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PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a Union certification system for aviation security screening equipment

Delegations will find attached document COM(2016) 491 final.

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2016/0236 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

establishing a Union certification system for aviation security screening equipment

{ SWD(2016) 259 final }

{ SWD(2016) 261 final }

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Objective of the proposal

The objective of the proposal is to contribute to the proper functioning of the EU internal market and to increase the global competitiveness of the EU industry by establishing an EU certification system for aviation security screening equipment.

A more competitive EU security industry will be able to offer technological solutions which will actively increase the security of European citizens and will contribute to the capacity of the European society to prevent and respond to security threats.

The certification system established by this proposal builds on the Common Evaluation Process (CEP), elaborated within the European Civil Aviation Conference (ECAC) to assess the conformity of aviation security screening equipment with the existing performance requirements established at the EU level, and combines it with an accreditation procedure for conformity assessment bodies. The aim is to establish a unique EU certification system based on EU type-approval and issuance of certificate of conformity by manufacturers, which would be valid in all the EU Member States, according to a principle of mutual recognition.

- **General context**

Aviation security screening equipment relates to the security equipment used for screening persons, cabin baggage, hold baggage, supplies, air cargo and mail. Screening equipment in the aviation security sector represents a considerable market, with an annual global turnover of 14 billion euro, 4.2 billion of which in the EU alone. Airports and air transport hubs are also among the sectors with the highest global growth potential, with a strong focus on Asian markets.

The EU Regulation (EC) No 300/2008 establishes the technical specifications and performance requirements for aviation security screening equipment used at EU airports. This legislation is based on standards developed by the Commission, which are continuously adapted to the evolving threat scenarios and risk assessments. In consideration of the possible consequences for the EU MS national security of making them widely known, these standards are classified and only made available to those (persons, companies, organisations etc.) who have an adequate security clearance as well as a valid justification ("need to know basis").

The above-mentioned legislation, however, is not accompanied by a legally binding EU-wide conformity assessment scheme to ensure that the required standards are met at all EU airports. Therefore, equipment certified in one EU Member State can be put on the market in that Member State only. Any other EU Member State is free to either recognise this certification or to require that the equipment is tested again to verify whether it meets the requirements prescribed by the EU legislation, or even to impede its use in its territory. In any case, there is no such a procedure as an automatic recognition of the certification issued by the first Member State.

Member States, in cooperation with the Commission, have partially addressed this fragmentation through the development of common testing methodologies for several categories of aviation security screening equipment to be applied in the framework of ECAC.

In 2008, ECAC put in place a Common Evaluation Process (CEP) for the testing of screening equipment used in the aviation sector. Since then, the CEP has been reviewed and improved in terms of effectiveness but still lacks a legally binding character for fully exploiting its potential.

- **Consistency with existing policy provisions in the policy area**

The **European Agenda on Security (COM(2015) 185 final)** adopted by the European Commission in April 2015, emphasises the need for a competitive EU security industry that can also contribute to the EU's autonomy in meeting security needs. In addition, the Union encourages the development of innovative security solutions, for example through standards and common certificates. The European Agenda on Security also states that Commission is considering further action, such as on alarm systems and airport screening equipment, to remove barriers to the Single Market and to enhance the competitiveness of the EU security industry in export markets.

This proposal will contribute to improve the competitiveness of the European Security Industry. As a consequence, a more competitive EU-based security industry will be able to offer more innovative and effective solutions to enhance the security of European citizens and make a substantial contribution to the resilience of the European society to security threats.

With specific regard to the aim of this proposal, the **Commission Communication “Security Industrial Policy Action Plan for an innovative and competitive Security Industry (COM (2012) 417)”** must be mentioned. In particular, Action 2 of the mentioned plan states that: “Subject to a thorough impact assessment analysis and consultation of stakeholders, the Commission would propose two legislative proposals: one to establish an EU wide harmonised certification system for airport screening (detection) equipment ; and one to establish an EU harmonised certification system for alarm systems. The objective is to achieve mutual recognition of certification systems.”

Aviation security screening equipment is included in the provisions of the **Regulation (EC) No 300/2008**, which establishes common rules in the field of civil aviation security, and its implementing acts, in particular the **Commission Regulation (EU) No 185/2010**, laying down detailed measures for the implementation of the common basic standards on aviation security.

Since there are already detailed performance requirements and testing methods for aviation security screening equipment, the proposal does not aim at adding more technical legislation. On the contrary, it clearly contributes to the implementation of the above-mentioned policy provisions by establishing an EU certification system for screening equipment. The latter would stipulate that compliance with the performance requirements has to be demonstrated by accredited testing laboratories applying a common testing methodology, such as the one elaborated within ECAC. The creation of an effective certification system would require the adoption of a legal act establishing the framework for it.

- **Consistency with other Union policies**

The proposal is consistent with the main EU policies in the single market area and the free movement of goods. In particular, **Regulation (EC) No 765/2008 of 9 July 2008** setting out the requirements for accreditation and market surveillance relating to the marketing of products and **Decision No 768/2008/EC of 9 July 2008** on a common framework for the marketing of products have been taken into account while drafting this proposal.

In addition to the above, the proposal is consistent with the European Commission priority of increasing the competitiveness of EU companies by overcoming the fragmentation of the EU security markets as outlined by **President Juncker in his Political Guidelines** ("A Deeper and Fairer Internal Market with a Strengthened Industrial Base").

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The basis for EU action is Article 114 TFEU, which deals with the approximation of laws of the Member States in order to achieve the objectives of Article 26 TFEU, i.e. the proper functioning of the internal market.

- **Subsidiarity**

The objective of this Regulation, namely to establish rules on the administrative and procedural requirements for the EU type-approval of aviation security screening equipment, cannot be sufficiently achieved by the EU Member States. Indeed, if Member States intended to launch such an initiative on their own, they would have already done it while setting up the ECAC CEP system. By reason of its scale and effects, the action of establishing a EU type-approval system entailing mutual recognition of the certification of conformity among Member States can only be done at the EU level.

The proposal therefore complies with the subsidiarity principle.

- **Proportionality**

The proposal complies with the proportionality principle since it does not go beyond what is necessary to achieve the objectives of ensuring the proper functioning of the Internal Market while, at the same time, improving the competitiveness of the EU industry active in the aviation security screening equipment sector.

Moreover, given the need to provide a level playing field to EU aviation security screening equipment manufacturers compared to their competitors on both EU and extra-EU markets, the establishment of a common certification system required to sell or put into use any such equipment in the EU seems to be proportional with the aim of the proposal.

- **Choice of the instrument**

The relevant legal basis, Art. 114 TFEU, does not prescribe the form of a particular legal instrument.

Nevertheless, in consideration of the aims of the proposal, the specific context and content, a regulation seems better suited than a directive to establish a clear framework for an EU certification system, based on the already existing regulations EC 300/2008 and EU 185/2010.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

• Stakeholder consultations

The proposal relies on a wide consultation of relevant stakeholders which was carried out through:

- An open **Public Consultation on the Certification of Aviation Security Screening Equipment** which ran from 5 March 2013 to 10 June 2013. The consultation was published on Your Voice in Europe and received 37 contributions. Despite this relatively low response rate, the results of the public consultation can be considered as representative since all the main stakeholder groups (national administrations, all types of enterprises (including SMEs), test laboratories, airport operators etc.) responded. Additionally, the main associations of the sector, such as the main airlines association, representing some 240 airlines or 84% of total air traffic, the main business association, representing most EU manufacturers, and several testing labs contributed to the consultation, effectively representing several hundred of stakeholders.

The main conclusions of the public consultation, summarized in the Impact Assessment accompanying the proposal are fully supporting the legislative approach embedded in it.

- A **workshop** which was organised on 25 September 2013 as a follow up to the public consultation. The workshop was attended by representatives from all the concerned stakeholder groups, including Member States, industry, ECAC and end-users representatives (Airports Council International Europe). The main conclusion of the workshop was the convergence of the results of the studies presented during the first session (see next paragraph), in terms of both problematic issues and potential solutions.

- Even though a certain time elapsed between the public consultation, the workshop and the submission of the Impact Assessment, the findings from these consultations about the lack of common legally binding procedures for the certification of aviation security screening equipment in the EU Member States remain valid. This has been confirmed in contacts with all relevant stakeholders over the course of 2015.

• Collection and use of expertise

While drafting the impact assessment for the proposal, the Commission has also relied on a study carried out by an external contractor and entitled: “Study on security R&D in major 3rd countries”. The study analysed in detail the certification and conformity assessment schemes in the EU and the world. It included also an assessment of the impacts of the policy options identified by the Commission. All the applicable conclusions of the study have been included in the impact assessment and duly considered for drafting the proposal.

A further survey on “**Detection Requirements and Testing Methodologies for Aviation Security Screening Devices in the EU and EFTA**” carried out by DG JRC (Institute for Reference Materials and Measurements in Geel), and published in spring 2013 was taken in due consideration for the preparation of the impact assessment.

- **Impact assessment**

The impact assessment is accompanying this proposal (reference to be added).

It was positively evaluated by the Regulatory Scrutiny Board of the Commission on 3rd July 2015.

Five policy options, including the baseline, were developed in the context of this impact assessment:

1. "Baseline scenario", the Commission would not launch any dedicated policy initiative.
2. A recommendation to Member States to mutually accept their national certification systems and/or to rely on the common evaluation process of the European Civil Aviation Conference.
3. "Legislation" - The Commission would prepare a legislative proposal which would allow producers to market and sell their products throughout the Union, once certified in one Member State.
 - 3.1. The "old approach", or "full harmonisation", characterised by a certification system to be implemented by national approval authorities and based on detailed specifications laid down in legislation: 1) performance requirements applicable to aviation security screening equipment; 2) common testing methodologies 3) accreditation of testing laboratories.
 - 3.2. The "new approach", not based on detailed specifications but on publicly available standards. The established certification system would be limited to essential requirements for aviation security screening equipment, written in general terms. This option was discarded since the existing EU performance requirements on which this approach should be based are classified and cannot be made public.
 - 3.3. The third option, "the centralised approach", according to which the established certification system would be pretty similar to option 3.1 but it would be applied centrally by an EU agency.

The preferred option is 3.1 "old approach", which would have significant positive impacts, while ensuring the broadest support among all stakeholders, including Member States.

According to this option, the certification of aviation security screening equipment would need to be done in only one Member State, as the issued certificate would be immediately valid in all 28 EU Members. This should raise the overall EU market efficiency in the aviation security screening sector and have a positive impact on the free movement of goods. The choice of customers (e.g. airport operators) should also be improved, given they could choose to procure any "EU certified" aviation security screening equipment, and not just those who were certified in their country. Single certification procedures should reduce the administrative burden of the manufacturers and improve their time to market. This should also have a positive impact on the global competitiveness of European manufacturers, in particular regarding their US competitors (estimated sales benefit of €22 million on average per year). The expected increase in competitiveness should lead to an overall increase of sales of EU manufacturers in third countries, which should in turn have a positive social impact on the overall employment figures in the sector.

The reduction of the need to test multiple times a single type or configuration of equipment should lead to a reduction of the number of tests a single laboratory would perform per year. This reduction of tests would lead to a reduction of income for the laboratories. This reduction of income should be lower than the costs savings of the producers outlined above, as not all the costs are directly related to the price of the certification as such (e.g. the shipping of the equipment)¹. None of the options would lead to measurable environmental impacts. The current environmental impacts of the development, production, testing or transportation would not be affected by a possible harmonisation on certification procedures. • **Regulatory fitness and simplification**

As already stated above, one of the two general objectives of the proposal is to increase the global competitiveness of the EU companies operating in the field of aviation security screening equipment.

In particular, the proposal aims at reducing the regulatory costs and the time to market by eliminating the need for multiple testing and for MS-specific modifications as well as by creating a more investment friendly environment for security technologies.

Furthermore, the proposal intends to enhance the image of the EU products on the global market by introducing a label showing compliance with EU regulatory requirements and creating a level playing field with US companies.

4. BUDGETARY IMPLICATIONS

The proposal has no implications for the Union budget

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

A sound system of monitoring and evaluation has been conceived and included in the proposal.

In detail, it envisages that every five years, the Commission will publish a general report on the implementation of this regulation.

This report will be based on a targeted survey aimed at all relevant stakeholders to assess the efficiency and effectiveness of the implementation of the regulation with respect to the operational objectives.

This survey will address the following indicators with a view to assess whether the implementation of the regulation led to: reduction of research and development costs; reduction of commercialisation costs; reduction of time to market of equipment; improving the competition with non-EU suppliers.

¹ See SER3Co study, chapter 3.2.4

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
establishing a Union certification system for aviation security screening equipment

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee²,

Having regard to the opinion of the Committee of the Regions³,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) The purpose of this Regulation is to ensure the free movement of civil aviation security screening equipment in the Union.
- (2) Civil aviation security screening equipment, such as metal detection equipment, security scanners and explosive detection systems, must fulfil a number of performance requirements before they can be made available or put into service. Conformity with those requirements is currently assessed by individual Member States and equipment certified in one Member State can be made available in that Member State only. It is necessary to enable such equipment to move freely within the internal market to enhance the competitiveness of the European security industry.
- (3) A more competitive EU security industry will offer solutions to enhance the security of European citizens and make a substantial contribution to the resilience of the European society to security threats. Union action can contribute to these goals by removing barriers to the internal market and by enhancing the competitiveness of the Union security industry in areas like aviation security screening equipment, through the promotion of common certification processes.

² OJ C , , p. .

³ OJ C , , p. .

- (4) In its Communication to the European Parliament and the Council "**Security Industrial Policy - Action Plan for an innovative and competitive Security Industry**" of July 2012⁴, the Commission identified aviation security screening equipment as an area where it would make the most sense to set up a Union-wide certification system to overcome market fragmentation, to boost competitiveness and employment in the Union and overall increase the security of the European society.
- (5) The **European Agenda on Security**⁵ emphasises the need for a competitive EU security industry that can contribute to the EU's autonomy in meeting security needs. A solid, competitive technological and industrial base for the EU is therefore essential to have a positive impact on the security of its citizens.
- (6) This Regulation should enable aviation security screening equipment to move freely within the internal market by establishing a single certification system based on certificates of conformity valid in all Member States. Where equipment is accompanied by such a certificate, it should be possible to make it available or put it into service throughout the Union without any restriction.
- (7) Each Member State should designate a body with responsibility for approving the compliance of aviation security screening equipment by issuing an EU type-approval certificate valid throughout the Union. Manufacturers of aviation security screening equipment should be free to choose a responsible body in any Member State.
- (8) To simplify access to the certification system and to make it more transparent each Member State should designate a single body - the national approval authority - even where there are two or more bodies involved in aviation security within a single Member State.
- (9) An EU type-approval certificate should attest that a specific type and configuration of aviation security screening equipment complies with the common rules and standards in the field of civil aviation security laid down in particular in Regulation (EC) No 300/2008 of the European Parliament and of the Council⁶.
- (10) To enable the free movement of aviation screening equipment throughout the Union, manufacturers should be able to issue certificates of conformity to accompany each piece of equipment produced in accordance with a type and configuration covered by an EU type-approval certificate.
- (11) Aviation screening equipment covered by an EU type-approval certificate should not need to undergo further assessment in other Member States. It is therefore important that the assessment and testing is uniform across the Union. This Regulation should therefore adequately take into account the work to define common testing methodologies that has been done in the framework of Common Evaluation Process of the European Civil Aviation Conference.

⁴ 4 COM(2012) 417 final

⁵ 5 COM(2015) 185 final

⁶ Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L97, 9.4.2008, p. 72).

- (12) Testing the equipment to assess compliance with the standards is essential for the certification system. Testing should therefore be performed by technical services which have the skills and technical knowledge necessary to perform conformity assessments by applying the relevant common testing methodologies.
- (13) In order to ensure the certification system is effective and to strengthen mutual trust among national approval authorities, this Regulation should determine the requirements for accreditation of those technical services.
- (14) Conformity of production is a cornerstone of the EU type-approval system. In order to monitor conformity of production, manufacturers should be regularly checked by an approval authority or by an appropriately qualified technical service designated for that purpose.
- (15) It is important to ensure a harmonized application of the common testing methodologies by the technical services. To that end, the Commission should establish and chair a sectoral group of technical services aimed at ensuring the necessary coordination and cooperation among designated technical services as well as providing training of the respective personnel and coordination with third countries.
- (16) Where it is discovered that aviation security screening equipment covered by an EU type-approval certificate presents a serious risk for users or the environment which was not identified by the approval authority, a Member State should be able to prevent the making available or putting into service of that equipment in its territory, for a limited period of time and subject to an assessment by the Commission as to whether the Member State measure is in line with Union legislation.
- (17) Where it is discovered that aviation security screening equipment accompanied by a certificate of conformity does not conform to the type and configuration covered by an EU type-approval certificate, the Member State which has issued the type-approval certificate should take the necessary measures to ensure that the manufacturer brings it into conformity and should inform the other approval authorities and the Commission of the measures taken.
- (18) Where it is discovered that aviation security screening equipment accompanied by a certificate of conformity does not conform to the type and configuration covered by an EU type-approval certificate issued by another approval authority, a Member State should temporarily stop the making available or putting into service of that equipment in its territory and should request the approval authority which issued the type-approval certificate to verify that equipment in production continues to conform to the approved type and configuration. The approval authority concerned should have a maximum delay of three months of the date of the request to take the requisite action. If the concerned approval authority finds out that the equipment conforms to the approved type and configuration, it should endeavour to settle the dispute. In the meantime the temporary measures remain in place.
- (19) For the purposes of better regulation and simplification and in order to avoid having to constantly update existing Union legislation on issues of technical specifications, it should be possible for this Regulation to make references to existing international standards and regulations without reproducing them in the Union legal framework.

- (20) With the aim of simplifying and accelerating the adoption of type-approval legislation, a new regulatory approach has been introduced, under which the legislator in the ordinary legislative procedure sets out only the fundamental rules and principles and delegates the establishment of further technical details to the Commission. With regard to substantive requirements, therefore, this Regulation should lay down only administrative provisions and general procedural requirements. The Commission should be given power to lay down the technical specifications, including the common testing methodologies and the requirements for accreditation of the technical services needed under the certification system established by this Regulation.
- (21) In order to supplement this Regulation with further technical details, the power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in order to reflect into this Regulation the possible introduction of new performance requirements for aviation security screening equipment as well as the development of scientific and technical knowledge. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (22) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.
- (23) The Commission should report to the European Parliament and the Council on the implementation of this Regulation, based on information provided by Member States.
- (24) In the interest of clarity, predictability, rationality and simplification and in order to reduce the burden for manufacturers of aviation security screening equipment, this Regulation should contain only a limited number of implementation stages for the introduction of administrative provisions and general technical requirements. Industry should be allowed sufficient time to adapt to the new provisions laid down in this Regulation and to the technical specifications and administrative provisions set out in the delegated acts adopted pursuant to this Regulation. Timely definition of requirements is essential to ensuring sufficient lead-time for manufacturers to develop, test and implement technical solutions for aviation security screening equipment produced in series, and for manufacturers and approval authorities in the Member States to put in place the necessary administrative systems.
- (25) Since the objectives of this Regulation, namely to lay down harmonised rules on the administrative and procedural requirements for the type-approval of aviation security screening equipment, cannot be sufficiently achieved by the Member States, and can therefore, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity, as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation should not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS REGULATION:

Article 1
Subject matter

This Regulation establishes a framework for a Union certification system for aviation security screening equipment.

Article 2
Scope

1. This Regulation applies to all aviation security screening equipment for use in civil aviation made available or put into service within the Union.
2. This Regulation does not apply to explosive detection dogs when used as alternative means of screening

Article 3
Definitions

For the purpose of this Regulation:

- (1) 'aviation security screening equipment' or 'equipment' means devices of a specialised nature used, individually or as part of a system, to detect prohibited articles as referred to in Regulation (EC) No 300/2008 and its supplementing or implementing acts.
- (1) 'civil aviation' means any air operation carried out by civil aircraft, excluding operations carried out by State aircraft referred to in Article 3 of the Chicago Convention on International Civil Aviation;
- (2) 'making available on the market' means any supply of a product 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;
- (3) 'placing on the market' means the first making available of a product on the Union market;
- (4) 'putting into service' means the first use, for its intended purpose, in the Union, of equipment;
- (5) 'EU type-approval' means the procedure whereby a Member State certifies that a type and configuration of equipment satisfies the performance requirements

referred to in Annex I and that the procedural requirements of this Regulation have been complied with;

- (6) ‘virtual testing method’ means computer simulations, whether or not requiring human intervention, which demonstrate whether aviation security screening equipment fulfils the performance requirements referred to in Annex I;
- (7) ‘EU type-approval certificate’ means the document whereby an approval authority certifies that a type and configuration of equipment is approved;
- (8) ‘certificate of conformity’ means a document certifying that a piece of equipment was manufactured in conformity with the type and configuration covered by an EU type-approval certificate.

Article 4

Sale and entry into service of equipment

Member States shall not impede the making available and/or putting into service of any equipment which is accompanied by a valid certificate of conformity issued in accordance with Article 5. They shall not impose additional requirements in respect of such equipment.

Article 5

Obligations of manufacturers

1. The manufacturer shall issue a certificate of conformity to accompany each piece of equipment that is manufactured in conformity with the type and configuration covered by an EU type-approval certificate.

2. The certificate of conformity shall be as set out in Annex II and shall be issued in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Any approval authority may request that the manufacturer translates the certificate of conformity into the official language or languages of the Member State of that approval authority.

3. The manufacturer shall complete the certificate of conformity in its entirety. The certificate of conformity shall not contain restrictions as regards the use of the equipment.

4. The manufacturer shall make the certificate of conformity to prevent forgery.

A duplicate of the certificate of conformity may be issued at the request of an approval authority. Only the manufacturer may issue the duplicate certificate.

The word ‘duplicate’ shall be clearly visible on the face of any duplicate certificate.

5. By issuing the certificate of conformity, the manufacturer shall assume responsibility for the compliance of the equipment with the approved type and configuration.

6. Manufacturers shall keep the technical documentation and the certificate of conformity for at least ten years after the equipment has been placed on the market.

7. The manufacturer shall affix visibly, legibly and indelibly an EU type-approval mark and number to equipment manufactured in conformity with the approved type and configuration.

8. The EU type-approval mark and number shall be as set out in Annex III.

9. Manufacturers shall ensure that procedures are in place for conformity of production. Changes in equipment design or characteristics and changes in the performance requirements by reference to which a type-approval certificate has been issued shall be adequately taken into account.

10. Manufacturers shall ensure that their equipment bears a type, batch or serial number or other element allowing their identification, or, where the size or nature of the equipment does not allow it, that the required information is provided on the packaging or in a document accompanying the equipment.

11. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the equipment or, where that is not possible, on its packaging or in a document accompanying the equipment other than the certificate of conformity. The address must indicate a single point at which the manufacturer can be contacted.

12. Manufacturers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

13. Manufacturers who consider or have reason to believe that equipment which they have placed on the market is not in conformity with the approved type and configuration shall immediately take the necessary corrective measures to bring that equipment into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the equipment presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the equipment available to that effect, giving details, in particular, of the noncompliance and of any corrective measures taken.

14. Manufacturers shall, further to a reasoned request from an approval authority, provide it with all the information and documentation necessary to demonstrate the conformity of the equipment, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by equipment which they have placed on the market.

Article 6

Approval authorities

1. Each Member State shall establish or appoint an approval authority.

The approval authority shall have competence for all aspects of the approval of equipment as well as for issuing, amending and withdrawing EU type-approval certificates.

Each Member State shall notify the Commission of the name, address, including electronic address, and area of responsibility of its approval authority.

2. An approval authority shall hold the facility security clearance required to handle EU classified information at the EU Confidential level or above as defined in Commission Decision No 2015/444/EC⁷.

Article 7

Applications for EU type-approval certificate

1. The manufacturer shall submit an application to an approval authority.
2. Only one application shall be submitted in respect of any given type and configuration of equipment. The application shall be submitted in only one Member State.
3. A separate application shall be submitted for each type and configuration to be approved.
4. An application shall consist of the information folder containing the concept of operation for the equipment and other relevant documents, data, drawings and photographs. The manufacturer may provide the information folder in paper or electronic form.
5. A manufacturer established outside the Union which wishes to apply for EU type-approval certificate shall appoint a representative established within the Union to represent it before the approval authority.

Article 8

Tests

1. Once it receives an application, the approval authority shall ensure that appropriate tests are carried out by a technical service to determine whether the type and configuration of equipment concerned comply with the performance requirements referred to in Annex I.
2. Tests shall be undertaken by a technical service notified under Article 21 and meet the requirements of the common testing methodologies referred to in Annex IV.
3. The approval authority may, by reasoned request, call upon the manufacturer to supply any additional information needed to facilitate the execution of those tests. The manufacturer shall provide such information within the time-limit fixed by the approval authority.
4. The tests shall be performed on equipment of the type and configuration to be approved.

The manufacturer shall make available to the approval authority as many pieces of equipment as are necessary to enable the approval authority to conduct the EU type-approval procedure

5. Virtual testing methods may be used for re-testing equipment which has undergone modifications only to the detection software.

⁷ Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p.53)

Those methods shall meet the requirements of the common testing methodologies referred to in paragraph 2.

Articles 9

Approval of the type and configuration of equipment

1. The approval authority shall approve the type and configuration of the equipment concerned if it complies with the performance requirements referred to in Annex I.
2. If an approval authority finds that a type and configuration of equipment present a serious risk to safety or a serious risk of harms to the environment or public health, it may refuse to approve that equipment even if it complies with the relevant performance requirements.
3. If an approval authority refuses to approve any equipment, it shall inform the approval authorities of the other Member States and the Commission thereof without delay and shall inform them of the reasons for the refusal.
4. In case of a refusal under paragraph 2, the Commission shall consult the parties concerned without delay and, in particular, the approval authority that refused to issue the EU type-approval certificate in order to assess whether the relevant requirements of paragraph 2 were correctly applied.
5. Where the Commission considers that the relevant requirements of paragraph 2 were incorrectly applied, it shall require the approval authority to take appropriate measures to comply with those requirements.

Article 10

Relation between the Commission and the body responsible for the elaboration of the common testing methodologies

1. The European Union [represented by the Commission] shall become a full member of the body responsible for the elaboration of the common testing methodologies referred to in Annex IV.

Article 11

EU type-approval certificate

1. The approval authority shall issue an EU type-approval certificate in respect of any equipment it approves .
2. The EU type approval certificate shall be drawn up in accordance with the model in Annex V.

In respect of each type and configuration of equipment, the approval authority shall:

- (a) complete all the relevant sections of the EU type-approval certificate;
- (b) compile the information package including: the index, the information folder accompanied by the test result and all other documents added by the technical service or by the approval authority;

(c) provide the completed certificate to the applicant without delay in paper or electronic or form.

3. For each type and configuration of equipment which it has approved, the approval authority shall, within 20 working days from issuance of the type approval certificate, send a copy of the EU type-approval certificate to the other approval authorities and the Commission, including the attachments. The copy may be in paper or electronic form.

4. If so requested by the approval authority of another Member State, the approval authority which issued a EU type-approval certificate shall, within 20 working days of receiving the request, send an additional copy of the EU type-approval certificate in question, including the attachments. The copy may be in paper or electronic form.

Article 12

Conformity of production arrangements

1. An approval authority which has approved a type and configuration of equipment shall take the necessary measures in accordance with Annex VI to verify, if necessary in cooperation with the other approval authorities, that adequate arrangements have been made to ensure that the equipment produced conforms to the approved type and configuration.

2. An approval authority which has approved a type and configuration of equipment shall take the necessary measures in accordance with Annex VI in relation to that approval to verify, if necessary in cooperation with the other approval authorities, that the arrangements referred to in paragraph 1 continue to be adequate and that produced equipment continues to conform to the approved type and configuration. Verification to ensure that products conform to the approved type may be limited to one or more of the procedures set out in Annex VI.

3. Where an approval authority which has approved a type and configuration of equipment establishes that the arrangements referred to in paragraph 1 are not being applied, deviate significantly from the arrangements agreed, or have ceased to be applied, although production is not discontinued, that approval authority shall take the necessary measures to ensure that the conformity of production procedure is followed correctly. Those measures may include the withdrawal of the EU type-approval certificate. The approval authority shall inform the other approval authorities and the Commission of any measures taken.

Article 13

Applications for amendment of EU type-approval certificates

1. Where it is necessary to change the particulars recorded in the information package as a result of changes to the equipment concerned, the manufacturer shall apply for an amendment of the EU type-approval certificate without delay.

2. The application for amendment shall be submitted to the approval authority that issued the original EU type-approval certificate.

Article 14
Types of amendment

1. If the approval authority finds that additional testing is necessary before an amendment can be made, it shall inform the manufacturer accordingly. The amendments shall only be made after the additional tests have been carried out.

2. An amendment shall be designated an 'extension of EU type-approval certificate', if one or more of the following apply:

- (a) additional testing is required;
- (b) any information on the EU type-approval certificate, with the exception of its attachments, has changed;
- (c) new performance requirements related to the approved equipment enter into force.

In such cases, the approval authority shall issue an updated EU type-approval certificate denoted by an extension number. The updated EU type-approval certificate shall show clearly the reason for the extension and the date of issue.

3. Where paragraph 2 does not apply the amendment shall be designated a 'revision of EU type-approval certificate'.

Article 15
Issue and notification of amendments

1. In the case of an extension, the approval authority shall update all relevant sections of the EU type-approval certificate, the attachments thereto, and the index to the information package. The updated certificate and its attachments shall be issued to the manufacturer without delay.

2. In the case of a revision, the approval authority shall issue the updated documents or the consolidated, updated version of the information package, as appropriate, to the manufacturer without delay. The approval authority shall mark each updated page of the information package to show clearly the nature of the change and the date of re-issue.

3. Whenever updated documents or a consolidated, updated version of the information package are issued, the index to the information package attached to the approval certificate shall be amended accordingly to show the date of the most recent extension or revision, or the date of the most recent consolidation of the updated version.

4. The approval authority shall notify any amendment made to EU type-approval certificates to the approval authorities of the other Member States and the Commission in accordance with Article 11(3).

Article 16
Termination of validity of EU type-approval certificates

1. An EU type-approval certificate shall cease to be valid when either or both of the following occur:

- (a) new performance requirements applicable to the approved equipment become mandatory for the sale or entry into service of new equipment, and it is not possible to update the approval accordingly;
- (b) production of the approved equipment is definitively discontinued voluntarily.

2. If production of the approved equipment is definitively discontinued voluntarily, the manufacturer shall notify the approval authority that approved that equipment. Upon receiving such notification, that authority shall inform the approval authorities of the other Member States and the Commission thereof within 20 working days.

Article 17

Procedure for dealing with equipment presenting a risk at national level

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

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

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

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

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the approval authorities of the other Member States and the Commission of the results of the evaluation and of the actions which they have required the manufacturer to take.

3. The manufacturer shall ensure that all appropriate corrective action is taken in respect of the equipment concerned that it has made available on the market throughout the Union.

4. Where the manufacturer does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all

appropriate provisional measures to prohibit or restrict the equipment being made available on their national market, to withdraw the product from that market or to recall it.

They shall inform the approval authorities of the other Member States and the Commission, without delay, of those measures.

5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the noncompliant equipment, the origin of the equipment, the nature of the noncompliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant manufacturer.

6. Approval authorities other than the approval authority of the Member State initiating the procedure shall without delay inform the approval authorities of the other Member States and the Commission of any measures adopted and of any additional information at their disposal relating to the non-compliance of the equipment concerned, and, in the event of disagreement with the notified national measure, of their objections.

7. Where, within 3 months of receipt of the information referred to in paragraph 4, no objection has been raised by either another approval authority or the Commission in respect of a provisional measure taken by the approval authority of a Member State, that measure shall be deemed justified.

8. Approval authorities shall ensure that appropriate restrictive measures are taken in respect of the equipment concerned, such as withdrawal of the equipment from their market, without delay.

Article 18

Union safeguard procedure

1. Where, on completion of the procedure set out in Article 17(3) and (4), objections are raised against a measure taken by the approval authority of a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the approval authority of the Member States and the relevant manufacturer and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not.

The Commission shall address its decision to the approval authorities of all Member States and shall immediately communicate it to them and the relevant manufacturer.

2. If the national measure is considered justified, the approval authorities of all Member States shall take the measures necessary to ensure that the non-compliant equipment is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the approval authority of the Member State concerned shall withdraw the measure.

Article 19
Equipment not in conformity with the approved type

1. An approval authority may verify at any time that equipment accompanied by a certificate of conformity or bearing an EU type-approval mark still conforms to the type and configuration it has approved.

That verification shall be carried out in accordance with Annex VI. However, it may be limited to one or more of the procedures set out therein.

2. If the approval authority finds that the equipment referred to in paragraph 1 does not conform to the type and configuration it has approved, it shall ensure that the manufacturer brings the equipment into conformity with the approved type and configuration by taking any necessary measures. Those measures may include the withdrawal of the EU type-approval certificate.

The approval authority shall inform the approval authorities of the other Member States and the Commission of the measures taken.

3. If an approval authority withdraws an EU type-approval certificate, it shall inform the approval authorities of the other Member States and the Commission of its decision and the reasons for it within 20 working days.

4. For the purposes of paragraph 1, deviations from the particulars in the EU type-approval certificate or the information package shall be deemed to constitute failure to conform to the approved type and configuration.

5. If an approval authority finds that equipment accompanied by a certificate of conformity or bearing an EU type-approval mark does not conform to the type and configuration approved by another approval authority, it shall temporarily stop the making available or put into service of that equipment in that Member State and request, without delay, the approval authority which issued the EU type-approval certificate to verify that equipment in production continues to conform to the approved type and configuration.

On receipt of such a request, the approval authority concerned shall take the requisite action as soon as possible and, in any case, within three months of the date of the request. It shall inform the other approval authorities and the Commission thereof.

6. If the approval authority that issued the EU type-approval certificate considers that the equipment concerned does conform to the approved type and configuration, it shall endeavour to settle the dispute. The Commission shall be kept informed by the two parties and, where necessary, shall hold appropriate consultations with a view to reaching a settlement. Until the solution is found, the temporary measures referred to in paragraph 5 are in place.

Article 20
Notification of decisions and remedies available

All decisions taken pursuant to Articles 17, 18 and 19 shall state the reasons on which they are based. Member States shall ensure that there is a remedy for any decision taken pursuant to these articles.

The approval authority shall notify any such decision to all the parties concerned and, at the same time, inform them of the remedies available to them under national law and of the time limits for the exercise of such remedies.

Article 21
Notification of technical services

1. At least one approval authority shall notify to the Commission the name, the address including electronic address, the responsible persons and the category of activities of each technical service for the purpose of Article 8. The approval authority shall notify the Commission of any subsequent modifications thereto.

2. A technical service shall carry out its tasks under this Regulation only if it has been notified to the Commission.

3. Approval authorities may designate any notified technical service for the purpose of Article 8.

4. The Commission shall publish a list and contact details of the approval authorities and technical services on its web-site.

Article 22
Requirements of technical services

1. The technical service shall carry out or supervise the tests required under Article 8. It shall not conduct tests or verifications in a category of activities for which it has not been notified to the Commission under Article 21.

2. There shall be four categories of technical services:

- (a) category A, technical service which carries out the tests referred to in Article 8(1) in its own facilities;
- (b) category B, technical service which supervises the tests referred to in Article 8(1), performed in the manufacturer's facilities or in the facilities of a third party;
- (c) category C, technical service which assesses and monitors, on a regular basis, the manufacturer's procedures for verifying conformity of production;
- (d) category D, technical service which supervises or performs tests or verifications in the framework of the conformity of production arrangements.

3. The technical service shall possess appropriate skills, specific technical knowledge and proven experience in its area of activity. Technical services shall also be able to procure or source all the materials needed to carry out the tests in accordance with Article 8(2).

In addition, technical services shall comply with the requirements of Annex VII.

4. Technical services shall ensure that the average time between the request to carry out a test of equipment and the provision of the test results to the approval authority is of a maximum period of 6 months. This time may be prolonged in exceptional cases or if formally requested by the manufacturer.

5. An approval authority may act as a technical service.

6. A technical service or an approval authority acting as a technical service shall hold the Facility Security Clearance required to handle EU Classified Information at the EU Confidential level or above as defined in Commission Decision No 2015/444/EC⁸.

7. An approval authority may designate a technical service based in a third country only in the framework of a bilateral agreement between the Union and that third country.

Article 23

Assessment of the skills of technical services

1. The skills referred to in Article 22(3) shall be demonstrated by an accreditation certificate issued by a national accreditation body.

2. The accreditation certificate shall be sent to the Commission upon request.

3. An approval authority which acts as a technical service shall demonstrate compliance with the skills referred to in Article 22(3) through documentary evidence, including an assessment conducted by auditors independent of the activity being assessed. Such auditors may be from within the same organisation provided that they are managed autonomously from personnel undertaking the assessed activity. The Commission may send auditors to check compliance with the provisions of Article 22(3).

Article 24

Coordination of technical services

1. Technical services shall organise mutual visits to their respective premises in order to exchange information and best practices in performing the tests required under Article 8 (1).

⁸ Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p.53.)

2. The Commission shall establish a sectoral group of technical services to ensure that appropriate coordination and cooperation between technical services is achieved. Approval authorities shall ensure that the technical services designated by them participate in the work of that group, directly or by means of designated representatives.

3. The Commission shall act as the Chair of the sectoral group.

4. The tasks of the sectoral group shall be in particular to:

- (a) establish quality guidelines for the application of the common testing methodologies referred to in Article 8(2);
- (b) coordinate and develop measures aimed at ensuring the harmonised implementation of Common Testing Methodologies by technical services, including single-source test materials, common formats for sharing documents and comparative testing campaigns;
- (c) design and organise training for staff of technical services;
- (d) coordinate technical harmonisation with third countries concerning conformity assessment of aviation security screening equipment.

Article 25

Changes to designations

1. Where an approval authority has ascertained that a technical service designated by it no longer meets the requirements laid down in this Regulation, or that it is failing to fulfil its obligations, the approval authority shall restrict, suspend or withdraw the designation as appropriate. The approval authority shall without delay inform the Commission and the other approval authorities. The Commission shall modify the list referred to in Article 21(4) accordingly.

2. Where the designation of a technical service is restricted, suspended or withdrawn, or the technical service has ceased its activity, the approval authority which designated the technical service shall take appropriate steps to ensure that the files of that technical service are either processed by another technical service or kept available for the competent national authority at its request.

Article 26

Challenge to the competence of technical services

1. The Commission shall investigate all cases where it has doubts, or doubts are brought to its attention, regarding the competence of a technical service or the continued fulfilment by a technical service of the requirements and responsibilities applicable to it.

2. The approval authority of the Member State that has notified the technical service shall provide the Commission, on request, with all relevant information.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigation is treated confidentially.

4. Where the Commission ascertains that the notified technical service does not meet or no longer meets the requirements for its accreditation, it shall inform the approval authority of the Member State which has notified the technical service accordingly and request it to take the necessary corrective measures, including withdrawing the notification if necessary.

Article 27
Amendments to the Annexes

The Commission shall be empowered to adopt delegated acts in accordance with Article 28 in order to amend the annexes as follows:

- (a) it may amend Annex I to reflect the introduction of new performance requirements for aviation security screening equipment;
- (b) it may amend the annexes where necessary to adapt them to the development of scientific and technical knowledge.

Article 28
Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 27 shall be conferred on the Commission for a period of ten years from [*the date of entry into force of this Regulation*].
3. The delegation of power referred to in Article 27 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
5. A delegated act adopted pursuant to Article 27 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

Article 29
Penalties

Member States shall lay down the rules on penalties applicable to infringements of this Regulation, in particular those of Article 5, 7 and 8 and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall notify the Commission of those rules and of those measures and shall notify it without delay any subsequent amendment affecting them.

Article 30
Transitional provisions

Until [three years after entry into force of this Regulation], Member States may continue to approve equipment under their national rules.

At the request of the manufacturer, an approval authority which approved a type and configuration of equipment under national rules before that date, shall issue an EU type-approval certificate in respect of that type and configuration of equipment if it was tested in accordance with Article 8(2).

Article 31
Assessment

1. By [four years after entry into force of this Regulation] at the latest, Member States shall inform the Commission of the implementation of this Regulation.
2. By [five years after entry into force of this Regulation], the Commission shall present a report to the European Parliament and the Council on the implementation of this Regulation accompanied, where appropriate, by relevant legislative proposals.

Article 32
Entry into force

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

It shall apply from [one year after entry into force of this Regulation]

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President
[...]

For the Council
The President
[...]