issued.

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, until the expiry of the validity of that certificate.

The Commission, the Member States and the other notified bodies may, on request, obtain from the notified body, a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain from the notified body, a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body may, on request, obtain a copy of these documents, as well.

- 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 the apparatus 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.

#### **PART B**

# 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 the apparatus concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive 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 apparatus with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

#### 3. CE marking and EU declaration of conformity

- 3.1 The manufacturer shall affix the CE marking to each individual apparatus that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
- 3.2 The manufacturer shall draw up a written EU declaration of conformity for each apparatus model and keep it at the disposal of the national authorities for 10 years after

the apparatus has been placed on the market. The EU declaration of conformity shall identify the apparatus model 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 no. 4

# EU declaration of conformity (No YYYY) (1)

- 1. Apparatus model/Product (product, type, batch or serial number): ...
- 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 apparatus allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the apparatus): ...
- 5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation: ...
- 6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared: ...
- 7. Where applicable, the notified body ... (name, number) performed ... (description of intervention) and issued the certificate: ...
  - 8. Additional information: ...

Signed for and on behalf of: ... place and date of issue:... name, function signature:

(1) It is optional for the manufacturer to assign a number to the declaration of conformity.