#### **DECISION**

#### on

#### electromagnetic compatibility

#### unofficially consolidated text containing the provisions coming into force from 8 August 2019 –

On grounds of the provisions of the Article 108 of the Constitution of Romania, republished, of Article 22 paragraph ( $1^1$ ) of the Government Ordinance no. 111/2011 on the electronic communications, approved with amendments and completions, by Law no. 140/2012, with the subsequent amendments and completions, as well as of Article II of Government Ordinance no. 8/2012 amending the Government Ordinance no. 20/2010 on the establishment of some measurements for the harmonised enforcement of the European Union legislation which harmonises the rules on products marketing, approved with amendments and completions by Law no. 55/2015,

#### The Romanian Government adopts the present decision

### Chapter I GENERAL PROVISIONS

**Article 1.** -(1) The subject matter of the present decision is to lay down:

- a) electromagnetic compatibility equipment requirements defined in Article 2 paragraph point 5;
- b) conditions for placing on the market, making available on the market and/or putting into service of equipment defined in Article 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 Article 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 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) the following aeronautical equipment, if these equipment fall within the scope of Regulation (EU) 2018/1.139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) no. 2.111/2005, (EC) no. 1.008/2008, (EU) no. 996/2010, (EU) no. 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) no. 552/2004 and (EC) no. 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) no. 3.922/91 and are intended for in-flight use only:
    - (i) aircrafts, other than unmanned aircrafts, and their engines, propellers, parts and non-installed equipment;
    - (ii) unmanned aircrafts, and their engines, propellers, parts and non-installed equipment whose design is certified in accordance with Article 56 paragraph (1) of the Regulation (EU) 2018/1.139 and which are intended for operation exclusively on assigned radio frequencies, in accordance with the Radio Regulations of the International Telecommunications Union, for protected aeronautical use;

- 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 the subsequent amendments, unless they are not made available on the market; kits of components assembled by radio amateurs and the equipment made available on the market and changed by radio amateurs for their own use shall not be considered equipment made available on the market;
- 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 equipment 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 designated for professionals to be used solely at research and development centres 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.
  - **Article 2.** -(1) For the purposes of this decision, the terms and expressions below shall mean:
- accreditation within the meaning of Article 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 of such devices 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 themselves unacceptable electromagnetic disturbances 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 whether the essential requirements provisioned in this decision relating to an apparatus were fulfilled;
- 7. *importer* any natural or legal person, established within the European Union who places on the market a radio equipment from a third country;
- 8. *immunity* the ability of equipment to perform as intended without degradation of its performances, 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* the first making available on the European Union market of the apparatus;
- 11. European Union harmonisation legislation in accordance with the definition provisioned in Article 2 point 21 of the Regulation (EC) no. 765/2008;
- 12. *EC marking* the marking by which the manufacturer indicates that the apparatus is compliant with the applicable requirements set out in the European Union harmonisation legislation, which provides for its affixing on the apparatus;
- 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* the manufacturer, the authorised representative, the importer and the distributor;
- 16. *conformity assessment body* the 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* according to the definition provisioned in Article 2 point 11of 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, to an unwanted signal or a change in the propagation medium itself;
- 19. *manufacturer* any natural or legal person who manufactures an apparatus or for which such an apparatus is designed or manufactured, and sells that equipment under his name or trade mark;
- 20. *making available on the market* any supply of an apparatus for distribution, consumption or use on the European Union market in the course of a commercial activity, whether in return for payment or free of charge;
- 21. putting into service the first use of radio equipment in the European Union by its end-user;
- 22. *recall* any measure taken in order to achieve the return of an apparatus that has already been made available to the end-user;
- 23. *authorised representative* any natural or legal person established within the European Union, who received a written mandate from a manufacturer to act on his behalf in order to fulfill specified tasks;
- 24. *withdrawal* any measure taken to prevent an apparatus in the supply and distribution chain from being made available on the market;
- 25. *technical specification* a document that prescribes the technical requirements to be fulfilled by radio equipment;
- 26. harmonised standard in accordance with the definition provisioned in Article 2 point 1 letter c) of Regulation (EU) no. 1.025/2012 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/EEC 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 repealing Decision 87/95/EEC 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, placing on the market and making available on the market of an apparatus;
- 28. *end-user* any person who puts into service or uses an equipment;
- 29. *device designed to produce electromagnetic disturbances* any apparatus designed and manufactured with the intention of producing electromagnetic disturbances, so as to degrade the operation of other equipment;
- 30. *durable support* any tool that allows end-users to access the information that is addressed to them, in a manner accessible for future reference for an adequate period of time, for information purposes, and that allows unaltered reproduction of stored information.
- (2) The following are considered as apparatus according to paragraph (1) point. 2:
  - a) components or sub-assemblies intended for incorporation into an apparatus by the enduser, which are liable to generate electromagnetic disturbances or whose operation is likely 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) The definitions provided by Regulation (EC) no. 765/2008 are also applicable herein.

- **Article 3**. (1) Equipment may be made available on the market by the economic operators, put into service and/or used only if they comply with the requirements of this decision and only when properly installed, maintained and used in accordance with their destination.
- (2) Notwithstanding the provisions of paragraph (1), display and/or demonstrations, temporary, with equipment which does not comply with the provisions of this decision, are allowed at trade fairs, exhibitions and other similar events, provided that a visible sign clearly indicates that such equipment may not be made available on the market and/or put into service before bringing it into compliance.
- (3) Demonstrations 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.
- **Article 4.** Making available on the market, putting into service or use of equipment which meet the requirements of this decision may not be banned by ANCOM, for reasons relating to electromagnetic compatibility.
- **Article 4¹** Manufacturing, importing, owning, advertising, placing on the market, making available on the market, putting into service and/or using equipment or devices intended to produce electromagnetic disturbances are banned on Romanian territory.
- **Article 5.** (1) ANCOM may apply, by decision, special measures relating to the putting into service or use of equipment, respectively:
  - a) measures to solve an existing or predicted at a location electromagnetic compatibility situation;
  - b) measures taken for safety reasons, to protect public electronic communications networks, the transmitters or receivers, when used for safety reasons in well-defined situations regarding the use of radio frequencies.
- (2) ANCOM informs the European Commission and the similar authorities for the relevant area in the Member States of the European Union 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 standards and technical regulations and of rules on information society services between Romania and the Member States of the European Union and the European Commission, with the subsequent amendments and completions.

## Chapter II OBLIGATIONS OF ECONOMIC OPERATORS

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

- a) to ensure that the devices they place on the market are designed and manufactured in accordance with the essential requirements set out in Annex no. 1;
- b) to 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 Article 13 or to delegate the authorised representative to carry it out;
- c) to draw up the EU declaration of conformity according to the provisions of Article 14 and to affix the EC marking, if the compliance of the device with the applicable requirements by the relevant conformity assessment procedure mentioned in Article 13 was demonstrated;
- d) to keep the technical documentation and the EU declaration of conformity for 10 years after the apparatus has been placed on the market;
- e) to ensure that there are procedures that ensure the continuous conformity of the production in series with the provisions of this decision;

- to ensure that changes in apparatus design or those on its characteristics and changes in the harmonised standards, provisioned in Article 12 paragraph (1), or changes in other technical specifications by reference to which conformity of the apparatus is declared, shall be properly taken into account;
- g) to ensure that apparatus which they place on the market bear the 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) to indicate, on the apparatus, the name, registered trade name or registered trade mark and the postal address at which they may be contacted or, where that is not possible, on the packaging or in a document accompanying the apparatus; the address mentioned by the manufacturer shall indicate a single contact point and the contact details shall be clear, accessible, intelligible, relevant and in Romanian;
- i) to ensure that the apparatus is accompanied by the instructions and the information referred to in Article 16 written in Romanian; the instructions and information, as well as any texts printed on labels, shall be clear, accessible, intelligible and relevant;
- j) to take immediately any corrective measures necessary to bring that apparatus into conformity, to withdraw it and/or recall it, as the case may be, if they hold clues or information that an apparatus which they placed on the market is not compliant with the provisions of this decision;
- k) to inform immediately the competent authorities of the Member States where the device was made available on the market, if they find that the device presents a risk which may affect its operation or the operation of other equipment or for safety reasons, mentioning the details, especially, regarding non-compliance and any corrective measures taken;
- further to a reasoned request from the market surveillance and control authorities, and within the term set by them, to provide, in paper or electronic form, all the information and documentation necessary to demonstrate the conformity of the apparatus with the provisions of this decision, presented in Romanian or in English language;
- m) to cooperate with market surveillance and control authorities, upon their request, on any action taken in view of eliminating the risks posed by the apparatus which they have placed on the market;
- n) to inform the notified body that holds the technical documentation relating to the EUtype examination certificate on all changes of the approved type that may affect the compliance of the apparatus with the essential requirements of this decision or with the validity conditions of that certificate.

**Article 7.** - (1) A manufacturer may, by a written mandate, appoint an authorised representative.

- (2) The obligations laid down in Article 6 letter a) and the obligation to draw up technical documentation referred to in Article 6 letter b) shall not form part of the authorised representative's mandate.
- (3) The authorised representative shall fulfill the goals specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:
  - 1. to keep the EU declaration of conformity and technical documentation at the disposal of the market surveillance and control authorities for 10 years after the device has been placed on the market;
  - further to a reasoned request from the market surveillance and control authorities, to provide, in paper or electronic form, all the information and/or documentation necessary to demonstrate the conformity of the apparatus, presented in Romanian or in English language;

3. to cooperate with the market surveillance and control authorities, upon request, on any action taken in view of eliminating the risks posed by the apparatus falling under the obligations specified in the mandate of the authorised representative.

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

- 1. to place on the market only compliant apparatus;
- before placing apparatus on the market, to ensure that the appropriate conformity assessment procedure referred to in Article 13 has been carried out by the manufacturer;
- 3. to ensure that the manufacturer has drawn up the technical documentation, that the apparatus bears the EC marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 6 letters g)-h);
- 4. if there are clues or information to believe that the apparatus is not compliant with the essential requirements set out in Annex I, until it has been brought into conformity and for safety reasons, to inform the manufacturer and the market surveillance and control authorities;
- to indicate on the apparatus their name, registered trade name or registered trade mark and the postal address at which they may be contacted or, where that is not possible, on its packaging or in a document accompanying the apparatus; the contact details shall be clear, accessible, intelligible, relevant and presented in Romanian language;
- 6. to ensure that the apparatus is accompanied by instructions and the information referred to in Article 16; instructions and information shall be in Romanian, accessible, intelligible, correct and complete;
- 7. to 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;
- to take immediately any necessary corrective action to bring the apparatus into conformity, to withdraw it and/or to recall it, as the case may be, if there are clues or information that a device placed on the market does not comply with the provisions of this decision;
- 9. to inform immediately the competent authorities of the Member States where the apparatus was made available on the market, if it presents a risk which may affect its operation or the operation of other equipment or for safety reasons, mentioning details, in particular, on non-compliance and any corrective measures taken;
- 10. to keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities for 10 years after the apparatus has been placed on the market, and ensure that the technical documentation can be made available to those authorities, upon request;
- 11. further to a reasoned request from the market surveillance and control authorities and within the term set by them, to provide, in paper or electronic form, all the information and documentation necessary to demonstrate the conformity of the apparatus with the provisions of this decision, presented in Romanian or in English language;
- to cooperate with the market surveillance and control authorities, upon request, on any action taken to eliminate the risks posed by the apparatus which they have placed on the market.

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

1. to ensure that the way in which apparatus is made available on the market is not likely to affect the essential requirements established by this decision.

- 2. before making apparatus available on the market, to ensure that the apparatus bears the EC marking, that it is accompanied by the required documents, instructions and information referred to in Article 16, drawn up in Romanian;
- 3. to ensure that the manufacturer and the importer have complied with the requirements set out in Article 6 letters q)-h) and Article 8 point 5;
- 4. not to make the apparatus available on the market, if there are clues or information that the apparatus does not comply with the essential requirements set out in Annex no. 1, before it is brought into conformity and, for safety reasons, to inform the manufacturer or importer, as well as the market surveillance and control authorities;
- to 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. to ensure that any corrective measures necessary to bring that apparatus into conformity or to withdraw it and/or recall it, as the case may be, are taken, when they have indications or information that an apparatus that they have made available on the market does not comply with the provisions of this decision;
- 7. to inform immediately the surveillance and control authorities of the Member States where the apparatus was made available on the market, if it presents a risk that may affect its operation or the operation of other equipment or for safety reasons, mentioning the details in especially, regarding non-compliance and any corrective measures taken;
- to provide, further to a reasoned request from the market surveillance and control authorities, and within the term set by them, in paper or electronic form, all the information and documentation necessary to demonstrate the conformity of the apparatus with the provisions of this decision, presented in Romanian or in English language;
- 9. to cooperate with the market 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.
- **Article 10.** The importer or the distributor shall be considered a manufacturer for the purposes of this decision and he shall be subject to the obligations of the manufacturer under Article 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 decision may be affected.
- **Article 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 the apparatus was supplied or after they supplied the apparatus.

# Chapter III CONFORMITY OF EQUIPMENT

- **Article 12.** (1) Equipment compliant with the provisions of the 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 compliant with the essential requirements set out in Annex I, covered by those standards or parts thereof.
- (2) The harmonised 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 Article 13 paragraph (1) of the Government Decision no. 1016/2004, with the subsequent amendments and completions.
- (4) In the situation provisioned at paragraph (3), ANCOM will give its reasons therefor, in a substantiated manner.
- **Article 13.** (1) Compliance of apparatus with the essential requirements set out in Annex I shall be demonstrated by means of either of the following compliance 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, for some aspects of the essential requirements the procedure referred to in paragraph (1) letter a) is applied.
- **Article 14.** (1) The EU declaration of conformity shall be made by the manufacturer only after demonstrating the fulfillment of the essential requirements set out in the Annex I.
- (2) The 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) The EU declaration of conformity is presented in Romanian or in English language.
- (4) Where apparatus is subject to more than one European Union acts requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up by the manufacturer in respect of all such European Union acts. That declaration shall contain notices on the identification of the 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 decision.
- **Article 15.** (1) The CE marking shall be subject to the general principles set out in Article 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 and legibly, indelibly and in a form impossible to be removed, to the apparatus or to its data plate. Where that is not possible or not warranted on account of the nature of the apparatus, the EC marking shall be affixed to the packaging and to the accompanying documents.
- **Article 16.** (1) The apparatus is accompanied, upon placing on the market or making available on the market, information on any specific precautions to be taken when assembling, installing, maintaining or using them to ensure, when to ensure when putting into service, compliance with the general requirements set out in section at point 1 of Annex no. 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 under paragraph (1) is provided to end-users as a user manual in Romanian language, on paper. Information may also be provided on a durable support as well, upon the end-user's consent.
- **Article 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 decision.

- (2) The requirements of Article 1 paragraph (2), Articles 6-11 and Articles 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 letters g)-h) and Article 8 point 5.
- (4) The person or persons in charge of the fixed installation must keep the documentation, which contains the good engineering practices provided in point 2 of the annex no. 1 at the disposition of the market surveillance and control authorities for inspection throughout the life of the fixed installation.
- (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 market surveillance and control authorities may:
  - a) 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) Market surveillance and control authorities shall take the necessary measures to identify the person or persons responsible for establishing the compliance of a fixed installation with the relevant essential requirements, based on scenarios which take into account the nature of the fixed installations and their location.
- (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 Article 45, paragraph (1), letter d).

# Chapter IV NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

- **Article 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 the field of 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.

#### **Article 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;
- 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 Article 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 the subsequent amendments and completions.

**Article 20.** - (1) On the purpose of notification, the conformity assessment body meets the following requirements:

- 1. is established by law and has legal personality;
- is 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;
- 3. does not act as a designer, manufacturer, supplier, fitter, purchaser, owner, user or in maintenance of those apparatus it assesses and does not represent the parties engaged in these activities; 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. is not directly involved in the design, manufacture or development, marketing, installation, use or maintenance of the equipment assessed and does not represent the parties engaged in these activities; the requirement also applies to staff with management positions and staff responsible for carrying out conformity assessment tasks and applies in particular to consulting services;
- 5. is not involved in any activity that affects their impartiality or integrity with respect to the conformity assessment activities for which they are notified; the requirement also applies to staff with management positions and staff responsible for carrying out conformity assessment tasks and applies in particular to consulting services;
- 6. 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. shall have at its disposal, how many times is nedded and for each conformity assessment procedure and for each kind or category of apparatus in relation to which it has been notified, the following:
  - necessary personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
  - b) necessary 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) necessary 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 the relevant standardization activities and in the activities of the coordinating group of notified bodies established under the relevant harmonisation legislation of the European Union or ensure that their staff responsible for carrying out the conformity assessment tasks are informed about these activities and put in place as a general guideline, the administrative decisions and documents made as a result of the activity 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;
  - appropriate knowledge and understanding of the essential requirements set out in annex 1, of the applicable harmonised standards provided in Article 12 paragraph (1) and of the relevant provisions of European 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 no. 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.

**Article 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 Article 20 in so far as the applicable harmonised standards cover those requirements.

**Article 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 Article 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.
- **Article 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 Article 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 Article 20.
- **Article 24.** -(1) MCSI may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 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:
  - 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 Article 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).
- **Article 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 Article 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 the subsequent amendments and completions.

**Article 26.** – If an investigation by the European Commission takes place, according to Article 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.

- **Article 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 decision;
  - 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 Article 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.
- (5) 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.
- **Article 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 the subsequent amendments and completions.
  - **Article 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.
- **Article 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

- **Article 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 authorised 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 the subsequent amendments and completions.
- (3) ANCOM and ANPC shall organise and carry out the surveillance and control activity in accordance with the provisions of Article 15 paragraph (3) and Articles 16-29 of Regulation (EC) no. 765/2008, including the apparatus sold by electronic means, intended for the end-user, for his own use, and which are subject to custom control.
- (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.
- (5) In the surveillance and control activity, ANCOM and ANPC may request the National Institute for Research and Development in Informatics, in the case of the register of domains and subdomains in the «.ro» field, to transmit the data or information that may lead to the identification of the persons who sell apparatuses through electronic means. The requested data are transmitted without delay to the market surveillance and control authorities in accordance with the legal provisions regarding the protection of personal data.

#### **Article 32.** – is repealed.

- **Article 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 Article 12 paragraph (1).
- (2) For the purpose of performing the tests in accordance with the provisions of paragraph (1), the manufacturer, his authorised representative, the importer or the distribuitor, as the case may be, has the obligation to allow the control personnel to retain, based on an official report, free of charge, a representative number of samples of the apparatus to be submitted to testing. Retain of samples may be also ordered on the apparatus/apparatuses to be found at the end-user, if there are sufficient indications that the respective apparatus/apparatuses produces/produce electromagnetic disturbances.
- (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 Article 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.
- **Article 34.** (1) Subsequently to carrying out technical tests under Article 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.
- **Article 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), that covers all the relevant requirements established by this decision, may also be performed as a result of the technical tests provided in Article 33 paragraph (1).
- (3) The economic operators over which control actions are taken in the context of paragraphs (1) and (2) have the obligation to cooperate, at the request of the market surveillance and control authorities.
- (4) The assessment provided in paragraph (1) also takes into account, as the case may be, data on: the identified risks associated with the respective apparatus, the possible data on the risks that have materialized in relation to the respective apparatus or the measures taken by the concerned economic operator in order to mitigate the risks.
- **Article 36.** (1) Where, in the course of the assessment referred to in Article 35, ANCOM or ANPC, as the case may be, finds that the apparatus does not comply with the requirements herein, the relevant economic operators are without delay required to take all necessary corrective actions to bring the apparatus into compliance with those requirements and to limit its making available on the market or to withdraw the apparatus from the market and/or to recall it within a reasonable term, commensurate with the nature of the risk, prescribed by ANCOM or ANPC, as the case may be.
- (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) Article 21 of Regulation (EC) no 765/2008 shall apply to the measures referred to in paragraph (1).
- (4) Corrective measures and restrictions established under paragraph (1) shall apply by means of a decision of ANCOM President, respectively by means of an order of ANPC President, as the case may be.
- **Article 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.
- **Article 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.
- **Article 39.** (1) Where the relevant economic operator does not take adequate corrective measures set in accordance with Article 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) if the non-compliance is due to the non-observance of the requirements regarding the protection of the public interest protected by the provisions of the present decision;
  - g) whether the non-compliance is due to shortcomings in the harmonised standards referred to in Article 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.

**Article 40.** – Without excluding measures ordered under Articles 35-39, ANCOM or ANPC shall require the relevant economic operator to end the nonconformity concerned, within 15 working days, in case of finding the following:

- a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 15 of this decision;
- 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;
- the information referred to in Article 6 letter h) or Article 8 point 5) is absent, false or incomplete;
- g) any other administrative requirements provided for in Article 6 or Article 8 are not fulfilled as the case.
- **Article 41.** (1) In the implementation of the provisions of this decision, the authorised personnel of ANCOM or ANPC, as the case may be, has the right to require from the economic operators or the end-user any information or documents necessary in order to exercise the powers relating to market surveillance and control.
- (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.
- **Article 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

**Article 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 manufacturer or the importer placed on the market equipment that is not compliant with the essential requirements provisioned in annex no. 1;
- 2) the manufacturer does not draw up the technical documentation provisioned under annex no. 2 or no. 3, in accordance with Article 6 letter b), or the EU declaration of conformity, or does not affix the EC conformity marking according to Article 6 letter c), respectively the authorised representative does not draw up the EU declaration of conformity or does not affix the EC marking, according to the received mandate;
- 3) the manufacturer does not fulfil the obligation under Article 6 letter b) to carry out the relevant conformity assessment procedure provisioned in Article 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 Article 6 letter d), Article 7 paragraph (3) point 1 or Article 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 Article 6 letter e);
- 6) the manufacturer or his authorised representative to observe the requirement provisioned under Article 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 Article 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 Article 6 letter h);
- 9) the manufacturer, his authorised representative or importer does not comply with the requirement to ensure instructions and information set in accordance with Article 16, in the form and conditions provisioned in Article 6 letter i), as well as in Article 8 point 6:
- 10) the deed of the economic operator not to take immediately any necessary corrective measure to bring that apparatus into conformity or to withdraw or recall it, if appropriate, where he holds indications or information that an apparatus he placed on the market and/or made available on the market is not compliant with the provisions of this decision, in accordance with Article 6 letter j) or Article 8 point 8, respectively not to ensure the fulfillment of the obligation established according to Article 9 point 6, as the case may be;
- 11) omission to inform ANCOM or ANPC, as the case, in accordance with Article 6 letter k), Article 8 point 9 and Article 9 point 7, where the economic operator considers that the apparatus placed on the market or available on the market presents a risk;
- 12) the economic operator does not comply with the obligation to provide further ANCOM or ANPC at their request, with all the information and documentation, as the case may be, under conditions provided in Article 6 letter I), Article 7 paragraph (3) point 2, Article 8 point 11 or Article 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 Article 6 letter m), Article 7 paragraph (3) point 3, Article 8 point 12 or Article 9 point 9;
- 14) the importer does not comply with the obligation provisioned under Article 8 point 2;
- 15) the deed of the importer to skip the verification provisioned in Article 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 Article 6 letters g)-h);

- 16) the importer does not fulfil the obligation to inform the manufacturer and the market surveillance and control authorities, if he holds indications or information that an apparatus does not comply with the essential requirements, according to Article 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 Article 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 Article 8 point 7 or Article 9 point 5;
- 19) the distributor does not comply with the obligations provisioned under Article 9 point 1:
- 20) the distributor does not comply with the obligations provisioned under Article 9 points 2 and 3;
- 21) the deed of the importer or distributor to place on the market, repectively to make available on the market an apparatus, if he holds indications or information that it is not compliant with the essential requirements provisioned in annex no. 1, previous to bring that apparatus into conformity, in accordance with the obligations provisioned in Article 8 point 4, repectively in Article 9 point 4;
- 22) the conformity assessment body does not comply with the obligations provisioned under Article 22 paragraph (2);
- 23) the conformity assessment body does not meet the obligations provisioned under Article 29 paragraphs (1) and (3);
- 24) refusal of the end-user to make available for the market surveillance and control authorities, under the provisions of Article 41, information and/or documents needed to verify the observance of the provisions of this decision;
- 25) the economic operators do not fulfil the obligations provisioned under Article 11, Article 40 or Article 41;
- 26) the person or persons having under his/their responsibility a fixed installation does not comply with the obligation provisioned under Article 17 paragraph (4);
- 27) the deed of the economic operators or end-user to refuse or to prevent to retain apparatus according to Article 33 paragraph (2);
- 28) the deed of the controlled economic operator not to take the corrective measures set in accordance with Article 38 or Article 39 paragraph (1);
- 29) the deed of the manufacturer or his authorised representative to affix the CE marking without complying with the provisions set in Article 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 Article 15;
- 31) the deed of the manufacturer not to inform the notified body in accordance with Article 6 letter n);
- 32) the deed of the end-user to put into service and/or to use equipment that is noncompliant with the requirements of this decision.
- 33) the distributor does not fulfil the obligation to inform the manufacturer or importer and the market surveillance and control authorities, if he holds indications or information that an apparatus does not comply with the essential requirements, under conditions set in Article 9 point 4;
- 34) manufacturing, importing, holding, advertising, placing on the market or making available on the market, putting into service and/or use of equipment or devices intended to produce electromagnetic disturbances.
- (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 15000;
- 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) in the case of the contraventions provisioned under paragraph (1) points 28 and 33, with fine ranging from RON 20,000 to 50,000;
- 21) that under paragraph (1) point 29, with fine ranging from RON 7,000 to RON 50,000;
- 22) in the case of the contravention provisioned under paragraph (1) point 34, with fine ranging from RON 15,000 to 50,000.

**Article 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:
  - 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 Article 43 paragraph (1) points 10, 11, 13, 16, 18, 19, 21, 24, 28 and 31;
  - b) by means of written resolution inscribed on the official report establishing the contravention and applying the sanction, by the president of ANCOM, for the contraventions assessed by the personnel of ANCOM, in those cases referred to under Article 43 paragraph (1) points 1-9, 12, 14, 15, 17, 20, 25-27, 29, 30, 32-34;
  - c) by means of the official report establishing the contravention and applying the sanction by the ascertaining agent, for the contraventions assessed by ANPC personnel, in those cases referred to under Article 43 paragraph (1) points 1, 11-13, 21, 24, 25, 32-34, where the equipment was purchased by the consumer;
  - 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 Article 43 paragraph (1) points 22 and 23.

- **Article 45.** (1) ANCOM or ANPC, as the case may be, may also order, by means of the official report establishing the contravention and applying the sanction, the following additional sanctions:
  - a) the use of the apparatus is banned until the equipment is brought in compliance with the essential requirements, in the event of the deed provisioned under Article 43 paragraph (1) point 32;
  - b) confiscation, in the case of the deed provisioned under Article 43 paragraph (1) point 34, under the conditions set in Article 5 paragraph (3) letter a) of the Government Ordinance no. 2/2001 regarding the legal regime of the contraventions, approved with amendments and completions by Law no. 180/2002, with the subsequent amendments and completions.
- (2) The additional sanctions provisioned under paragraph (1) shall be applied by the persons specified under Article 44 paragraph (2) letters b) and c).
- **Article 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.
- **Article 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

- **Article 48.** Annexes no. 1-4 are part of the present decision.
- **Article 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.<sup>1</sup>
- **Article 50.** (1) The present decision shall enter into force within 30 days after it is published in the *Official Journal of Romania*, Part I.
- (2) The Government Decision no. 57/2015 on electromagnetic compatibility, published in the *Official Journal of Romania*, 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.

¹ In the case of Article 49 a transitional measure was adopted through Article III paragraph (1) of the Government Decision no. 431 of 20 June 2019 for amending and supplementing Government Decision no. 487/2016 on the electromagnetic compatibility and the Government Decision no. 740/2016 on making available on the market of radio equipment, which provides the following: "The equipment placed on the market prior to the date of entry into force of this decision, that meets the provisions of the Government Decision no. 57/2015 on electromagnetic compatibility, may be made available on the market and/or put into service".

#### **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.

#### **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 satisfies the requirements of this decision 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, subassemblies, 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 Article 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 decision, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards provisioned in Article 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. EC 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 decision.
- 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.

# 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 submit 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;
- 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 possible to assess the compliance of the apparatus with the applicable requirements of this decision 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, subassemblies, 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 Article 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 decision, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, provisioned in Article 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 is possible only with the agreement of the manufacturer.
- 6. Where the type meets the requirements of this decision 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 decision, 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 decision, 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 decision 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

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 meets the requirements of this decision 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 decision that apply to them.

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

- 3.1 The manufacturer shall affix the EC 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 decision.
- 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.

#### **EU Declaration of Conformity (No YYYY)**<sup>2</sup>

- 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 color 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 European 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: ...

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<sup>&</sup>lt;sup>2</sup> It is optional for the manufacturer to assign a number to the declaration of conformity.